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Development and Initial Testing of a Low-Cost, Electronic, Microprocessor-Controlled Prosthetic Knee

Lucas Jonathan Galey
University of Texas at El Paso, ljgaley@miners.utep.edu

DEVELOPMENT AND INITIAL TESTING OF A LOW-COST, ELECTRONIC, MICROPROCESSOR-CONTROLLED PROSTHETIC KNEE

LUCAS JONATHAN GALEY

Master's Program in Biomedical Engineering

APPROVED:

Roger V. Gonzalez, Ph.D., Chair

Jerome Hausselle, Ph.D.

Meagan Vaughan Kendall, Ph.D.

Charles Ambler, Ph.D.
Dean of the Graduate School

Dedication

Dedicated to my father, George Thomas Galey; my mother, Gabriela Galey; and my wife, Gina Nichole Galey. Pop, thank you for your leadership and guidance, and for teaching me how to conduct myself as a man and to apply myself to fixing things. Mama, thank you for your love and support, and for cultivating a passion in me for healing. Gina, thank you for your ceaseless encouragement and loving support, and for your tremendous editing skills.

DEVELOPMENT AND INITIAL TESTING OF A LOW-COST, ELECTRONIC, MICROPROCESSOR-CONTROLLED PROSTHETIC KNEE

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LUCAS JONATHAN GALEY, B.S.

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Finally, I would like to thank my God and Savior, Jesus Christ, for only by Him and through Him did I find the strength to finish this thesis.

> *"Oh, the depth of the riches both of the wisdom and knowledge of God! How unsearchable are His judgments and unfathomable His ways! For who has known the mind of the Lord, or who became His counselor? Or who has first given to Him that it might be paid back to him again? For from Him and through Him and to Him are all things. To Him be the glory forever. Amen" (Romans 11:33-36 NASB)*

Abstract

Cost-effective lower-limb prostheses have been successful in restoring mobility, independence, and a way of life to millions of global amputees who do not have the means to afford more sophisticated prosthetics. Comprehensively, the current above knee (AK) prosthetic market is segmented into two extremes – very affordable relief style knees that offer basic functionality with high risk of accident due to falls, and very expensive styles that offer electronic microprocessor stumble control and adaptive cadence. There remains a gap for a middle-ground system that provides stumble control and greater stability within an achievable price bracket for the developing world. This project develops and tests a low-cost AK prosthetic with microprocessor stumble control.

The first phase of this study was the creation of the low-cost microprocessor knee using a combination of an existing polycentric four-bar relief knee and an Arduino-controlled hydraulic clamping mechanism. The system was created to mimic the natural motion and kinematics of a healthy limb by offering greater stability. The second phase was experimentally testing the prototype with patient trials, which compared walking and stumble control performance between the prototype, the polycentric four-bar LIMBS M3 knee, and the Ottobock C-Leg. Two patients were selected for the trials that involved walking across force plates to analyze ground reaction forces during gait and during a simulated stumble trial with the prototype knee.

The results of the patient trial concluded that the prototyped microprocessor solution was successful in adding stance stability and stumble control, while also offering natural gait comparable to the gold standard C-Leg. The conclusions of this work can be incorporated into future development of the prototype with the addition of dynamic cadence control and expanded patient trials comparing the low-cost solution to other currently available high-end systems.

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Chapter 1: Introduction

1.1 Significance

Lower limb loss is a life-altering change that severely hampers one's mobility and independence. Globally, an estimated 36 – 58 million people have suffered limb loss due to illness, natural disaster, or human conflict according to the World Health Organization's most recent report in 2011. In the United States, approximately 185,000 people lose a limb annually (Amputee Coalition 2012). Transfemoral limb loss accounts for 25% of all amputations, which, in the United States, means the number of transfemoral amputees is growing by 46,000 yearly (Michael 2001; Center for Orthotic & Prosthetic Care 2008).

Given the large numbers of transfemoral amputees living in the developing world who have limited access to healthcare or means of affording expensive prosthetic systems, there is a need for a low-cost prosthetic knee solution that includes greater stability and performance (Ravallion 2010). The current reality is that as a prosthetic knee system becomes more functional the cost considerably increases. There remains a gap for a cost-effective prosthetic knee that offers greater stability than a low-end system and the basic features of a high-end system.

1.2 Background

For a lower-limb amputee, mobility can be restored through a properly fitting and functioning prosthetic leg. There are two general types of lower-limb amputations: above knee and below knee (AK and BK, respectively). For an AK amputee, the knee, foot, and majority of the leg need to be included in the prosthetic solution (Sagawa et al. 2011). For a BK amputee, the patient's knee is still intact and only the lower shaft and foot need to be included in the prosthetic. The prosthetic interfaces with the patient's residual limb through a custom-made socket that fits around the limb and attaches to a pylon rod as part of the prosthetic (Sagawa et al. 2011).

For the knee joint, the first gold standard for prosthetic movement was passive mechanical control (discussed later in this chapter). In the last twenty years we have seen the emergence of

microprocessor-controlled knees, which have beneficial dynamic control of flexion and extension, often in mid-swing, and are much preferred, 82%, by amputees (Hafner et al. 2007). According to a 2005 study by Johansson et al., a Rheo Knee (further discussed in section 1.2.5) with microprocessor control was shown to decrease energy expenditure by 5% when compared to the passive variation. Benefits of microprocessor knees mainly include increased stability and decreased biomechanical asymmetry. However, while offering significant benefits to patients, they are currently set at a price point (approximately $20,000) that makes them an unaffordable luxury in the developing world; 80% of world's population live on less than $10 a day (Ravallion 2010).

Prosthetic knee joints mimic the articulation of natural limb joints. Although muscle loss diminishes movement and control, prosthetic systems aim to compensate by regulating the flexion and extension of the limb. Controlling flexion and extension is essential in producing a normal gait (walking cadence). Normalizing the gait cycle and leg movement improves walking smoothness, reduces hip work, and increases stability (Johansson et al. 2005). Gait smoothness and hip work are dependent on lateral rotation of the pelvis while walking. However, amputees generally show increased levels of lateral pelvic rotation that results in a musculoskeletal imbalance. This imbalance can lead to overcompensation elsewhere in the body that can cause a secondary injury like osteoarthritis in the intact limb and back pain (R. Gailey et al. 2008).

Microprocessor knees benefit all amputees with their stumble prevention capabilities; however, more active patients receive the greatest benefits from the dynamic walking responses of these devices. In the United States, amputees are categorized by Medicare according to their activity level (K level). There are five functional stages ranging from K0 to K4. An amputee who does not have the ability or potential to benefit from a prosthesis is classified at a K0 activity level. K1 is characterized by a fixed cadence and level surface ambulation. A patient that can navigate low-level environmental barriers is classified K2. While K3 is considered "community ambulation," meaning that the amputee can traverse most environmental barriers with variable cadence. Patients with potential to exceed basic ambulatory skills, such as athletes, active adults, and children, are classified as K4 (R. S. Gailey et al. 2002). Because Medicare reimbursement

classifies microprocessor knees as devices that restore dynamic cadence, only level K3 and K4 amputees are considered eligible; despite the benefits stumble control can offer lower K level patients.

1.2.1 Mechanical Shape

The mechanical function of the prosthetic device is heavily dependent on the means of rotation the knee utilizes. By geometric design, single axis devices do not offer the native stability of polycentric devices. Single axis means that the center of rotation for the knee occurs at one point, which means that without some form of supplementary system of preventing knee joint rotation, a single axis knee is prone to collapse. Polycentric knees have moving centers of rotation where the exact point depends on time and the geometry of the knee. Polycentric designs have several advantages including stance stability, flexion appearance, and toe clearance (Gard, Childress, and Uellendahl 2008). These knees depend on mechanical structure to lock into a stable position when the knee is fully extended, providing native stability and toe clearance.

The most common type of polycentric knee is the four-bar system (Figure 1.1)(Chauhan and Bhaduri 2011). As a polycentric knee flexes, the center of rotation shifts anteriorly, effecting a slight decrease in prosthesis length (Tang et al. 2008). While the decrease in length is not significant overall, the change is enough to provide ground clearance while swinging the leg and preventing stumbling. Furthermore, increased ground clearance means less required hip rotation and decreased risk of secondary injury than with a single axis system (Gard, Childress, and Uellendahl 2008; R. Gailey et al. 2008).

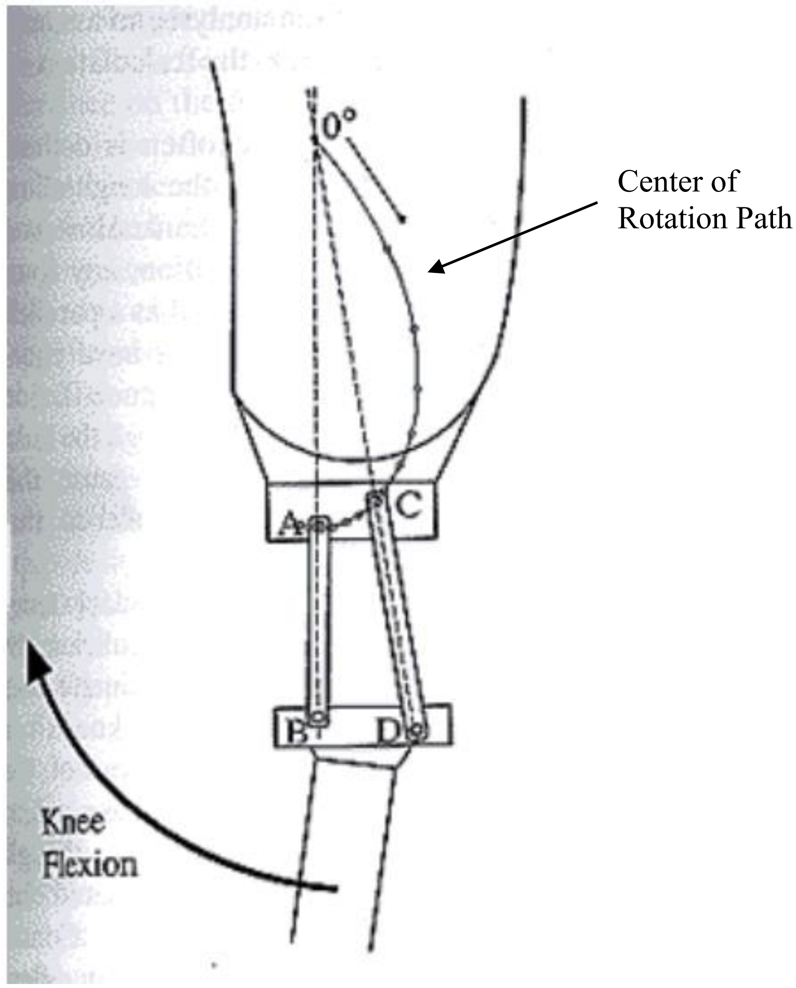

Figure 1.1: Four-bar knee mechanism. Dotted lines indicate the moving center of rotation. Path of center of rotation throughout flexion is given. Photo from (Gard, Childress, and Uellendahl 2008).

Another type of polycentric knee is the six-bar system (Figure 1.2). It functions by the same premise as the four-bar system by loading the knee in a mechanically stable condition, but offers advantages in increased stance stability. Unlike four-bar polycentric knees, the six-bar stance stability is capable of maintaining stability under interference, such as physical impact to the knee mechanism (Jin et al. 2003).

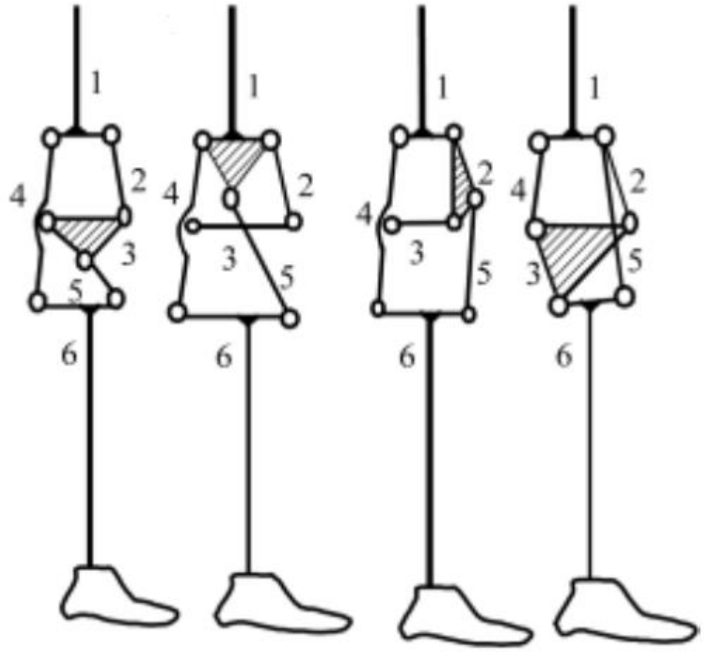

Figure 1.2: Example configurations of six-bar mechanism. Photo from (Jin et al. 2003).

1.2.2 Knee Control Methods

Historically, passive knee systems have been affordable and provided simple essential mobility (Hafner et al. 2007). Such knees have the basic required functionality but lack the stability and gait variability of the microprocessor-controlled active knee systems. In general, knee systems are controlled by regulating the angular rotation of the knee. Though inexpensive, mechanical swing control is not durable for long-term applications. Pneumatic systems are ideal for patients with low mobility needs (Bellmann, Schmalz, and Blumentritt 2010). Magnetorheological and hydraulic systems have been found to be versatile and functional in a variety of high ambulatory situations. They provide a decrease in metabolic rate when compared to passive systems, and are able to prevent collapse. When comparing single axis and polycentric systems, single axis costs less and is easier to develop, while polycentric, by nature of its mechanical geometry, mimics more natural gait, requires less energy, provides more stability, and more closely emulates the natural knee (Chauhan and Bhaduri 2011).

Passive Control

Passive control systems are nonreactive to the gait cycle. Controlling knees through passive means had been the only viable method until the mid-1990s when microprocessor knees were introduced (OttoBock HealthCare LP 2016). Currently, it is used as a more affordable alternative to the microprocessor controlled versions. With passive systems, this can be through friction, hydraulics, magnetism, or other methods. The important differentiation between passive and active control is that in passive control the controlling force is not adaptive, which limits the maximum benefits of the knee to only one optimal gait speed (Kenton R. Kaufman et al. 2008). In some passive knees, flexion and extension speed can be regulated with a mechanical adjustment that allows the user to alter the friction or other swing control mechanism. The usefulness of manual adjustments is limited by the necessity of interrupting gait to make changes. Adjustable mechanics are complex, more expensive, and prone to wear out quickly. Generally, having only one optimal speed hampers patients from experiencing full mobility and expend more energy (Datta, Heller, and Howitt 2005). Therefore, passive control offers affordable functionality, but is constricting to mobility and requires more energy.

Active Control: Microprocessor Control

Active control allows for dynamic adjustment of knee parameters, such as stumble control and/or adaptive cadence. Microprocessors can provide the computational power for this type of control. Through precise regulation, normal gait and balance can be restored (K R Kaufman et al. 2007). Many microprocessor knees include the ability to recognize the current phase of the gait cycle and control the swing to match the patient’s walking speed. Though the cost for this type of system is much higher, the constant control over swing resistance is much desired (Martinez-Villalpando and Herr 2009). Research has shown that the metabolic rate of patients can be inconsequentially decreased by as much as 5% from usage of microprocessor knees compared to a hydraulic passive knee (Johansson et al. 2005).

Arguably the greatest benefit of microprocessor-control is stability. With electronic sensors detecting a rapid collapse or a large force, the microprocessor can immobilize the knee to prevent the patient from falling or stumbling. This is especially pertinent when half of the amputee population falls hazardously, while the other half expresses lack of mobility due to caution and fear of falling (Miller, Speechley, and Deathe 2001). Because actively-controlled knees are reactive to external influences, they are able to mimic natural gait at any walking speed while also detecting and preventing stumbles or falls.

1.2.3 Swing Control Methods

Swing control is what dictates how the knee flexes and extends during gait. The most common forms of swing control, or knee flexion control, ordered from low to high cost, are: mechanical, pneumatic, hydraulic, and magnetorheological. Both passive and active knee systems can use any of these swing control methods; however, magnetorheological systems are rarely used without some form of microprocessor. While most active knees simply control gait cadence dynamically, a growing amount of research is investigating methods of adding mechanical energy to assist with motions such as walking up stairs (Kapti and Yucenur 2006).

Mechanical

In active control knees, mechanical swing control regulates lower-limb motion through electronics. Swing control is achieved by attaching a motor or break-pads to the knee joint to actively slow the movement. Additionally, a generator or motor unit may be used to generate, and store, electricity when the knee bends, resulting is less energy lost. Brake pads, such as those in a car, are not usually implemented because of long-term wear. Mechanically-controlled swing systems can add energy to the step and often require a large amount of power to implement, and therefore are limited to laboratory settings where an external power source can be used. Due to this limitation, mechanical swing control systems are difficult to implement in the field (Sup et al. 2008).

Less sophisticated mechanical swing systems implement controlled friction, springs, or similar methods. Such control can be adjusted by varying the friction or spring strength. The LIMBS M3 knee is an example of a passive polycentric four-bar mechanical system that uses friction to control swing (Figure 1.3). Such knees are the affordable variants to their adaptive counterparts discussed above. The M3, specifically, is adjusted by tightening (or loosening) the screws in a specific joint. While such control is inexpensive and provides relief to many developing regions, it is unable to provide stumble support and encourages disadvantageous gait (K R Kaufman et al. 2007).

Figure 1.3: Passive four-bar mechanical knee. M3 Knee by LIMBS International.

Pneumatic

Knees that are regulated by pneumatic force employ compressible fluids (such as air) within a pressurized system to control the joint. It is commonly implemented as a pneumatic cylinder attached between the thigh and lower leg with an actuator to supply pressure (Sup, Bohara,

and Goldfarb 2008). This configuration can also add mechanical energy to the knee movement, thus aiding in the patient’s walk. Nevertheless, the energy requirements of using the actuator to supply additional pressure often exceed the capacities of currently available batteries. Therefore, the most common way of using a pneumatic system is to have a self-contained damper that includes an electronically-controlled release valve between two chambers (Radcliffe and Lamoreux 1968). The electronically controlled release valve then determines when the knee can and cannot move. In an active control system, the constant control of the swing phase and the compressibility of the air, this system provides a very smooth gait. However, compressibility also results in a less responsive system that falls prey to high-impact or fast moving situations. Therefore, pneumatic systems are limited to patients with lower ambulatory rates (Tang et al. 2008). Figure 1.4 is an example of a pneumatic four-bar prosthetic knee system.

Figure 1.4: Ottobock 3R106. Example of a pneumatic four-bar system. Photo from (Ottobock 2016)

Hydraulic

Similar to the pneumatic swing control is the hydraulic swing control, which uses non-compressible fluids (like oils) within a pressurized system to control gait. Hydraulic methods often operate at much higher pressures than pneumatic systems offering more instantaneous forces with higher dampening effects. Though they are more expensive, hydraulic devices have become the most common swing control method for prosthetic knees due to their reliability. They are most often used as pistons, which are outfitted as dampers (James 1996).

Figure 1.5 is an example of a passive hydraulic knee prosthesis. In such devices, hydraulic dampening is achieved by a valve between both hydraulic chambers with a set diameter. The valve allows fluid to be exchanged as the piston is extended and retracted. The diameter and viscosity of the non-compressible fluid enable regulated dampening. The primary differentiation in the hydraulic component between passive and active (microprocessor) control is the valve system. For active knees to function, the dampening must be adaptive and dynamic throughout gait. Thus, in active control systems, the valve is electronically controlled and varies the dampening on account of differences in voltage or current feedback loops.

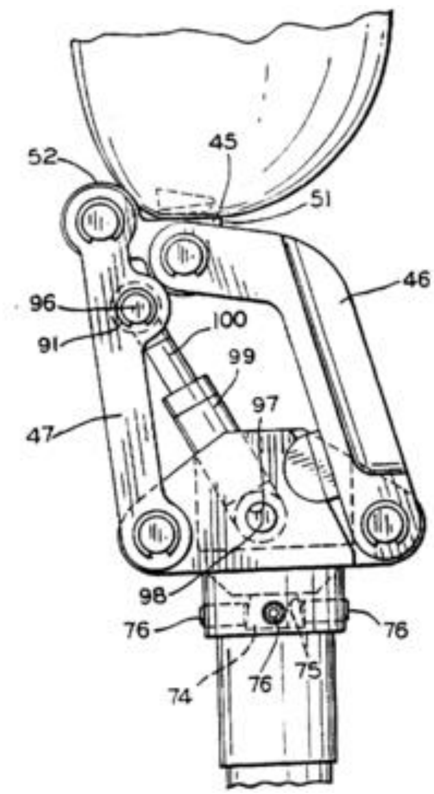

Figure 1.5: Patent for passive hydraulic knee. Photo from (Kramer, Srinivasan, and Swanson 1998)

Functionally, hydraulic devices are used in the same manner as the pneumatic devices. These systems, as well as microprocessor-controlled systems in general, are often cited for mimicking natural gait (Bellmann, Schmalz, and Blumentritt 2010). This not only affects the amputated side and its hip flexion and extension, but also the healthy side. Altered forces acting on the healthy side can lead to severe degenerative conditions (R. Gailey et al. 2008). Comparing two hydraulic systems, the microprocessor Ottobock C-Leg and the passive Mauch SNS, has shown that the microprocessor results in a 3% decrease in metabolic rate (Johansson et al. 2005). While this may not be a significant decrease in energy expenditure, the active system is able to dynamically adapt to stumbles and gait speed. Additionally, hydraulic systems are able to withstand impacts and speed much more readily than pneumatic systems, making them useful to patients with more active lifestyles (Tang et al. 2008).

Magnetorheological

The most abstract of the four swing control methods, magnetorheological (MR) control, works through magnetic filaments suspended in fluid. Through the use of electromagnets, the fluid's viscosity can be manipulated. Increasing the magnetism by inputting more current increases the fluid's viscosity and results in a slower moving fluid. This can be used in the same way a pneumatic and hydraulic system would use a piston (Ochoa-Diaz et al. 2014); however, it also offers a unique knee system of its own (Figure 1.6). By having circular plates in a cylinder through which the knee axis of rotation goes, the changing viscosity can be used to slow flexion or extension (Deffenbaugh et al. 2004). The disadvantage of this system is the cost and the amount of energy needed to provide the magnetic field.

As seen in Figure 1.6 below, the MR knee rotates on an axis with one set of disks, inner spline, traveling opposed to a second set of disks, outer spline. The MR fluid fills the gaps between the inner and outer disks. When activated, the electromagnets transform the MR fluid into "torque-producing chains" between the sets of disks (Herr and Wilkenfeld 2003), meaning that the MR fluid acts as a magnetic link between the inner and outer spline. Increasing the current also increases the magnetic attraction and thus torque. The general range of torque supplied by this system is 0.5 to 50 newton-meters. The efficiency of this system in the Össur Rheo knee has been shown to decrease metabolic rate by 5% from a hydraulic-based passive knee (Johansson et al. 2005). Like hydraulic systems, magnetorheological systems function well under very active conditions.

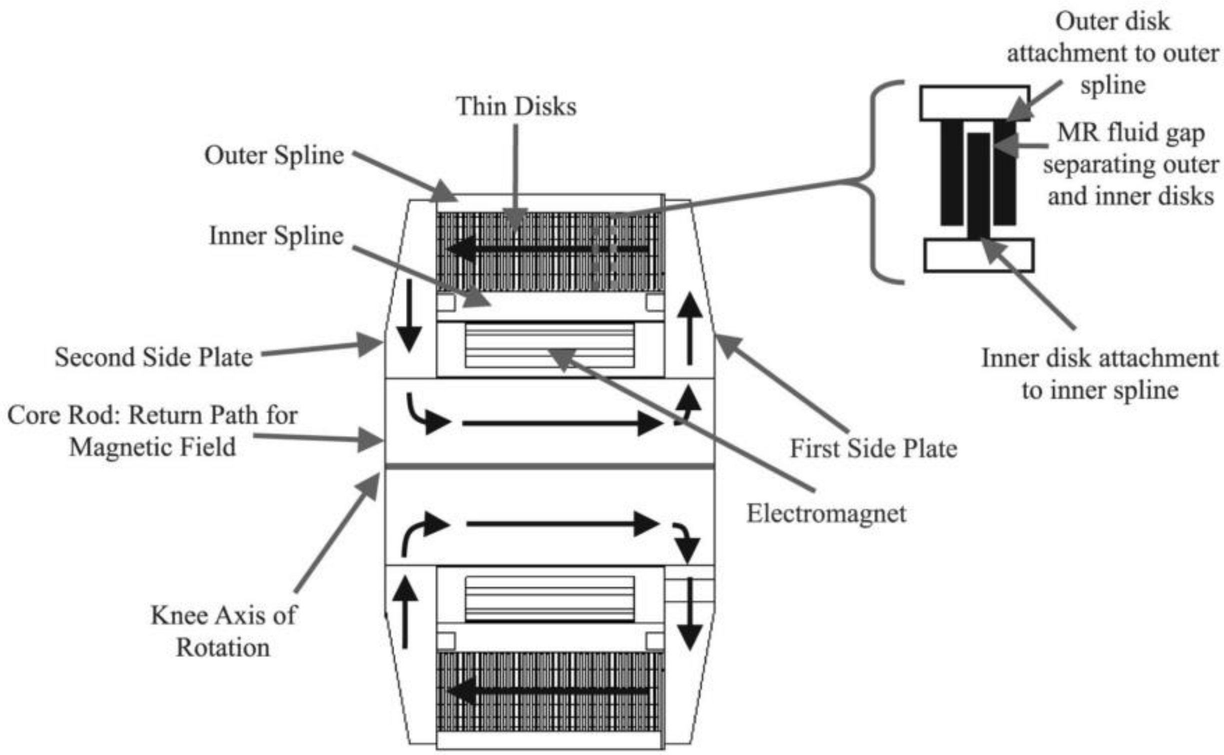

Figure 1.6: Rotating knee design of magnetorheological knee. Photo from (Herr and Wilkenfeld 2003)

In summary, mechanical, pneumatic, hydraulic, and magnetorheological swing control methods have been discussed. At their core, these methods seek to emulate natural gait as closely as possible.

1.2.4 Ground Reaction Forces and M3 Stability

Ground Reaction Forces

The gait cycle, gait analysis, and changes in gait due to lower-limb loss are highly studied and understood topics. Ground reaction forces (GRFs) are the vertical (Z), horizontal (Y), and lateral (X) forces that are exerted upon the patient by the ground. Horizontal forces are also known as fore/aft and breaking/accelerating. Because lateral forces are typically a small percentage of body weight, less than 5%, when walking in a straight line they are not examined or compared to one another (Giakas and Baltzopoulos 1997). The repeatability of GRFs and noninvasive methods

of obtaining them, make them ideal candidates for gait normality comparison. Healthy gait has very distinctive GRFs, and prosthetic GRFs can be compared to healthy and other prosthetic devices to ascertain quantitatively the normality of patient's gait.

Sides A and B in Figure 1.7 show the standard form of presenting GRF data and the repeatability of sound walking. GRF data is displayed in terms of body weight percentages (BW %) versus stance phase percentages. Stance phase is the entire time one limb is in contact with the floor during gait; it begins with heel strike and ends with toe off for a particular limb. Single stance is the time during the step in which only one limb is in contact with the ground. Double stance is both feet being in various stages of stance. The double peak shape of the vertical forces is a distinct indication of healthy gait. The first peak is the maximum heel strike force and the second is the maximum toe off force. As walking speed increases, the valley between the two peaks decreases, leaving a single larger peak, indicative of running and not having both feet on the ground at the same time and thus having only one very large impact. Likewise, at slower speeds, the valley increases and eventually becomes almost flat (Keller et al. 1996). For healthy gait, fore and aft forces cross the axis at 50% of stance. If the gait speed is constant and the limbs are intact, the first 50% of stance is spent breaking from the previous step and the second 50% of stance is spent accelerating for the next step (Giakas and Baltzopoulos 1997). Therefore, for intact limbs and constant speed, the summation integral of the breaking and accelerating forces should be equal to zero. Likewise, if gait speed is constant, the summation of both limb integrals should also equal zero. The integral divided by the patient's mass is equal to the change in patient speed (m/s).

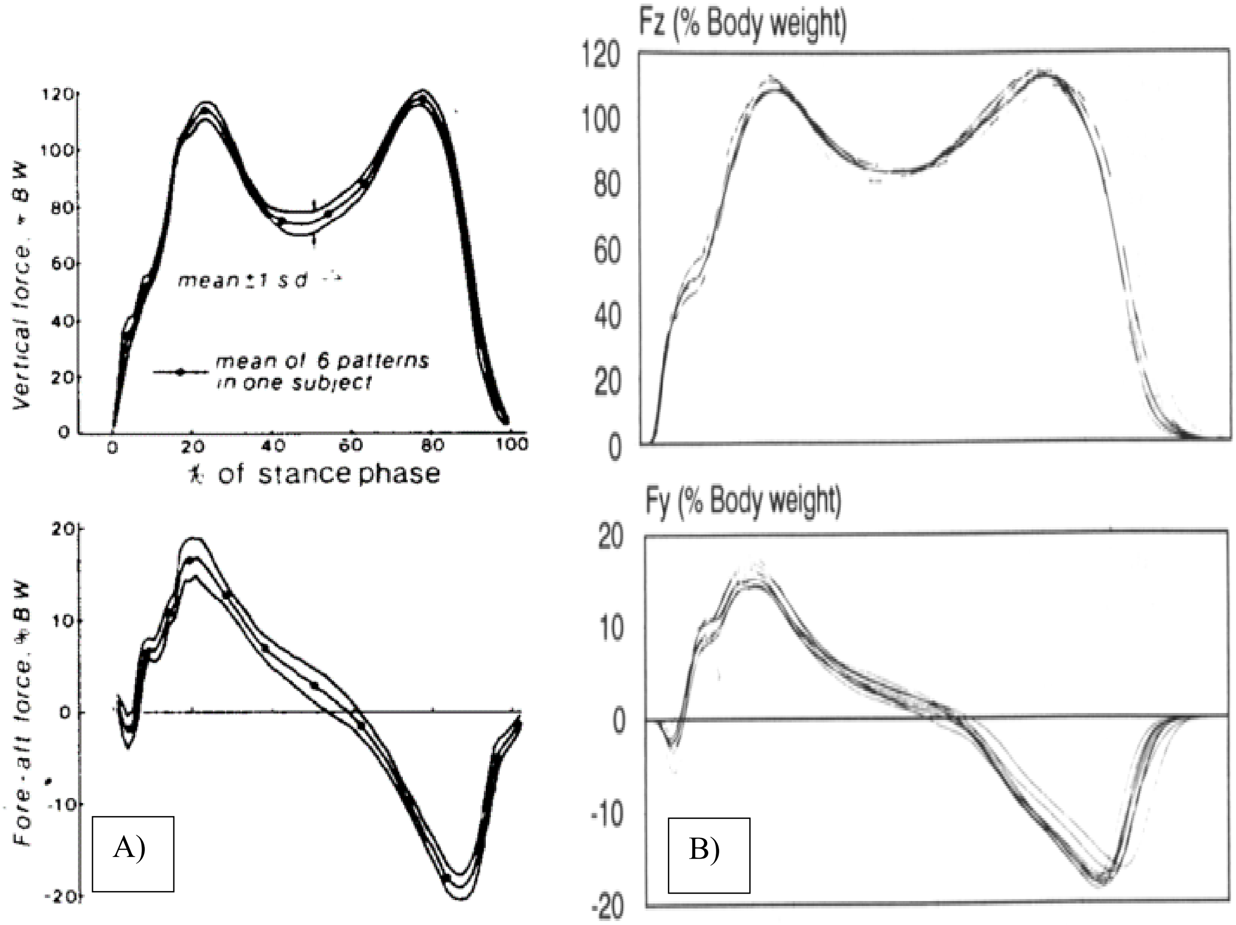

Figure 1.7: Traditional ground reaction force, body weight percent versus stance phase percent. A) (Chao et al. 1983) B) (Giakas and Baltzopoulos 1997)

Four-Bar Knee Stability

Four-bar knees are made up of four linkages connected in a four-sided polygon where the length and movement restraints of each of these links determines how the mechanism functions. Some knees seek to increase stance stability, toe clearance, or to conserve more energy (Greene 1983). With such wide variability, the mechanically stable range for each knee varies completely by both design geometry and prosthetic fitting. The geometry allows polycentric knees to have a moving instantaneous center of rotation (ICR) that benefits toe clearance and gives the knee its stance stability; however, it also makes the instability threshold angle difficult to locate. According to Greene, the simplest way to determine the stability of a polycentric system is to compare the

ICR to an imaginary line drawn from the trochanter, a bony protrusion at the proximal and lateral end of the femur, to the ankle (resulting in a T.A. Line). If the ICR is anterior to T.A. Line, then the system is mechanically unstable. Figure 1.8 shows the ICR, yellow dot, being anterior to the T.A. Line for the LIMBS M3 knee. This indicates that the shown knee angle is mechanically unstable. The M3, which the geometry of the prototype relies on, becomes unstable at an angle of 6 degrees. Note that polycentric knee stability is highly dependent on each patient's prosthesis alignment (Greene 1983). If the prosthesis is shifted anteriorly or posteriorly, the T.A. line shifts, changing the angle of mechanical stability.

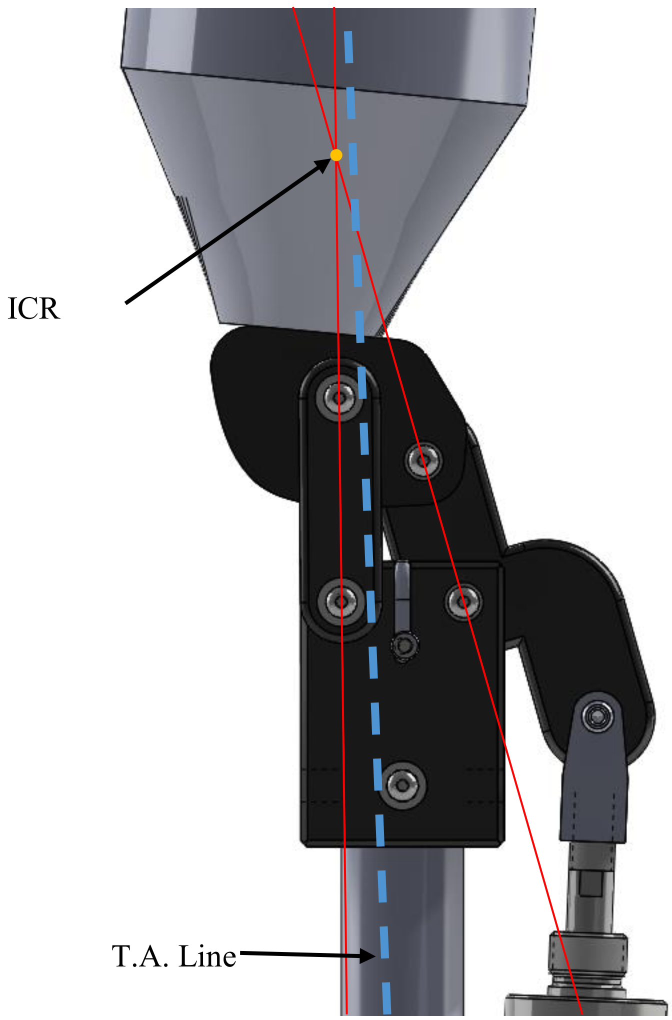

Figure 1.8: LIMBS M3 knee with red lines crossing to find the instantaneous center of rotation (ICR), marked by the yellow dot. The dashed blue line represents the

trochanter-ankle line (T.A. Line).

1.2.5 Current Products

Three of the most popular current microprocessor-controlled prosthetic knees are Freedom Innovations' Plié® 3, Ottobock's C-Leg® 4, and Össur's Rheo® Knee 3 (seen in Figure 1.9). Each knee offers stumble recovery and knee flexion and stance control.

Figure 1.9: Sample of current microprocessor knees. From left to right: Freedom Innovations' Plié® 3, Ottobock's C-Leg® 4, and Össur's Rheo® Knee 3. Photos from (Freedom Innovations 2015; Ottobock 2016a; Össur Americas 2016)

Table 1.1 compares various specifications such as device weight, height, and microprocessor response time between these three knees. While each knee can be used at lower activity levels, Medicare requires at least K3 for microprocessor knees because such patients can

more fully utilize the variable cadence (Össur Americas 2016). While not widely known, at least one four-bar microprocessor knee system exists, the ALLUX by Nabtesco. Although it has the four-bar mechanism advantages, it is not analyzed because of lack of popularity and no consequential difference in price point from the other current products.

Table 1.1: Comparison of various design specifications for Plié 3, C-Leg 4, and Rheo Knee 3. Specifications obtained from manufacturers websites (Freedom Innovations 2015; Ottobock 2016a; Össur Americas 2016).

	Plié 3	**C-Leg 4**	**Rheo Knee 3**
Knee Weight (kg)	1.24	1.24	1.61
Max Patient Weight (kg)	100	136	136
Knee Flexion (Deg)	120	130	120
Build Height (cm)	23.5	28	23.6
Battery Capacity (hr)	>24	40-45	24-48
Microprocessor Response (ms)	10	100	1
Activity Level (K)	K3-K4	K3-K4	K3-K4
Mechanical Shape	Single Axis	Single Axis	Single Axis
Environmental Protection	Water Proof (30 min)	Weatherproof	Weatherproof
Price ($)	$18,992	$21,538	$21,538

The greatest variability in the specification is seen in microprocessor response. The Rheo Knee offers the fastest response time at 1 ms (Bellmann, Schmalz, and Blumentritt 2010). Although the Plié prides itself on having a tenfold decrease in response time, a literary review shows the C-Leg performs remarkably well at 100 ms (Highsmith et al. 2010). Price levels are based on the Medicare reimbursement codes, with additional materials and services subtracted. Thus, prices shown are those of the actual prosthetic as reported to prosthetists, not patients. Since prices are based on Medicare reimbursement values, the actual patient cost for each knee system may be higher than those shown above.

Chapter 2: Methods

Prototyping a new knee was the first step in addressing the need for a low-cost, stable prosthetic solution. The specific design criteria and specifications, along with the validation through experimental trials of the prototyped prosthetic knee are discussed in this chapter. The prototype will be referred to as the "E-Knee" throughout this study. Though the "E" commonly refers to "electronic," this prototype is an electronic knee that is more specifically classified as an active-control microprocessor knee.

2.1 Design Criteria

Amputees' greatest concerns are fear of falling, slow walking speed, and restrained hip movement (Miller, Speechley, and Deathe 2001). The passive knees most commonly used in developing countries have lower flexion stability and no form of stumble control, posing a higher risk when compared to the developed world and the available high-end products. This research focuses on combining stability control with microprocessor knee benefits, previously mentioned, to develop a low-cost prosthetic device with stumble control.

Throughout this study, stability is defined as the amount of control the patient maintains over the prosthetic knee during any type of flexion, so that increasing stability helps prevent stumbling. Stability will be examined qualitatively through patient feedback and quantitatively through collapse awareness – does the knee support the patient's weight during gait. In the past, improvements such as these have not been approached with cost-efficiency in mind; therefore, this project seeks to accomplish these improvements with a low materials budget.

Before physical work began, a list of features was selected, by the investigators based on experience and research of prosthetic devices, and their relative significance to the project was determined (Table 2.1 and 0). These features' weights helped identify which method of swing control this project would focus on and were used in a decision matrix (0). Weights were determined by the relative importance that the researchers attributed to each feature. Realistically, the target demographic has the greatest influence over weights. Aesthetics, for example, are the

lowest rated feature of prosthetics in the US at 60.8% importance (Legro et al. 1999); yet, according to LIMBS International representatives, aesthetics are considered very important in developing countries, possibly due to social stigma associated with injury. The matrix presented the possibility of each swing regulation method accomplishing each required feature. The control-method scores were based on how well (from 1-10) or if possible or not (1 or 0) each method was anticipated to meet each feature. As shown in 0, the binary features were water resistance, immediate support on first step of stairs, supportive yield for sitting down, variable cadence, and knee locking.

Table 2.1: Decision Matrix features and weights.

Feature	Weight (1-10)
Stability	10
Durability	9
Maintenance ease	9
Cost	8
Environmental	8
Water resistant	8
Variable Cadence	8
Implementation ease	7
Immediate support on first step of stairs	6
Supportive yield for sitting down	6
Knee locking	6
Redesign amount	5
Aesthetics	5
Degree of Flexion	5
Weight	3

Table 2.2: Decision Matrix features and descriptions.

Feature	Description	Scale or Binary
Stability	Will it prevent the user from falling or give time to catch himself?	Scale
Durability	How long is this type of design expected to last?	Scale
Maintenance ease	How easily/cheaply will this system be fixed? I.e. Do developing countries have the capability to fix it?	Scale
Cost	How much do materials and manufacturing cost?	Scale
Environmental	How easily can dirt, water, or other corrosive material affect the system?	Scale
Water Resistant	More in depth than the "environmental", will the system withstand complete submersion?	Binary
Variable cadence	Will the swing control be able to adjust to different speeds of walking?	Binary
Implementation ease	How well does investigator understand this type of system, and what knowledge is required to use it?	Scale
Immediate support on first step of stairs	Will knee recognize stair situation and be able to lock/yield accordingly?	Binary
Supportive yield for sitting down	Will system recognize how to provide a decreasing amount of yield?	Binary
Knee locking	Can knee lock at any moment?	Binary
Redesign amount	How drastically will this system be different from the previous mechanical knee?	Scale
Aesthetics	How nice does the knee look?	Scale
Degree of flexion	How far back can the knee bend?	Scale
Weight	What is the combined weight of all parts of knee system?	Scale

Table 2.3: Decision Matrix comparing hydraulic, pneumatic, magnetorheological, and mechanical system. Left column shows features each type of solution must address. Weight column indicates relative importance of that feature. Hydraulic solution considered baseline, increases or decreases from baseline indicate superior and inferior performance, respectively.

Feature	**Weight (1-10)**	**Hydraulic**	**Pneumatic**	**Magnetorheological**	**Mechanical**
Stability	10	5	4	5	5
Durability	9	5	3	4	2
Maintenance ease	9	5	4	2	6
Cost	8	5	7	2	6
Environmental	8	5	5	4	3
Water resistant	8	5	5	5	4
Variable Cadence	8	1	1	1	1
Implementation ease	7	5	5	4	6
Immediate support on first step of stairs	6	1	0	1	1
Supportive yield for sitting down	6	1	1	1	1
Knee locking	6	1	1	1	1
Redesign amount	5	5	5	5	3
Aesthetics	5	5	5	5	5
Degree of Flexion	5	5	5	7	7
Weight	3	5	6	4	5
Final Result		411	387	343	384
Normalized		**100**	**94**	**83**	**93**

In the decision matrix, the benchmark was established as the hydraulic system. Therefore, the hydraulic system received an average score of 5 for each feature. How well each other swing control method could theoretically accomplish the features was then compared to the benchmark and scored accordingly. This method allows for a relative comparison between the different control methods based on the features and their respective importance. Though the results were predictable, the process of creating the decision matrix helped quantify microprocessor knee features and methods.

The individual components of the mechanical design were chosen based on capability and reviews of their respective literature. Other than the decision matrix, no formal engineering methods were utilized. The project was driven by specific specifications, described in next section,

to determine individual component needs. To this end, the engineering design process was heavily utilized throughout the decision making process: component needs were analyzed, researched, resolved, and prototyped. After testing and evaluation, the prototype was redesigned as necessary. In section 3.1, the final selections for the prototype will be discussed.

2.2 Design Specifications

Based on the decision matrix shown above in 0 and the technical specifications demonstrated by the currently available products, the design specifications represent specific aims that the prototype should accomplish. The following features from 0 were considered outside of the scope of an initial prototype, but not disregarded for future product development: environmental, water resistant, and aesthetics. Table 2.4 lists the features and specific aims for a microprocessor prosthetic knee solution. Specifications were based on current M3 capabilities, such as the durability, and predicted minimum acceptable values.

Table 2.4: Design specifications by feature, ordered by decision matrix weight. Features excluded due to scope of initial prototype include: environmental, water resistant, and aesthetics.

Feature	Specification
Stability	Provide mechanism to arrest flexion.
Durability	Support patient of 80 kg.
Maintenance ease	Use retail parts available throughout world.
Cost	Cost less than $1000.
Variable cadence	Include mechanism for variable swing control.
Immediate support on first step of stairs	Must be able to detect step.
Supportive yield for sitting down	Include mechanism for variable knee resistance.
Knee locking	Must have immediate effect from stability mechanism.
Redesign amount	Redesign M3 minimally.
Degree of flexion	Minimum 90 degrees of flexion.
Weight	Weigh less than 2.27 kg (5 lb).

2.3 Experimental Data Collection

2.3.1 Objectives

Prosthetic knee stability was primary among both design criteria and patient need. The biomechanical polycentric nature of the LIMBS M3 knee provides excellent stability during stance (Gard, Childress, and Uellendahl 2008); however, as previously discussed, this type of design adds no benefit to gait stability or stumble prevention. The E-Knee prototype seeks to overcome such instability by updating the passive M3 knee into an active-control knee with the addition of a clamping mechanism and Arduino microprocessor. Experiments were designed to validate whether the E-Knee was capable of such stability by monitoring patient knee angles during gait. To minimize gait instability and hip work, knee prosthesis should biomechanically mimic the normal kinematics of the leg. Experimentally, this was determined by comparing GRF data to the healthy double peak and to the benchmark, C-Leg. Consequently, the two objectives of the testing were to validate the gait stability and determine similarity to intact leg biomechanics.

2.3.2 Testing Protocol

Subjects for the validation trial were found through local prosthetists in El Paso, Texas who identified active and experienced patients using microprocessor-controlled knees. Patients were not undergoing current medical problems, and were rated at an activity level of K3 or higher. Licensed prosthetists helped fit the patients for the different knees used in the trials before testing began. Trials were sanctioned by the Institutional Review Board (IRB) at the University of Texas at El Paso, and were conducted accordingly. For comparison purposes, patients performed the trials with three different prosthetic knees: LIMBS M3, E-Knee prototype, and the Ottobock C-Leg ®.

Patient Walking Experiment

Subjects were given a familiarization period with each prosthetic device, and asked to do the walking trials only when they felt comfortable with the knee. The trial consisted of walking, at a self-selected speed, across Bertec™ force plates while wearing body markers for a Northern

Digital™ Investigator® 3D motion-capture system. To minimize walking acceleration, patients made a complete step with each limb prior to the first step on the force plates. Before data collection began, the patients were allowed to practice landing their steps naturally on the force plates. At the beginning of the each knee trial, the patients stood still with each foot on one force plate for calibration. The motion capture data was examined in real time, and the patients were asked to repeat the walk until a total of five passes with continuous waveforms were collected (did not contain significant breaks in the motion capture data).

Microprocessor-Locking Experiment

While the patients had on the E-Knee, a physical block, henceforth referred to as "Angle Lock," was inserted between the back link and the bottom block (Figure 2.1). The Angle Lock prevented the four-bar mechanism from assuming a mechanically stable position, which allowed us to test the microprocessor's ability to lock the knee during a stimulated stumble. During stumble, the lower leg does not fully extend, therefore preventing a passive knee from becoming mechanically stable. To simulate stumble, the Angle Lock, seen in Figure 2.1, prevents knee extension; at a measured 10 degrees, which exceeds the point of mechanical instability for the system. The 10 degree extension block was chosen because it considerably exceeds the 6 degree angle of instability, as demonstrated in the background. Realistically, microprocessor response time and physical flexibility of the M3 components allow for a slightly greater angle. Patients were asked to stand one stride length away from the force plates and then take one step, leading with the prosthetic. Once again, this was done until at least five passes were complete without breaks in the motion capture data.

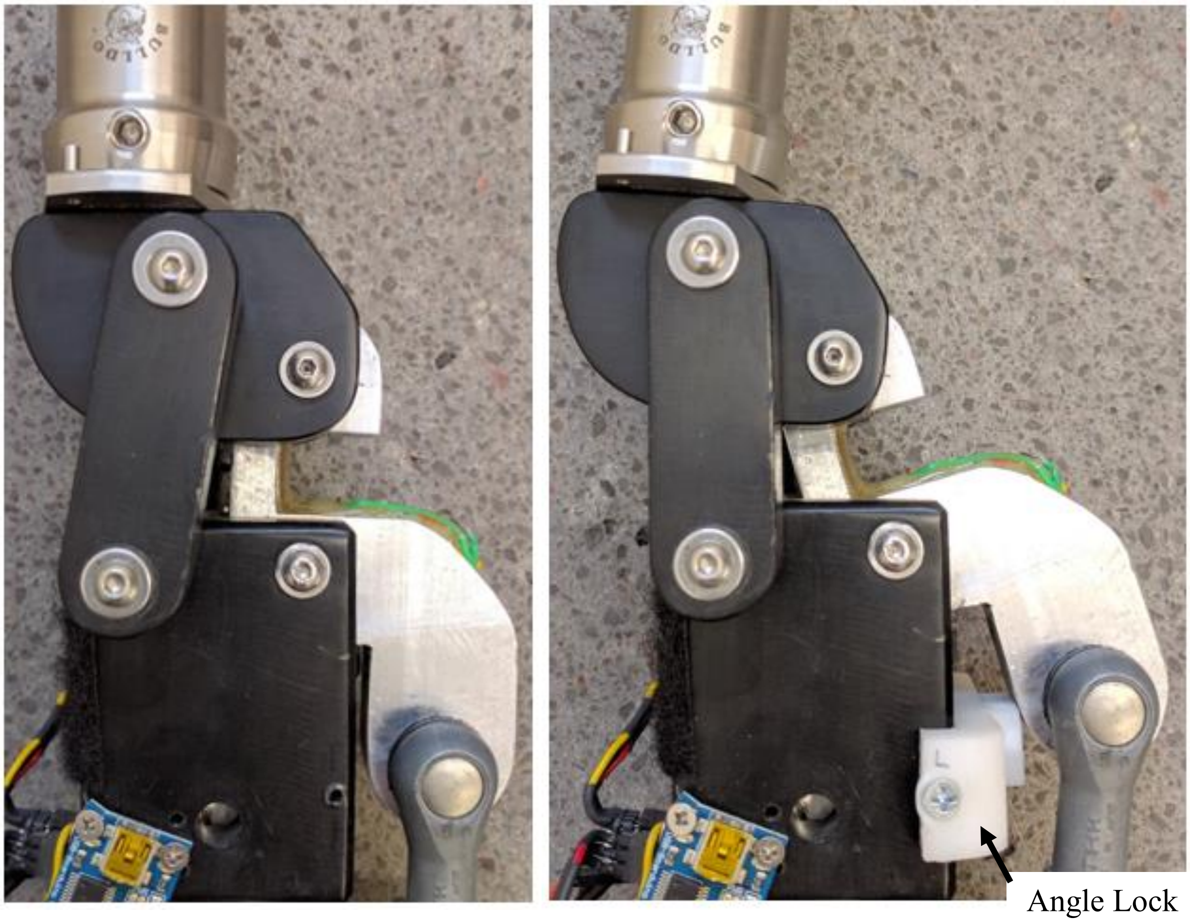

Figure 2.1: E-Knee fully extended (left) and E-Knee extended, 10 deg, with Angle Lock in place (right).

2.3.3 Data Collection

The software, NDI First Principles (Northern Digital Inc.), was used to collect data from Bertec™ Force Plates and an Investigator 3D Motion Capture system. The force plate data was collected at a rate of 2000 Hz. The patients had enough room to complete a full stride before and after the force plates so that the captured gait was neither the beginning nor the end of the movement. The force plates captured the GRFs, which are used to ascertain the kinetic symmetry between legs (Silverman et al. 2008). During each pass, the patient stepped on two force plates, which allowed for GRFs to be collected for both the prosthetic and the intact leg. Although the force plates collect force and moment data in all three dimensions, the vertical and fore/aft GRFs were deemed sufficient for adequate analysis. X directional force data is generally less than 5% of

body weight and inconsistent even within the same subject samples (Giakas and Baltzopoulos 1997).

Table 2.2 below shows the experimental force plate setup and the visualization software used to analyze the GRFs in real time for each pass. The patient walked across the force places from the left of the screen moving towards the right.

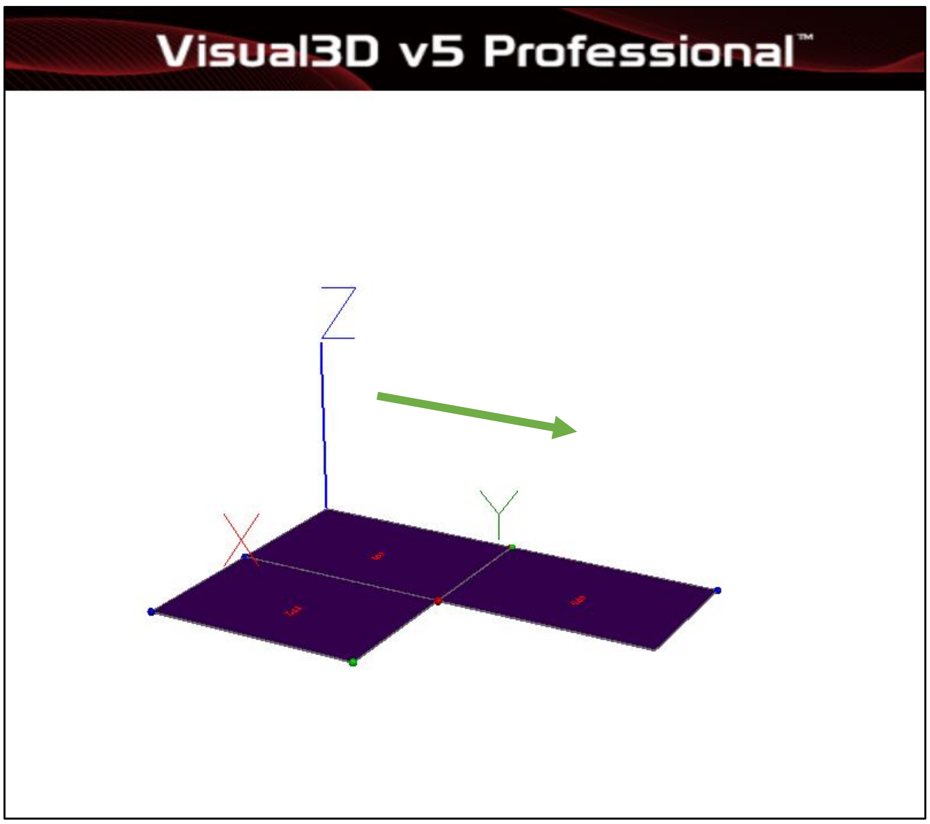

Figure 2.2: Force plate setup in the gait lab. Z is vertical, Y horizontal to the patient, and X is lateral. Green arrow shows walking direction (Y axis). Screen shot of Visual3D (C-Motion Inc.)

The Investigator 3D motion capture data was collected at 100 Hz. As seen in Figure 2.4 and Figure 2.3, clusters of three markers were placed on each leg of the patient in order to collect kinetic data. The marker distribution is based on a modified Helen Hayes configuration – each relevant body segment was represented by at least one three-marker set. Marker sets were oriented for maximum camera exposure. The left side of each diagram in Figure 2.3 shows the location of

the digitized markers, which are mathematically calculated based on the position of the physical clusters of three on the corresponding limb section. The clusters of three on the right side of Figure 2.3 show the location of the physical markers for each limb (but excludes the digitized markers for that side for simplicity). Since the digitized markers depend on the mathematical distance from the physical markers, if any of the three physical markers was obscured by clothing or wire, the digital marker disappeared as well. This was the cause of repeat trials to secure continuous tracking data. While trials were repeated, the ratio of discontinuous to continuous trial occurrence was approximately 1:1. Additionally, patients were given frequent rests, even before they gave any indication of fatigue.

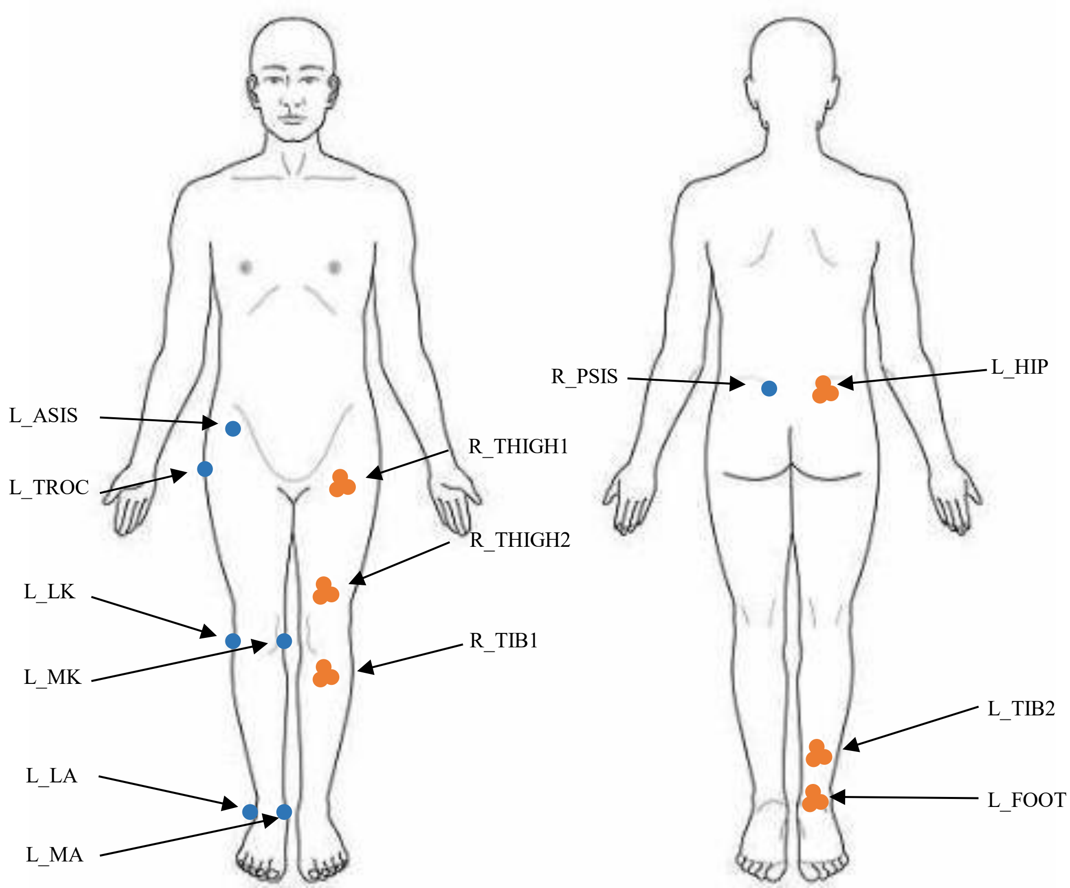

Figure 2.3: 3D marker placements. The picture left side of each figure shows single point digitized markers (blue). The right side shows physical cluster of three markers (orange). Photo modified from “http://humananatomy.co/human-body-anatomical-position/”

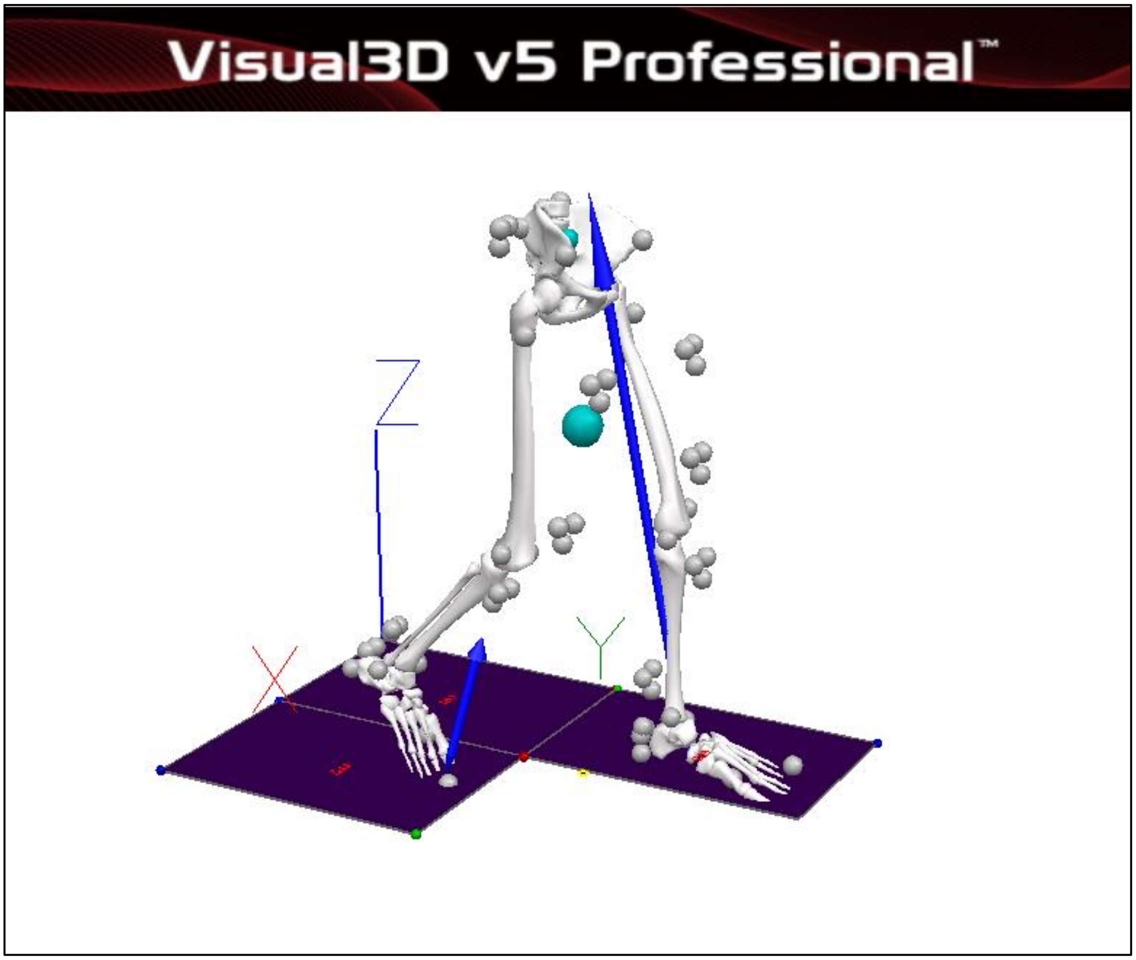

Figure 2.4: Example of collect patient data. Blue arrows represent the GRFs, and the white dots are the virtual marker points for the Investigator 3D motion capture system. Screenshot of Visual3D (C-Motion Inc.).

2.3.4 Data Processing

Ground Reaction Force Data

Data from the Bertec™ Force Plates was outputted in terms of voltage per frame reference. Voltage was scaled according to the individual force plate calibration matrices to output force data in Newtons. The resulting forces were analyzed and the individual GRFs on each force plate were isolated. To average the data from the five trials, the GRFs from each plate were resampled, and the average and standard deviation of each trial per limb was calculated. To preserve the integrity of the data, the resampled points were evenly distributed and matched the curve of the surrounding

data. Additionally, the fore and aft forces were integrated to determine breaking and acceleration forces, respectively. Isolation and calculations were done manually and with formulas in Microsoft Excel.

Kinetic Knee Angle Data

Visual 3D (C-Motion Inc.) was used to analyze the motion capture data. Using two markers on each the thigh and the leg, simulated lines representing the thigh and lower leg were digitally created. The sagittal plane angle between the two simulated lines in the sagittal plane was then equal to the knee angle. This calculation was applied for the E-knee walking trials and microprocessor-lock test. For each of the five trials within the E-knee tests, the first peak value for vertical GRF was manually selected and exported with the corresponding knee angle at the same time point. The five trials for each test were then averaged. Thus, the resulting data is the average prosthetic knee angles at the maximum heel strike forces for the E-Knee walking tests and microprocessor-locking test.

2.3.5 Patient Follow-up

Patients were asked to complete the first thirteen questions of the Amputee Mobility Predictor (AMP), found in the Appendix I, following the knee trial, to establish relative mobility amongst the knees. The AMP is a reliable indication of mobility (R. S. Gailey et al. 2002; Wurdeman et al. 2014), and the first thirteen questions focused on mobility facets not addressed during the experiments, such as standing up from a chair or picking up an object off the ground. This adaptation of the AMP resulted in a comparative mobility between subjects and knees, but not a full indication of mobility.

Subjects were also given a questionnaire, adapted from Appendix II: LEGS Functional Parameters Questionnaire, to measure satisfaction with each knee (list of questions shown in Table 2.5). The patients had an understanding of the terminology of the questionnaire, but any questions they had were answered. Patients recorded their responses by making a tick mark along a line (seen in Figure 2.5) that ranged between two options (shown in parentheses in Table 2.5). The closer the

tick was to a given option, the stronger the patient agreed with that remark. The responses were quantified as percentages of the whole line length by measuring the distance from the left starting point to the tick mark, and then dividing by the total line length.

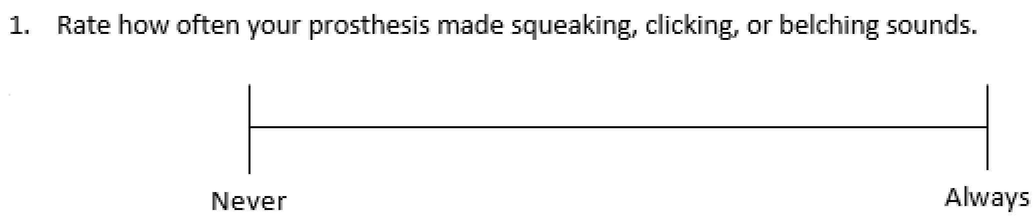

Figure 2.5: Question 1 of the patient questionnaire. Subjects placed vertical mark on the line to indicate their answer.

Table 2.5: Prosthetic knee questionnaire. Patient responses were marked along a line, given with the options shown in parentheses at each end, which indicated how they felt about the prosthesis.

1. Rate how often your prosthesis made squeaking, clicking, or belching sounds. (never/always)
2. Rate how heavy your prosthesis feels to you. (very light/very heavy)
3. Rate your overall discomfort while walking. (very comfortable/very uncomfortable)
4. Rate how much effort it takes to walk. (little effort/much effort)
5. Rate how difficult it was for you during the heel strike phase of your walk. (very easy/very difficult)
6. Rate how difficult it was for you during the stance phase of your walk. (very easy/very difficult)
7. Rate how difficult it was for you during the toe off phase of your walk. (very easy/very difficult)
8. Rate how difficult it was for you during the swing through phase of your walk. (very easy/very difficult)
9. Rate any pain you feel while walking. (no pain/very painful)
10. Rate how stable you felt using your prosthesis when standing. (very stable/unstable)
11. Rate how stable you feel when walking. (very stable/unstable)
12. Rate how much energy it took to walk for as long as you needed to. (little energy/much energy)
13. Rate how normal you feel you look while walking with this prosthesis. (very normal/very abnormal)
14. Rate how often you feel that you might fall with this knee. (very rarely/very often)
15. Rate how difficult it is to sit down and stand up. (very easy/very difficult)
16. Rate how satisfied you are with how you are walking with this prosthesis. (very satisfied/unsatisfied)

Chapter 3: Results

3.1 E-Knee Prototype

3.1.1 Mechanical Design

The final prototype's physical components were: LIMBS M3 knee with a modified back link, power supply, magnetic sensor, Arduino, variable damper, and clamping mechanism. Figure 3.1 shows the fully assembled prototype. Because the design was a prototype, components were fully functional, but not aesthetically designed or spatially optimized. Each component was chosen based on availability, function, and cost. Table 3.1 shows the established design specifications along with the component that satisfied each requirement. Following the format of the technical specifications of the current commercial knees, Table 3.2 compares the E-Knee prototype with its benchmark, the Ottobock C-Leg.

Figure 3.1: Fully assembled prototype. Knee is flexed and Niagara foot is attached. Photo curtesy of Aaron Nystrom.

Table 3.1: Fulfillment of design specifications.

Specification	E-Knee Component
Provide mechanism to arrest flexion	Clamping Mechanism
Support patient of 80 kg	Walking test of 112.5 kg
Use retail parts available throughout world	No custom components
Cost less than $1000	Retail component cost of $507.23
Include mechanism for variable swing control	Variable Damper
Must be able to detect step	Hall Effect Sensor for angle. Microprocessor extrapolates step conditions
Include mechanism for variable knee resistance	Variable Damper
Must have immediate effect from stability mechanism	20 ms microprocessor response resolution
Redesign M3 minimally	Only back link redesigned
Minimum 90 degrees of flexion	90 degrees of flexion
Weigh less than 2.27 kg (5 lb)	1.97 kg (4.34 lb)

Table 3.2: Comparative design specifications. E-Knee versus benchmark, C-Leg 4.

	C-Leg 4	E-Knee
Knee Weight (kg)	1.24	1.97
Max Patient Weight (kg)	136	100
Knee Flexion (Deg)	130	90
Build Height (cm)	28	34.3
Battery Capacity (hr)	40-45	~2.5
Microprocessor Response (ms)	100	20
Activity Level (K)	K3-K4	N/A
Mechanical Shape	Single Axis	Four-Bar
Environmental Protection	Weatherproof	N/A
Price ($)	$21,538	$507.23

LIMBS M3 and Back Link

Based on the design criteria and simplicity, the LIMBS M3 knee was chosen to be the foundation of the system. As previously discussed, its four-bar mechanism provided stance stability and toe clearance. The original M3 back link was modified to provide a linkage between the M3 and any type of swing control, such as a hydraulic piston (Figure 3.2). Due to the distinctive mechanical and rotary properties of a four-bar mechanism, the joint with the most knee rotation control was the rear bottom axle. Therefore, the back link was extended to add control of rotation

about that axis. Due to the nature of the damper interaction with the modified bank link, the further the link was extended, the more effective the damper was. However, the further the back link extended, the more it interfered with knee flexion. A balance was struck between damper effectiveness and knee flexion interference.

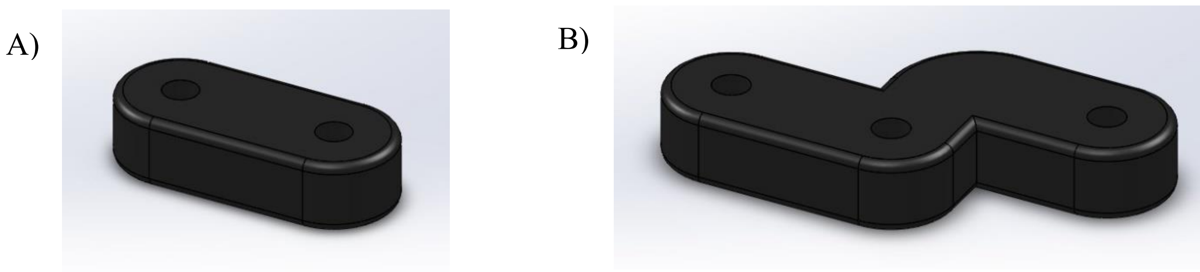

Figure 3.2: A) Original M3 back link. B) Modified back link.

Power Supply

Eight AA batteries powered the prototype. The batteries supplied approximately 12V, which was the maximum voltage the variable damper could safely utilize. The 12V power line supplied the variable damper and a 5V voltage regulator. The regulator supplied the required voltages for the clamping mechanism, magnetic sensor, and Arduino. The AA batteries were chosen for their longevity under the load conditions, but other batteries would have been considered if a shorter usage and charging cycle were needed.

Sensing

To be detect knee angle, the prototype measured the relative distance between the extension of the back link and the bottom block with a linear Hall Effect sensor which was affected by the magnetic field of a small magnet mounted in the back link extension (shown in Figure 3.3). The Hall Effect sensor outputted a voltage between 0 and 5 volts to indicate the nearness of the magnet. Since the output followed a logarithmic formula, the voltage was correlated to the angle of the knee. This correlation can be represented by the following formula:

$$Angle = 1.609 * e^{(0.4897 * Voltage_{Hall})} + 1.77E - 13 * e^{(13.15 * Voltage_{Hall})}$$

The equation was found by experimentally collecting knee angle data with a goniometer, and comparing it to the corresponding voltage of the Hall Effect sensor. A Matlab (MathWorks Inc.) function was used to determine the logarithmic formula that best matched angle to voltage. This formula was applied continuously as the Arduino registered the input voltage from the Hall Effect sensor, expected deviation was less than 2 degrees. Some additional conversion factors were added in the programming to account for the Arduino's bit consideration of analog inputs.

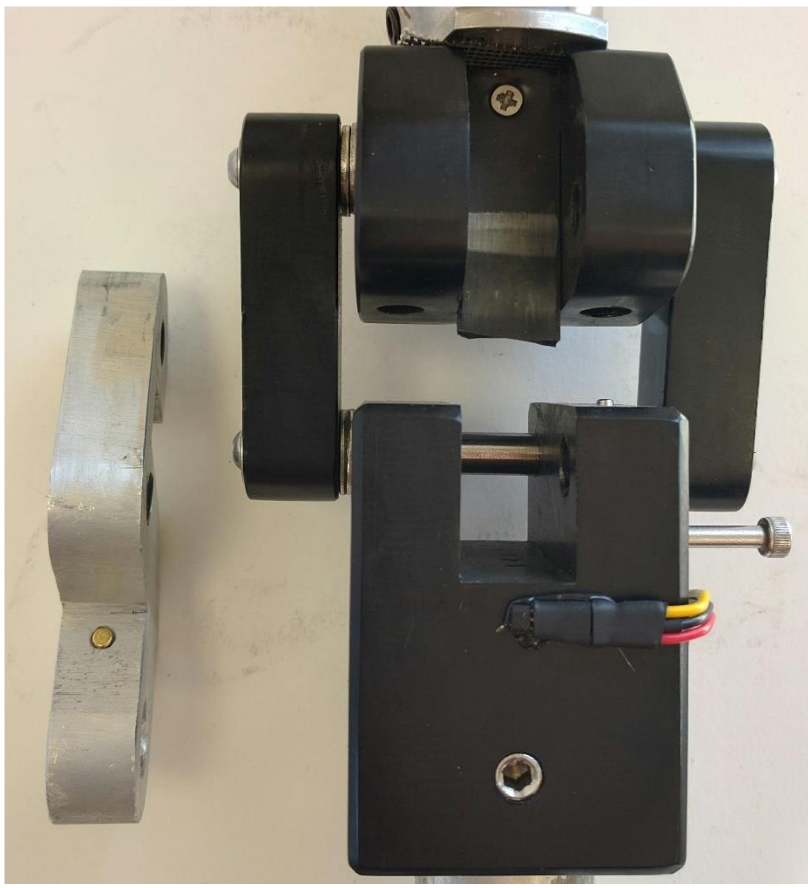

Figure 3.3: M3 knee with modified back link and magnetic sensor. The back link contains a small magnet which aligns to be in close proximity to the sensor when assembled.

Processing System

The computational center of the prototype was the Boarduino v2.0 by Adafruit, which is a prototyping Arduino that utilizes the commonly implemented ATmega328P microprocessor chip. The board's miniUSB jack interface allowed for rapid programming reconfiguration. The microprocessor's capabilities far exceeded the requirements of the prototype; of the twenty inputs and outputs only three were used. Based on the magnet sensor feedback as the only input, the Arduino calculated the appropriate action for its two outputs (the variable damper and clamping mechanism).

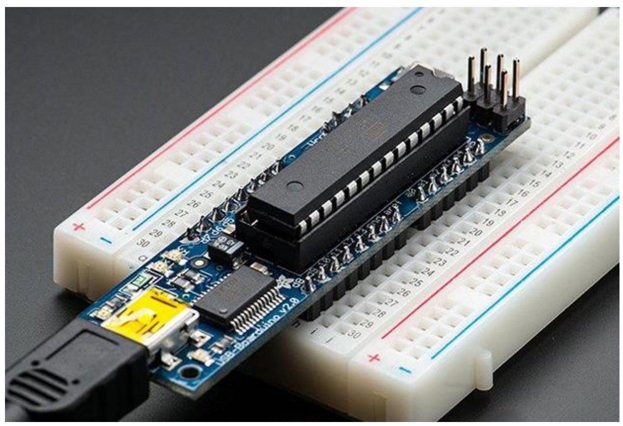

Figure 3.4: Arduino processing system. Adafruit Boarduino v2.0. Stock photo https://www.adafruit.com/products/91.

Variable Damper

The hydraulic dampening system came from a Suzuki 2011 GSX-R750. It was originally manufactured to be a motorcycle steering stabilizer, but here was used as a knee swing controller. Inside the damper, hydraulic fluid moves through two chambers as the piston rod moves back and forth. With electric current, a solenoid can apply a flow restricting pin to the orifice connecting the two chambers. The solenoid applied force depending on the current and voltage supplied. Through a TIP120 transistor, the Arduino was able to regulate the amount of voltage supplied to the damper, thus regulating the damping force. It should be noted that while the solenoid pin can restrict the hydraulic fluid flow, it cannot arrest it. Also note that the damper, while providing vital functionality for variable cadence in future designs, received no electrical input in the present

prototype. Mainly, the damper functioned as a passive system leg swing resistance and provided the binding surface for the clamping mechanism. The variable cadence functionality exists, yet was disabled due to lack of calibration data. With the collection of experimental data from this study, the calibration will be a part of future work.

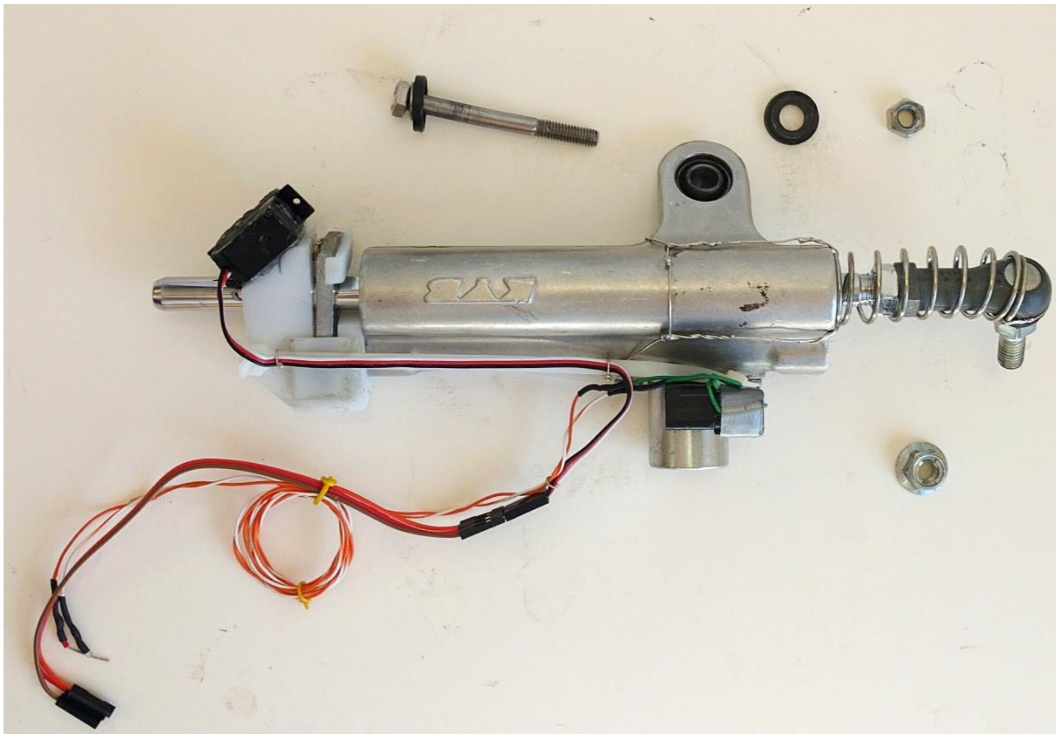

Figure 3.5: Suzuki GSX-R750 electronic, hydraulic variable damper. Clamping mechanism is attached to rod at left end of body.

Clamping Mechanism

The greatest limitation of the damping system was that the damping device could not stop the knee from flexing – it only slowed down the process. In order to prevent stumbling and collapse, the prototype system must be able to halt flexion. Therefore, a mechanical clamp was developed. Through a basic moment arm binding action, the movement of the damper rod was stopped in one direction by a small plate of steel applied at an angle (Figure 3.6). Electronic control of a small solenoid allowed the binding to be engaged or disengaged. When the plate, and therefore the edges of the hole the rod traveled through, was flat, no binding occurred. Whenever the

solenoid was not pushing, a small spring ensured that the plate resorted to being angled, and thus bound with the rod. Therefore, when the solenoid was not powered, the clamping mechanism was engaged.

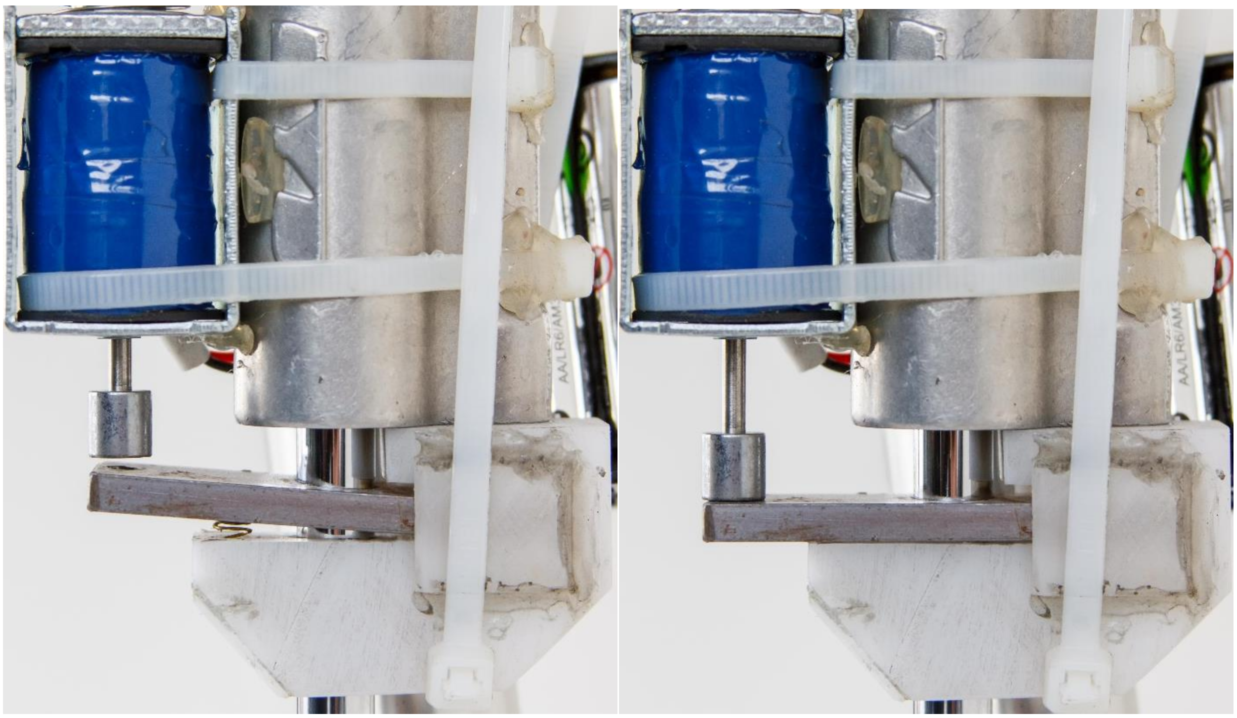

Figure 3.6: The left shows the clamping mechanism engaged – solenoid has resumed original position and allows spring to bring plate and rod into binding position. The right shows the clamping mechanism disengaged – solenoid pushes downward, unbinding plate and rod, allowing knee flexion. Photos curtesy of Aaron Nystrom.

3.1.2 Software Design

The programming code (Appendix III: Prototype Program Code) was written in the Arduino program, which uses a variant of C++. At its core, the designed code had three cases, "Weight Off," "Weight On," and "Swing," which distinguished the parts of the patient's gait cycle. Each case had programmed inputs that cued it to switch cases.

Case 1: Weight Off

As the name indicates, the Weight Off case came into play when the patient was not relying on the knee for support. During this phase, the clamping mechanism was disengaged and the leg

could swing freely. Using the formula provided in the above "Sensing" section, the knee angle was constantly calculated at a temporal resolution of 20 milliseconds. If the patient extended the knee to the point of four-bar mechanical stability, the case switched to Swing. However, if the knee was not extended to mechanical stability, and began to flex, the locking mechanism engaged and the case was switched to "Weight On". This was the programming prediction for a stumble.

Case 2: Weight On

The Arduino switched to Case 2, Weight On, when flexion of the knee indicated a stumble. Therefore, the locking mechanism was engaged until the knee extended again, indicating that the patient had recovered. As an additional precaution, the variable damper was set to maximum resistance. The program automatically recorded the length of the gait while the knee was in this case. Extension of the knee switched the case to "Swing."

Case 3: Swing

The Swing case ensured that the knee swung freely during the flexion phase of gait. Once the knee began to extend again the case reverted back to Case 1, "Weight Off."

3.2 Cost Breakdown

One of the primary design criteria for this research was for the E-Knee to cost less than $1,000 to produce (Table 2.4). LIMBS International provided the foundation of the knee, the LIMBS M3, which has a production cost of $20. The back link and miscellaneous modifications were purchased from McMaster-Carr and machined to size. The Arduino was purchased from Adafruit for $28. The magnetic sensor, solenoid electromagnet, and batteries were purchased from Amazon. The miscellaneous electronics were purchased from Mouser and Digikey. The hydraulic cylinder was a Suzuki GSXR 750 electronic steering stabilizer. Though it was purchased used from eBay for $55, its retail value was $420. Though the Suzuki model has become relatively obsolete, a replica is being used in a different motorcycle and is called the Yamaha R1 electronic steering stabilizer. Because the current prosthetic is still in a prototype phase, the total labor to

manufacture the knee was approximated to be 8 hours. Overall, the total cost of materials was $507.23 with the itemized bill of materials shown in Table 3.3 and percent of total cost given by component type shown in Figure 3.7 below.

Table 3.3: A Bill of Materials for the E-Knee Prototype. Listed prices are retail prices.

Item	Quantity	Price	Total Cost
LIMBS M3 Knee	1	$20.00	$20.00
Back Link	1	$1.67	$1.67
Hydraulic Damper	1	$420.00	$420.00
Misc. Modifications	1	$13.18	$13.18
Arduino	1	$28.00	$28.00
Magnetic Sensor	1	$2.16	$2.16
Batteries	8	$0.28	$2.25
Solenoid Electromagnet	1	$9.97	$9.97
Misc. Electronics	1	$10.00	$10.00
		Total Materials	**$507.23**

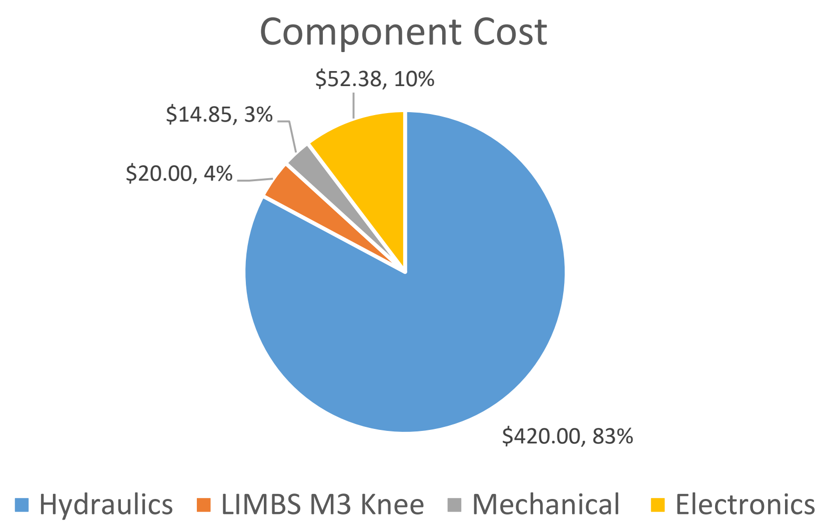

Figure 3.7: Percent of total cost for knee prototype categorized by component type.

3.3 Experimental Results

For each patient, three different prosthetic knees were tested: M3, E-Knee, and C-Leg. Congruently, data was collected for the healthy leg as well. In the following charts and figures,

data will be referred to as "prosthetic" and "intact," prosthetic side and healthy side, respectively. The tests took place in the afternoon for both patients.

3.3.1 Quantitative Data - Subject 1

The following two sets of three graphs show the GRFs of Subject 1 (Figure 3.9 and Figure 3.10). Each trend line represents the average of 5 trials. The shaded grey area around each line is the standard deviation. Vertical forces are represented by the green line, and fore and aft are represented by the blue line. The GRF is represented by percentage of BW. Each graph shows the entirety of time that a foot was on a force plate, thus the independent variable is represented by stance percentage. At the end of each set of three graphs, a fourth summary graph is given (graph D in Figure 3.9 and Figure 3.10). Figure 3.11 then summarizes all six sets, showing both prosthetic and intact vertical GFRs and their overlap during a step.

Subject 1 was a 62-year-old, unilateral transfemoral (left) amputee. The subject was male, weighed 91.2 kg, had an activity level of K3, though he was K4 within the last two years, and was very active. Subject 1's current prosthesis was a C-Leg 3 and he was healthy with no medical conditions. Subject completed IRB informed consent according to the regulations of University of Texas at El Paso (UTEP). Figure 3.8 shows the subject during walking trials on the E-Knee. The prosthetic limb average E-Knee graph, Figure 3.9: B, was out of 4 trails because one trial was an outlier. The latter half of the outlier trial matched the typical gait pattern exhibited by the other trials and the established pattern found in Figure 1.7. While the first half matched the appropriate peaks, it appeared to be skewed temporally. Because this indicated rapid acceleration or breaking, one trial of Figure 3.9: B, average E-Knee GRFs, was discarded. It should be noted that the C-Leg specifications given previously pertain to the C-Leg 4, which is what Subject 2 uses. Subject 1 uses the C-Leg 3, but according to its specifications there are no discernable differences for walking between the C-Leg 3 and the C-Leg 4.

Figure 3.8: Subject 1 during walking trial on E-Knee. Posterior (left) and sagittal (right) views.

Prosthetic

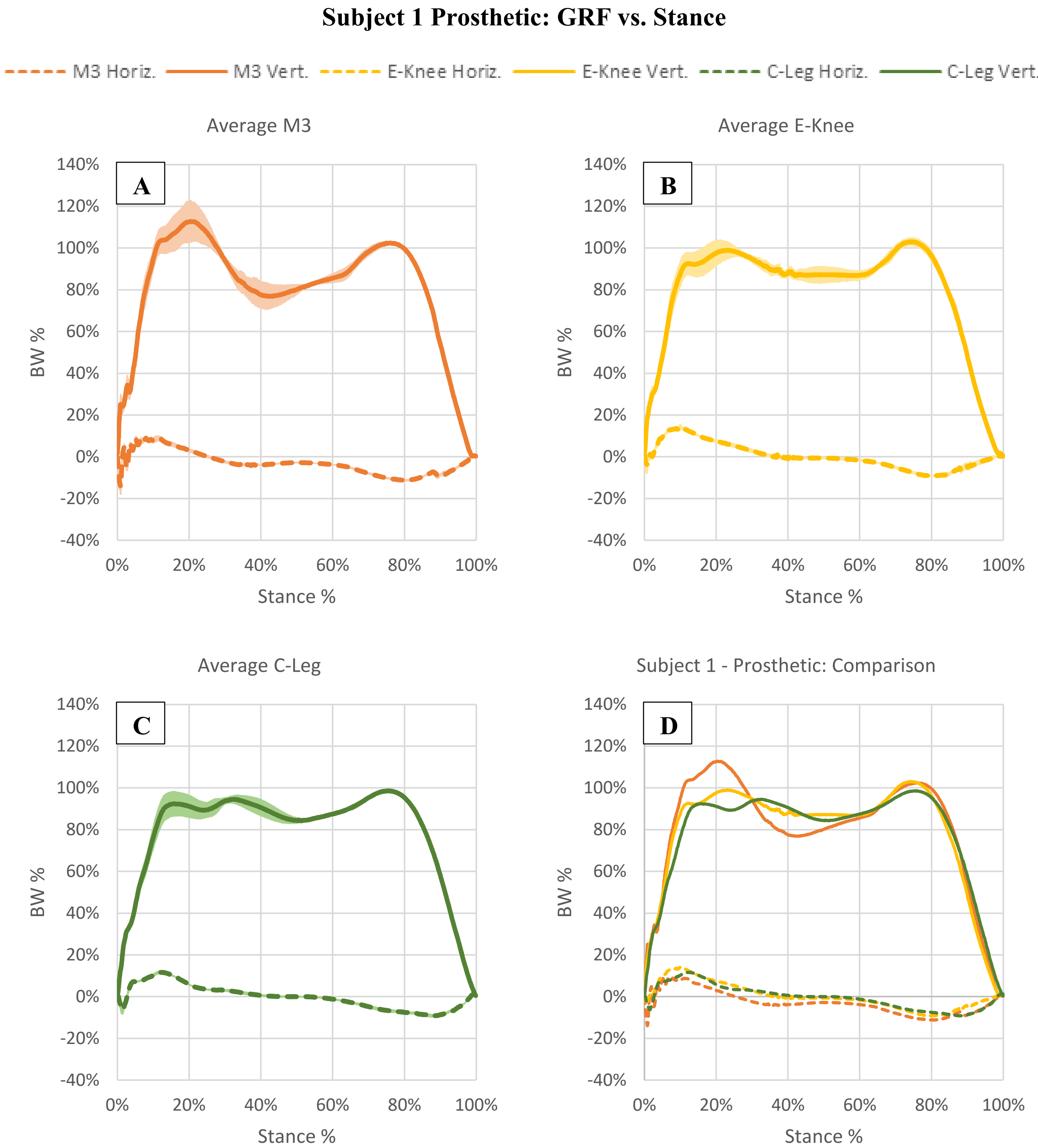

Figure 3.9: Ground reaction forces in the vertical (vert.) and horizontal (horiz., fore/aft) directions (dashed and solid lines), represented as percent of body weight (BW) versus percent of stance for Subject 1's prosthetic limb – averaged over five trials. A) M3, B) E-Knee, C) C-Leg, and D) Prosthetic: Comparison. The shaded regions are the standard deviation. B is out of four trials.

Intact

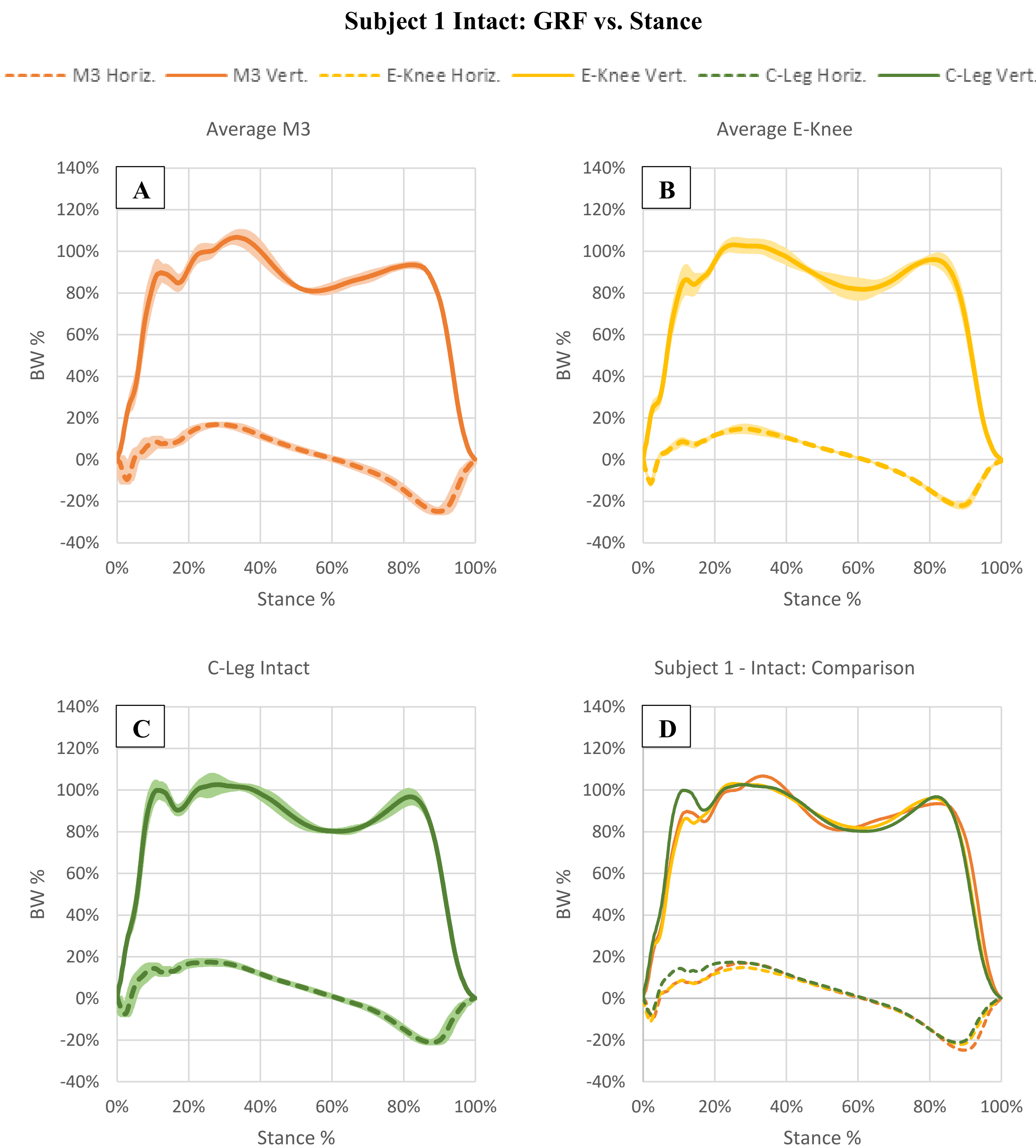

Figure 3.10: Ground reaction forces in the vertical (vert.) and horizontal (horiz., fore/aft) directions (dashed and solid lines), represented as percent of body weight (BW) versus percent of stance for Subject 1's intact limb – averaged over five trials. A) M3, B) E-Knee, C) C-Leg, and D) Intact: Comparison. The shaded regions are the standard deviation.

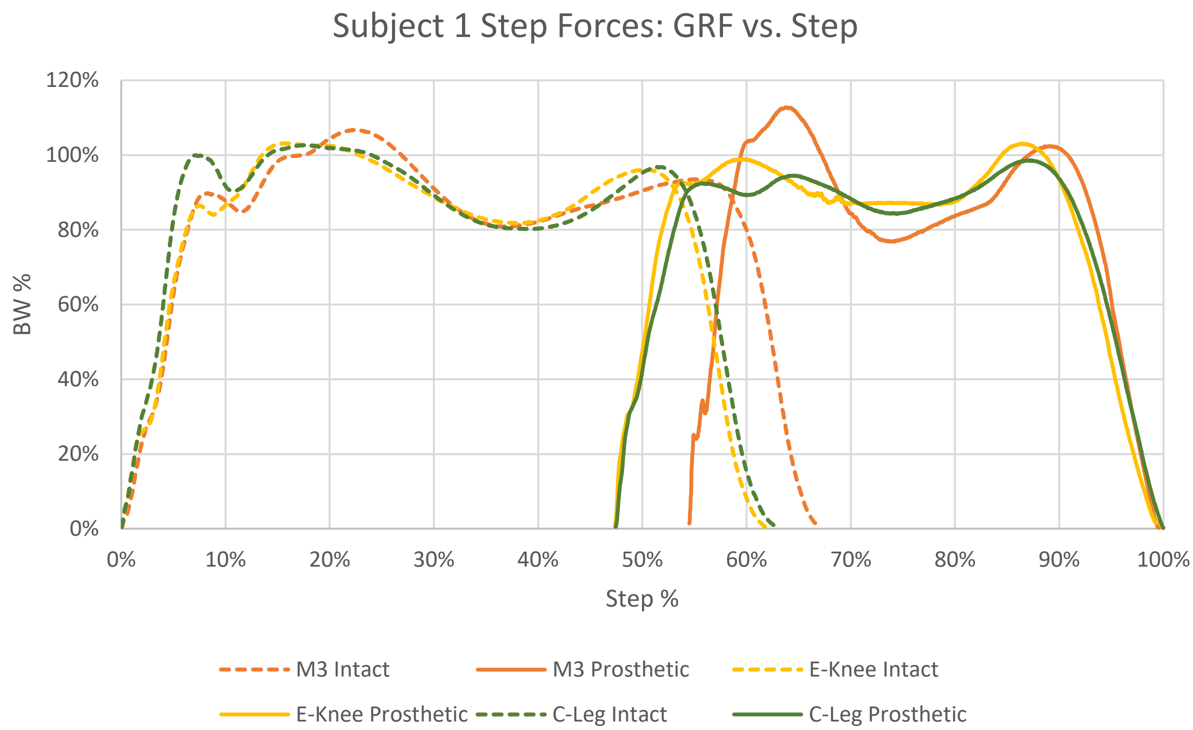

Figure 3.11: Subject 1 overview of vertical GRFs for each prosthetic trial shown in two parts: the intact first stance (dashed), and the prosthetic second stance (solid). Given in body weight percentage (BW %) over one step (time from intact heel strike to prosthetic toe off).

3.3.2 Quantitative Data - Subject 2

The following two sets of three graphs show the GRFs of Subject 2 (Figure 3.13 and Figure 3.14). Each trend line represents the average of 5 trials. The shaded grey area around each line is the standard deviation. Vertical forces are represented by the green line, and fore and aft are represented by the blue line. The GRF is represented by percentage of BW. Each graph shows the entirety of time that a foot was on a force plate, thus the independent variable is represented by stance percentage. At the end of each set of three graphs, a fourth summary graph is given (graph D in Figure 3.13 and Figure 3.14). Figure 3.15 then summarizes all six sets, showing both prosthetic and intact vertical GFRs and their overlap during a step.

Subject 2 was a 70-year-old, unilateral transfemoral (left) amputee. Subject was male and weighed 112.5 kg. Subject had an activity level of K3 and was a capable walker. Subject 2's current

prosthesis was a C-Leg 4 and he was healthy. The subject completed IRB informed consent according to the regulations of UTEP. Figure 3.12 shows the subject during walking trials for the M3, E-Knee, and C-Leg. The prosthetic limb average M3 graph, Figure 3.13: A, was out of 4 trails because one trial was an outlier. For the most part, the outlier trial matched the typical gait pattern exhibited by the other trials and the established pattern found in Figure 1.7. The latter half contained a gait irregularity. There appeared a sharp increase in force during the decreasing toe-off force, causing the gait pattern to be elongated and thus skewing the scaling factors applied to the graphs. The most likely cause was a lack of full extension, not beyond the mechanical stability, but enough that when the moment forces of the toe off occurred, the knee slipped into full extension. It was noted that this occurred to Subject 2 several times during the M3 and E-Knee trials. Therefore, one trial of average prosthetic M3 GRFs, Figure 3.13: A, was discarded.

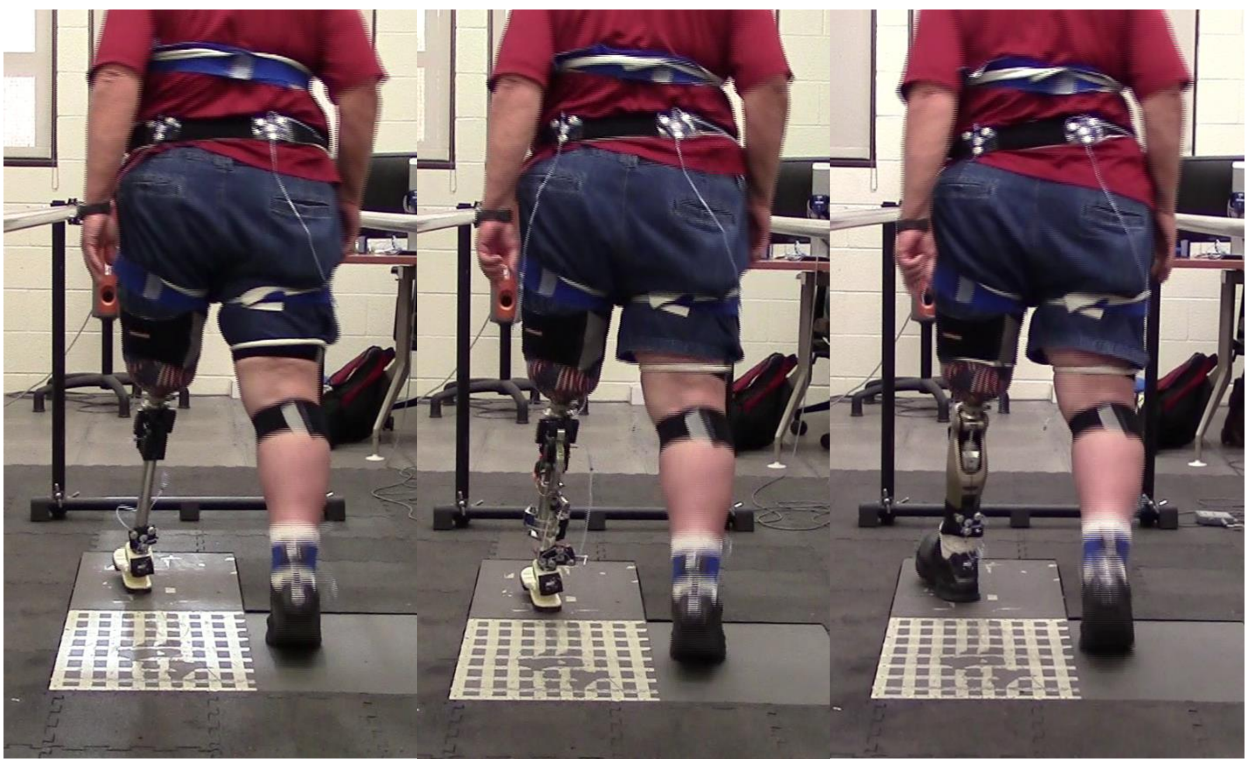

Figure 3.12: Subject 2 during walking trials on M3 (left), E-Knee (middle), and C-Leg (right).

Prosthetic

Figure 3.13: Ground reaction forces in the vertical (vert.) and horizontal (horiz., fore/aft) directions (dashed and solid lines), represented as percent of body weight (BW) versus percent of stance for Subject 2's prosthetic limb – averaged over five trials. A) M3, B) E-Knee, C) C-Leg, and D) Prosthetic: Comparison. The shaded regions are the standard deviation. A is out of four trials.

Intact

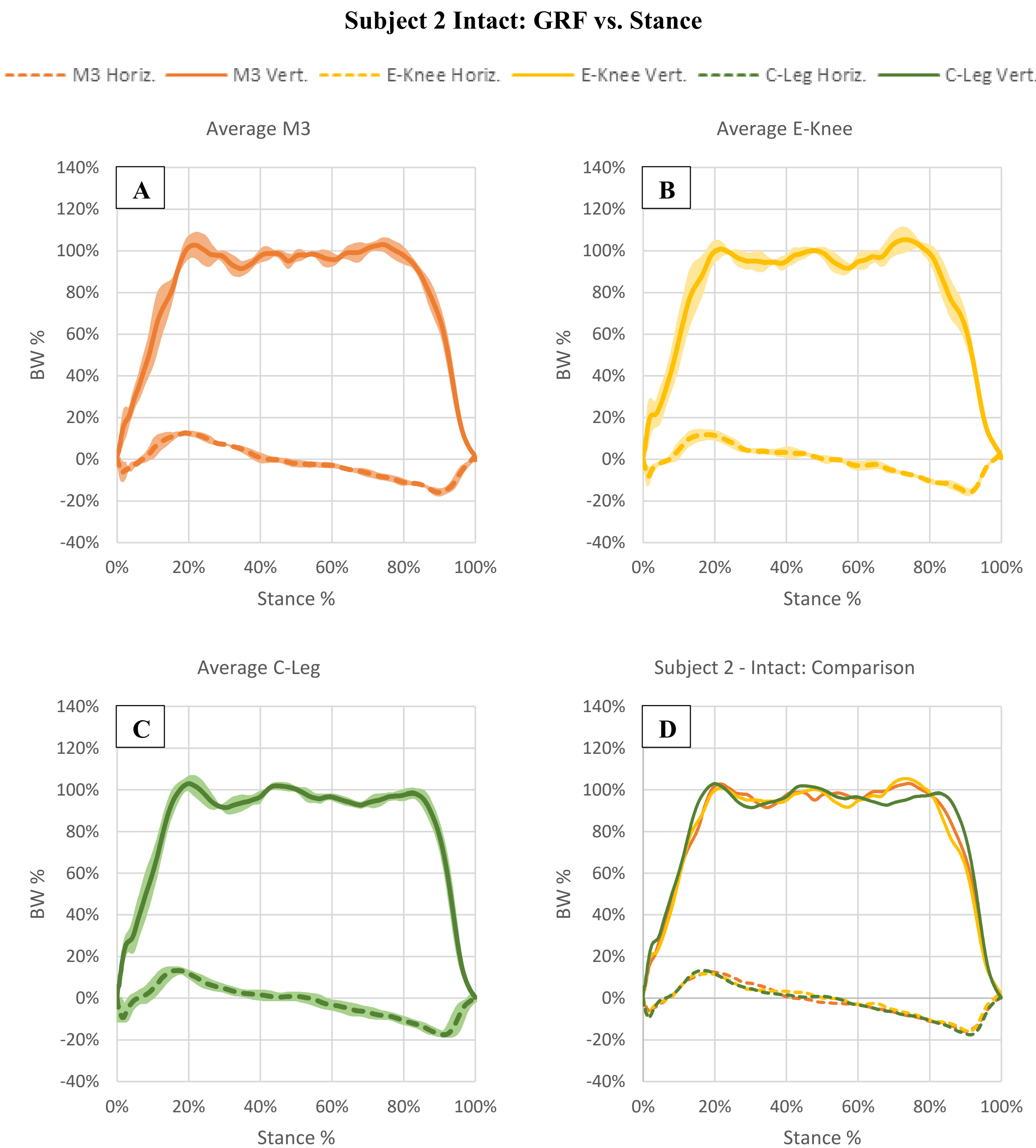

Figure 3.14: Ground reaction forces in the vertical (vert.) and horizontal (horiz., fore/aft) directions (dashed and solid lines), represented as percent of body weight (BW) versus percent of stance for Subject 2's intact limb – averaged over five trials. A) M3, B) E-Knee, C) C-Leg, and D) Intact: Comparison. The shaded regions are the standard deviation.

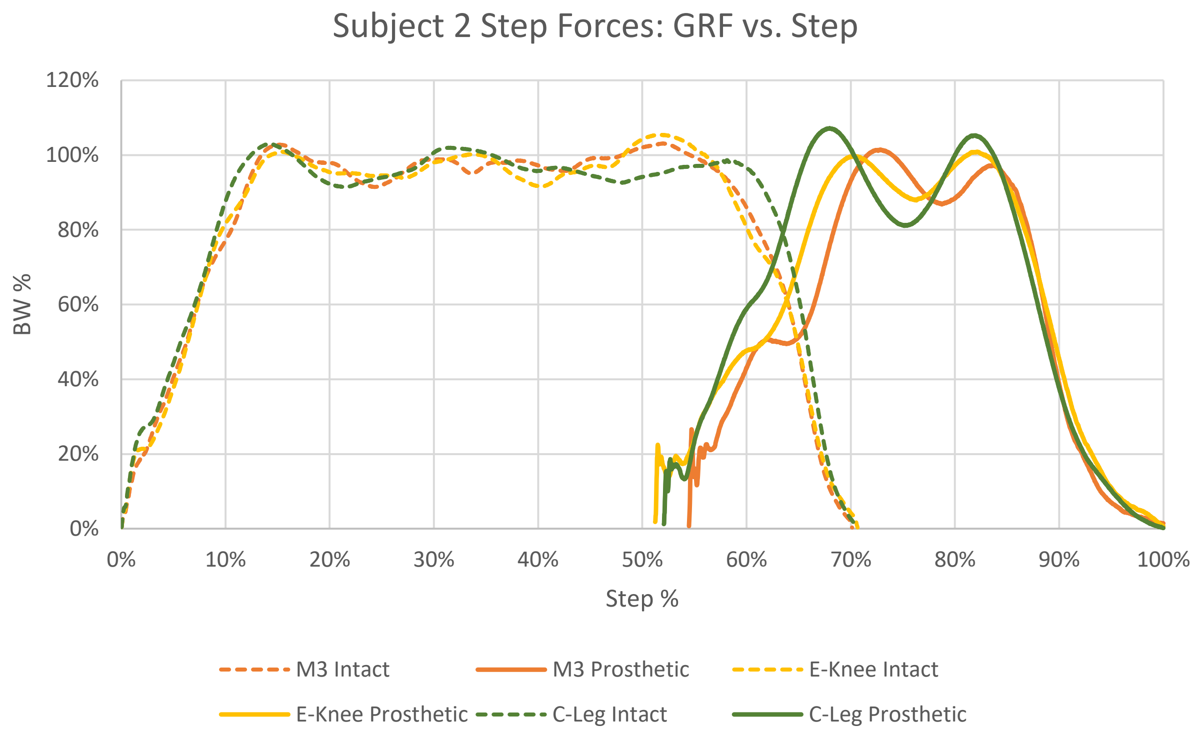

Figure 3.15: Subject 2 overview of vertical GRFs for each prosthetic trial shown in two parts: the intact first stance (dashed), and the prosthetic second stance (solid). Given in body weight percentage (BW %) over one step (time from intact heel strike to prosthetic toe off).

To compare the average deviation in the GRFs in the vertical and fore/aft directions for all three prosthetics, the absolute value of the differences between each set of averaged GRF curves was taken for each patient (Table 3.4). As seen in the table, the E-Knee consistently deviated less from the C-Leg than from the M3 during breaking and propulsion. Subject 2's intact vertical force is the only instance where the M3 was more similar to the C-Leg than the E-Knee was to the C-Leg. Breaking and propulsion forces unfailingly deviated less than their vertical counterparts.

Table 3.4: Comparison of the average deviation the GRF graphs have from each other. M3 vs. E-Knee vs. C-Leg. Vertical force is compared to fore/aft force.

Intact Fore/Aft	**Deviation Comparison (BW %)**			**Prosthetic Fore/Aft**	**Deviation Comparison (BW %)**		
		E-Knee	**C-Leg**			**E-Knee**	**C-Leg**
Subject 1	**M3**	1.15%	1.99%	Subject 1	**M3**	3.25%	2.97%
	E-Knee		1.85%		**E-Knee**		1.40%
Subject 2	**M3**	1.37%	1.21%	Subject 2	**M3**	1.12%	1.63%
	E-Knee		1.12%		**E-Knee**		1.45%
Intact Vertical				**Prosthetic Vertical**			
		E-Knee	**C-Leg**			**E-Knee**	**C-Leg**
Subject 1	**M3**	3.20%	4.57%	Subject 1	**M3**	5.60%	7.42%
	E-Knee		2.88%		**E-Knee**		4.01%
Subject 2	**M3**	2.50%	4.11%	Subject 2	**M3**	3.17%	7.82%
	E-Knee		4.90%		**E-Knee**		6.50%

3.3.3 Quantitative Data - Comparison

Gait Characteristics

The following figures and tables contain both Subject 1 and Subject 2 gait comparison data, derived from the GRF data. With the exceptions mentioned above, each result is the average of 5 trials the patients performed with each limb. Figure 3.16 shows the maximum vertical GRF in terms of BW percentage for each subject on each knee. For Subject 1, the patient stepped the hardest, with the prosthetic limb, while wearing the M3. Subject 2 showed no considerable difference in maximum vertical GRF for either the prosthetic or intact limb on any of the knees.

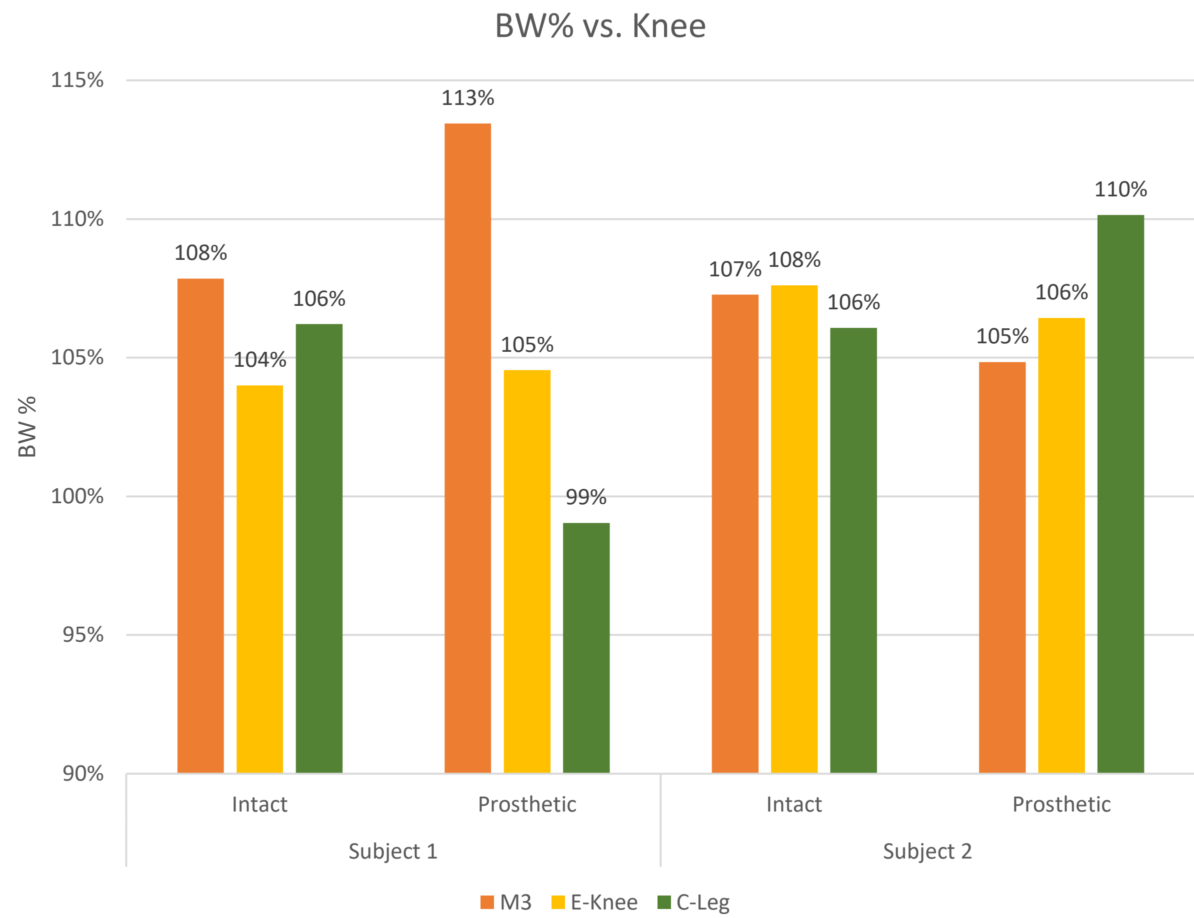

Figure 3.16: Maximum vertical GRF in terms of BW% for subjects on M3, E-Knee, and C-Leg.

Figure 3.17 examines the percent of stance duration for each subject wearing each knee for the intact and prosthetic limbs. The duration of an entire step was defined as the time between intact heel strike to prosthetic toe off, which is less than a typical full stride. Overall, the intact limb was in contact with the ground for the majority of the full step for both patients, regardless of prosthetic knee.

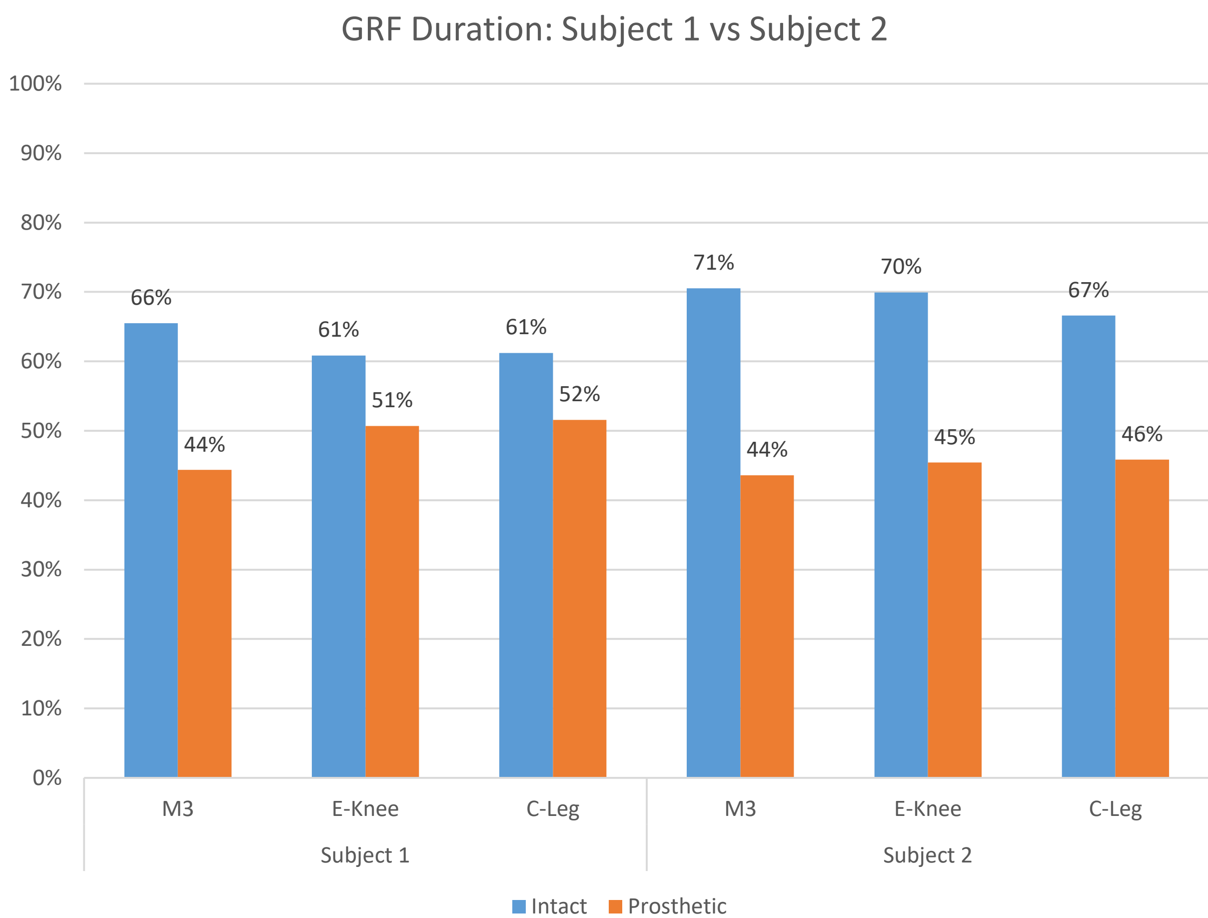

Figure 3.17: Single stance duration of subjects when compared to entire step duration (intact heel strike to prosthetic toe off) on M3, E-Knee, and C-Leg.

Next, the normalized step duration from intact heel strike to prosthetic toe off was measured per subject and knee (Figure 3.18). The data was normalized with respect to the M3 because it had the longest step duration of all three of the knees. Both patients had the shortest step duration while wearing the C-Leg.

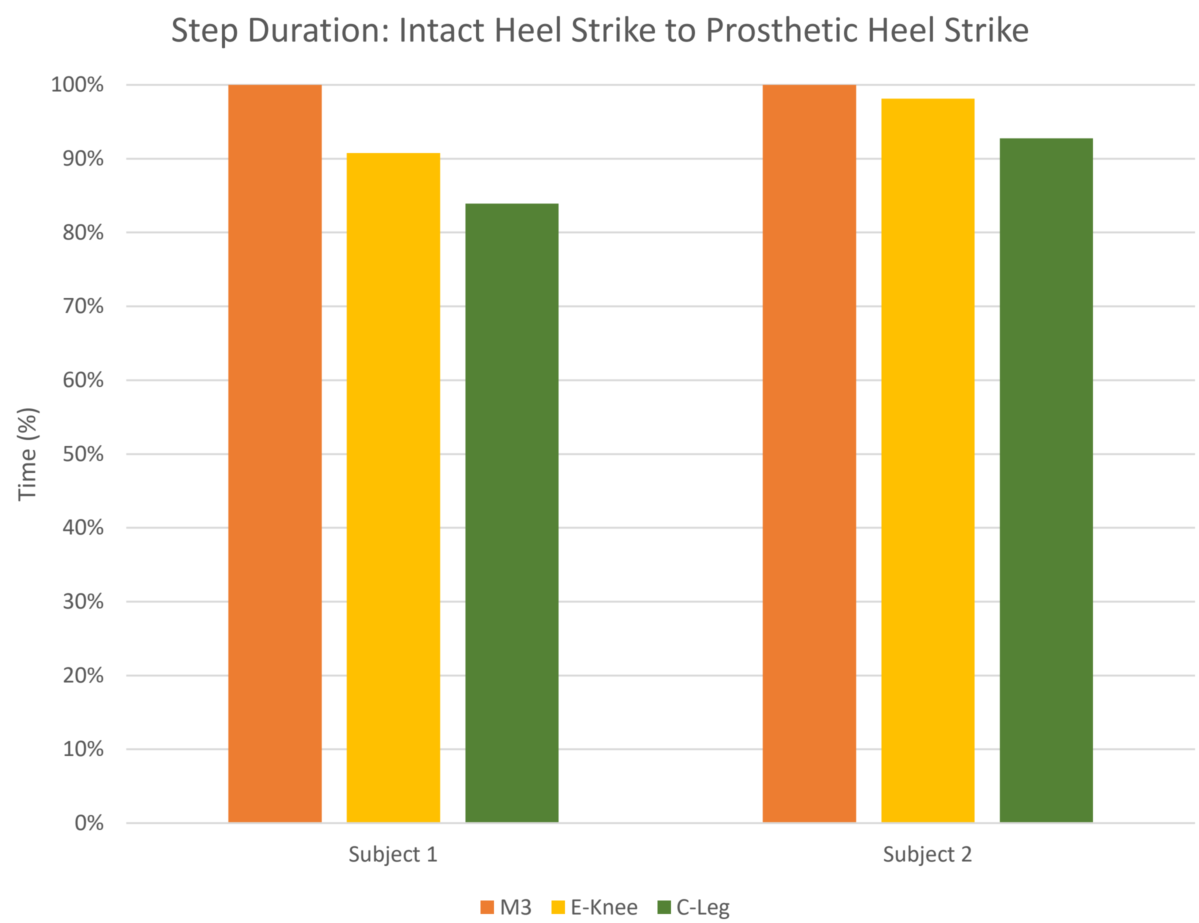

Figure 3.18: Normalized step duration (intact heel strike to prosthetic toe off) for subjects on M3, E-Knee, and C-Leg.

In comparison, Figure 3.19 shows the normalized speed of each patient from intact heel strike to prosthetic toe off for each knee. The data was normalized to the C-Leg because it had the fastest speed. This graph shows that both subjects walked fastest on the C-Leg. Subject 1 had a speed increase from the M3 to the E-Knee, whereas Subject 2 decreased by 3%.

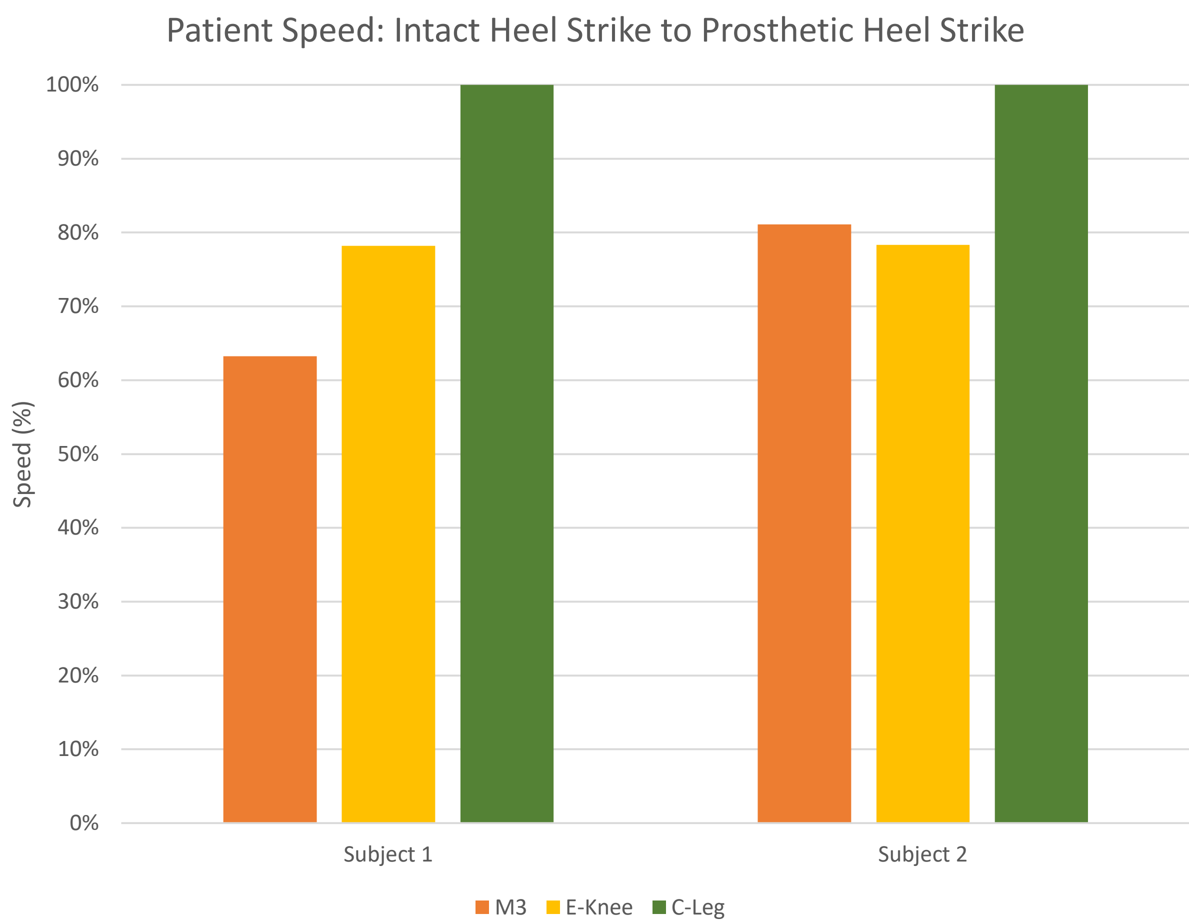

Figure 3.19: Normalized patient speed (intact heel strike to prosthetic toe off) for subjects for M3, E-Knee, and C-Leg.

To quantify fore and aft acceleration during the trials, the GRFs in these directions were integrated over time. A negative value of the integration represented breaking. The results of this integration and their differences between each knee for each subject are shown in Table 3.5. Each subject was aiming to reproduce the same walking pattern during each trial. The closer each delta is to zero in the table below the more successful the patient was in reproducing the same walking speeds between trials. It is seen that the M3 change in velocity was the greatest for both subjects (with an overall deceleration between 24% and 27% of the patients' total average velocity during the trials). Subject 1 was the most consistent on the E-Knee, while Subject 2 was the most

consistent on the C-Leg (about 9% overall acceleration for Subject 1 and 3% overal deceleration for Subject 2).

Table 3.5: Integration of fore/aft of average GRFs for subjects on M3, E-Knee, and C-Leg. Negative values are breaking and positive are acceleration. Results are change in velocity (m/s). "Summed" values for prosthetic and intact limbs, show the total change in velocity for the patient. Parentheses indicate percent change from total patient average velocity.

		M3 Velocity Delta (m/s)	E-Knee Velocity Delta (m/s)	C-Leg Force Velocity Delta (m/s)
Subject 1	**Prosthetic**	-0.22	0.02	-0.02
	Intact	0.05	0.05	0.22
Subject 2	**Prosthetic**	0.13	0.22	0.25
	Intact	-0.23	-0.15	-0.26
Subject 1	**Summed**	-0.18 (-26.6%)	0.07 (8.9%)	0.20 (19.2%)
Subject 2	**Summed**	-0.10 (-24.2%)	0.08 (19.0%)	-0.02 (-3.0%)

3.3.4 Qualitative Data

Patient questionnaires and AMPs were given to the patients after all trials were completed for each knee. Therefore, a total of three questionnaires and three AMPs were reviewed for each subject.

Questionnaire

For each question on the patient feedback questionnaire, the responses were marked along a line that indicated agreement with a remark at either end of the line. Figure 3.20, Figure 3.21, and Figure 3.22 show the patient questionnaire responses for each knee for Subject 1, Subject 2, and averaged, respectively. The higher the percentage for each question, the more the patient agreed with the right-hand option on the line, which was associated with more negative feedback.

The M3 had the most negative responses for Subject 1; Subject 2 marked the E-Knee with negative feedback more often than either of the other two knees. On average between both patients

(Figure 3.20), the M3 had the greatest negative feedback, followed by the E-Knee, and the C-Leg had the lowest overall percentages (most positive comments).

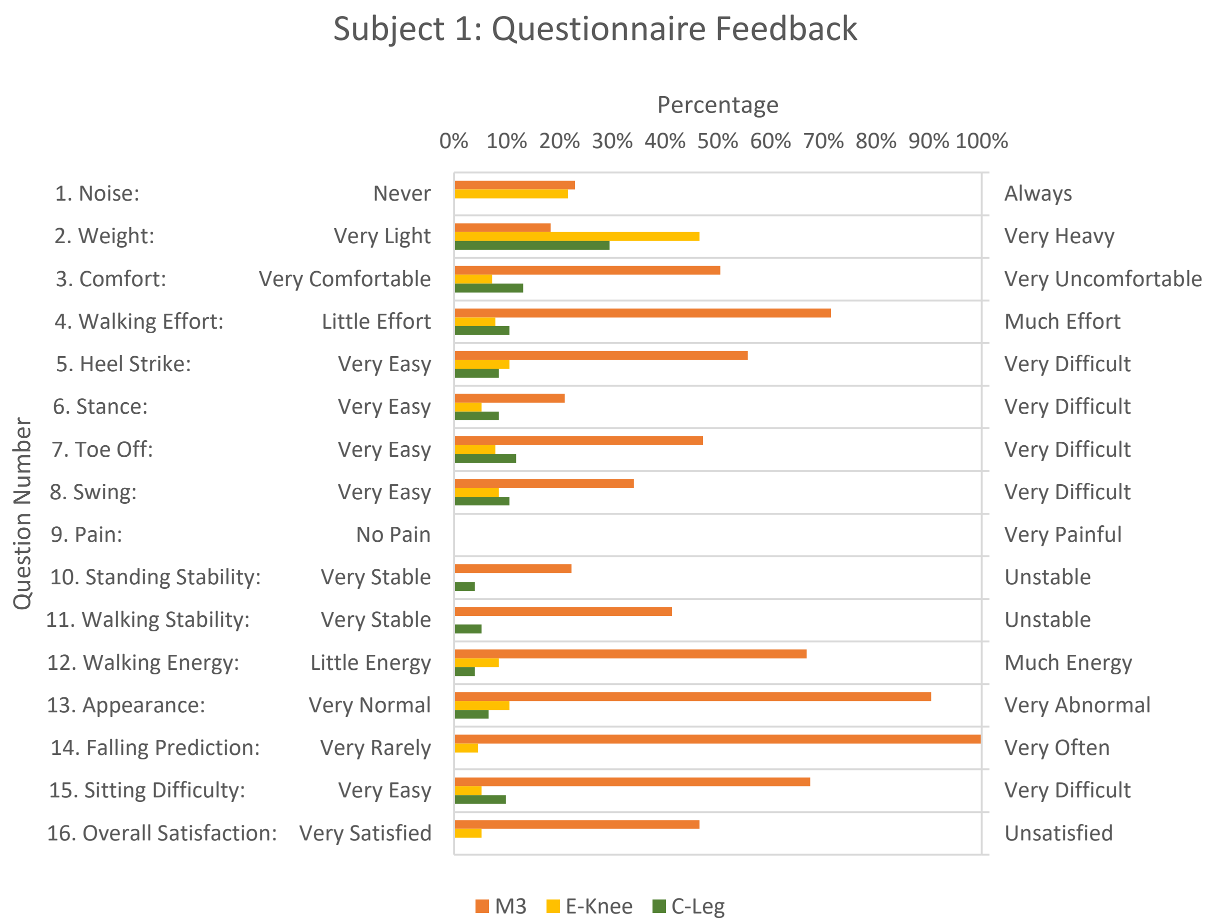

Figure 3.20: Subject 1 questionnaire responses M3, E-Knee, and C-Leg. Responses recorded along a line are represented as percentages of the whole line length; increase in percentage represents poorer outcome. Note: If a bar is not present for a question, it means that the patient response was 0.

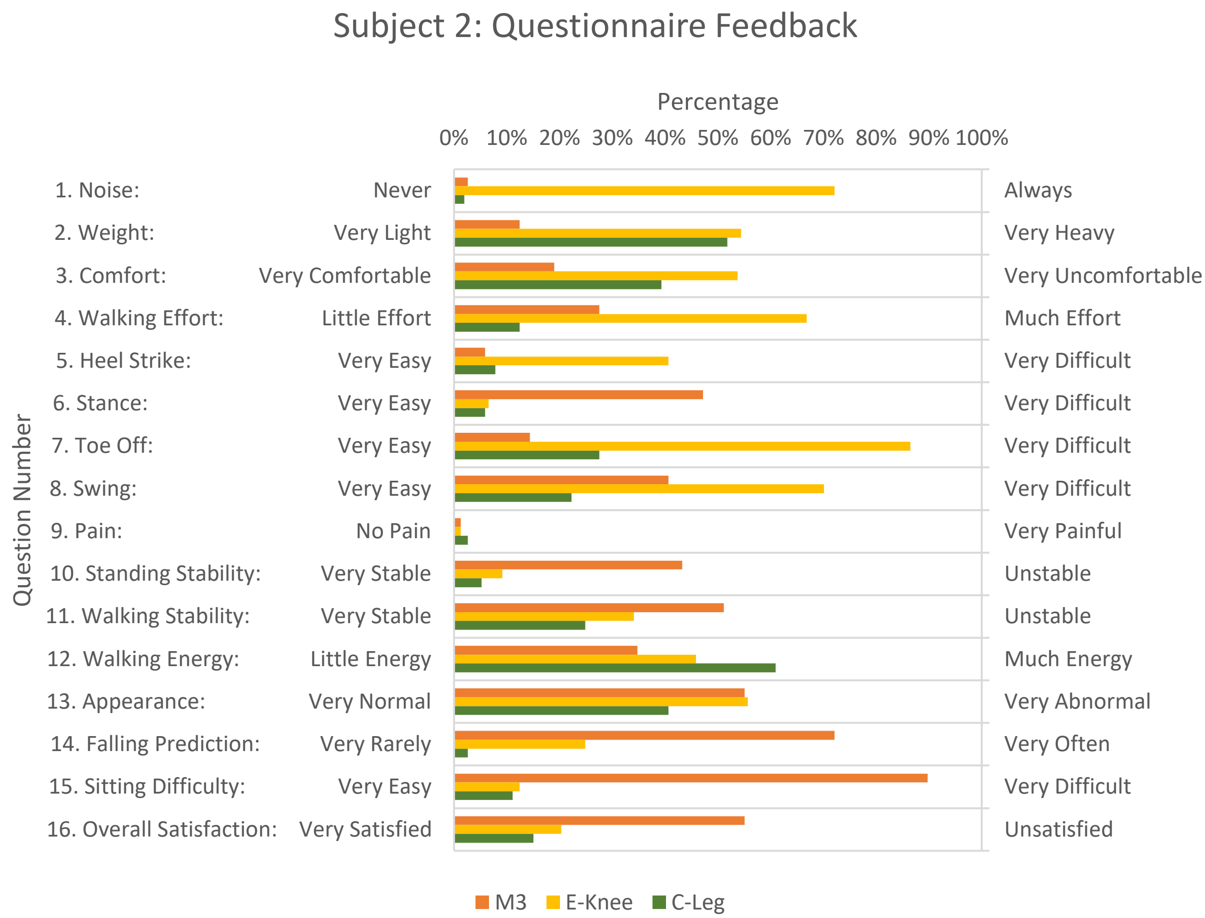

Figure 3.21: Subject 2 questionnaire responses M3, E-Knee, and C-Leg. Responses recorded along a line are represented as percentages of the whole line length; increase in percentage represents poorer outcome. Note: If a bar is not present for a question, it means that the patient response was 0.

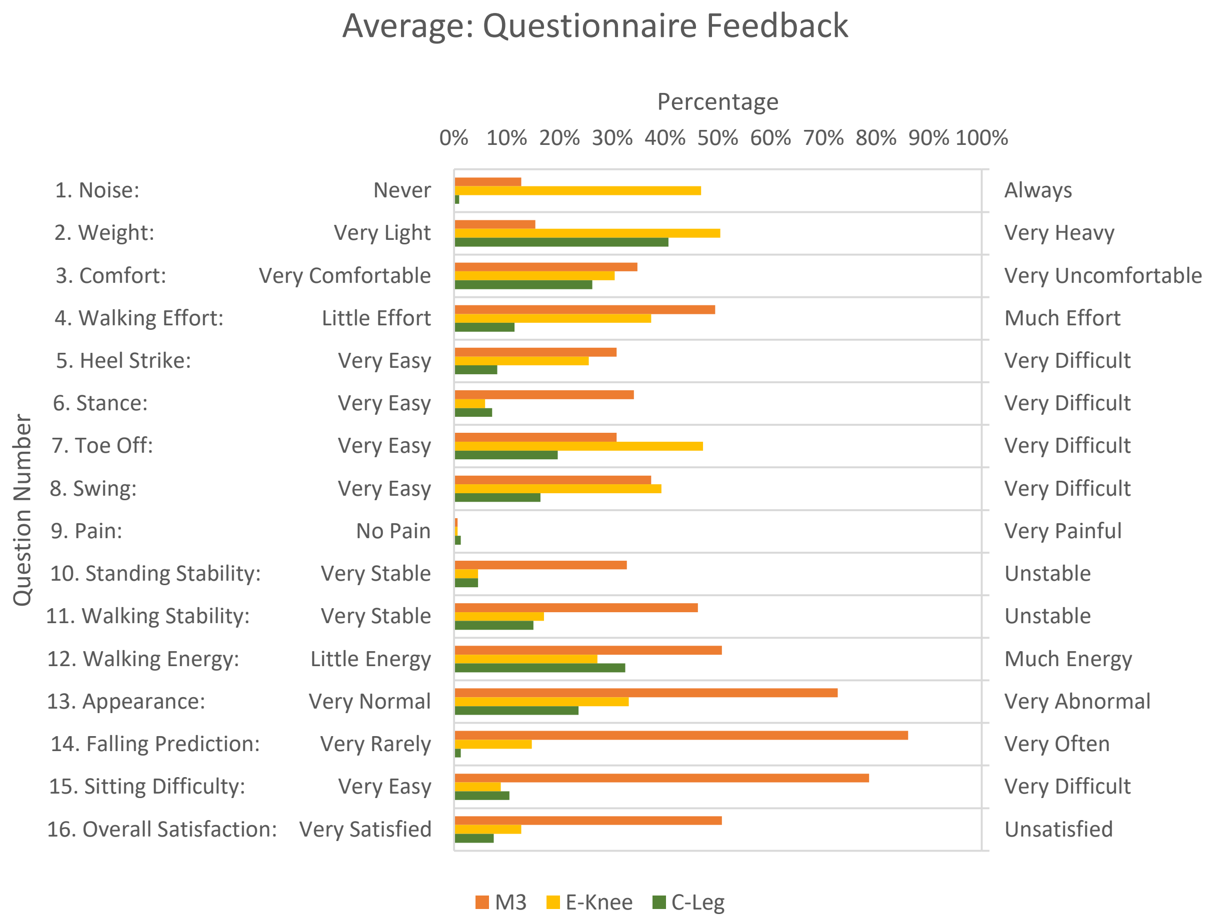

Figure 3.22: Average questionnaire responses M3, E-Knee, and C-Leg. Responses recorded along a line are represented as percentages of the whole line length; increase in percentage represents poorer outcome. Note: If a bar is not present for a question, it means that the patient response was 0.

Table 3.6 summarizes the percent change between each knee as recorded in the subjects' questionnaires (Figure 3.20 and Figure 3.21). 0 shows the overall average between the two subjects. Comparisons between the knees are given as "secondary knee vs. primary knee," where the percent change was calculated by subtracting the primary from the secondary. This gives the percent increase or decrease in the secondary's performance compared to the primary's. Positive percentages in Table 3.6 indicate poorer performance of the secondary knee.

For Subject 1, the E-Knee showed significant improvement for difficulty during gait, questions 5 through 8, when compared to the M3. Subject 2, however, only found improvement

during stance, question 6. For stability questions, 10 and 11, both subjects recorded notable improvement for the E-Knee in comparison to the M3. Subject 1 felt more stable on the E-Knee than the C-Leg during both standing and walking (4% and 5% increases, respectively). Subjects felt 95% and 47% more confident in not falling (question 14) while wearing the E-Knee over the M3, for Subject 1 and 2, respectively. It should be noted that during Subject 1's walking trial, the M3 made uncharacteristic squeaking noises on each step.

Table 3.6: Percent change in patient response. Within each response, M3, E-Knee, and C-Leg are compared as Secondary vs Primary. Percentages are reported as change from the primary knee.

Subject 1 Question	**M3 vs. C-Leg**	**E-Knee vs. C-leg**	**M3 vs. E-Knee**	**Subject 2**	**M3 vs. C-Leg**	**E-Knee vs. C-leg**	**M3 vs. E-Knee**
1	23%	22%	1%		1%	70%	-69%
2	-11%	17%	-28%		-39%	3%	-42%
3	37%	-6%	43%		-20%	14%	-35%
4	61%	-3%	64%		15%	54%	-39%
5	47%	2%	45%		-2%	33%	-35%
6	12%	-3%	16%		41%	1%	41%
7	35%	-4%	39%		-13%	59%	-72%
8	24%	-2%	26%		18%	48%	-29%
9	0%	0%	0%		-1%	-1%	0%
10	18%	-4%	22%		38%	4%	34%
11	36%	-5%	41%		26%	9%	17%
12	63%	5%	58%		-26%	-15%	-11%
13	84%	4%	80%		14%	15%	-1%
14	100%	5%	95%		69%	22%	47%
15	58%	-5%	62%		79%	1%	77%
16	47%	5%	41%		40%	5%	35%

Table 3.7: Average percent change in patient response. Within each response, M3, E-Knee, and C-Leg are compared as Secondary vs Primary. Percentages are reported as change from the primary knee.

Average Question	M3 vs. C-Leg	E-Knee vs. C-leg	M3 vs. E-Knee
1	12%	46%	-34%
2	-25%	10%	-35%
3	9%	4%	4%
4	38%	26%	12%
5	23%	17%	5%
6	27%	-1%	28%
7	11%	28%	-16%
8	21%	23%	-2%
9	-1%	-1%	0%
10	28%	0%	28%
11	31%	2%	29%
12	18%	-5%	24%
13	49%	10%	40%
14	85%	13%	71%
15	68%	-2%	70%
16	43%	5%	38%

Amputee Mobility Predictor

Table 3.8 shows the results of the first thirteen questions of the AMP. The data was collected to qualitatively compare the mobility of each patient per each knee and per each other. Subject 1 achieved a perfect score with the E-Knee and the C-Leg. He lost one point during balancing on the M3. Subject 2 scored the same on both the E-Knee and the C-Leg as well, once again losing one point during the balancing portion on the M3.

Table 3.8: Results of first thirteen questions of the Amputee Mobility Predictor (AMP) (Appendix I) for subjects on M3, E-Knee, and C-Leg. Integer range of answers for each question given within the parenthesis.

Subject 1 Question	**M3**	**E-Knee**	**C-Leg**	**Subject 2**	**M3**	**E-Knee**	**C-Leg**
1 (0-1)	1	1	1		1	1	1
2 (0-2)	2	2	2		2	2	2
3 (0-2)	2	2	2		1	2	2
4 (0-2)	2	2	2		2	2	1
5 (0-2)	2	2	2		2	1	2
6 (0-2)	2	2	2		2	2	2
7 (0-2)	2	2	2		2	2	2
8.1 (0-2)	2	2	2		1	1	1
8.2 (0-2)	1	2	2		0	1	1
9 (0-2)	2	2	2		2	2	2
10 (0-2)	2	2	2		2	2	2
11 (0-1)	1	1	1		1	1	1
12 (0-2)	2	2	2		2	2	2
13 (0-2)	2	2	2		2	2	2
Total (0-26)	**25**	**26**	**26**		**22**	**23**	**23**

3.3.5 Stability Validation

Knee angle data was calculated from the Visual3D kinetic motion files in conjunction with GRF data. From this the maximum heel strike vertical force and the corresponding knee angle were calculated. Normal is the designation for the standard E-Knee walking test the patients performed. Angle Lock was the separate test conducted only on the E-Knee prototype, which prevented the E-Knee from fully extending and thus not resting within the M3 innate mechanical stability. To prevent injury, patients were permitted to brace themselves. The weight difference was calculated to demonstrate that the clamping mechanism was still subjected to a large percentage of the patient's weight during this test. As seen in Table 3.9, Subject 1 had a difference of 11.3 degrees of flexion during the maximum heel strike force. The difference in weight (28.6 N) shows that he applied nearly the same amount of weight as normal during the Angle Lock test. Subject 2 showed a difference 5.9 degrees, and also applied noticeably less weight (difference of 215.9 N). Note that during Subject 2's standard E-Knee trial, the lower leg swing did not fully

extend the knee several times. This may be the source of inconsistent data for Subject 2's angle difference.

Table 3.9: Results of Angle Lock and standard E-Knee trials. Table shows the angle (deg) at maximum heel strike force (N). M3, and by extension E-Knee, has mechanical stability up to 6 degrees. Angle Lock trials tested whether the system would support weight outside of innate mechanical stability.

	Subject 1		**Subject 2**	
	Angle (Deg)	Weight (N)	Angle (Deg)	Weight (N)
Normal	188.0	893.8	179.4	1136.6
Angle Lock	176.8	865.2	173.5	920.7
Difference	**11.3**	**28.6**	**5.9**	**215.9**

Chapter 4: Discussion

4.1 E-Knee Prototype

4.1.1 Design Specifications

The prototype prosthetic knee met the design specifications established in Table 3.1. The knee was able to arrest flexion successfully through activation of the clamping mechanism. While maximum load tests have not yet been performed, the prototype functioned successfully with a 112.5 kg patient, who applied his whole body weight to the prototype. None of the knee components are custom machined, and all components are readily available in a retail capacity – ensuring ease of maintenance. The total retail component cost was \$507.23, which is half the original budget and 2.4% of the cost of the benchmark C-Leg.

While currently not a feature, the E-Knee has the capability to have variable knee resistance and variable cadence. The microprocessor system has the functionality to detect angle, within an acceptable 2 degree variation, via the Hall Effect Sensor, and to give rapid response to external factors (20 ms as shown in program appendix). Therefore, the E-Knee fulfills the design requirements for a low-cost actively-controlled microprocessor knee with stumble control.

The prototype lacks aesthetic, environmental, and battery capacity refinements and must be improved before overcoming the differences between the E-Knee and the C-Leg, highlighted in Table 3.2. While the experimental results of Subject 2 demonstrated the ability to function with 113 kg, the M3 has only been rated for 100 kg. Though based on the M3 model, the E-Knee has not undergone max weight testing. Future work should include fatigue testing, failure analysis, and maximum load testing. The design specification of 90 degrees of flexion was chosen for patient sitting comfort. The redesigned back link of the E-Knee prevents flexion further than 90 degrees, even though the M3 can natively reach 150 degrees. Future work will include redesign, perhaps moving linkages internally, to further approach the M3's greater range of flexion. Internal linkages potentially allow the E-Knee to have the full M3 range of flexion. Battery capacity, while an important features for final design, was not prioritized in the prototype. The prototype solenoid

was set to a state of always-on, except when engaging the clamping mechanism. Redesign will include energy efficiency analysis and reconfiguration when considering the clamping mechanism. Hence, the prototype is deficient in max patient weight, maximum knee flexion, and battery capacity. Despite these three shortcomings, the E-Knee successfully matched the design specifications, offering basic functionality of the C-Leg at drastically reduced price.

4.1.2 Components

M3 and Back Link

The mechanical stability of the M3 foundation proved to be crucial to the E-Knee's success. The system allowed toe clearance while reducing the impact on the clamping mechanism. The M3 foundation offered standing stability and natural gait, while the microprocessor and electrical components added gait and stumble stability. The redesigned back link, while functional, prevented flexion of the knee past 90 degrees. This did not hamper gait, movement, or sitting in a chair, as shown by AMP. However, such restrictions could negatively impact patients in developing countries that might perform tasks that require them to squat. Decreasing the back link's impact on flexion angle and moving back to the M3's native 150 degree flexion, will be a focus of future redesign work.

Sensing

The magnetic sensor for the detection of knee angle worked well; however, the physical nearness of the magnet and the sensor caused a loss of resolution. The sensor had greater resolution in the higher angles than in the initial angles of knee flexion, which caused programming to be more hard-coded and inflexible when it came to stumble detection. The magnet and sensor will be further separated in future iterations. Patient interactions and observation during the Microprocessor-Lock test demonstrated that in special circumstances the stumble detection algorithms of the knee could be circumvented. To address this, new iterations of the prototype will include a sensor, such as a vibration sensor, to detect step impact. Recognition of every prosthetic

foot impact, whether it be normal gait or stumble, will allow the microprocessor system to more accurately adapt to prevent stumble.

Processing System

The Arduino microprocessor performed well during trials and prototyping. While not expensive, especially considering bulk purchase and implementation prices, the device can be reduced to a smaller and less powerful version without sacrificing computational power or current functionality. The 20 ms processing speed proved to be effective the prototype. The range of response times in other systems, 1 – 100 ms, indicates response time is dependent on system components. Considering the popularity of the C-Leg and its response time, 100 ms, it may not necessarily linked to performance.

Variable Damper

While not currently providing variable damping, the damper was preliminarily tested and does provide the correct functionality. It was chosen for functionality and its status as a retail product, but given the percentage of cost of the total system that it represents (83%, Figure 3.7), it will be reevaluated. Custom machined solutions exist at similar price points and greater functionality, namely performing the function of clamping mechanism as well.

Clamping Mechanism

The clamping mechanism, while simple in design and implementation, has undergone these tests without failure; however, the component will begin to wear due to forces transmitted through the mechanical binding. Environmental factors, while not applicable in regulated prototype situations, can induce the possibility of slippage, which would render the stability of the knee during stumble void. Possible combination with the variable damper for a complete system will be considered.

In summary, the individual components of the E-Knee prototype functioned well for these tests performed. To address various issues and possible failure modes, future work will include redesign of the back link to increase flexion range, implementation of a step detection sensor to

better identify stumble, attempt to reduce price of variable damper through custom solutions, and redesign or reconfiguration concerning the clamping mechanism to decrease risk of slippage.

4.2 Experimental Data

4.2.1 Ground Reaction Force Data

Ground reaction force data gains its significance from the proven repeatability of its patterns among the scientific community (Chao et al. 1983). Since mimicry of healthy systems reduces risk of continued injury (R. Gailey et al. 2008), the aim was to develop a knee system that most closely achieved that goal. While mimicry of a healthy system was the ultimate goal, the E-Knee system was mainly compared to the M3 and C-Leg. M3 comparisons showed whether the E-Knee had overcome the M3's limitations and improved its baseline. Extensive review has shown that the C-Leg drastically decreases falls, stumbles, and increases balance by 64%, 59%, and approximately 68%, respectively (Highsmith et al. 2010); comparison of the E-Knee to the C-Leg, therefore, validates improvement from passive mechanical to active microprocessor-controlled prosthetic knee. Theoretically, the improved toe clearance and knee center of rotation of a four-bar knee should permit such a system to have more natural gait than a single-axis device; however, this is not observed in this study.

Table 3.4 considers the deviation of the forces between the different knees; the following section references it exclusively. Every value, except Subject 2's intact vertical forces, shows that the E-Knee successfully emulated the C-Leg closer than the M3 did. When comparing the deviation between E-Knee/M3 and the deviation between E-Knee/C-Leg, the E-Knee was closer to the C-Leg 50% of the time. This demonstrates a marked improvement over the M3, and further supports the E-Knee's achievement as a middle-ground device between the M3 and C-Leg. With the exception of Subject 1's intact fore/aft E-Knee to C-Leg comparison, the intact limbs deviated less amongst themselves, and the prosthetic deviations were more substantial. The similar GRFs on the intact limb indicate patient consistency and highlight greater variance among their prosthetic limb counterparts. The vertical force deviations show that both Subject 1's intact and prosthetic

limbs diverged less from E-Knee to C-Leg than from M3 to E-Knee, showing that with Subject 1, the E-Knee was more similar to the C-Leg than to the M3. Subject 2's vertical forces show the opposite. While Subject 2's vertical prosthetic forces show that the E-Knee was closer to the C-Leg than the M3 was to the C-Leg, the E-Knee was more similar to the M3 than to the C-Leg. To Subject 2, therefore, the E-Knee had more natural GRF data than the M3, but only barely. Given Subject 2's gait style, the E-Knee somewhat improves gait normality from the M3.

The GRF data for Subject 1 shows a significant improvement from M3 to E-Knee; in fact, the data shows that the E-Knee is nearly comparable to the C-Leg for single speed, flat surface walking. Combining step duration (Figure 3.18), in which the M3 had the longest duration, and GRF duration (Figure 3.17), which showed that Subject 1 spent 44% of total step percentage on the prosthetic, it appears that the patient is distrustful of the M3. When patients are more comfortable and trusting with a knee, their self-selected walking speed increases (Hafner et al. 2007). Thus, a lower percentage of total step time on the knee, while also walking slower, indicated by duration, indicates that the patient is not confident in the knee. As seen in Figure 3.9: D and Figure 3.11, Subject 1 exerted significantly more force on the M3 during heel strike than on the E-Knee or C-Leg. These two findings support one another. The M3 must be fully extended in order to be locked, and a forceful heel strike can ensure that. Additionally, the slower self-selected walking speed (Figure 3.19) and less time spent on the prosthetic limb (Figure 3.17, 44% versus E-Knee: 51% and C-Leg: 52%) indicate a hesitancy to trust the M3 knee. Alternatively, Subject 1's E-Knee and C-Leg both have step forces that are similar to each other and mimic the shape of their intact counterparts. For a healthy patient, Figure 3.17 would show equal GRF duration percentages for both limbs, if the GRF duration were a function of total stride, the percentage would be 50%. With the data available, the most symmetric outcome is having the lowest difference between intact and prosthetic GRF durations. For Subject 1, the differences for the E-Knee and C-Leg are both 10%, a drastic improvement over the M3's 21%. While Subject 1 expressed confidence in the C-Leg during step duration (Figure 3.18), a 7% decrease from E-Knee to C-Leg, his maximum vertical GRFs for the C-Leg dropped by 7% from intact to prosthetic

(Figure 3.16). The lower forces indicate either a bad gait habit or a gait characteristic of the C-Leg. In contrast, the patient has balanced maximum vertical GRFs on the E-Knee, similar to a regular gait.

Subject 2, on the other hand, very clearly indicated strong confidence in the C-Leg, some confidence in the E-Knee, and the least confidence in the M3. This is supported by the maximum vertical GRFs (Figure 3.16) dropping for E-Knee and M3, but rising for C-Leg between the intact and prosthetic limbs; by the GRF durations differences (Figure 3.17) steadily decreasing from M3 to E-Knee to C-Leg, 27% to 25% to 21%, respectively; and the step duration (Figure 3.18) steadily decreasing from M3 to E-Knee to C-Leg, 100% to 98.1% to 92.8%, respectively. The maximum vertical GRFs for Subject 2 do not exhibit the same drastic impact as Subject 1's M3, which indicated lack of confidence; therefore, the slight trend of Subject 2's increased GRFs indicates confidence. However, it should be noted that Subject 2 trusted all of the prosthetic knees less than Subject 1 did. This is seen by the significant difference in GRF durations (Figure 3.17). For Subject 2, the difference between M3 and E-Knee is not nearly as distinct as the difference between C-Leg and M3 or C-Leg and E-Knee. This is especially well highlighted in self-selected walking speed (Figure 3.19) where the E-Knee was 3% slower than the M3 opposed to being 22% slower than the C-Leg. This difference could be a result of the patient knowing that the M3 and E-Knee were less advanced than the C-Leg, which could have reinforced his caution to walk confidently on the two devices as compared to the familiar C-Leg.

Table 3.5 shows that the walking trials were not at a constant speed for either patient. The most prominent reaction was that both Subject 1 and Subject 2 slowed down by a significant percentage of their total speed, 26.6% and 24.2% respectively, for the M3 trials. This could indicate distrust, since both subjects expressed feelings of instability on the questionnaire with the M3. The conclusion that can be drawn from this data is that the experimental method was inadequate – this data is not intended to be reflective of acceleration or deceleration. Since the patients were accelerating and breaking, their gait speeds had not been properly established. Future work must include a longer walking approach to the force plates to allow patients to establish a consistent

walking speed. An approach would be to allow patients to self-select a speed, and then provide audible cues to prompt consistent gait speed. While the activity levels of the patients were sufficient, future studies should include younger patients who have demonstrated sufficiently normal gait. While not invalidating the studies, the irregularity of Subject 2's gait prevented more precise gait comparisons between the two subjects. Additionally, though the C-Leg is widely accepted as a benchmark for commercialized microprocessor knees, studies should be conducted to compare other microprocessor knees to the E-Knee and M3.

4.2.2 Kinematic Angle Data

The results for the Angle Lock Experiment can be seen in Table 3.9. The experiment was aimed at answering two questions: can the microprocessor system detect stumble and engage the mechanical clamp to prevent it; and can the mechanical clamp withstand the heel strike impact force. The difference in angles for Subject 1 shows that the Angle Lock device kept the knee from extending past 11.3 degrees flexion. At this angle, the E-Knee is far past its point of mechanical stability (6 degrees). Thus, the only thing preventing the collapse of the patient was the clamping mechanism – showing both that the microprocessor detected the stumble and enabled the clamping mechanism, since the knee was conclusively not in a stable mode, and that the clamping mechanism can support 865.2 Newtons of force. Since the Angle Lock device was used for both Subject 1 and 2 and it physically prevents the flexion angle from being less than 10 degrees, Subject 2's angle data (5.9 degrees) is suspect. As previously mentioned, it was observed that due to Subject 2's slow gait, the E-Knee would sometimes not extend fully from the swing. Therefore, angle data collected from the normal E-Knee trials had a chance of already including some flexion, decreasing the difference between the set Angle Lock and the normal trial. Nevertheless, while relying on the mechanical clamp, Subject 2 subjected the system to 920.7 Newtons of force (93.9 kg of mass) without experiencing collapse. This validates the E-Knee's ability to detect and prevent stumble and collapse under controlled conditions.

Future work should include an alternative method of collecting angle data, such as calibrated goniometers, so that there is a reference point for the Angle Lock data outside of the difference with the normal knee trial.

4.3 Qualitative Data

Questionnaire

While questionnaires are highly subjective, translating patient feedback into quantitative measurements allows us to compare the different knee performances. Although reporting the feedback as a percent of total line length is a useful method of measuring responses quantitatively, it should be noted that percent differences should not be overestimated – a 10% difference in data is equal to a 7.7 mm difference on paper. Therefore, differences greater than 10% should be considered significant.

Overall, Subject 1 felt that the E-Knee improved considerably (41%) over the M3 and was qualitatively comparable to the C-Leg (5%) (Figure 3.20 and Table 3.6). Subject 1 reviewed the E-Knee favorably. Weight was the only category where the E-Knee did not improve over the M3. Realistically, question 1 should also be in favor of the M3 because during the experiment the M3 made an uncharacteristic squeaking noise. Other than noise and weight, the E-Knee differed from the C-Leg by at most 6%, indicating that Subject 1 felt that the E-Knee was highly comparable to the C-Leg. By contrast, the M3 compared to the C-Leg had its lowest difference at 12% (excluding pain, which was 0% for all three knees) and was commonly over 30%.

Largely, Subject 2's qualitative feedback shows the E-Knee exceeded the M3 concerning stability, but was less preferred overall under non-ideal gait, as compared to Subject 1 (Figure 3.21 and Table 3.6). Subject 2 was generally satisfied with the E-Knee according to question 16; however, the C-Leg was preferred (20% average increase). Subject 2 marked the E-Knee as improved to the M3 on four questions: two concerning stability, one in falling, and the last in sitting down. Ergo, Subject 2 regarded the E-Knee more stable than the M3 (44% average increase). During walking and standing, Subject 2 reported the E-Knee had comparable stability

to the C-Leg, less than 10% difference. During gait, Subject 2 preferred the M3 over the E-Knee, questions 5 through 8, by an average of 24%. However, Subject 2 spent much less time in the prosthetic stance than in the intact stance for all the prostheses (Figure 3.14 and Figure 3.16) – indicating low prosthetic confidence overall. Note that during the experiments, the patient did not allow much flexion during gait, preferring for the knee to remain extended. This pattern of gait is not uncommon among amputees, though non-ideal, and in no way invalidates Subject 2's data, but rather shows that the E-Knee did not improve the M3 under non-ideal gait conditions.

Amputee Mobility Predictor

The extent to which the AMP was applied to the patients was not enough to establish K-level classification. Rather, it will be used as a supplemental point of reference for the comparative activity levels between the two subjects, as well as a comparison of how the M3, E-Knee, and C-Leg affected the activity levels. As expected by given K-levels, Subject 1 had a baseline higher mobility score than Subject 2 (Table 3.8). Subject 1 achieved a perfect score of 26 with both the E-Knee and C-Leg, and lost one point due to balance on the M3. Subject 2 scored 23 for the E-Knee and the C-Leg, but could not achieve Subject 1's level of balance with either. Both patients scored one point lower with the M3, than with the E-Knee or C-Leg. The point loss can likely be attributed to balance; both patients found it more difficult to balance on the M3. Future work should include full K-level evaluation to further define the areas of mobility that are troublesome with the M3, E-Knee, and C-Leg. Full mobility prediction would most likely have predicted the irregularity of Subject 2's gait.

4.4 Limitations

The proof-of-concept nature of this study resulted in limitations that should be addressed in future studies.

E-Knee Prototype

During the prototype design phase, the greatest drawback was a lack of patient collaboration. We based the design features and specifications on secondhand accounts and literature reviews. This study has provided an abundance of qualitative and quantitative patient feedback, which will be beneficial for further product development, such as weight and maximum flexion angle. However, further efforts must be made to understand patient needs.

The angle sensing system accomplished its goal for this study; yet, the low resolution of the initial flexion angle data prevented the programming from being more intuitive about knee collapse. Future work must include an increase in resolution.

Experimental Data

The primary limitation of the experimental setup was the limited space in the gait lab. Both patients commented on a desire for a longer walkway. As shown by fore and aft GRF integrations, the patients accelerated and decelerated during the trials. This led to an indefinite analysis between the prosthetic knees. Ideally, patient walking speed would be fully established before contact with the force plates and continue for several steps after the force plates. Therefore, a future study must include a longer walking area with matching length handle bars, which do not have cross bars near the end of the force plates, as was the case in this study. The setup must be adjusted to allow full stride data collection. This study was limited by the marker to camera angle, and thus could not capture full stride for comparison. Increasing the walking distance would also improve the quality of the GRF data because it would decrease the occurrence of patients targeting the force plates for their steps.

Further studies would also benefit from a regulation of knee awareness and walking speeds. While preliminary trials must give patients knowledge of the knee system, future work should incorporate a blind study between microprocessor knees. Trials should also include patients with a variety of prosthetic knees, including native passive knee users. Since walking speeds and patient confidence depends largely on familiarity, trials including native passive knee users and long-term

testing of different knees would provide beneficial analysis of true confidence as opposed to unfamiliarity. GRF patterns depend on the patient ambulatory speed; therefore GRF comparisons can be improved by regulating walking speed between the prosthetic devices. For instance, Subject 2's prosthetic steps were much slower than Subject 1's, which highlighted Subject 2's vibration data seen during step onset on prosthetic limbs.

To increase accuracy, each test should have at least 10 trials instead of 5. The majority of patient trial time is from the marker setup; thereafter, the test proceeds much quicker. Patients would be needed marginally longer, but this would result in double the confidence in the data from each subject.

Finally, for further validation of stumble control stability, the experimental setup must include both greater accuracy of knee angle, either through goniometer or internal knee feedback, and knee feedback for the activation of the stumble control system. As it is, it can be said with reasonable certainty that the microprocessor prevented knee collapse during the Microprocessor-lock test; however, shifting centers of mass and force application from the amputee could theoretically create a stable reaction in a polycentric knee without full extension. Therefore, knee stability systems must be quantifiably enabled.

Qualitative Data

Through this study it became clear that the adapted AMP was a weak comparison of mobility. Though it further confirmed the patient's relative mobility to each other, it was not definitive. Future studies must well consider further mobility indicators.

Chapter 5: Conclusion

With the transfemoral amputee population growing by 44,400 a year in the United States alone and typical microprocessor knees costing approximately $20,000, there exists a need for a joining of affordability and performance. The aim of this research was to develop a low-cost microprocessor-controlled prosthetic knee with basic active-control stumble prevention to improve existing passive prosthetic knee systems. Based on the initial need, the design criteria, the experimental results, and patient responses, the E-Knee prototype was found to be a feasible solution.

The prototype fulfilled the design specifications, created to develop a knee with the acceptably reduced function of a commercial microprocessor knee system while offering greater stability and a more natural gait pattern than a passive-knee system. The patient trials provided two avenues of validation: gait analysis compared to two other knee systems (the LIMBS M3 and Ottobock's C-Leg) and controlled simulated stumble testing. Qualitatively, the two subjects praised the stability of the E-Knee system, finding it comparable to the C-Leg. Quantitatively, the Angle Lock test validated the ability of the microprocessor to engage the mechanical clamp during a simulated stumble to support a patient weighing more than 100 kg. Experimental results of the ground reaction forces for Subject 1 showed that the E-Knee performed comparatively to the C-Leg. Subject 2's experimental results showed definite improvement over the M3, though less than Subject 1. Current microprocessor knee technology is offered at price that makes it an impossible amenity in developing countries. At 2.4% of the cost of the industry standard, and the E-Knee has the potential to greatly improve the lives of thousands of amputees around the world.

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Appendix I: Amputee Mobility Predictor Scoring Form

Amputee Mobility Predictor Questionnaire

Initial instructions: Testee is seated in a hard chair with arms. The following maneuvers are tested with or without the use of the prosthesis. Advise the person of each task or group of tasks prior to performance. Please avoid unnecessary chatter throughout the test. Safety first, no task should be performed if either the tester or testee is uncertain of a safe outcome.
The Right Limb is: ☺ PF ☺ TT ☺ KD ☺ TF ☺ HD ☺ intact. The Left Limb is: ☺ PF ☺ TT ☺ KD ☺ TF ☺ HD ☺ intact.

1. Sitting balance: sit forward in a chair with arms folded across chest for 60s.	Cannot sit upright independently for 60s Can sit upright independently for 60s	–0 –1	______
2. Sitting reach: reach forward and grasp the ruler. (Tester holds ruler 12in beyond extended arms midline to the sternum.)	Does not attempt Cannot grasp or requires arm support Reaches forward and successfully grasps item	–0 –1 –2	______
3. Chair to chair transfer: 2 chairs at 900. Pt may choose direction and use their upper extremities.	Cannot do or requires physical assistance Performs independently, but appears unsteady Performs independently, appears to be steady and safe	–0 –1 –2	______
4. Arises from a chair: ask pt to fold arms across chest and stand. If unable, use arms or assistive device.	Unable without help (physical assistance) Able, uses arms/assist device to help Able, without using arms	–0 –1 –2	______
5. Attempts to arise from a chair (stopwatch ready): if attempt in no. 4was without arms then ignore and allow another attempt without penalty.	Unable without help (physical assistance) Able requires >1 attempt Able to rise 1 attempt	–0 –1 –2	______
6. Immediate standing balance (first 5s): begin timing immediately.	Unsteady (staggers, moves foot, sways) Steady using walking aid or other support Steady without walker or other support	–0 –1 –2	______
7. Standing balance (30s) (stopwatch ready): For items nos. 7 & 8, first attempt is without assistive device. If support is required, allow after first attempt.	Unsteady Steady but uses walking aid or other support Standing without support	–0 –1 –2	______
8. Single-limb standing balance (stopwatch ready): time the duration of single limb standing on both the sound and prosthetic limb up to 30s. Grade the quality, not the time.	Nonprosthetic side Unsteady Steady but uses walking aid or other support for 30s Single-limb standing without support for 30s	 –0 –1 –2	______
Sound side ____seconds Prosthetic side ____seconds	Prosthetic Side Unsteady Steady but uses walking aid or other support for 30s Single-limb standing without support for 30s	 –0 –1 –2	______
9. Standing reach: reach forward and grasp the ruler.(Tester holds ruler 12in beyond extended arm(s) midline to the sternum.)	Does not attempt Cannot grasp or requires arm support on assistive device Reaches forward and successfully grasps item no support	–0 –1 –2	______
10. Nudge test (subject at maximum position #7): with feet as close together as possible, examiner pushes firmly on subject's sternum with palm of hand 3 times (toes should rise).	Begins to fall Staggers, grabs, catches self, or uses assistive device Steady	–0 –1 –2	______

Content has been exerpted from Gailey RS, Roach KE, Applegate EB, et al. The amputee mobility predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate. *Arch Phys Med Rehabil.* 2002;83(5):613-627.

11. Eyes closed (at maximum position #7): if support is required grade as unsteady.	Unsteady or grips assistive device	=0
	Steady without any use of assistive device	=1
12. Picking up objects off the floor (pick up a pencil off the floor placed midline 12in in front of foot).	Unable to pick up object and return to standing	=0
	Performs with some help (table, chair, walking aid, etc)	=1
	Performs independently (without help from object or person)	=2
13. Sitting down: ask pt to fold arms across chest and sit. If unable, use arm or assistive device.	Unsafe (misjudged distance, falls into chair)	=0
	Uses arms, assistive device, or not a smooth motion	=1
	Safe, smooth motion	=2
14. Initiation of gait (immediately after told to "go").	Any hesitancy or multiple attempts to start	=0
	No hesitancy	=1
15. Step length and height: walk a measured distance of 12ft twice (up and back). Four scores are required or 2 scores (a & b) for each leg. "Marked deviation" is defined as extreme substitute movements to permit clearing the floor.	a. Swing foot	
	Does not advance a minimum of 12in	= 0
	Advances a minimum of 12in	= 1
	Prosthesis Sound	
b. Foot clearance	Foot does not completely clear floor without deviation	= 0
	Foot completely clears floor without marked deviation	= 1
	Prosthesis Sound	
16. Step continuity.	Stopping or discontinuity between steps (stop & go gait)	= 0
	Steps appear continuous	= 1
17. Turning: 1800 turn when returning to chair.	Unable to turn, requires intervention to prevent falling	= 0
	Greater than 3 steps but completes task without intervention	= 1
	No more than 3 continuous steps with or without assistive aid	= 2
18. Variable cadence: walk a distance of 12ft fast as safely as possible 4 times. (Speeds may vary from slow to fast and fast to slow, varying cadence.)	Unable to vary cadence in a controlled manner	= 0
	Asymmetrical increase in cadence controlled manner	= 1
	Symmetrical increase in speed in a controlled manner	= 2
19. Stepping over obstacle: place a movable box of 4in. in height in the walking path.	Cannot step over the box	= 0
	Catches foot, interrupts stride	= 1
	Steps over without interrupting stride	= 2
20. Stairs (must have at least 2 steps): try to go up and down these stairs without holding on to the railing. Don't hesitate to permit pt to hold on to rail. Safety first, if examiner feels that any risk in involved omit and score as 0.	Ascending	
	Unsteady, cannot do	= 0
	One step at a time, or must hold on to railing or device	= 1
	Steps over step, does not hold onto the railing or device	= 2
	Descending	
	Unsteady, cannot do	= 0
	One step at a time, or must hold on to railing or device	= 1
	Steps over step, does not hold onto the railing or device	= 2
21. Assistive device selection: add points for the use of an assistive device if used for 2 or more items. If testing without prosthesis use of appropriate assistive device is mandatory.	Bed bound	= 0
	Wheelchair	= 1
	Walker	= 2
	Crutches (axillary or forearm)	= 3
	Cane (straight or quad)	= 4
	None	= 5

	AMPPro	AMPnoPro
K0	N/A	0-8
K1	15-26	9-20
K2	27-36	21-28
K3	37-42	29-36
K4	43-47	37-43

Total Score 0 /47   K level =

Trial ☺ no prosthesis ☺ with prosthesis   Observer ______

Date______ Abbreviation: PF, partial foot; TT, transtibial; KD, knee disarticulation; TF, transfemoral; HD, hip disarticulation; Pt, patient.

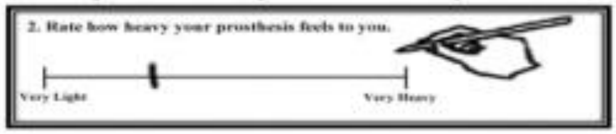
Content has been exerpted from Gailey RS, Roach KE, Applegate EB, et al. The amputee mobility predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate. *Arch Phys Med Rehabil.* 2002;83(5):613-627.

Appendix II: LEGS Functional Parameters Questionnaire

Name ______________________________ Type of prosthesis________

L.E.G.S. Functional Parameters Questionnaire; Visual Analogue Questions

INSTRUCTIONS: Place a vertical mark on the line below each question to indicate your answer.
An example of how one person answered question 2:



1. Rate how often your prosthesis made squeaking, clicking, or belching sounds.

NEVER ALWAYS

2. Rate how heavy your prosthesis feels to you.

VERY LIGHT VERY HEAVY

3. Rate your overall discomfort while walking.

VERY COMFORTABLE VERY UNCOMFORTABLE

4. Rate how much effort it takes to walk.

LITTLE EFFORT MUCH EFFORT

5. Rate how difficult it was for you during the heel strike phase of your walk.

VERY EASY VERY DIFFICULT

1

Name ______________________________ Type of prosthesis_________

6. Rate how difficult it is to walk on rough, rocky or sandy ground.

7. Rate how difficult it was for you during the stance phase of your walk.

VERY EASY VERY DIFFICULT

VERY EASY VERY DIFFICULT

8. Rate how difficult it was for you during the toe off phase of your walk.

VERY EASY VERY DIFFICULT

9. Rate how difficult it was for you during the swing through phase of your walk.

VERY EASY VERY DIFFICULT

10. Rate any pain you feel while walking.

NO PAIN VERY PAINFUL

11. Rate how stable you felt using your prosthesis when standing.

VERY STABLE UNSTABLE

12. Rate how stable you feel when walking.

VERY STABLE UNSTABLE

13. Rate how much energy it took to walk for as long as you needed to.

Name ______________________________ Type of prosthesis_________

LITTLE ENERGY MUCH ENERGY

14. Rate how normal you feel you look while walking with this prosthesis.

VERY NORMAL VERY ABNORMAL

15. Rate how difficult it is for you to walk in tight spaces.

VERY EASY VERY DIFFICULT

16. Rate how difficult it is to go up and down stairs.

VERY EASY VERY DIFFICULT

17. Rate how difficult it is to walk up and down a slope.

VERY EASY VERY DIFFICULT

18. Rate how often you feel that you might fall with this knee.

VERY RARELY VERY OFTEN

19. Rate how difficult it is to sit down and stand up.

VERY EASY VERY DIFFICULT

Name ______________________________ Type of prosthesis_________

20. Rate how satisfied you are with how you are walking with this prosthesis.

VERY SATISFIED UNSATISFIED

Appendix III: Prototype Program Code

```
int piston = 5;
int clamp = 3;
int magnet = A0;
int change1 = 0;
int change2 = 0;
int changed = 0;
int reset = 0;
int counter = 0;
int cadence1 = 0;
int cadence2 = 0;
int cadence3 = 0;
int average = 0;
int weight = 0;
int damp = 0;
int mstimescale = 20;
int threshold = -5 * mstimescale / 1000;
int swing = 0;
int mode = 2;

// Out of 1023
int thresholdvoltage = 117;
int variance = 10;
// Milliseconds
int stridetime = 800;


void setup()
{
  Serial.begin(9600);
  pinMode(piston, OUTPUT);
  pinMode(clamp, OUTPUT);
  pinMode(magnet, INPUT);
  Serial.print(threshold);
  Serial.print(" ");
  Serial.print(abs(threshold) / 2);
  Serial.print("\n");
}

void loop()
{
  switch (weight)
  {
    case 0:  //Weight off
      Serial.print("Off");
      Serial.print(", ");
```

```
    digitalWrite(clamp, HIGH);
    swing = 0;

    damp = 0;
    analogWrite(piston, damp);

    change2 = change1;
    change1 = 10 * (1.609 * exp(.4897 * analogRead(magnet) * 5.0 / 1023.0) + 1.77E-13 *
exp(13.15 * analogRead(magnet) * 5.0 / 1023.0));
    changed = change2 - change1;



    if ( change1 >= 20 && change1 < 339)
    {
     if (changed >= threshold)
     {
      digitalWrite(clamp, HIGH);
     }

     if (changed < threshold)
     {
      digitalWrite(clamp, LOW);
//        Serial.print("Clamp, ");
//        Serial.print(changed);
      reset = 0;
      delay(500);
      weight = 1;
     }
    }

    if ( change1 < 20)
    {
     //       Serial.print("\n");
     //       Serial.print("release, ");
     weight = mode;
    }

    delay(mstimescale);
    break;

   case 1: //Weight on
    Serial.print("On");
    Serial.print(", ");
    digitalWrite(clamp, LOW);
```

```
      analogWrite(piston, 255);

      change2 = change1;
      change1 = 10 * (1.609 * exp(.4897 * analogRead(magnet) * 5.0 / 1023.0) + 1.77E-13 *
exp(13.15 * analogRead(magnet) * 5.0 / 1023.0));
      changed = change2 - change1;



      if (changed <= abs(threshold) / 2)
      {
        counter++;
        delay(mstimescale);
        if (counter > stridetime) counter = stridetime;
      }

      if (changed > abs(threshold) / 2)
      {
        //      Serial.print("\n");
        //      Serial.print("release, ");

        weight = mode;
      }

      if (reset == 0)
      {
        change1 = 0;
        change2 = 0;

        cadence3 = cadence2;
        cadence2 = cadence1;
        cadence1 = counter;

        if (cadence3 == 0)
        {
          if (cadence2 == 0)average = cadence1;
          else average = (cadence1 + cadence2) / 2;
        }
        else average  = (cadence1 + cadence2 + cadence3) / 3;

        reset = 1;
        counter = 0;
      }
      break;

    case 2: //Leg Swing
```

```
      Serial.print("Swing");
      Serial.print(", ");
      digitalWrite(clamp, HIGH);

      change2 = change1;
      change1 = 10 * (1.609 * exp(.4897 * analogRead(magnet) * 5.0 / 1023.0) + 1.77E-13 *
exp(13.15 * analogRead(magnet) * 5.0 / 1023.0));
      changed = change2 - change1;

      delay(mstimescale);

      if (changed < - 16)
      {
        swing = 1;
      }

      if (swing == 1 && changed > 16)
      {
        weight = 0;
        Serial.print("\n");
      }

      break;

  }
}
```

Circulum Vita

Lucas Jonathan Galey was the firstborn son of Tom and Gabi Galey on June 8, 1992. His mother homeschooled him through the 10th grade, and he graduated from Cassville High School in Missouri in 2010. Lucas earned his Bachelor of Science, Magna Cum Laude, with a Biomedical Concentration from LeTourneau University in May 2014. In Fall of 2014, Lucas followed his professor, Dr. Roger Gonzalez, from LeTourneau to The University of Texas at El Paso; and began pursuing his M.S. in Biomedical Engineering.

Permanent address: 350 N Festival Dr.
Apt. 1009
El Paso, TX 79912

This thesis was typed by Lucas Jonathan Galey.