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

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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.

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by

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THESIS

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> *"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).

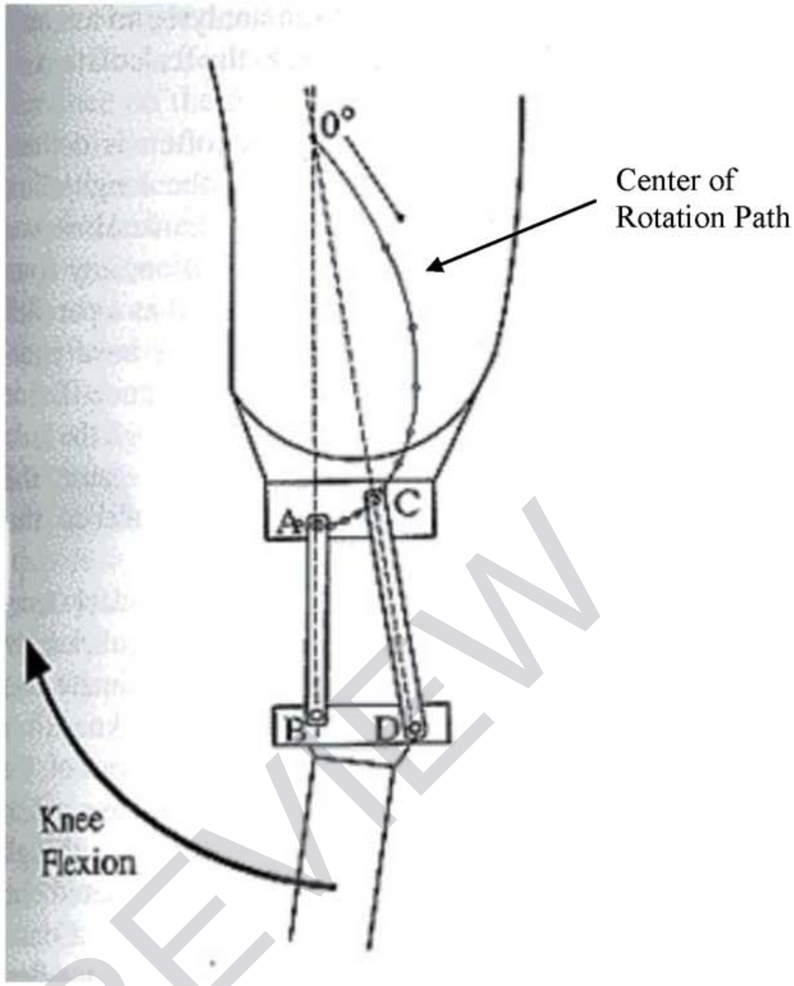

Figure 1.1: Four-bar knee mechanism. Dotted lines indicate the moving center of rotation. Path of center of rotation throughout flexion is given. Photo from (Gard, Childress, and Uellendahl 2008).

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).

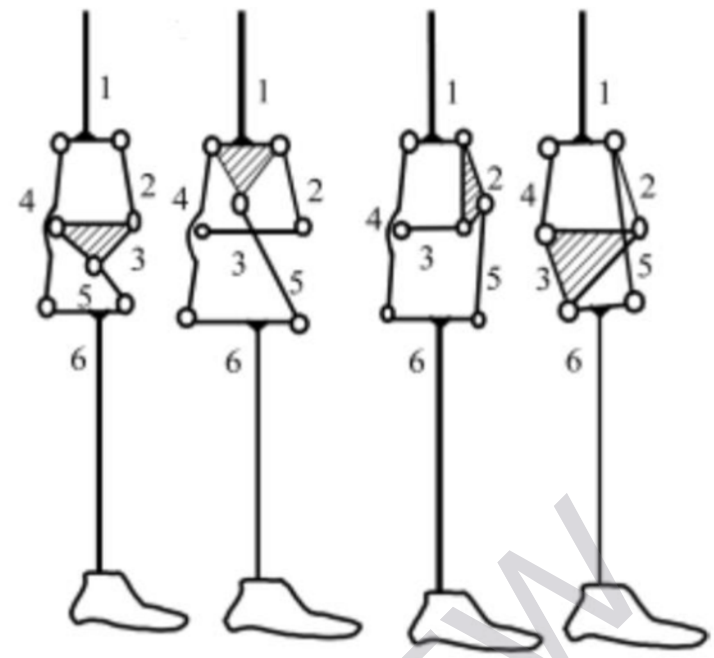

Figure 1.2: Example configurations of six-bar mechanism. Photo from (Jin et al. 2003).

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.