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Comparative Outcomes Assessment of the C-Leg and X2 Knee Prosthesis

by

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A dissertation submitted in partial fulfillment
of the requirements for the degree of
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Dedication

First and foremost, I would like to dedicate this work to my wife, Kimberlee for her unwavering support and understanding. Without her, this would not have been possible. The dedication extends also to my three sons: Lance, Toby and Miles. I hope one day they will grow to be critical thinkers and hard workers. They, too, have sacrificed throughout this time.

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Abstract

Background

There are more than 300,000 persons in the U.S. living with transfemoral amputation (TFA). Persons with TFA use a knee prosthesis for gait and mobility. Presently, the C-Leg microprocessor knee prosthesis is the standard of care. C-Leg has significantly improved safety and cost efficacy and has created modest gains in gait efficiency. Recently, a new prosthesis has introduced a new sensor array and processor that reportedly improves knee motion, stair function and standing stability. Early claims of the reported functional benefits of the new Genium knee (formerly X2) have not been validated in a rigorous clinical trial. Therefore, the purpose of this project was to determine if the Genium knee improves safety, function and quality of life compared to the current standard of care (C-Leg).

Methods

The study is a randomized AB crossover with a control group. Subjects must have used (and still be using) a C-Leg for a minimum of 1yr prior to enrollment. Inclusion criteria beyond this are unilateral transfemoral or knee disarticulation amputation for any etiology, community level ambulation (Medicare level 3 or above), independent ambulation and ability to independently provide written, informed consent. Once enrolled subjects utilize their same socket but receive a study foot (Trias or Axtion). Subjects are randomly assigned to either stay with their C-Leg or be fit with a Genium knee. Subjects accommodate and test (A phase) then crossover to the other knee condition and repeat

the testing (B phase). A follow up phase of the study beyond the B phase is ongoing to study longer term preference. For AB assessment, three domains were assessed: Safety, function and quality of life. For safety, the PEQ-A survey of stumbles and falls, posturography (Biodex SD limits of stability and postural stability tests), 4 square step test and 2 minute ramp stand test were completed. For function, a series of timed walking tests, the amputee mobility predictor, kinematic gait assessment and physical functional performance-10 tests were conducted. For quality of life, the socioemotional and situational satisfaction domains of the population specific and validated PEQ (prosthesis evaluation questionnaire) were completed.

Results

<u>Safety</u>: Posturographic assessment revealed impairment between transfemoral amputees and non-amputees. Stumbles and semi-controlled falls decreased with Genium but were not significantly different. Four square step testing was significantly ($p \leq 0.05$) improved from 12.2s(3.3) to 11.1s(3.4) for the C-Leg and Genium respectively.
<u>Function</u>: Kinematic asymmetry was minimally different between knee conditions. The AMP mean(SD) scores while subjects used C-Leg was 40.8(3.6; 33-45) and 43.3(2.6) [p<0.001]. PFP scores (cumulative), upper body function and endurance scores were improved with Genium compared with C-Leg at 9.1%(p=0.03), 8.7%(0.01) and 10.3%(0.04) respectively.
<u>Quality of Life</u>: For quality of life, situational satisfaction favored Genium ($p < 0.001$) which included subject’s satisfaction with gait, training and quality of life in general.

Conclusion

C-Leg and Genium promote static weight bearing beyond asymmetric values reported in the literature. In terms of limits of stability, TFA’s are clearly impaired, primarily over the amputated side posteriorly however the Genium seems to enable posterior compensations that coincide with multi-directional stepping improvements. Anteriorly, the C-Leg's toe triggering requirements seem to improve limits of stability but come at the cost of discomfort on ramp ascent. With regard to safety, it seems that both knee systems represent good options for the community ambulating TFA.

The largest improvements with Genium were in the activities of daily living assessment; predominantly balance and upper body function. It seems that the combination of multi-direction stepping with starts and stops and stair ascent are key areas of improvement.

In conclusion, the sensor array in the Genium knee prosthesis promotes improved function in activities of daily living. Specifically improved in this context were balance, endurance, multi-directional stepping, stair ascent and upper limb function in highly active transfemoral amputees.

Chapter One: Overview of Functional Performance and Impairment in Persons with Transfemoral Amputation

Anatomic knee function

The hip, knee and ankle joints comprise the primary sagittal articulations of the lower extremity. Human joints including the anatomic knee (tibiofemoral joint), articulate in all three cardinal planes.[1] The knee joint produces its largest motion in the sagittal plane where it routinely can move from 0-140˚ of active range of motion. The following functional activities require a considerable range of motion[2]:

1. gait; stance phase- 15-20˚
2. gait; swing phase- 60˚
3. stair climbing- 83˚
4. sit to stand- 93˚
5. picking up objects from the floor, donning socks while seated- 117˚

The muscles controlling the knee joint manage environmental forces acting about the knee, produce and control movement of the knee to adapt joint position as is situationally required.[3] At times, the knee can be stabilized passively. During quiet standing for instance, the body's weight line falls anterior to the knee joint's sagittal center of rotation and is passively stabilized by posterior ligaments minimizing the need for muscular effort.[4] During other activities, such as sitting down from standing, the loading response of gait and stair descent, the muscles of the knee produce eccentric, lengthening contractions to dampen the rate of knee flexion. Oppositely, concentric contractions of knee muscles are utilized when the knee is required to extend under load.[1] Examples of loaded knee extension activities include climbing stairs, standing up from sitting and kicking a ball. Passive recoil of muscles that are stretched, in addition to momentum can also drive knee movement. For instance, in terminal stance, the hip is extended and the knee is flexed and thus the rectus femoris and quadriceps femoris are stretched. Tension and energy stored within these muscles are returned as the limb is advanced forward and the knee extended in preparation for initial contact.[1] Finally, the knee plays a role in fall prevention. People are aware of the position and movement of the knee at critical events during movement, due to proprioceptive and kinesthetic awareness. During quiet standing an ankle strategy is most commonly utilized to manage posture and the associated perturbations. If proprioceptive input is impaired, the ankle strategy is commonly replaced by a hip strategy. In healthy individuals, the knee is not typically recruited to manage routine postural perturbations however it is recruited during falls.[5]

Key Topics in Transfemoral Amputation

Amputation of the lower extremity is a medical intervention for pathologies and trauma of the lower limb that can be life threatening. When situations require amputation above the knee, mobility and stability are impaired.[6] Presently, no commercially available exoprosthetic knee systems directly integrate neuromuscular input as a control system. Instead, prosthetic knee systems move in response to gross residual limb movement rather than through specific neural control to the prosthesis. Osseointegration is a direct skeletal attachment to the prosthetic components or in the case of above knee amputation, connection to the knee system. Osseointegration is currently being studied worldwide; however it is not yet an option for persons with amputation in the United States.[7,8] Presently in the U.S., physical connection to the prosthetic knee system is by way of a prosthetic socket (or interface). The person with transfemoral amputation (TFA) will place their residual limb inside the socket. Weight bearing forces, such as those experienced during stance phase are managed by way of pressure distribution in the socket in accordance with its design. For instance, total surface bearing socket theory implies that if pressure were to be measured at two random places about the socket, the pressure readings would be the same. Conversely, a specific weight bearing socket would preferentially load pressure tolerant areas (i.e. lateral femoral shaft, femoral triangle) and minimize load on pressure sensitive areas such as the distal cut end of the femur.[9] Distraction forces are managed through a suspension system such as suction, vacuum and locking liners. These suspension systems keep the prosthesis attached to the body during the swing phase of gait.[6]

There are numerous impairments and comorbidities associated with transfemoral amputation. Some of these include skin maladies[10], gait impairment[11], safety issues and decreased function to name a few[12].

Persons with lower limb amputation, including TFA will experience dermatopathology of the residual limb. Skin problems occur for many reasons with prosthetic use.[10] The anatomic foot is the interface between ground and lower extremity joints. Numerous tissues intervene in this typical anatomic configuration including the calcaneal fat pad, the ligaments that support the arches of the foot, the arced shape of the long bones of the leg and thigh, articular cartilage of the joints and more. When the foot, ankle joint, leg, knee and part of the thigh are amputated, different anatomic structures have to substitute for the weight bearing function in place of the lost anatomy. Commonly, the tissue envelope consisting of thigh muscles and tendons, fascia and subcutaneous fat are sutured to and across the transected femur. Ideally, this residual limb is cylindrically shaped which enables broad weight bearing across the entire limb.

Even when ideally shaped, the residual limb is not as adequately designed for weight bearing as is the foot and therefore the forces associated with weight bearing and gait are far more destructive to the transfemoral residual limb even when the prosthetic socket is well fitted.[6] For this reason decubitus ulcers are common in the TFA population.[10] Placing the residuum within a non-ventilated prosthetic socket is also conducive to the accumulation of heat in which case evaporative cooling is not possible.[13,14] Perspiration accumulates, macerating tissue and making skin at increased risk of shear damage and infection. Alignment also plays a role in skin health. Proper alignment minimizes force coupling stress risers. Therefore, an improperly aligned prosthesis can further compromise skin health and adversely affect prosthetic wear, utilization and satisfaction.[10]

Persons with transfemoral amputation experience a number of gait alterations compared to non-amputees. For instance, the energy cost of ambulation with TFA is greater than that of non-amputees.[15] In order to maintain a comfortable level of ambulatory energy consumption, the person with TFA will decrease their walking speed. In addition to the added energy cost, typical TFA gait is characterized by a shorter than typical step duration with the prosthetic side.[11] The shorter step duration is thought to be associated with potential socket discomfort and poor ability to stabilize the prosthesis with the residual limb. Conversely, the step length on the prosthetic side is commonly longer than that of non-amputees. The increased prosthetic side step length is thought to be associated with tight or contracted hip flexors on the residual limb that are uncomfortably stretched when the prosthesis goes into terminal stance and the involved side hip is extended.[16,17] In some persons with TFA, the lumbar spine is hyperextended to create a comparably equal step length artificially at the expense of excess compression forces to the lumbar spine.[6,17] Incidentally, there is a considerable prevalence of back pain in this population.[18]

When all the anatomy is intact and a human body is of typical proportion and mass, the center of mass is believed to be concentrated just anterior to the second sacral vertebra.[1,5] When anatomy is amputated, the center of mass is relocated in a direction opposite of the missing anatomy.[6] In the case of the person with TFA, the center of mass is relocated mediolaterally away from the amputated side and proximodistally toward the head. Stability and thus balance are maintained within quiet standing by managing subtle perturbations where the center of mass moves within the base of support but is always kept within the base (the area bounded by the feet). The ankle joints are most commonly utilized to manipulate the center of mass so that it stays within the base of support.[5] Moving the center of mass higher above the floor, such as with TFA, multiplies the effect of slight postural perturbations during standing and during walking. Additionally, one of the ankles is missing which impairs the ability to manipulate the center of mass particularly over the amputated side. A hip strategy has to be employed to some extent which is the same strategy utilized by persons with diabetic neuropathy. Both populations are at risk of increased falls.[19,20]

The aforementioned altered position of center of mass and change from ankle to hip strategy provide some explanation for falls associated with non-ambulatory standing conditions but offer little explanation for falls during transitional movements, turning maneuvers and walking. Several authors have offered some explanations for falls that happen in persons with TFA during more dynamic instances. These are necessary because in the prosthetic rehabilitation literature, Miller et al.[21-23] famously reported that in community ambulating persons with lower limb amputation, 52% had fallen in the past 12 months, 49% had a fear of falling, and 65% had low balance confidence scores. Additionally, a recent study determined more specifically that persons with TFA stumble 3 to 7 times and fall between 1 and 3 times every 60 days.[12] Some of the explanations for falls in dynamic situations in persons with TFA include decreased gait velocity[12], decreased spatiotemporal gait symmetry[11], decreased biomechanical symmetry during transitional movements[24], decreased ability to control gait initiation and termination[25-28] and due to preferential unidirectional turning a decreased ability to turn in the opposite direction during gait[6,29-31].

Epidemiology

Military Epidemiology

There are many misconceptions among lay people, as well as the medical community about the incidence, prevalence, cause of, and location of amputation in the military population. For instance, many presume that there has been a higher incidence and prevalence of amputation while this country has been engaged in a time of war. The United States has been engaged in two wars over more than the last 10 years. Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) have consequently caused the loss of life of more than 6,400 US service members.[32] While that number is significant, advanced vehicle and body armor design, improved surgical care techniques, and enhanced medical and troop training, have contributed to the highest war injury survival rates in the history of the United States military. For comparison, the World War II survival rate was 70.7%.[33] In 2011, for the wars in Iraq and Afghanistan, the survival rate was 89.7%.[34]

When survival rates increase subsequently, wounded soldier rates also increase. If there are less combat killed in action, there will obviously be an increase in soldiers living with combat sustained war injuries. In the wars in Iraq and Afghanistan there have been more than 48,000 service members who have sustained combat injuries. More than 70% of combat wounded service members suffered extremity trauma.[35] The US military integration database indicates that as of April 2012 nearly 1500 injured US service members required limb amputation. Of these, 438 experienced multiple limb loss and 1015 of them experienced single limb loss.[34] These traumatic amputations represent more than 2% of all battlefield injuries and greater than 7% of major extremity injury associated with military service.[36,37] Specific to the current wars in Iraq and Afghanistan, the number of amputees is variable between studies.[36-38] Stansbury et al.[37] report 423 soldiers receiving amputation(s) between 2001 and 2006 while

448 are reported by Stinner et al.[39] Potter and Scoville reported 381 surviving amputees with a cumulative 441 major amputations from the start of OIF/OEF through 2005.[36] As of July 2009 a different source, the Veteran Administration's OIF/OEF Amputee Dashboard, reports a total of 792 registrants. This does not account for those currently on active duty status.

The military amputation rate is lower now than in all other previous combat reports. Conventional thinking is that successful limb salvage is preferable to amputation. Surgeons have been trained to salvage limbs and the mindset that a functionally compromised but salvaged limb is superior to an amputated one prevails.[40-43] Amputation is therefore viewed as an operative failure. Some who practice in the reconstructive profession, or who have been through the decision process of a limb reconstruction, may disagree. Additionally, a vast majority of the literature with conclusions supporting limb salvage predates the enormous advancements in contemporary prosthetics such as microprocessor ankles, knees, and energy storing feet. Therefore, considering amputation as a failure may be an aging concept as amputation is increasingly viewed as a viable option when function is to be gained. The sacrifice of these US military members is monumental, however the number of military amputees is considerably small when viewed in a national context.

<u>US Epidemiology and Etiology</u>

A recent study estimated the prevalence of limb loss in the United States and projected these numbers into the future.[44] They concluded that the number of people living with the loss of a limb will continue to increase, driven in particular by the aging of the population and the associated increase in the incidence of diabetes mellitus and dysvascular disease. Additionally they concluded the need for effective programs and policies that will guarantee access to prosthetic limbs, assistive devices, and appropriate health and prosthetic services to ensure the well-being of the already large number of persons living with the loss of a limb.[44]

Presently, in the United States there are an estimated 1.6 million persons living with limb loss.[15,44] Of these, 86% or approximately 1.3 million, have amputation of the lower extremity. In the United states, an estimated 185,000 persons undergo an amputation of an upper or lower limb each year.[15,44] Although patterns in the incidence of limb loss secondary to diabetes mellitus,[12,33,35,45-54] dysvascular disease[33,55-60], trauma[33,61-63], and malignancy of the bone and joint[33,64] have been explained over the past 30 years, little is known about prevalence or the number of persons currently living with the loss of a limb.[15] Slightly more than half of all lower extremity amputees are either transtibial or transfemoral amputees. Twenty eight percent of lower extremity amputees, or approximately 380,000 individuals have a transtibial level amputation.[32,33] Approximately 72% of transtibial amputations (TTA) in the U.S. are attributable to vascular disease.[32,33] Of the remaining 18%, 7% of TTA's are the result of trauma.[32,33] Twenty-six percent of lower extremity amputees, or approximately 360,000 individuals have a transfemoral level amputation.[15,32,33] Ninety-five percent of transfemoral amputations (TFA) are attributable to vascular disease and diabetes related vascular disease. The remaining five percent of TFAs are attributable to trauma, malignancy, and congenital limb deficiencies.[15,32] There is a higher incidence and prevalence of dysvascular related amputation with advancing age. African-American individuals have the highest incidence of any particular group.[32,33]

The predominant single level of amputation is the transtibial level, followed closely by the TFA.[32,39] This is important because it highlights the need to learn more about the specific rehabilitative needs of this group of amputees. Both levels will require a prosthetic interface and foot, with the component difference being the knee. In the private sector, it can be inferred that the predominant functional level[65] of amputation is at some point between the household and community levels of ambulation.[16,65-67] This is in contrast with the military amputee who is far more likely to be functioning at the K4 level.[39,65] The ambulatory abilities and needs are different between the two groups. However, while needs may be different, the function of missing a knee is the similarity that associates them. The military's adopted protocol in the past was to fit the newer TFA into a higher functioning microprocessor knee, and then transition them to a non-microprocessor knee. In the private sector, new amputees will begin training on the non-microprocessor knee, and transition to microprocessor knees like C-Leg and Genium.[68]

TFAs who achieve successful ambulation are more likely to do so with upper extremity aids and may develop an adapted gait pattern, even while walking on level ground.[35] It is important for amputees to feel stable and safe while walking with their prosthesis. It is also desirable to achieve the maximal functional level possible. Transfemoral amputees use a prosthetic knee for ambulation. Prosthetic knees are generally available with or without microprocessor control. Microprocessor-controlled prosthetic knees (MPK) are commonly equipped with sensors to continuously detect the position, range and forces acting upon the knee throughout the stance and/or swing phases of gait and other activities. Such sensors provide input to the microprocessor so that the knee can appropriately accommodate the particular activity or phase and velocity of gait. This allows virtually instantaneous adaptation to different walking speeds, terrain, and environmental conditions.

Development of the X2 and Genium Knees

The Department of Defense's increase in extremity injuries, specifically amputation, has heightened its interest, time and resources towards developing projects like the development of the DARPA arm and a new microprocessor knee, called the X2. For the X2 project the Department of Defense collaborated with Otto Bock (Otto Bock; Duderstadt, Germany), a leading manufacturer of prosthetic components. The foundational development for the X2 came from the C-Leg, the current standard of care in prosthetic knees. The X2 and C-Leg are microprocessor controlled knees that control stance and swing phase and adjusts to the requirements of the prosthesis wearer at a rate of fifty times per second, or higher in the case of the X2. The addition of a microprocessor to rapidly regulate stance and swing phase could improve ambulatory functions such as safety and energy efficiency. Such technological advancements usually come at considerable cost to the healthcare system. Several studies have evaluated the safety, energy efficiency and cost efficacy of the C-Leg compared to other prosthetic knees. In some studies it has been reported to actually increase the level of function as well as independence.[12,45] The success of the C-Leg was the impetus behind developing a newer more advanced technology, using more input sensors and applied to a different version of microprocessor prosthetic knee technology: the X2.

The subsequent benefit of the DoD X2 prosthetic knee project, has been the development of the private sector version called the Genium knee. At the time of development of the protocol for this study there was only one new microprocessor knee available from Otto Bock, called the X2. Near the recent conclusion of this study, the X2 knee was renamed for branding purposes, for the private sector version of the knee, which is now called the Genium knee. Both the X2 and Genium knees are structurally and functionally the same, with the two exceptions: The X2 has an additional running mode added to the algorithms. Secondly, the X2 cover is different which makes the knee slightly more water resistant. It has the same technology to protect a transfemoral amputee (TFAs) from falling (for instance) by accurately sensing and recognizing gait patterns.

While the X2 knee has helped many service members become active and be able to ambulate, run, and even return to duty, the most common application of this technology lies with the Genium knee, which benefits a much larger population of amputees in United States who have received an amputation because of peripheral vascular disease, a more common cause of amputation. For the remainder of this document, the experimental knee will be referred to as “Genium”.

This chapter has sought to provide an overview of some key functions of the anatomic knee within a broader functional context and to compare it to that of persons who live without an anatomic knee and instead utilize an artificial, exoprosthetic knee. The next chapter will focus on how many individuals in the United States live with transfemoral amputation and what are the processes responsible for their limb loss.

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Chapter Two: A Review of Component Classification Systems for Prosthetic Knees

Prosthetic knee components are currently described by several classification schemes.[1,2] Significant technological advancement, including microprocessor knees which presently represent the standard of care and introduction of the hybrid knee concept have confounded present classification schemas. The purpose of this chapter is to provide an update of presently available classification systems used for describing prosthetic knee joints. The chapter will also identify their limitations and propose modifications to account for state of the art components.

Joan Edelstein wrote:

> *"Familiarity with the characteristics of current prosthetic foot-ankle assemblies will enable physical therapists to participate more effectively in the management of individuals with lower limb amputation."*[3]

This is true for prosthetic foot-ankle assemblies and all prosthetic componentry. It also extends beyond physical therapists as well and includes many professionals such as physicians, prosthetists, engineers, researchers and others that work with clients with amputation.

The number of available prosthetic components is staggering. In order to have a framework for selecting components, it is useful to think of them in terms of one of several classification systems based on a given quality or set of qualities. Similar to prosthetic feet and other prosthetic components, there are several ways to describe, list and classify prosthetic knees.[1,2] Contemporarily common methods include (in the United States) the Medicare Functional Modifier system[4,5], a system based on a hierarchy of stability versus control[6], a system describing swing and stance control media[7] and a more comprehensive descriptive system.[6,8]

Medicare Functional Modifier System

The most simplistic way of classifying prosthetic knees is done with Medicare's functional modifier, or "K" scale system.[4,5] (Table 2.1) Under this classification system, knees are subdivided into three very general categories; Basic knees, Fluid/Pneumatic and "Any" knee.

Basic knees for the household ambulator (K1) include such units as the manual locking unit or weight activated stance braking (WASB) knee. Excluded from the definition of K1 and K2 levels of ambulation is the operant phrase "variable cadence". This is introduced at the K3 level, which is the point that fluid friction is introduced. Therefore it is presumed that all knee components in the K1 and K2 categories (Basic Knees) will likely afford only single speed ambulation as cadence control features are introduced with fluid mediated friction units at the

Table 2.1: Abbreviated outline of Medicare's Functional Modifier Classification system or "K" scale.

K Level	Functional Description	Prosthetic Feet	Prosthetic Knees
K0	Non-ambulatory. Not a prosthetic candidate.	None	None
K1	Limited and unlimited household ambulation. Level surfaces. Fixed cadence. Transfers and therapeutic use.	Basic Feet: External Keel, SACH, Single Axis	Basic knees
K2	Limited community ambulation. Able to traverse low-level environmental barriers (curbs, ramps, stairs, uneven surfaces).	Multi-axial feet, Flexible Keel feet, Axial rotation (ankle) unit	
K3	Community ambulation. Variable cadence gait (or potential). Most environmental barriers.	Dynamic response feet	Fluid & Pneumatic knees
K4	Children. Those with Bilateral involvement. Active adult. Athletes. Exceeds basic use.	Any	Any

K3 level. It should be pointed out that fluid friction is not always mechanically regulated. Today, it may be controlled via microprocessor. Use of the term *any*, introduced at the K4 ambulatory level, implies that atypical situations may present that require equally atypical intervention. Therefore there are no restrictions on which type of knee may be utilized at the K4 level.

Because it was not intended to do so, knee classification by the Medicare system does not adequately capture stark differences between available knees. This system is not truly a knee classification system. It is better suited to delineate differences between ambulatory abilities and provide broad guidelines from which components may be appropriately prescribed and reimbursed at a given ambulatory level. Essentially, the Medicare system is utilized more to restrict funding based on ambulation requirements. In practice however, it is used as a classification system. For example a component such as the manual locking knee may be referred to as a “K1 or Basic knee”.

Hierarchy (or Continuum) of Stability Versus Control

Moving to a system better suited for actual knee component classification, a continuum of inherent stability versus voluntary control, has been proposed.[6]

Table 2.2: Hierarchy of stability; in this defined group of components, as inherent stability increases, voluntary control decreases.

<table>
<tr><th colspan="3">Hierarchy of Prosthetic Knee Stability vs Control</th></tr>
<tr><td rowspan="5">Most Inherent Stability/
Least Voluntary Control

Most Voluntary Control/
Least Inherent Stability</td><td>1.</td><td>Manual Locking Knee</td></tr>
<tr><td>2.</td><td>Polycentric Knee</td></tr>
<tr><td>3.</td><td>Weight Activated Stance Braking Knee (WASB)</td></tr>
<tr><td>4.</td><td>Single Axis Constant Friction Knee</td></tr>
<tr><td>5.</td><td>Outside Hinges</td></tr>
</table>

This list (Table 2.2) identifies the selected knees in order of *most* inherently stable (the manual locking knee) to *least* inherently stable (outside hinges). To discuss the knees from *least* inherently stable to *most* inherently stable, the list is simply reversed.

This classification provides a perspective of more functional value than the previous system but it too is not all-inclusive and can be a bit misleading as it is not always hierarchical in terms of matching patient abilities. For example, many polycentric knees are designed for individuals with short residual limbs needing higher inherent stability and ground clearance at mid-swing. Conversely, some polycentric knees are designed for individuals with knee disarticulation level amputation who are highly active. Such people may prefer a relatively unstable alignment that affords a high quantity of voluntary control. If such a person's condition improved such that decreased component stability was needed then changing to a weight activated stance brake knee, as indicated in this hierarchy, would actually be an increase in inherent stability rather than a decrease. The increased function may require switching to a single axis knee with fluid friction or outside hinges in order to decrease inherent stability. The point is that this method also does not fully account for all available products and in select cases, may be hierarchically incorrect.

Another example may be in describing a microprocessor knee; todays standard of care. Many microprocessor knees, according to this classification system may best be described as a single axis knee however the friction is not necessarily constant. Also, microprocessor knees can be set up or programmed to be much more or less stable than comparably aligned knees from other classes.

System for Describing Swing and Stance Controls

Wilson[7] describes prosthetic knee units as having roles in stability during standing, flexion during sitting but ultimately as having two "major and distinct" functions: 1) joint control during the stance phase of gait and 2) shank control during the swing phase of gait. He presented what he referred to as “a rather simplified” approach to prosthetic knee classification by identifying swing and stance control media (Figure 2.1).

The schematic presentation is a user friendly means for describing the control options available by swing and/or stance phase but also has limitations. It does not account for extension assist, microprocessor control, the possibility of combined control (hybrid systems) and others. Some of this system’s shortcomings are undoubtedly due to rapid technologic advancement.

Comprehensive Descriptive System

A descriptive classification system[6,8], lists the following as knee categories:

1. Axes
2. Friction
3. Braking or Locking Mechanisms
4. Microprocessor Control

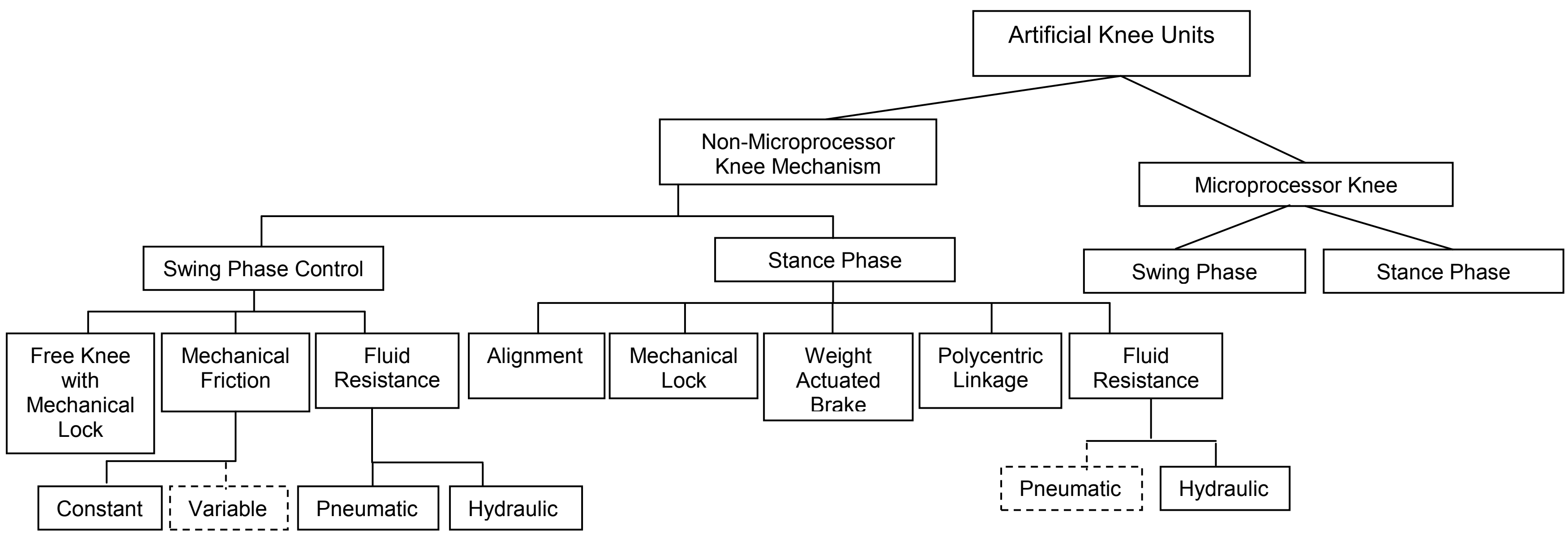
An additional category, *Extension Aids*, has been described.[6] As the name implies, this schema is more of a descriptive method for discussing and classifying prosthetic knee joints. Most of the five main headings have subheadings. The entire layout, with subheadings is presented in Table 2.3. A brief review of each category follows.

<u>Axes</u>

Single Axis Knees

Prosthetic knee joints are either single or multi-axial. Knees from this class have traditionally had three basic subclasses; exoskeletal, outside hinge designs, and

Figure 2.1: A prosthetic knee classification system that describes swing and stance control media. Media within dashed boxes are not represented in commercially available prosthetic knee units.



endoskeletal (modular). Single axis knees were historically among the most simple in design but today can be quite complex. Microprocessor knees for example, are technically modular, single axis knees (Figure 2.2).

Table 2.3: Commonly described aspects of prosthetic knee joints including subheadings.

Comprehensive Descriptive Classification System of Prosthetic Knee Joints
1. Axes A. Single Axis i. Modular/Endoskeletal 1. Knee Cage 2. Stand Alone Unit ii. Exoskeletal iii. Outside Hinges B. Polycentric
2. Friction A. Fluid i. Hydraulic ii. Pneumatic B. Sliding i. Constant ii. Variable (not represented prosthetically)
3. Braking or Locking Mechanisms A. Manual Locking B. Weight Activated Stance Braking (WASB) C. Geometric Lock
4. Microprocessor Control
5. Extension Aids A. Internal B. External

Figure 2.2. Otto Bock 3C88 C-Leg (left) and Ossur Rheo Knee). They are examples of highly technical, modular, microprocessor controlled knee units that are of a single axis design.

Traditional exoskeletal single axis knees are among the oldest design of knee units available. (Figure 2.3) They were typically indicated for heavy duty use or when a previous wearer wished to continue using them.[6] They incorporate a simple hinge positioned between thigh and shin. Exoskeletal thigh and shin sections may be made from wood, foam, or laminate materials. Historically, exoskeletal knee units have been available with constant friction, fluid friction, manual locks, and extension aids. Low market demand seems to be decreasing their availability.

Figure 2.3. Otto Bock exoskeletal Single Axis 3P19 knee. The knee mechanism is integrated into wooden shin and distal thigh sections. The knee mechanism is a single axis, constant friction unit. *Photo courtesy of Otto Bock Healthcare*.

Classic outside hinge designs (Figure 2.4) were historically recommended for knee disarticulation length amputees.[6,8,9] Outside hinges offer no stance control beyond alignment and voluntary residual limb abilities. With classic outside hinges, swing control is also non-existent beyond joint friction, which may be problematic in variable cadence ambulators.

With regard to modular, single axis knees, there are two designs: the cage design which houses a separate fluid cylinder, and non-cage, self-contained units. Alone, knee cages may be little more than a hinged frame. Some single axis knee cages offer a braking mechanism and others offer a stance flexion

Figure 2.4. Leather socket prosthesis with outside hinges for individual with knee disarticulation amputation. *Photo courtesy of Thomas Karolewski, CP, FAAOP.*

feature. Many knee cages provide home to fluid friction cylinder units. Cages combined with hydraulic units provide many options for swing and stance control and some have options for low profile build heights and low resistance motion. This is a very popular option for higher functioning users but this is not requisite as they are also available for lower functional users.

Self-contained, modular single axis knee units may be augmented with various forms of swing and stance control. In a very basic unit, stance control is afforded by alignment and is therefore not technically a knee feature. This is not the rule as other single axis units offer a true stance control feature. Examples of stance control afforded by self-contained, single axis units include microprocessor control, fluid control and weight activated braking.

Polycentric Knees

Multi-Axial knee joints are referred to as *polycentric* (whereas single axis units may be referred to as monocentric). Polycentric prosthetic knees mimic anatomic knee arthrokinematics in that both have a center of rotation (COR) that changes position throughout joint movement. When the anatomic knee’s COR changes position, it is technically correct to refer to it as an *instantaneous center of rotation* (ICOR). The COR of a polycentric prosthetic knee is also described as an ICOR. Several benefits are reportedly associated with polycentric knee joints.

Polycentric knee joints tend to have multiple bars, or linkages (typically four or five but as much as seven) that connect various pivot points between the distal and proximal segments of the unit. Typically, the ICOR is found by drawing lines, sagittally, that connect the proximal and distal pivot points of the given bars (generally the anterior and posterior bars). The point at which these lines intersect is the ICOR (Figure 2.5).

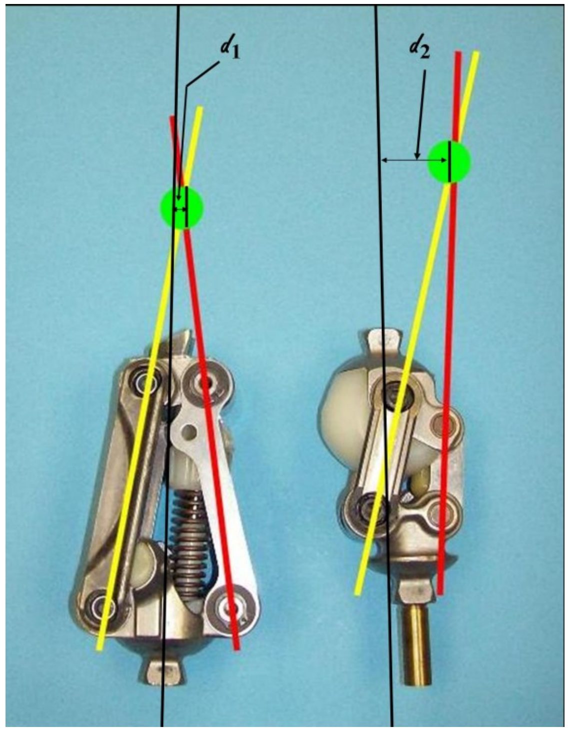


Figure 2.5. Polycentric knees. At left is the Otto Bock 3R30 knee unit, which is indicated for the knee disarticulation amputation level as the ICOR (green dot- located by intersection of line extending anterior and posterior links) in full extension is close to the distal end of the residual limb (and mechanical knee axis) and only slightly posterior to the body's weight line ($\mathbf{d}_1$, the distance between the body's weight line (black line) and the ICOR, is very small). This knee requires a high quantity of voluntary control and offers less alignment stability in extension. At right is the Otto Bock 3R36 knee unit. This knee unit's ICOR in full extension is well proximal of the mechanical knee axis (closer to the anatomic hip joint than knee disarticulation models such as the 3R66) and well posterior of the body's weight line($\mathbf{d}_2$, the distance between the body's weight line (black line) and the ICOR, is relatively large). Having the ICOR in such a location offers a higher quantity of stability, initially affording less voluntary control.

When typical polycentric prosthetic knees extend, the ICOR position tends to be well proximal and posterior to the distal midline of the mechanical knee axis. Moving the ICOR proximal to the anatomic knee center offers a leverage advantage which eases the task of flexion initiation.[7,10] Having the ICOR posterior to the weight line in extension affords a stable alignment due to induction of an extension moment about the knee.[11]

These knee units are not forced to pivot on a fixed point distal to the residual limb. Therefore, during high degrees of flexion, the proximal aspect of the shin relocates posterior to the distal residual limb. This is beneficial in positioning the knee center and shin while sitting (Figure 2.6). Additionally, this serves to effectively shorten the length of the shin during swing phase assisting with toe clearance.[12]

Friction

Friction, a force that resists motion, is used in prosthetic knee joints to alter the rate of knee cycling. It is incorporated primarily to match side-by-side cycling thereby optimizing the cycling rate on-demand. Friction present in prosthetic knees is basically of two types; fluid and sliding.

Fluid friction is provided by pneumatic and hydraulic media. A common goal of both fluid mediums is to provide responsiveness to variable cadence. In order to do this, resistance to movement must generally increase as the velocity of movement increases.[8] With regard to fluid friction, there are differences between pneumatic and hydraulic fluid. The fact that liquids are incompressible and pneumatic fluid (air) is compressible has implications in performance.[1,6] The

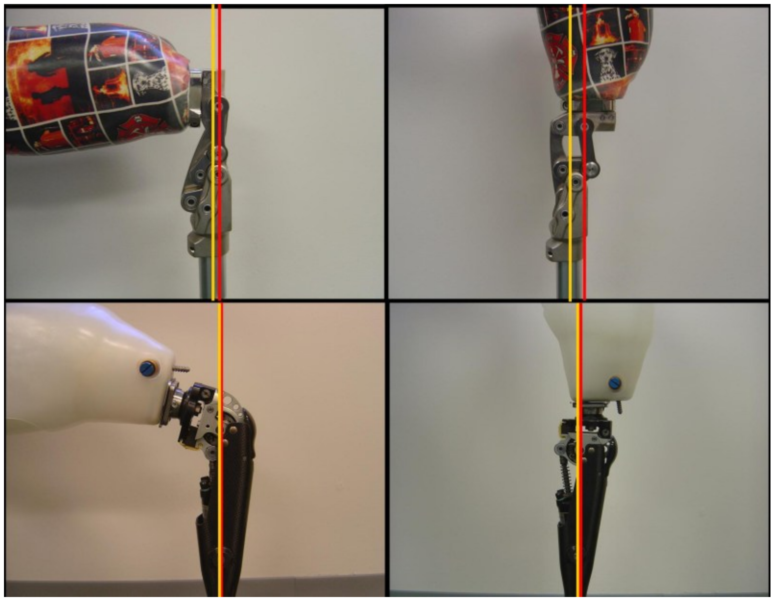


Figure 2.6. Sagittal view, polycentric knee unit flexed to approximate sitting (top left). This demonstrates that when a polycentric knee mechanism is flexed, the pylon (yellow line approximates center of pylon) is able to relocate beneath the distal femur as opposed to simply hinging beneath the joint (red line depicts a line perpendicular to the floor running through the center of rotation) such as when using a single axis knee (bottom left). Benefits are realized cosmetically during sitting and functionally during swing clearance in gait.

compressible nature of air affords an "air-spring effect" at higher cycling velocities.[6] This causes the knee to tend to extend upon being unweighted from a flexed position. Highly active users and those with higher body mass tend to overpower the resistance offered by typical pneumatic systems. This makes hydraulic friction a potentially superior choice in such cases.

Hydraulic friction units do not offer an extension bias due to compression of their fluid. Instead, extension may be augmented with the mechanical assistance of a spring which can induce knee extension upon unweighting.[6,8] Hydraulic knees tend to weigh and cost slightly more than less technical knee systems but are well known for their cadence responsiveness and ability to assist with stance control.[1,6]

The second type of friction, sliding friction, is typically used with single speed ambulators.[1,6-9] By definition, sliding friction may be either constant or variable.[6,7] These knee units are designed with some form of a pinch assembly that applies friction to an axle (Figure 2.7). Because of this design, once the friction is set, it must be manually re-set to affect a change in the knee cycling rate. Therefore, variable sliding friction is not represented in commercially available prosthetic knee units.[7] Sliding friction is constant, once the knee is adjusted.

<u>Braking or Locking Mechanisms</u>

This knee category provides component options for the lowest and highest functional users. Presently, there are three available systems in this category: the manual locking knee, the weight activated stance control knee and the geometric lock.[6]

The manual locking knee prevents knee flexion by locking the joint in the fully extended position. It includes a manual release to unlock the knee when flexion is desired such as for sitting. Some manual locking knees incorporate an extension assist to facilitate full extension upon standing.

Figure 2.7. Otto Bock 3R49 knee unit. It is a single axis design with sliding, constant friction that offers only single speed cadence per setting. Stance control afforded by this unit is via weight activated stance braking. This means that after a threshold quantity of load is applied to the knee (presuming the knee is in approximately ≤15˚ of flexion), it will not flex further which could cause buckling. This form of stance control requires the prosthesis to be unloaded prior to swinging the leg forward. This swing requisite is commonly associated with gait deviations such as hip hiking and lateral trunk bending.

The next subtype is the braking mechanism. Considered to be the third most stable on the stability hierarchy, this unit is commonly referred to as a weight activated stance braking/control knee. The most popular version of this type of knee is a single axis, constant friction joint. When loaded, generally with no greater flexion than 10-15˚, the knee will lock and flex no further. So long as the knee remains loaded, it will remain locked and resist further flexion. Once the knee is unloaded, it is permitted to flex for swing phase. This type of knee can also include swing phase control. The knee should be adjusted regularly as the braking mechanism tends to wear with use and may lead to falls.

The final subtype in this category is the geometric lock. Swing control can be via elastic polymer, sliding friction or fluid media. Several units are available ranging from pediatric to heavy duty options. These options allow coverage of single or variable speed ambulators, as well as children and adults. The geometric lock engages as the knee reaches terminal extension. At that instant, linkage alignment prevents knee buckling. Typically, a knee hyperextension moment is necessary to disengage the lock to permit knee flexion.

Microprocessor Control

Presently, several microprocessor controlled knees are available. Options include microprocessor control for swing phase only, or for both swing and stance phases. More options include single axis or polycentric designs and more recently, power actuation has emerged.

Current microprocessor controlled prosthetic knee units sample data between 50 and 1000 times per second to make adjustments to flexion/extension resistance or joint angle limits in some cases.[13,14] In some of these units, a second or alternate mode (or modes) are available that would enable the user to switch from a more traditional “walking” setup to a specially adjusted mode for unique applications such as heavy lifting or bicycling. The ability to instantaneously increase or decrease gait velocity from one extreme to another without manually adjusting the component or completing a full knee cycle, is new to this knee class. Some computerized knees have been shown to enable reciprocal ramp and stair descent most comparable to the anatomic knee. Such knees tend to offer a stance feature that is able to sense a break in cadence or rhythm that may be associated with a fall and react by engaging a safe mode that affords users the opportunity to catch themselves. Most recently, power actuation has emerged offering the promise of improved biomechanics for activities requiring active knee extension such as that produced via concentric contraction of the quadriceps femoris associated with activities such as stair climbing, ramp climbing, sit to stand and kicking a ball. Many of these claims remain unsubstantiated today.[15]

Extension Aids

Extension aids or the extension assist feature of a prosthetic knee may be located internally or externally. They may be an integral part of the knee's design or added on "after-the-fact" in some units. Certain aspects of a prosthetic user's gait pattern indicate the need for an extension assist. For instance, extension assist may be considered if the user displays excessive heel rise or delayed knee extension. Knee resistance (friction) against flexion may be too low or friction against knee extension may be too great and thus present similar issues. The extension assist will facilitate knee extension by opposing heel rise and knee flexion in pre-swing and promote knee extension once the shank begins forward movement in swing phase.

The Hybrid Concept

Prosthetic knees may have features from several of the latter categories. This is the basis of the hybrid concept.[9,16] An example may be as simple as incorporating fluid swing control with weight activated braking for stance control. However, examples may be as complex as combining pneumatic swing control, hydraulic stance control in a polycentric design, controlled by a microprocessor. Hybrid prosthetic knees incorporate unique features from one or more select knee components and combines them with the benefits of features from other knees. The goal of such combinations would be a maximal return to function and hopefully, participation in activities previously not possible with a less technically complex component.

Conclusion

There are numerous classification systems for which to describe prosthetic knees. Many of these are historic and do not adequately describe or reflect the function of contemporary components. This is especially true with the rapid technological advancements in microprocessor knee components. The purpose of this chapter was to provide an overview of the knee classification systems in use today to demonstrate the myriad of prosthetic knee options available. The next chapter will discuss the comparative efficacy of the C-Leg as the standard of care for current practice.

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Chapter Three: A Literature Review on the Standard of Care for Prosthetic Knees

This chapter was published and can be found in Appendix 1. In accordance with the permission to reproduce the material for this document, the full article citation is:

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Persmission was granted to include this published article by SAGE Publishing and can be found in Appendix 4.

Chapter Four: Mechanical Differences between the Genium Knee and the C-Leg

The C-Leg was the first swing and stance microprocessor controlled knee in the United States.[1] It was introduced in the U.S. in 1999 as a class II medical device. Most prosthetic components are considered class I medical devices and do not require FDA approval, as they are fitted to the patient externally.[2] Adding microprocessor control to a prosthetic knee allows changes to be rapidly made to the hydraulic valves regulating fluid flow through the knee cylinder that control the sagittal resistance to movement. Two sensors are used in the knee. One sensor provides kinematic data regarding knee angle, while the other sensor provides pylon strain data from the section above the foot. The microprocessor can interpret sensor data and determine where the knee is in the gait cycle at a rate of 50Hz. This microprocessor interpretation has been called real-time gait analysis. Through this interpretation, the microprocessor then changes the hydraulic controls accordingly to prepare the user for the next movement (e.g. step, fall, stairs, etc.). The addition of microprocessor control and the ability to rapidly change the hydraulic valves has led to a safer and more physiologically accurate gait.[3] For instance, if the knee senses a disruption or perturbation in the swing or stance phase it will rapidly change the hydraulic valves to close, which dampens or locks the knee, facilitating re-attainment of balance and ideally, avoid a fall.(Figure 4.1) This feature is known as stumble recovery.[4] The original C-Leg also featured a second mode (Table 4.1). This allowed the user to use a specialized toe

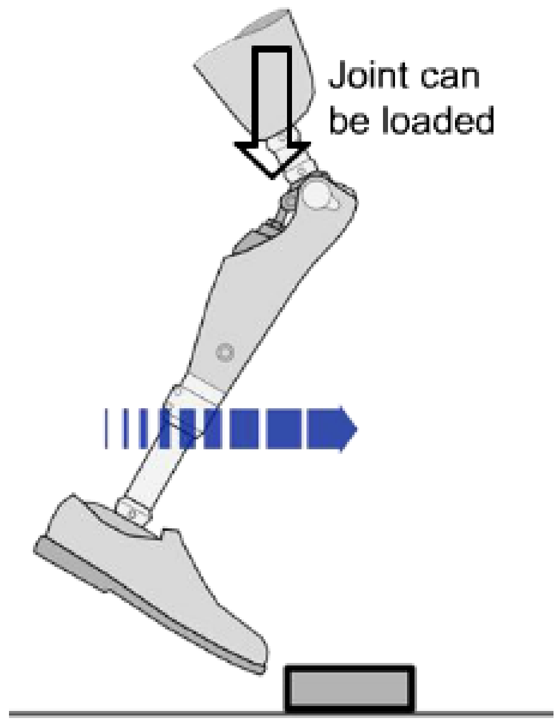

Figure 4.1. Obstacle obstructing the foot and thus knee from extending. Photo courtesy of Otto Bock Healthcare.

loading sequence or a remote control to change to an alternative knee resistance. Some examples of the use of this feature include locking the knee in slippery conditions, or unlocking the knee to use in riding a bicycle.

The Genium knee was first introduced to the U.S. commercial market in the summer of 2011.[1] The Genium knee and C-Leg are mechanically similar in that they are fluid controlled mechanisms utilizing microprocessor sensory input to determine hydraulic control. According to the manufacturer, the main difference is that new sensor technology and increased sensors have been applied to the microprocessor control strategy. Additionally, new algorithms are used to determine the valve positions based on the sensory input and microprocessor interpretation. There are six sensors (Table 4.1)incorporated into the Genium knee compared with two in the C-Leg. The Genium axial load sensor determines how much axial load is applied to the pylon.(Figure 4.2) The ankle moment sensor determines if the ankle is getting a dorsi- or plantarflexion moment during the stance phase of gait.(Figure 4.3) The knee moment sensor comparably determines the sagittal moment magnitude at the knee axis.(Figure 4.4) A two axis accelerometer is used to determine what direction the knee is traveling.(Figure 4.5) It can determine if the knee is traveling up, down,

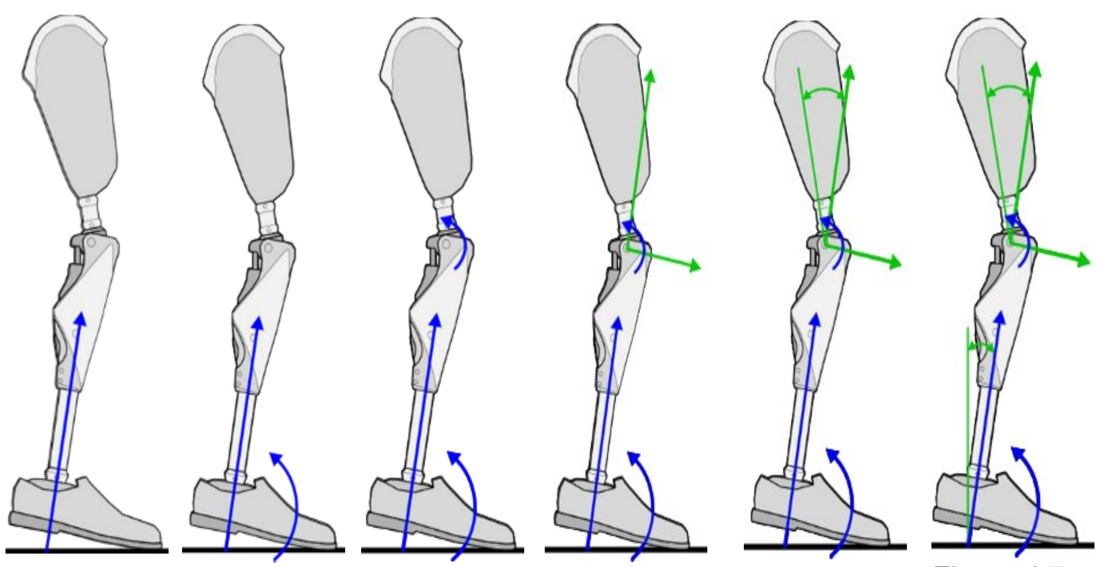

Figure 4.2. Figure 4.3. Figure 4.4. Figure 4.5. Figure 4.6. Figure 4.7.

Figure 4.2. Axial load. Figure 4.3. Dorsiflexion moment. Figure 4.4. Knee extension moment. Figure 4.5. Green arrows depicting direction of travel. Figure 4.6. Angular position of knee. Figure 4.7. Angular position of ankle. Photos courtesv of Otto Bock Healthcare.

backwards or forwards. The knee angle sensor provides kinematic data about the knee's angular position.(Figure 4.6) Additionally, the knee angle sensor relays cycling rate data to the microprocessor. A gyro is used in conjunction with the two axis accelerometer to determine if the knee is tilted forward or backwards.(Figure 4.7)

The sensor data is then used by the microprocessor to calculate the orientation of the ground reaction forces. From this information the foot's center pressure and distance the ground reaction force vector lies from the center of the knee axis is determined. In short, this microprocessor knee uses the moment of the ankle and knee to calculate the orientation of the ground reaction forces.(Figure 4.8) The manufacturer claims that this sensory input and subsequent microprocessor control of the hydraulic valves results in a more physiological gait. The manufacturer refers to this function as *optimized physiological gait* (OPG) (Table 4.1). Some specific results of this function are initiation of knee flexion independent of knee angle, gait speed, or toe load. The knee is preflexed 4° in preparation of axial load of the knee and loading response. The valves are changed nearly instantaneously throughout the gait cycle because of constant input from the sensors and interpretation by the microprocessor. One practical example of this is that users can initiate swing flexion while the knee is not fully extended and loaded. Previously with the C-Leg, users would have to develop a prescribed gait pattern of full knee extension and a toe load of 60% body mass to initiate knee flexion for swing phase.

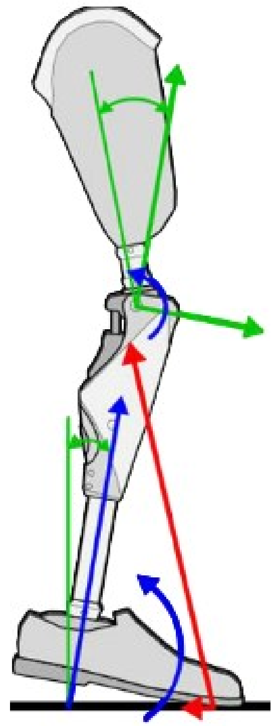

Figure 4.8.

Figure 4.8. Depiction of hypothetical ground reaction force (long red arrow) determined based on moments at ankle and knee. Photo courtesy of Otto Bock Healthcare.

One feature of the OPG function, is that the knee can adjust the peak flexion angle during different speeds of gait. This ensures that the gait pattern stays consistent independent of subjects gait speed. Figure 4.9 displays that as gait speed increases, the knee angle remains consistent.[5] In other knees, increased momentum will result in angular knee changes associated with differing gait speeds.

Proposed functional features provided by the Genium's sensor array, microprocessor, and associated algorithms may translate into a broader range of adaptation to activities of daily living that include: the ability to ascend stairs step over step (Figure 4.10), a feature that blocks flexion while standing potentially

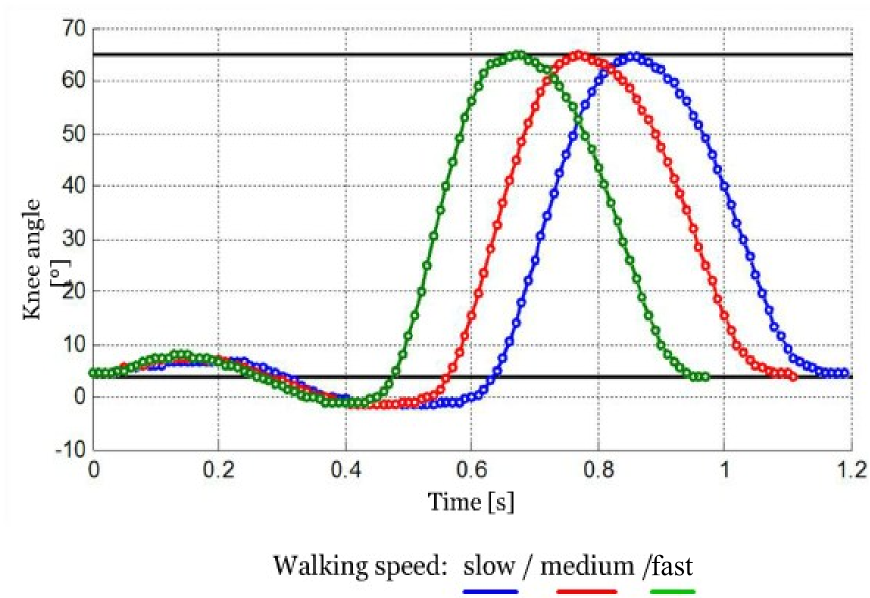

Figure 4.9. Comparable peak swing phase knee flexion regardless of gait speed. Photo courtesy of Otto Bock Healthcare.

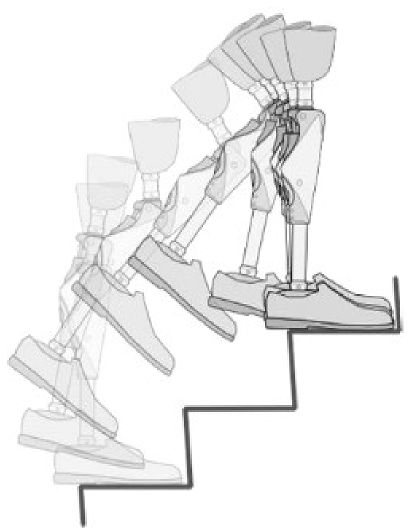

Figure 4.10. Flexion valving blocked for stair ascent while extension remains available. Photo courtesy of Otto Bock Healthcare.

allowing maintenance of a flexed knee position to lift objects or stand still, adaptive yielding control, (Figure 4.11) stance release on ramps, a sitting function that allows unresisted swing whereas the C-Leg knee maximally resists flexion during sitting and transitional movements, and an increased battery life due to the additional sensors determining when valve opening and closing of the hydraulic knee is needed.

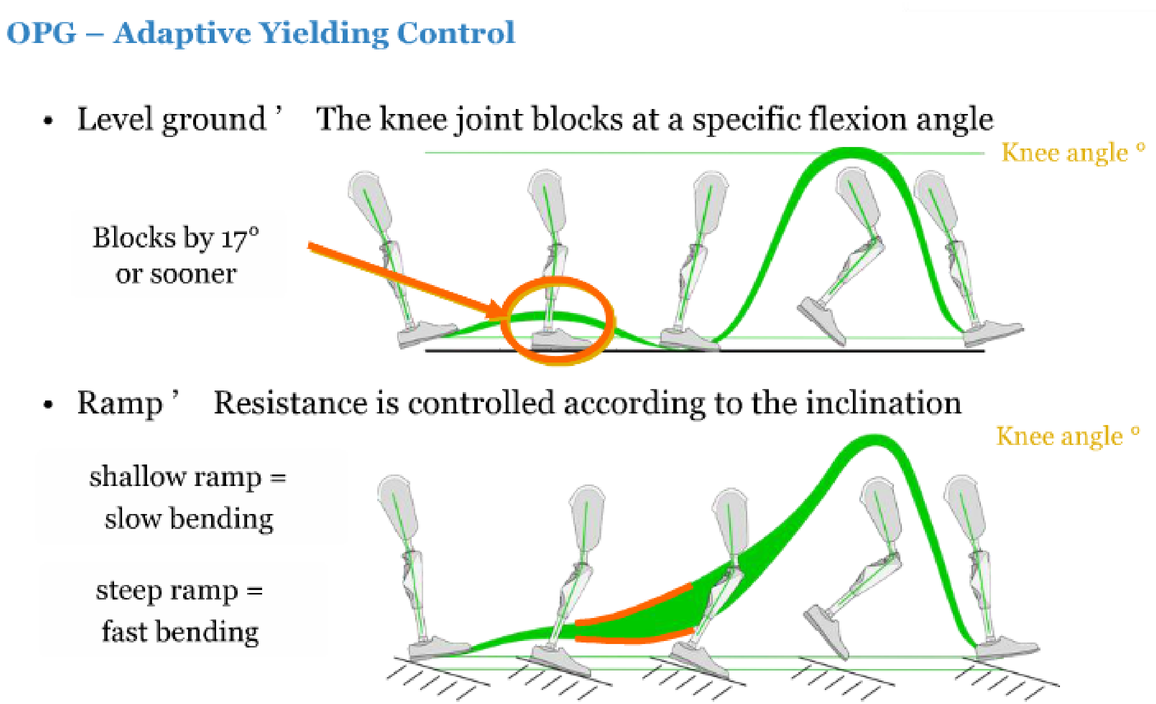

Figure 4.11. Knee flexion angle rate is adjusted based on slope. Photo courtesy of Otto Bock Healthcare.

Additional features of the Genium knee are five (5) second modes which can be used for activities such as holding a flexed position, locking the knee, bicycling, table tennis, skiing, and others. Additionally, the Genium casing reportedly offers higher protection when exposed to water, higher impact protection when exposed to activities such as jumping and running, and a sensor sampling rate of 100Hz. Further, inductive charging on Genium versus plug-in with C-Leg may result in improved cosmetic covering, water resistance, and recharge component reliability. A newly designed component software package is used by the prosthetist to adjust knee settings. This software does not require a Bluetooth adapter, and gives real-time kinetic and kinematic gait and loading data to inform the prosthetist during prosthetic knee adjustment. The Genium has only one pylon that is length adjustable, whereas the C-Leg has four different lengths of pylons based on patient height and these cannot be adjusted. As with C-Leg, the manufacturer recommends prosthetic feet from a limited list that are FDA approved for use with the Genium knee.

This chapter has sought to highlight similarities and differences in the design of the C-Leg and Genium knees to be studied in this project. The next chapter will discuss the study’s hypotheses, design and parameters of the protocol.

Table 4.1. Summarization of Genium and C-Leg function and differences.

Feature	Genium	C-Leg	Note
OPG Function	X		Preflexion, Adaptive yielding control, Stance release on ramps, Adaptive swing phase control. Dynamic swing phase control automatically enabled.
PreFlex	X		The knee is flexed 4˚ at the end of swing phase in preparation for loading response. "Vaulting" over a fully extended knee may be decreased. Stance flexion is increased, flexion valve is opened more at faster cadences decreasing the braking forces with a fully extended knee at loading. Genium can completely block the flexion valve during stance flexion. The flexion valve will block at a maximum of 17˚ when loaded in stance flexion.
Adaptive Yielding Control	X		Auto adaptive stance and swing extension resistance. The stance flexion resistance is dependent on the slope or incline when walking downhill. Adaptive stance flexion may allow reliance on the knee for stability when walking on slopes or inclines. The stance flexion resistance is dependent on the slope or incline when walking downhill. Less hip extension moment is required to stabilize a flexed knee on hills and ramps. The microprocessor uses sensor data to auto adapt the stance extension resistance needed to dampen knee extension following knee flexion in loading response. An auto-adaptive swing flexion angle feature can maintain symmetry in heel rise as terrain and gait speeds change.
Stance Release on Ramps	X		The knee will release stance on hills and ramps to allow for greater knee flexion which may improve swing phase clearance, and require less hip flexion force needed to bring the shank into extension. This feature may improve safety while descending ramps and hills. It may not be necessary to force the knee into extension in preparation for the next step downhill.

Feature	Genium	C-Leg	Note
Adaptive Swing Phase Control	X		The knee will rapidly adapt to varied walking cadences to ensure attainment of the swing flexion target angle within (+/-) 1˚. The swing extension and flexion resistance is adaptive and varies, depending on the sensor inputs received by the microprocessor. The knee does not default to pre-programmed resistances. This may assist if accommodating variable shoe weights. Flexion resistance does not kick initiate until termination of axial loading. This can decrease resistance in pre-swing. The knee is capable of dynamic resistance adaptations.

Feature	Genium	C-Leg	Note
Dynamic Stability Control (DSC)	X	X*	Stance release criteria determine when the knee will release stance during unstable conditions. The knee's additional sensors can determine if the knee is moving up, down, forward, or backward. C-Leg sensors measure knee angle and ankle moments. DSC ensures the knee will not release stance resistance during biomechanically unstable static and dynamic conditions. DSC is running throughout the gait cycle and makes the decision for the knee to switch from stance to swing. Because DSC is always monitoring knee function, multi-directional movement and walking backward are also possible with less risk of stance release. Stepping backwards, reverse walking, and walking in confined work areas (bathrooms and kitchens) is potentially done with improved safety. Standing on ladders for instance can be done with less fear of accidentally putting weight through the toe and initiating swing flexion. This feature may also allow initiation of swing phase during short steps independent of surface conditions. *With C-Leg, only two criteria must be met to initiate swing: knee fully extended, and 60% of the user's maximum dorsi-flexion moment calculated by foot size (lever) and body weight. Genium's sensor array allows for more thorough sampling, which may translate into improved safety. All the following criteria must be met to release stance with Genium: Knee fully extended, shank tilted forward, Shank moving forward, 60% of users body weight through the toe, ground reaction force close to the middle of the foot, and the knee cannot be flexing or extending. C-Leg can misinterpret when to release stance. Genium's additional sensors potentially decrease this risk, which may translate into a more stable knee. Backward walking and multi-directional motion is less reliable using the C-Leg sensor technology.

Feature	Genium	C-Leg	Note
Stairs & Obstacles Functions	X	X*	May provide the ability to load a flexed knee while traversing obstacles and ascending stairs in a more physiological way. Active PreFlex during stair descent resembles sound side function. This feature potentially allows stair ascent and traversing environmental barriers in a more natural and safe way. *With C-Leg contact is made in full extension. C-Leg users can have their knee programmed in to allow them to go up stairs (Low stance Flexion resistance & and Low toe Load), but they would be sacrificing safety damping on level and uneven ground in order to ascend stairs.
Sitting Function	X		This function activates free swing in the knee while sitting to allow uninhibited knee flexion and extension. Sitting function engagement also causes the knee to go into battery save mode. Sitting function will engage when the following conditions are met: the user's thigh is parallel to the ground, Genium is motionless for five seconds and the pylon is mostly un-weighted. The knee will re-engage stance when a user stands and the knee reaches a point close to full extension. This may improve sitting comfort/ cosmesis for the user while extending the life of the battery.

Feature	Genium	C-Leg	Note
Intuitive Stance Function	X	X*	Gross motor function, such as reaching down to activate or deactivate a knee lock, requires cognitive effort. The locked knee is activated by slightly flexing the knee and ceasing motion. It is deactivated by moving. Reduced hip extensor force may be necessary to stabilize a flexed knee while standing at length on uneven surfaces, ramps, or hills. Increased stability during ADLs, multi-tasking, and movement in confined areas may result. This may have implications with comorbid neuropathy who may benefit from a locked knee, and are unable to lock a knee using conventional levers or switches. This feature allows less active users the benefit of stance resistance during unlocking of the knee. * The C-Leg requires use of a remote control to block flexion. Alternatively, gross hip and knee motor function can generate a lock to flexion. This can be difficult to gain proficiency and utilize.
Improved Clearance	X		Minimum clearance with a Low Rider foot is 12 ½”. Minimum clearance needed for C-Leg is 13 ¾” with a Low Rider foot.
Improved Range of Flexion	135˚	125˚	Improved range of motion may improve kneeling, sitting, transfers and cosmesis.
Fewer programming parameters	2	7	C-Leg has 7 parameters whereas Genium only requires 2 parameters to be programmed when shipped from the manufacturer.
Wireless Inductive charger	X magnetic charger	plug	May improve cosmetic cover options. There are no charging ports in the anterior proximal portion of the knee. The inductive charger is located on the knee’s posterior distal aspect. Eliminating the ports on the front of the knee may improve splash resistance. E.g. washing a car or walking in the rain

Feature	Genium	C-Leg	Note
Modes	5	2	More programming modes are available. C-Leg has 2 additional modes and Genium has 5. The knee may be adaptable to a wider range of alternative activities.
Weight limits	330 lbs	275 lbs	
Bluetooth	Integrated	Adapter *	Allows for wireless communication during programming of the knee * C-Leg requires a plug-in Bluetooth adapter
Default stance resistance	X	X*	Default stance flexion resistance can be set lower. The resistance chosen will activate upon drain of the battery or knee malfunction. The knee can be programmed to walk with a free swinging knee or any set resistance to flexion. * C-Leg default resistance is not programmable. If the battery runs out or the knee malfunctions, the knee defaults to the stance flexion resistance.
Battery life	4-5 days	2-4 days	Genium has battery saving. Most of the sensors get shut down during inactive periods. When the knee is at rest and extended with low axial load, the knee will go into a battery saving mode. Battery save mode is also active when the thigh is parallel to the ground, motionless, and has low axial load; this feature is active even if sitting function is not selected in the software. Movement of the knee initiates basic mode when any of the battery saving features are active.
Remote	X		Remote controls can pair with up to 4 knees. Limited adjustments can be made to the 5 additional modes, swing, and stance phase adjustments. The remote also provides battery level indication for the knee and remote. A step counter is also accessible via the remote.

Feature	Genium	C-Leg	Note
Sensors	6	2	C-Leg has only 2 sensors to include an ankle moment and knee angle sensor. Genium has an ankle moment, knee moment, axial load, knee angle, two-axis accelerometer, and gyro. Improved sensor technology may maximize Dynamic Stability Control. Genium is able to determine the axial load, ankle moment, knee moment, linear accelerations, knee angle (velocity), and shank inclinations. Genium calculates ground reaction force, center of pressure on the foot, and distance of force vector to knee axis.

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<u>Chapter Five: Protocol</u>

Primary Hypothesis

The Genium knee prosthesis is superior to the current standard of care knee prosthesis (C-Leg) in improving function for the transfemoral amputee.

Specific Aims

1. To determine if transfemoral amputees of varied etiology will demonstrate increased *function* following accommodation with a Genium knee prosthesis.

2. To determine if transfemoral amputees of varied etiology will demonstrate increased *safety* following accommodation with a Genium knee prosthesis.

3. To determine if transfemoral amputees of varied etiology will demonstrate increased *quality of life* following accommodation with a Genium knee prosthesis.

Study Design

The study design was a randomized A-B crossover with subjective follow-up. All the prosthetic components were kept constant during all phases of the trial, except for the knees being tested. At enrollment, subjects were randomly assigned, off-site to either continue with their C-Leg knee prosthesis or be fitted with a Genium knee prosthesis. The study principal investigator scheduled prosthetic fittings and using Microsoft Excel's (Redmond, WA, USA) random number generator to assign knee conditions, notified the study prosthetist of the knee assignment via telephone on the day of the knee fitting. Prosthetic fittings and adjustments were performed by the study prosthetist who was state licensed and certified by the American Board for Certification in Orthotics, Prosthetics and Pedorthics as well as by Otto Bock Healthcare (Duderstadt, Germany) for fitting C-Leg and Genium knee prostheses.

Study Foot

Once a subject was determined to meet inclusion, consented and was enrolled, their prosthetic foot was exchanged for the study foot to control for confounding of this component. The study foot was the Trias (Otto Bock Healthcare. Duderstadt, Germany). This was a multi-function energy storing foot that met the functional needs of the proposed study sample as well as the manufacturer's requirement of utilizing the study knee only with feet from a select list. In the event that component build height or residual limb length prohibited use of a Trias foot, the Axtion foot (Otto Bock Healthcare. Duderstadt, Germany) was selected prospectively as the low profile alternative. The same foot was used for both assessment points in the study.

Alignment, Inclusion/Exclusion Criteria, Accommodation and Follow Up

All subjects had their alignment recorded which included the sagittal knee joint position in quiet standing relative to a vertical ground reaction line via the LASAR system (Otto Bock Healthcare. Duderstadt Germany). Subjects used the same foot for both knees. Following crossover and accommodation, subjects underwent Phase B data collection. For the follow-up portion of the trial, subjects were returned to their original C-Leg and given a 60 day follow-up. At follow-up (this portion of the study still ongoing), subjects were asked to complete additional subjective measures on preference and function. In addition to the amputee subjects, a sample of non-amputee control subjects were recruited to provide a functionally “normal” context for which to compare the amputee subjects’ performance.

This study design utilizes subjects as their own control. It was chosen because it most closely mimics a true clinical practice scenario while simultaneously upholding a maximally rigorous class II / level B study design.

All subjects were enrolled following a minimum of 1y of C-Leg utilization. To be considered for enrollment, subjects had to be free from socket and skin related issues for a minimum of 90 days initially by self-report and confirmed on visual inspection at consent. Inclusion and exclusion criteria were as follows:

Inclusion criteria

- Unilateral transfemoral or knee-disarticulation amputee
- 18 to 85 years of age
- Medicare Level 3 (community) ambulators
- Current use of and experience with the C-Leg for at least 1 year
- Ability to descend stairs and hills without caregiver and assistive devices
- Be able to independently provide informed consent
- Be willing to comply with study procedures

Exclusion criteria

- History of acute or chronic skin breakdown on the residual limb
- Prosthetic socket adjustment within 90 days
- Conditions that would prevent participation and pose increased risk (e.g. unstable cardiovascular conditions that preclude physical activity such as walking)
- Use of assistive devices/walking aids to ambulate
- Unwillingness/inability to follow instructions

Inclusion criteria for able-bodied subjects

- 18 to 85 years of age
- Able to provide independent, informed consent
- Independent community ambulation

- Free of any health ailment that would impair physical function

Exclusion criteria for able-bodied subjects

- Younger than 18 or older than 85 years of age
- Requires assistive device for ambulation
- Orthopaedic, neurologic or cardiac issues that impair physical function

Following enrollment, installing the study foot and alignment recordings, subjects were informed that they would be able to come back to visit the study prosthetist and physical therapist as many times as they deem necessary for adjustment, alignment and training. Training is the subject of the next two chapters of this document. If subjects randomized first to C-Leg, they were given two weeks to accommodate with the study foot prior to returning for phase A training. If subjects were randomized to Genium first, they were invited to return however many times they deemed necessary to assist them in getting accommodated with the foot and knee but that they would be tested no sooner than 2 weeks following Genium fitting or not later than 3 months. Once fit with a Genium knee, subjects were contacted weekly to ask if they felt they were able to walk without personal assistance on:

1. level ground
2. inclines
3. declines
4. stairs/steps
5. uneven ground

Subjects were also invited to contact investigators at any point following the two week minimum to declare that they were prepared to demonstrate accommodation as opposed to waiting for the scheduled, weekly telephone call. Once subjects verbally acknowledged the ability to ambulate independently on all 5 conditions, then they were scheduled to come in and demonstrate the actual ability to ambulate on all terrains (the accommodation test). If subjects successfully performed the accommodation test, at that point they were considered to be 'accommodated' and testing was scheduled. The period of accommodation time was recorded for later discussion. Following test/retest (A and B phases) subjects were switched back into their C-Leg prosthesis to complete the follow up portion of the study. The follow up portion is still ongoing.

Outcome Measures

In order to address **Specific Aim #1** regarding **functional differences** between knee components, the following outcome measures were utilized:

Amputee Mobility Predictor (AMP)

The AMP[1] is a brief physical assessment (≈15min to administer) to objectively determine a lower extremity amputee's functional level.[1] Subjects are assessed by progressing through a hierarchy of mobility tasks including sitting balance, standing balance, obstacle crossing, variable gait speed and stair gait. A score of 0-47 (depending on multiple factors) is achieved and correlates with Medicare functional levels as well as the 6 minute walk test. It is a validated instrument with high inter- and intra-rater reliability. It is clinically friendly, requiring no instruments other than a stop watch, and can be administered by a variety of healthcare professionals.

Timed Walking Tests

Previously, it has been reported that microprocessor technologies have improved walking speed as well as the energy demands associated with walking with a prosthesis.[2] Distance-based ambulatory tests are reportedly more clinically usable than metabolic data and were therefore used in this study.[3] As outlined in a previous clinical trial, this protocol collected data for four distance-based walking tests: 75 m self-selected walking speed (SSWS) on even terrain, 75 m fastest possible walking speed (FPWS) on even terrain, 38 m FPWS on uneven terrain, and 6 m FPWS on even terrain. Each walking test was repeated 3 times with a 2 minute rest between trials. Immediately after each test and during inter-test rest periods, subjects were asked to rate the perceived exertion of the walk using Borg's 6-20 rating of perceived exertion.[3,4]

Physical Functional Performance Test (10-item version) PFP-10

The PFP-10 test is a standardized assessment of ten activities of daily living.[5] The ADL activities include stair climbing, stair climbing with groceries, getting up from the floor, moving laundry from washer to dryer, a 6 minute walk test and more. Units of measure are in time, distance and mass. The test ultimately scores in major thematic areas including upper and lower extremity strength, balance and endurance. The test is processed in a licensed software and results in a score of 0-100 where scores of 57 or greater indicate a likelihood to function independently, scores of 48-56 indicate increased risk of functional dependency and scores below 48 indicate a high likelihood of dependency in functional tasks. The test must be administered by a credentialed practitioner.

Motion Capture/Biomechanical Measures

An 8 camera Vicon (Oxford, UK) motion analysis system was used to collect data of subjects performing gait tasks. Anthropometrics and prosthetic side (non-dominate for control subjects) were recorded. Passive reflective markers were attached to subjects using a combination of neoprene straps and double side adhesive collars. Table 5.1 (and Figure 5.1) provides a description of each marker.

Table 5.1. List of Markers

Name	Description
RBAK	Middle spine of the right scapula
CLAV	Jugular notch
STRN	Xiphoid Process
T1	1^{st} Thoracic Vertebra
T10	10^{th} Thoracic Vertebra
LASI	Left anterior superior iliac spine of the pelvis
RASI	Right anterior superior iliac spine of the pelvis

LPSI	Left posterior superior iliac spine of the pelvis
RPSI	Left anterior superior iliac spine of the pelvis
LIC	Left medial crest of the ilium
RIC	Right medial crest of the ilium
LGT	Left greater trochanter
RGT	Right greater trochanter
LTH1-4	Left thigh cluster markers
LLK	Left lateral epicondyle of the femur
LMK	Left medial epicondyle of the femur
LSK1-4	Left shank cluster markers
LLA	Lateral malleolus of the left ankle
LMA	Medial malleolus of the left ankle
LTOE	Superior to the distal head of the 2nd metatarsal of the left foot
LHEE	Left calcaneus at the same height as the LTOE while standing
RTH1-4	Right thigh cluster markers
RLK	Right lateral epicondyle of the femur
RMK	Right medial epicondyle of the femur
RSK1-4	Right shank cluster marker
RLA	Lateral malleolus of the right ankle
RMA	Medial malleolus of the right ankle
RTOE	Superior to the distal head of the 2nd metatarsal of the right foot
RHEE	Right calcaneus at the same height as the LTOE while standing

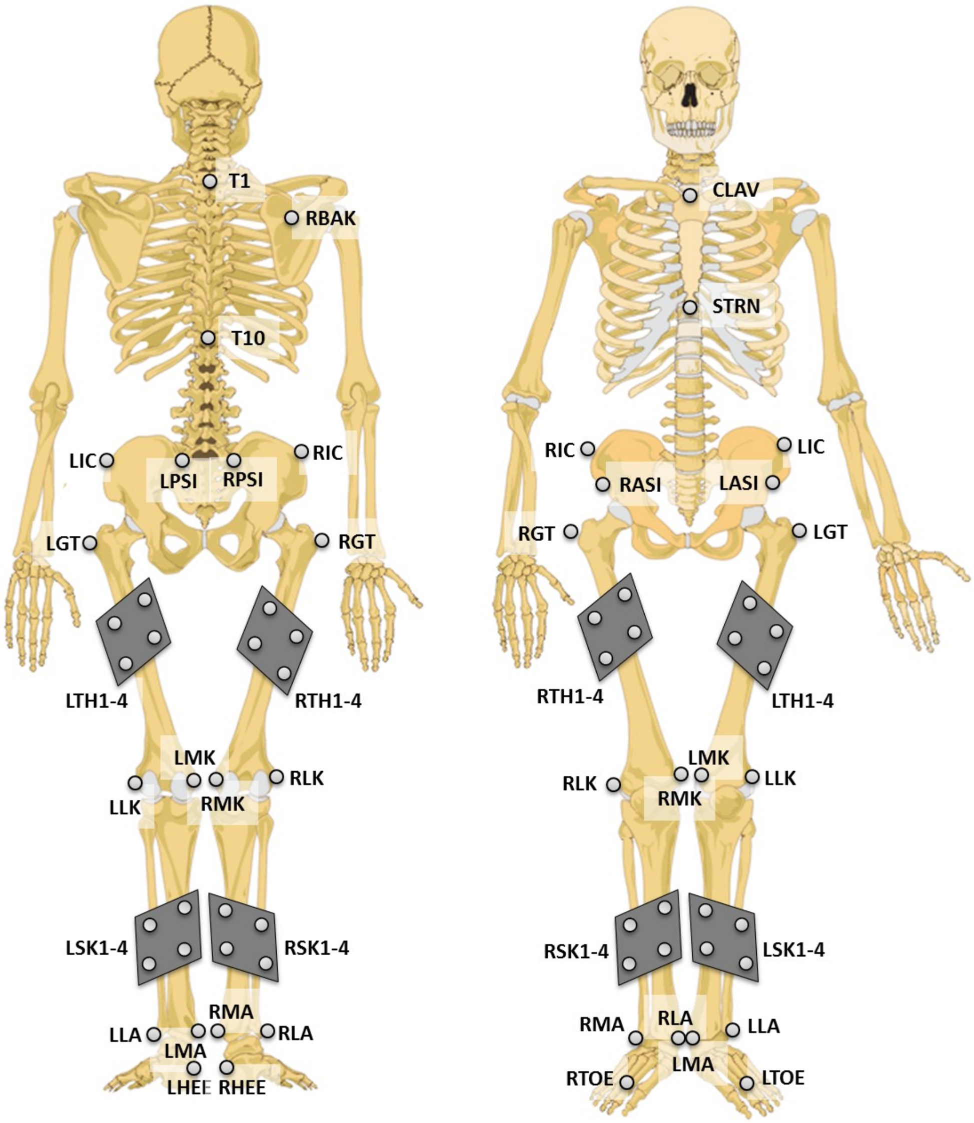

Figure 5.1. Marker Positions

Control subjects underwent motion capture data collection once whereas amputee subjects repeated the data collection twice (once on C-Leg and once on Genium in their respective, individually randomized order).

In the motion analysis laboratory, subjects performed the following tasks:

- self-selected walking speed(SSWS), and fastest possible walking speed(FPWS). Each speed was repeated so that left and right foot contacts were recorded.
- Ramp incline and descend were recorded at self-selected and fast speeds. Each speed was repeated so that left and right foot contacts were recorded.
- Ramp testes were collected with the ramp set to a 5 then 10° degree slopes.

Motion capture trials were divided into 3 sessions, walking, up ramp, and down ramp. The Vicon cameras were calibrated before each session, and a static trial was collected at the start of each session in accordance with manufacturer's recommendations.

Data Processing

Segment Definition and Tracking

The tracking markers were used to define tracking segments for the body. For example, the pelvis included the following markers: LASI, RASI, LPSI, RPSI, LIC, RIC, LGT, RGT.

Data from the motion capture was imported from the *.c3d files into Visual 3D (C-motion, Inc., Germantown, MD) software. A model of the subject was created in Visual 3D using marker positions from the static trials recorded at the start of each session (walking, up ramp, and down ramp). The International Society of Biomechanics recommendations[6] for the lower limb were used as a reference in defining the segments in V3D.

<u>Optimization of flexion axis for knee angle.</u>

To determine the most appropriate axis of flexion for the knee joint the tracking frames of the thigh and the shank were used to determine the orientation of axis of rotation for the axis of rotation by optimizing the knee axis of rotation (kx, ky, kz), for each session.

<u>Matlab</u>

Due to its precision and efficiency, a custom Matlab (The MathWorks, Inc.Natick, MA) script was used to process and plot motion data, on a subject node basis in Matlab.

In order to address <u>**Specific Aim #2**</u> regarding <u>**differences in safety**</u> between knee components, the following outcome measures were utilized:

Prosthesis Evaluation Questionnaire-Addendum (PEQ-A) (see Appendix 2). The PEQ-A[7] is a brief, 14-item survey of stumbles, falls and ambulatory mental energy. This instrument has been used in prosthetic knee comparative efficacy trials in this population previously to study self-reported safety incidents. The

PEQ-A predominantly relies on visual analogue input but has three open recall answers related to stumbles, semi- and un-controlled falls.[7]

Limits of Stability and Postural Stability on the Biodex Balance System SD. The Biodex Balance SD system (Biodex Medical Systems. Shirley, NY)[6] is a posturographic assessment tool widely used in clinical rehabilitation settings to measure many different aspects of balance, posture and stability. The instrument provides specific ankle knee and hip postural strategy training with external biofeedback as a guide to minimize balance impairment in balance compromised populations, such as persons with amputation. The Biodex SD incorporates a hemispherical suspended force platform that can tilt in any direction up to 20˚ from the horizontal.[8] The platform includes gridlines for test-retest positioning reliability and also includes a screen to provide center of mass data in real time to the patient visually. This protocol utilized the postural stability test first. The postural stability test operates on the platform's highest stability level, level 12 (levels 1[lowest stability] to 12[highest stability]) in which a high amount of force is required to tilt the platform. The platform's microprocessor controlled actuator releases from a locked position to level 12 stability at the start of the test and this stability is maintained for 20 seconds. During this time, the subject is asked to maintain their center of mass in the center of the platform (and screen) for the duration of the test. During this time, tilt directions and magnitude are recorded to indicate the subject's preferred directions of loading. Among other measures, the postural stability test reports the percentage of time during the assessment that subjects maintained loading upon the fore or hind foot of each foot. Following completion of the third postural stability assessment, subjects remained on the platform to complete the limits of stability (LOS) assessment. Following postural stability assessment, the LOS were assessed in 8 directions [forward (FW), backward (BW), right(RT), left(LT), forward-right(FW-RT), forward-left (FW-LT), backward-right (BW-RT) and backward-left (BW-LT)]. Poor directional control was indicated again by large variance. Each subject had to maintain the center of mass in the middle of a concentric circle which appeared on a screen positioned in front of the subject at a comfortable height. The LOS assessment consisted of three trials, each of 20 seconds duration with 25s rest periods between trials. LOS has been defined[8-10] as the area over which a subject could safely move without changing the base of support. The Biodex SD tests LOS by displaying an onscreen target placed in front of the subject. The target appears randomly in eight different directions only once, indicated when the respective target blinks in an alternating color (yellow to red) onscreen. The subjects are instructed to move their center of mass toward the target, without changing foot position. The system permits three range levels of difficulty for this task (100%, 50% and 25%) depending on the degree of ankle motion required to reach the target. Pilot testing was used to select the appropriate level at which pilot subjects could reach the targets safely without loss of balance. For safety reasons following pilot data assessment, we selected the 25% difficulty level which required platform tilt of 2 degrees anteriorly, 1 degree posteriorly, 2 degrees towards right, and 2 degrees towards left. Sway required to reach each target from the center by the perfect shortest vertical or horizontal path is recorded by the instrument and scored. A score of 100 is the maximal achievable score in any direction. In each of LOS test, the system computes the 8 directional LOS scores and an overall LOS score as a percentage of the maximal score which is 100. A lower score indicates greater sway. The system also calculates the time it takes for the subject to reach all 8 directional targets completing the assessment.

Four Square Step Test[11]

The four square step test (4SST) is a brief assessment of multi-directional stepping. Subjects must step forward, backward and to each side while stepping over canes. In older adults, scores of ≥12s are associated with fall risk whereas in unilateral TTA's, ≥24s are associated with fall risk.

2 Minute Declined Ramp Stand

In order to assess the perceived utility of the standing feature of both knee systems, subjects were asked to stand facing down hill on a stationary treadmill set to a 7˚ slope for 2 minutes. At the end of the 2 minutes, subjects were asked to rate the perceived exertion of the standing task using Borg's 6-20 rating of perceived exertion.[4]

In order to address **Specific Aim #3** regarding **differences in quality of life** between knee components, the following outcome measures were utilized:

Preference

Preference is a crucial element in determining the true reaction an amputee has to a component.[3] Several researchers have complimented the subjective aspect of a study with a question of preference. These researchers state that studies where a component choice is indicated can be complemented by the question of preference. The answer can be used to strengthen or refute findings of a study[3]. Asking which component is preferred might very well discourage an answer the subject thinks the investigator wishes to hear. Asking this question can identify the actual component the participant wishes to take home for long-term use. Following completion of the B phase assessment, subjects will be switched back to their original C-Leg for 2 months. At the end of the two month period, subjects will be asked which knee they prefer and to list 3 strengths and weaknesses of both knees regardless of their preference using an ad hoc survey custom designed for this study. The question of preference is part of the long-term subjective follow-up and is on-going.

Prosthesis Evaluation Questionnaire (PEQ)

The prosthesis evaluation questionnaire[12] is a population-specific, valid and reliable instrument used with lower limb amputees to measure perceived function and quality of life. The freely available PEQ is divided into 7 groups of questions. Psychometric evaluation has been performed on each group and each section has fair to strong reliability and internal consistency. Because our primary interests are in physical function, we have opted to minimize subject burden at this time and specifically to target the following two question groups:

1. Group 3: Social and Emotional Aspects of Using a Prosthesis
2. Group 5: Satisfaction with Particular Situations

These two groups ask subjects to rate their satisfaction with walking and training as well as their quality of life. To simplify scoring, Resnik and Borgia[13] evaluated conversion of the traditional visual analog approach on PEQ to 1-7 (circle the number) ratings and found no adverse effect in the instrument's performance but considerable improvement on scoring. We converted the scoring per this finding.

Statistical Analysis

All data were entered into a database and verified prior to data analysis. All data was examined for normalcy using NCSS/PASS's omnibus calculation of skewness and kurtosis (2004 ed. Kaysville, UT, USA). Descriptive statistics were calculated (including means and standard deviations) whenever possible. Comparisons between knee conditions were dependent and therefore, paired *t*-tests were used when data were normally distributed and at the interval or ratio scale level. If not, then the Wilcoxon Signed-Rank test for differences in medians was used. For comparison of prosthetic knee groups to control group performance, since these groups are independent, independent samples *t*-test were used again with normally distributed data at the interval scale level or higher. Otherwise, the non-parametric equivalent, Wilcoxon Signed-Rank test for differences in medians was used. Except for the test for data normality, all statistical analyses were performed using SPSS 2012 v.20(Armonk, NY, USA) and the protocol's *a priori* level of significance was 0.05.

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Chapter Six: Stair Descent Training

This chapter was published and can be found in Appendix 3. In accordance with the permission to reproduce the material for this document, the full article citation is:

Highsmith MJ, Kahle JT, Lewandowski AL, Kim SH, Mengelkoch LJ. A method for training step-over-step stair descent gait with stance yielding prosthetic knees: A technical note. J Prosthet Orthot 2012;24(1):10-15.

Permission was granted to include this published article by Lippincott; Wolters Kluwer Health and can be found in Appendix 4.

Chapter Seven: Stair Ascent and Ramp Ascent & Descent Training

Outcomes instruments and instructional materials as well as outcomes data are available to guide clinicians in training and rating the transfemoral amputee on stair descent using either step to step or reciprocal patterns.[1-8] While the literature has biomechanical data available on stair ascent[9], and textbooks describe the stepping pattern used for stair ascent[5], specific information for stair ascent and ramp training are not as readily available as stair ascent has not been a focus area of contemporary prosthetic knees until recently. As prosthetic knee systems enable increased functional abilities and performance in reciprocal stair ascent and on ramps, such information will become increasingly needed by the rehabilitation community.

Recently, the Genium knee was the first microprocessor knee to facilitate reciprocal stair ascent without power actuation. Improvements on stair ascent and ramp gait were demonstrated with use of the Genium knee system.[9,10] For stair ascent, a reciprocal climbing pattern was used by 8 of 10 variable cadence ambulators.[9] Specifically, by enabling the step over step ascent pattern and with 1 day of training, the stride duration was longer, the contralateral knee was required to produce less power and the movement pattern was generally more similar to non-amputee controls than that utilized when subjects climbed with a traditional step-to gait using the C-Leg. Investigators point out that their sample was small (n=10; 8 learned the technique) and that the training was excessively short and that their sample may not be representative.[9] During 10° inclined and declined ramp gait, the Genium knee increased stance knee flexion angles, increased involved side knee joint moments and decreased contralateral knee joint moments suggesting improved prosthetic side weight bearing.[10] The purpose of this project is to describe the steps necessary to train subjects to utilize the reciprocal stair climbing and ramp gait features of the Genium knee.

Technique

<u>Staircases, Railing and Guarding</u>

Bilaterally railed therapy stair cases are recommended for stair ascent training. These are routinely no more than 5 steps which can minimize patient anxiety regarding heights. Additionally therapy stair sets have a high friction tread finish to minimize slipping of the foot.[1] In stair descent training, handrails played roles in security, confidence, haptic feedback and on occasion, weight-bearing support.[1,11-13] If structurally permanent building stair-cases only permit reach of a single rail at a time, patients may be more successful initially utilizing the rail opposite the prosthesis to mirror assistive device training. It may be desirable to eventually practice using either side.[5] If no railing is available stair ascent may be practiced with an assistive device or by holding onto the shoulder of a person walking in front of the patient. This sacrifices the safety of having a therapist guarding from below and unlike stair descent training, may be better suited in stair ascent training in higher skilled patients.

As in stair descent training, standard practice is to guard from below the patient.[5] In this more likely higher functioning group and unlike stair descent training, a single therapist guard was found to be optimal. The training therapist, guarding from below, can stand off to the uninvolved side and hold onto a standard gait belt appropriately applied to the patient's waist.[5]

Genium Knee Stair Ascent Mode

From an engineering perspective, the Genium's stair climbing mode is a six phase process initiated by satisfying two criteria[9] as follows:

1. Axial unloading with simultaneous
2. Posterior acceleration of the prosthesis

These criteria must be met to initiate the necessary targeted damping for reciprocal stair ascent. The following are the six phases of stepping for stair ascent as described by Bellman et al.[9] Once the microprocessor recognizes stair ascent mode engagement, flexion/extension resistances are accommodated throughout the six phases of the stepping process as follows:

1. Phase 1 is normal stepping on the approach to the stairs until the last normal prosthetic step as the stairs are approximated. Flexion and extension resistance are both set as normal for flat ground gait on the approach.

2. At the end of Phase 1, the prosthesis is in stance phase just in front of the first step and the sound foot is in swing phase preparing to be placed on the first stair tread. Once the sound foot is placed, the prosthetic side begins unloading (criteria 1 of 2 to switch to stair climbing mode). Once prosthetic swing is initiated, the prosthetic foot must be swung slightly backward via either hip extension or posterior pelvic rotation transversely (criteria 2 of 2 to initiate stair climbing mode). Bringing the foot rearward is phase 2 and during this prosthetic swing phase there is no damping of knee flexion. The slight muscular action, inertia of the distal segment and release of flexion damping are what creates and permits the rearward prosthetic movement.
3. The slight rearward motion from Phase 2 also assists in helping the amputee to clear the prosthetic toes as the limb is returned forward during prosthetic swing for placement on the first step. Phase 3 begins when the limb ceases rearward travel and forward movement is initiated. When the limb begins to move forward (and upward) by way of hip flexion, damping in both prosthetic knee flexion and extension are minimized. This permits the action of hip flexion to flex the prosthetic knee to mimic normal stair kinematics.
4. Phase 4 involves extending the knee from its peak swing phase flexion so that the foot can be suitably placed for climbing. Therefore, knee extension is unrestricted. Conversely in phase 4, knee flexion resistance is maximized to the extent that any movement in the direction of flexion

would be hydraulically blocked. That is because the shank needs to travel forward at this time and further movement toward flexion could result in the user attempting to load a flexed limb.

5. In Phase 5, since the limb is positioned upon the step, it will now be loaded then both the hip and knee must be extended in order to elevate the body to the next step. Therefore, flexion is hydraulically blocked as extension is the desired direction. Extension resistance is increased but not fully blocked. This is so the user will not experience a hard extension stop at terminal knee extension.
6. Phase 6 is the point at which the prosthesis has fully accepted the body weight and the hip and knee have reached their terminally extended positions.

This has described the 6 phases necessary for stair climbing through one full step cycle. In order to continue climbing additional stairs, the entire process must be repeated with the triggering criteria from Phase 2 being the initiating actions. It is important to note, that the user has the ability to abandon stair climbing mode at any point should they elect to do so, become fatigued or lose the movement repetition as the knee’s microprocessor is designed to recognize the break in sequence and to default to normal walking mode with hydraulic stance flexion damping prepared to delay a flexion collapse. These technical steps are foundational knowledge for the rehabilitation specialist but are unnecessarily complex to relay to the patient. Subsequent sections will outline steps more practically for use in patient training.

Initial Patient Position for Learning Stair Ascent Activation and Foot Placement

The initial position for stair ascent training with the Genium is at the base of the stairs and the feet are in line at a comfortable distance apart (10-15cm). The patient will need to initiate the knee's stair ascent mode and familiarize themselves with it on a single step prior to engaging multiple, repeated steps. Authors have found that at this early period, the therapist should kneel at the involved side foot and place a sheet of paper beneath the prosthetic foot. The patient should be instructed to "sling the paper backwards" which offers a readily attainable cue to satisfy both criteria to initiate climbing. Hard surface finishes (tile, wood, vinyl) optimize this technique. In order to literally move the paper from beneath the foot, some unloading has to take place prior to backward movement. Instruct the patient that they will experience the knee quickly flexing and the foot will rise behind them. Return the paper and repeat the stair ascent activation sequence until it can be done without the paper beneath the foot.

Once stair ascent activation is mastered, the next task is to quickly place the foot upon the step. Instruct the patient to initiate stair climbing mode and when the knee flexes and the foot rises, they should quickly flex the hip and aim the thigh at the next stair nosing. This alignment of the thigh will be the approximate angle the hip must flex to so that when the knee extends, dropping the foot from behind, it will be in approximately the correct location on the stair tread. The patient will likely have to adjust either their hip flexion angle or transverse pelvic position to perfect the foot placement. The sound foot has not yet moved in this practice sequence. Have the patient return the prosthetic foot to the starting position and repeat the initial activation and foot placement from the ground to the first step. It is important to note that this sequence is repeated for every step that must be climbed with the prosthetic foot. Therefore, it is logical to have the patient repeat it from the safety of the ground before attempting repeated stair climbing. Prior to instructing and practicing repeated stair climbing, this can often be incorporated as a home exercise task and repeated climbing attempted on subsequent training sessions in the rehabilitation setting.

Initial Reciprocal Climbing

Once the patient can demonstrate stair ascent initiation and prosthetic foot placement they are ready to practice stepping up and repeating the sequence on a stair set. Start as outlined above with feet together at the base of the stairs. Unlike previously, it is recommended to take the initial step up with the prosthesis in stance and placing the sound foot for this early practice. Eventually, the patient should be able to initiate climbing with either side but leading with the sound side will likely result in the smoothest transition from normal gait to stair climbing. Once the sound foot is on the next step, the patient must unload and generate a slight rearward hip extension as weight is transferred to the sound foot. When the

Genium flexes and the foot rises behind the patient, the patient will then flex the hip and prepare to place the swinging foot. Once the foot is placed, weight is shifted to the prosthesis and the patient must extend the prosthetic hip vigorously in order to accept load on and extend the prosthetic knee, elevate the body and place the sound foot. Commonly, the amputee leans forward toward the prosthetic toes to minimize the external knee flexion moment caused by their posteriorly positioned body weight.

It is also recommended that the therapist stand toward the sound side and firmly hold the gait belt for support. In this position, the therapist will not block the knee from flexing and foot from rising. The patient is also holding the railing on the sound side. The process is repeated for as many steps as necessary to initiate motor learning of the pattern for repetition. The therapist should be mindful and make the patient aware that this new movement sequence may result in muscle fatigue or soreness. Additionally, this is best practiced with supervision until proficiency is attained but the patient should also be made aware that because the sequence is based on repetition of each step, the sequence can be stopped at any point at which case normal gait settings are re-engaged.

Advanced Reciprocal Climbing

Once reciprocal climbing is mastered from a stand still at the base of the stairs, the next phase is to transition to climbing from walking. As previously described, the patient should start climbing with the sound foot being placed first upon the stairs. To accomplish this timing, the patient can start as above in *Initial Reciprocal Climbing*, where the feet are side by side at the stair base. While the therapist holds onto the gait belt on the patient's sound side, step back leading with the sound side and take three to five steps back for the necessary pre-climbing steps. The therapist continues to hold onto the gait belt (sound side) as the patient approaches the stairs. The last step at the base should be the prosthetic foot so that the sound foot is the first lifted and placed upon the stairs. Once placed, the prosthetic foot is raised and kicked rearward to initiate stair climbing mode then the process is executed as detailed above. Repeat this as necessary. Once mastered, consider practicing leading the climb with the prosthetic side. Finally, consider practicing from varying random distances ahead of the stair base, at randomly called out approach speeds and stopping and starting while on the stairs. More advanced skills can include changing the stair climb pacing (e.g. with a metronome[14]), and climbing while carrying a load. As with stair descent practice, the stair cases practiced on should be altered to introduce varied step size, environmental distraction, railing access, and environmental conditions. The same technique is utilized for obstacle crossing in the Genium. Authors practiced obstacle crossing with subjects utilizing a 10cm tall (4in) board following mastery of stair ascent.

Technique – Ascending and Descending Ramps

Initial practice can be performed on a therapy ramp. A therapy ramp is typically constructed of wood and covered with high-friction grip tape to prevent slipping. Availability of handrails on therapy ramps is variable. There are many instances within the community in which case it is not common to have a handrail available when ascending or descending an incline.

When practicing ramp ascent, the physical therapist should stand behind the patient with one hand firmly on the gait belt. The patient should be instructed to lead with the sound leg when ascending the ramp. As the patient places the sound foot in front of the prosthetic foot, the patient should lean their trunk forward slightly. This will decrease the extensor moment on the prosthetic knee that is caused by the incline causing the prosthetic shank to lean posteriorly. The patient must then forcefully flex the hip of the prosthetic limb to bring the prosthetic leg forward and prevent the toe of the prosthetic limb from catching the ground. Once the prosthetic foot is firmly on the ground, the patient should extend the hip of the prosthetic limb in order to extend the knee, stabilizing the prosthetic limb; the patient can then move the sound limb forward, and repeat this pattern up the ramp. The C-Leg requires a threshold toe load in order to initiate swing flexion whereas the Genium knee does not. For this reason, the patient must stay on the prosthetic foot slightly longer in the C-Leg which may cause the anterior proximal portion of the socket to be forced into the anterior portion of the hip near the inguinal ligament or socket trimline area. If swing phase flexion is not initiated because the prosthesis is lifted axially too soon, the patient will be forced to advance the limb with the knee extended which could lead to falls, gait deviations or a generally uncomfortable and energetically inefficient ramp gait pattern.

When practicing ramp descent, the physical therapist should stand in front of the patient, between the patient and the ground. Again, the therapist should be holding onto a gait belt that is placed around the patient's waist. During ramp descent, the patient may be apprehensive as to the stability of the prosthetic knee. The downward angle of the ramp will cause the prosthetic foot to seek foot flat so the forefoot will drop, the prosthetic shank will tilt forward sagitally and the knee will flex all due to the angle of the surface and the fact that the body mass is falling posterior to the knee, placing a flexion moment on the prosthetic knee. The patient must use hip extension of the residual limb to stabilize the prosthetic knee by extending in preparation for ramp descent.

The therapist should instruct the patient to lead with the prosthetic limb when descending the ramp. As the patient places the prosthetic limb in front of the sound limb, the patient should carefully grade their weight shift onto the prosthetic limb due to the knee flexion moment that the downward ramp angle imparts on the prosthetic knee. As the patient increases weight bearing on the prosthetic limb, they can forcefully extend the hip of the residual limb to extend the prosthetic knee. However microprocessor controlled flexion damping permits graded flexion resembling an anatomic knee. The patient will then flex the hip and knee of the sound limb to advance it in front of the prosthetic limb. The patient repeats this pattern as they descend the ramp. In the cases of both ramp ascent and descent, step length, arm swing and potential temporal asymmetries should be monitored for and verbally corrected immediately before poor habit patterns emerge.

Advanced Ramp Training

Once the patient is familiarized with the component, its basic functionality and the particular practice ramp, additional benefits may be available by increasing the patient's independence with the task as well as the task's complexity and variance. Some suggestions include the therapist moving away from a more protective role in exchange for a lead role for the patient to follow. This can start by having assistance from a second therapist. One will walk in front of the patient while the patient holds onto the shoulder of the leading therapist and the trailing therapist holds the gait belt as before for protection but much less noticeably in advanced practice. The lead therapist should be certain to challenge the patient either with an alternate walking speed, step length, decreased rail support or other verbal cues. Other challenges to increase the task complexity could include practice on alternative slopes, using different surfaces (e.g. wood, tile, concrete, gravel), varying the environment (e.g. indoor, outdoor) or having the patient complete the task while carrying an object. Still further challenges could include randomly calling out stops, starts, velocity or step length alterations while on the ramp.

Discussion and Results

The purpose of this technical note was to introduce and document the technique used to train Genium knee users how to walk reciprocally upstairs and on ramps. As part of the component training and accommodation for a comparative efficacy trial, we trained 19 unilateral transfemoral amputees on stairs and ramps. For stair ascent, throughout the course of the training and accommodation period we observed that 7/19 of our subjects demonstrated some ability to climb stairs reciprocally. Many factors should be considered when evaluating a TFA in their potential to complete this task. Some factors include how often stairs are encountered, how active and what functional level are they, what is the patient’s ability to balance, how much hip extensor strength do they have, how sensitive and long is their residual limb? Our sample included predominantly unlimited community ambulators of traumatic etiology however none of them lived in multi-story homes. A sample of 19 subjects where the majority live in multi-story homes may produce a greater number of subjects who would develop the ability to utilize this function. Nevertheless, of the subjects who did demonstrate pre-test ability to use the reciprocal stair climbing feature, they also subjectively reported being pleased to have another stair stepping pattern and that they believed the practice improved their ability to cross obstacles as the movements are similar. Biomechanical and functional assessments are ongoing to determine if there are quantifiable advantages to utilizing this stepping pattern.

Also during the training portion of the study with regard to ramp gait, we made two observations of functional significance:

1. The majority of subjects verbalized that when training to use the Genium knee for ramp ascent, less focal pressure was experienced near the anterior aspect of their hip regardless of the slope's inclination angle.
2. During ramp descent at 5°, subjects could utilize one of two stepping strategies but steeper ramps (7 and 10°) tended to result in a characteristic stepping pattern.

We hypothesize two potential explanations for the subjective experience of less focal stress at the anterior hip. The first is that because the Genium knee is more liberal in its forefoot loading requirement than other toe triggering knee systems (i.e. C-Leg) subjects can activate knee flexion with less of an extension moment when transitioning to swing. A second possible explanation is that the additional 4° of flexion bias incorporated into the Genium promotes knee flexion during the loading response while also minimizing the magnitude of knee extension on initial contact.

In the second observation of two different stepping patterns on 5° declines, one strategy with observational similarities to the C-Leg, results in subjects progressively flexing the knee throughout stance phase. Subjects initiate stance on a modestly flexed knee and progressively increase knee flexion throughout stance phase. In the second strategy, the more active walkers appeared to utilize a stepping strategy more similar to a typical, flat ground strategy. The normal flat ground stepping pattern in non-amputees is characterized by two sagittal knee flexion peaks; the first is ≈15° in the loading response and the second is ≈60° in the transition to swing phase.[15] A double knee flexion pattern seemed to be visually discernible at 5° declines in active walkers that was not discernible on previous knee systems, in lower activity members of the sample or at all in steeper declines. Further, the magnitude of these knee flexion peaks remains unknown at present pending completion of the ongoing clinical trial.

Technological developments in assistive technologies continue to outpace rehabilitation strategies to maximize their utilization and implementation. Clinical rehabilitation techniques remain limited. This technical note presents strategies for training the transfemoral amputee how to utilize the reciprocal stair ascent and ramp gait functions of the Genium knee. Additional training suggestions for further advanced training with these skills are also discussed. These functional training strategies introduced here were specifically used with the Genium knee in high functioning patients. Therefore, they may not be appropriate for all transfemoral amputees based on component or functional level so clinical judgment and patient goals are vital in the decision of whether or not to include such training in the course of an amputee's therapy. We maintain that ramp and stair training in a broader context may be functionally important even if a patient indicates these obstacles are not routinely encountered in their usual routines.

This is because it is difficult to determine when daily activities require out-of-the-ordinary settings. Supervised practice and familiarity may improve safety should the situation arise.

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Chapter Eight: Accommodation

Subjects

The protocol was approved by the University of South Florida's Institutional Review Board and listed in a federal clinical trials registry (www.clinicaltrials.gov; #NCT01473992). Twenty four (n=24) subjects consented to participate in the study; nineteen subjects had unilateral transfemoral amputation and five non-amputees served as controls. The five non-amputee controls included 3 males and 2 females with a mean (SD; Range) age of 57.2y(15.7; 37-77), body mass of 66.6kg(9.4; 54-78) and height of 170.2cm(8.6; 157-177). Three of the control subjects were employed and two were retired. The control group had no known neuromusculoskeletal pathologies or impairments in gait and balance. All five control subjects were right hand and leg dominant. The 19 subjects with TFA included 3 females and 16 males with a mean (SD; Range) age of 46.5y(14.2; 24-75), body mass of 82.9kg(15.9; 57-112) and height of 177.0cm(9.6; 154-192). Ten of the TFA subjects were employed, two were students, two were retired and the remaining five were governmentally classified as being 'disabled'. The mean time since amputation was 17.7y(15.6; 3-47). Thirteen subjects' amputation etiology was trauma, four lost their leg due to malignancy and the remaining two lost their leg due to peripheral vascular disease. One additional subject developed comorbid peripheral vascular disease subsequent to their traumatic amputation. The average residual limb length was 70% (30; 15-100) of the sound side femur and the average hip flexion contracture angle was 12.8°(7.7; 0-27) as measured by the Thomas Test.[1]

For prosthetic sockets, thirteen subjects utilized ischial ramus containment sockets, three used sub-ischial (brimless) designs and one utilized a quadrilateral socket. Two subjects with knee disarticulation utilized brimmed sockets that provided ischial support but lacked medial containment of the ischial tuberosity. Subjects' prostheses were suspended with the following systems; 9 locking liners (including one Seal-In® system and 8 pin locks), 7 suction sockets and 3 were suspended by elevated vacuum (1 mechanical and two electronic pumps).

Training Visits and Accommodation Time

Beyond the necessary study visits for consent and testing, subjects returned for 0.7±1.0 with a range of 0 to 4 visits for post-fitting prosthetic adjustments. For gait training on flat or uneven ground and on ramps and stairs, subjects returned for 3±1.8 with a range of 1 to 8 visits. When subjects randomized to test with their C-Leg all testing was scheduled as close as possible to two weeks given that the C-Leg was the knee of choice for all subjects and they had a minimum of 1 year of experience with the device. The two weeks permitted accommodation with the study foot, time for the potential influence of being enrolled in a study to pass and, in the case where subjects tested on the Genium first, to re-accommodate with their former C-Leg knee system. With regard to the Genium, subjects required 67.9±27.1 with a range of 18 to 119 days to pass the accommodation assessment. The reason the range passed the prescribed 90 day mark is because one subject was within the Genium accommodation period which spanned a holiday which included travel. The subject indicated readiness to assess within the 90 day period but was logistically unable to demonstrate it until his return home from holiday associated travel.

Knee Alignment

The study prosthetist recorded subjects' sagittal knee alignment with a LASAR alignment tool[2] (Otto Bock Healthcare. Duderstadt, Germany) when subjects entered the study while on the C-Leg. Alignment was recorded again at the point when subjects randomized to the Genium. Subjects stood on a force plate with the prosthetic side while the sound side was on a moveable step to match the height of the force plate. Feet were placed at a comfortable width comparable to a comfortable base for gait. The LASAR projects a laser line vertically in accordance with ground reaction force. The prosthetist hand measures the distance between the knee center and the laser line. The sample mean (SD; Range) distance between knee center and ground reaction force vector (sagittal knee alignment) when subjects were on the C-Leg was 3.1cm(2.3; -4.0 to 8.0) where the force vector was anterior to knee center. When on the Genium, the sagittal knee alignment was 2.5cm(2.8; -3.4 to 6.8). Alignment data were normally distributed and were not significantly different ($p>0.05$) between knee conditions.

Discussion of Sample, Accommodation and Alignment

The sample in this study is characteristic of previous studies of microprocessor technologies where mean ages tend to be in the 4th and 5th decades of life and the predominant etiology is trauma.[3] While this is characteristic of prior microprocessor knee studies, it should be noted that the sample is not representative of the largest demographic of lower limb amputees which tend to be elderly and of dysvascular etiology.[4,5] Oppositely by age, this sample is a bit older than military amputees, however the functional levels and etiologies are more similar. Our sample did include three cases with peripheral vascular disease and seven of the nineteen were aged 55yrs or greater. Given these differences in this sample and those of the larger group of transfemoral amputees within society or the military, the generalizability of these data will be limited to the higher functioning demographic of middle aged persons with amputation that ambulate frequently within the community. The specific contexts of the group's functionality are the subjects of subsequent chapters.

It is important to control for as many confounders as possible including alignment. In the recent decade of prosthetic knee research, alignment has been either not reported, editorially described as being set by an experienced prosthetist or recorded and adjusted with a LASAR alignment tool.[3,6] This study had the benefit of both the experienced and credentialed prosthetist as well as the alignment tool to assure similarities with alignment. If knee components are mechanically similar, it is likely that their alignment would also be similar. Bellman et al. recently found alignment similarities in a sample of accommodated C-Leg users who switched to a Genium for brief training and biomechanical assessment.[7] In their sample, they found a difference in alignments of 0.3cm whereas we showed a difference between conditions of 0.6cm and neither were significantly different between conditions.

Accommodation to a new prosthetic device has been reported in the literature to be as brief as a few weeks, or that it may take several months.[3] Acclimation to a prosthetic component for re-testing rather than for component acceptance or mid- to long-term use is even more variable, being reported as very low, on the order of minutes in some cases if reported at all in others.[8-10] The more widely reported value is on the order of weeks to months regardless if the purpose is merely for re-test or larger acceptance and use.[3,6,11] With a knee prosthesis, English et al.[12] report that at least one week be permitted to normalize angular velocity of the knee and reduce ground reaction force variability prior to deciding about acceptance or rejection of a component or adjustment change but that improvements may continue as more time passes.[12] We provided a formal test of accommodation adapted from Hafner et al.[13] requiring subject's attestation of ability and then physical proof of it by the ability to ambulate on multiple different terrains independently. In every case, when a subject reported the ability to ambulate independently on a given surface, they were able to demonstrate it as well. The duration of our prescribed Genium accommodation timeline of 2 weeks to 3 months is reasonable given English et al.'s recommendation.[12] We calculated the interquartile range for accommodation time in approximate days from the 17 papers comprising our previous literature review[3] and found that the 135 days is considerably high compared to our current sample's mean accommodation time of 67.9 days. The likely difference is because studies in the literature review were investigating performance differences when subjects learned to use a new microprocessor knee (C-Leg) following many years typically, of using non-microprocessor knee systems. Therefore, many users had to learn to accept entirely new movement patterns not possible in the older mechanical knee systems.

Additionally, the literature review included 3 mid- to long-term economic comparisons of the mechanical and C-Leg systems where retest was undertaken more than a year from baseline in one study[14] which pulls the overall interquartile range toward a considerably higher value. Finally, considerations for the more modest accommodation observed here include the fact that all of these subjects utilized the C-Leg for at least one year prior to enrollment. Therefore, features such as reciprocal stair descent, knee flexion in stance phase and others are already accepted. Given this prosthetic history and the sample's relatively younger age and higher level of function, it is logical that the accommodation would be shorter for a study such as this. Regarding accommodation, it is important to note that there was no attrition in the study.

The purpose of this chapter was to report the outcomes associated with the sample, their prostheses, alignment, and accommodation times. The next chapter will report results of the outcomes selected to evaluate functional differences between the C-Leg and Genium knee systems.

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Chapter Nine: Results

Amputee Mobility Predictor (AMP)

The AMP provides ordinal level data so non-parametric assessment was conducted and control subjects were not tested with this measure. The score's scale is 0-47. The group mean(SD; Range) of AMP scores while subjects were using C-Leg was 40.8(3.6; 33-45). The group mean(SD; Range) of AMP scores while subjects were using Genium was 43.3(2.6; 36-46). This difference was significant at $p<0.001$. No subject in the study was able to single limb balance for 30 seconds on their prosthetic side so the group's range stopped at 46. There was a difference of 2.5 between group means, however the minimum detectable change is reportedly 3.4.[1]

Kinematic Assessment of Gait

Control subjects displayed larger knee movements in every case with the non-dominant side. Only in two instances during stance flexion while ascending the 5° ramp (figure 9.2), did asymmetry exceed 10%.(Table 9.1) Larger non-dominant movements in stance flexion could be the result of a strength or control differential favoring the dominant side that allows larger excursion prior to arresting knee movement. In swing phase, the slight asymmetry toward the non-dominant side may also be related to strength and control but again, differences were less than 10% in the great majority of cases.

Amputee subjects oppositely displayed asymmetry toward the sound side as anticipated. Asymmetry toward the sound side ranged generally from as low as 2% to as high as 67% with the C-Leg. For Genium, asymmetry toward the sound side ranged from 1 to 75%. There were no significant differences in knee kinematic asymmetries between the two prostheses. Compared to controls, asymmetry in the Genium was significantly greater in five instances compared to seven instances in the C-Leg. Six of these differences with C-Leg were related to stance phase knee flexion. Four of the differences between Genium and controls were related to stance as well. Nine of the twelve differences between amputee subjects and controls occurred while ascending ramps (figures 9.2 and 9.3). During ramp ascent, asymmetries were of the highest reported (Table 9.1) ranging from 37 to 75%.

Table 9.1. Degree of asymmetry results with *p* values. Degree of asymmetry (DoA) is calculated for three ground conditions: flat ground, 5° and 10° ramps. Ramps were traversed up and down and included bilateral railing for use at their discretion. In each condition, subjects walked at their fastest possible walking speed (FPWS) and again at their self-selected walking speed (SSWS). Results are shown as a DoA between sides as mean(SD). Between group comparative *p* values are shown in the three columns to the right of the table 9.1. Statistical significance was set at $p \leq 0.05$. Significant comparisons are noted by an asterisk(*). Data were abnormally distributed.

DoA Scores			Condition			Comparison *p* value		
			C-Leg	**Genium**	**Control**	**Genium vs. C-Leg**	**C-Leg vs. Control**	**Genium vs. Control**
Flat Ground		FPWS- Stance Flexion	0.31(0.39)	0.18(0.44)	-0.09(0.14)	0.32	*0.014	0.11
		FPWS- Swing Flexion	-0.01(0.08)	0.01(0.06)	-0.04(0.06)	0.42	0.43	0.16
		SSWS- Stance Flexion	0.39(0.43)	0.31(0.37)	-0.06(0.19)	0.61	*0.02	*0.03
		SSWS- Swing Flexion	0.02(0.10)	0.01(0.07)	-0.03(0.06)	0.68	0.16	0.24
5° Ramp	Up	FPWS- Stance Flexion	0.37(0.32)	0.50(0.23)	-0.11(0.13)	0.35	*<0.001	*<0.001
		FPWS- Swing Flexion	0.03(0.10)	0.04(0.11)	-0.04(0.06)	0.87	0.14	0.11
		SSWS- Stance Flexion	0.46(0.31)	0.62(0.22)	-0.15(0.51)	0.09	*0.05	*0.02
		SSWS- Swing Flexion	0.07(0.10)	0.04(0.11)	-0.03(0.16)	0.41	0.26	0.43
	Down	FPWS- Stance Flexion	0.05(0.42)	0.05(0.29)	-0.09(0.08)	0.98	0.34	0.21
		FPWS- Swing Flexion	0.05(0.14)	0.06(0.11)	-0.03(0.04)	0.93	0.15	0.07
		SSWS- Stance Flexion	0.12(0.40)	0.07(0.34)	-0.09(0.11)	0.57	0.16	0.23
		SSWS- Swing Flexion	0.12(0.27)	0.02(0.08)	-0.05(0.06)	0.33	0.09	0.06
10° Ramp	Up	FPWS- Stance Flexion	0.63(0.22)	0.72(0.19)	-0.09(0.13)	0.38	*<0.001	*<0.001
		FPWS- Swing Flexion	0.08(0.10)	0.07(0.14)	-0.02(0.07)	0.39	0.06	0.14
		SSWS- Stance Flexion	0.67(0.17)	0.75(0.22)	-0.07(0.26)	0.24	*<0.001	*<0.001
		SSWS- Swing Flexion	0.18(0.18)	0.11(0.19)	-0.03(0.11)	0.20	*0.02	0.09
	Down	FPWS- Stance Flexion	-0.15(0.22)	-0.01(0.41)	-0.03(0.10)	0.45	0.22	0.90
		FPWS- Swing Flexion	0.15(0.20)	0.18(0.32	-0.02(0.04)	0.70	*0.04	0.10
		SSWS- Stance Flexion	-0.10(0.14)	-0.05(0.21)	-0.05(0.10)	0.34	0.45	0.97
		SSWS- Swing Flexion	0.07(0.20)	0.05(0.08)	-0.05(0.04)	0.79	0.12	*0.01

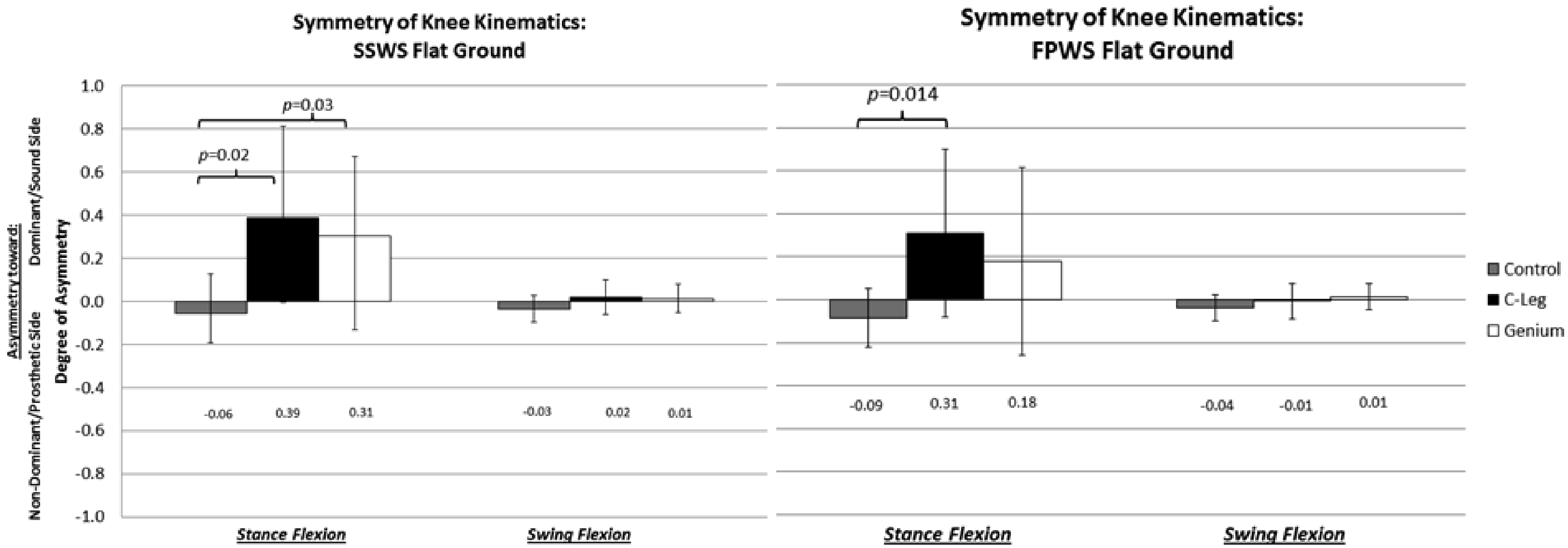

Figure 9.1. Degree of asymmetry on flat ground.

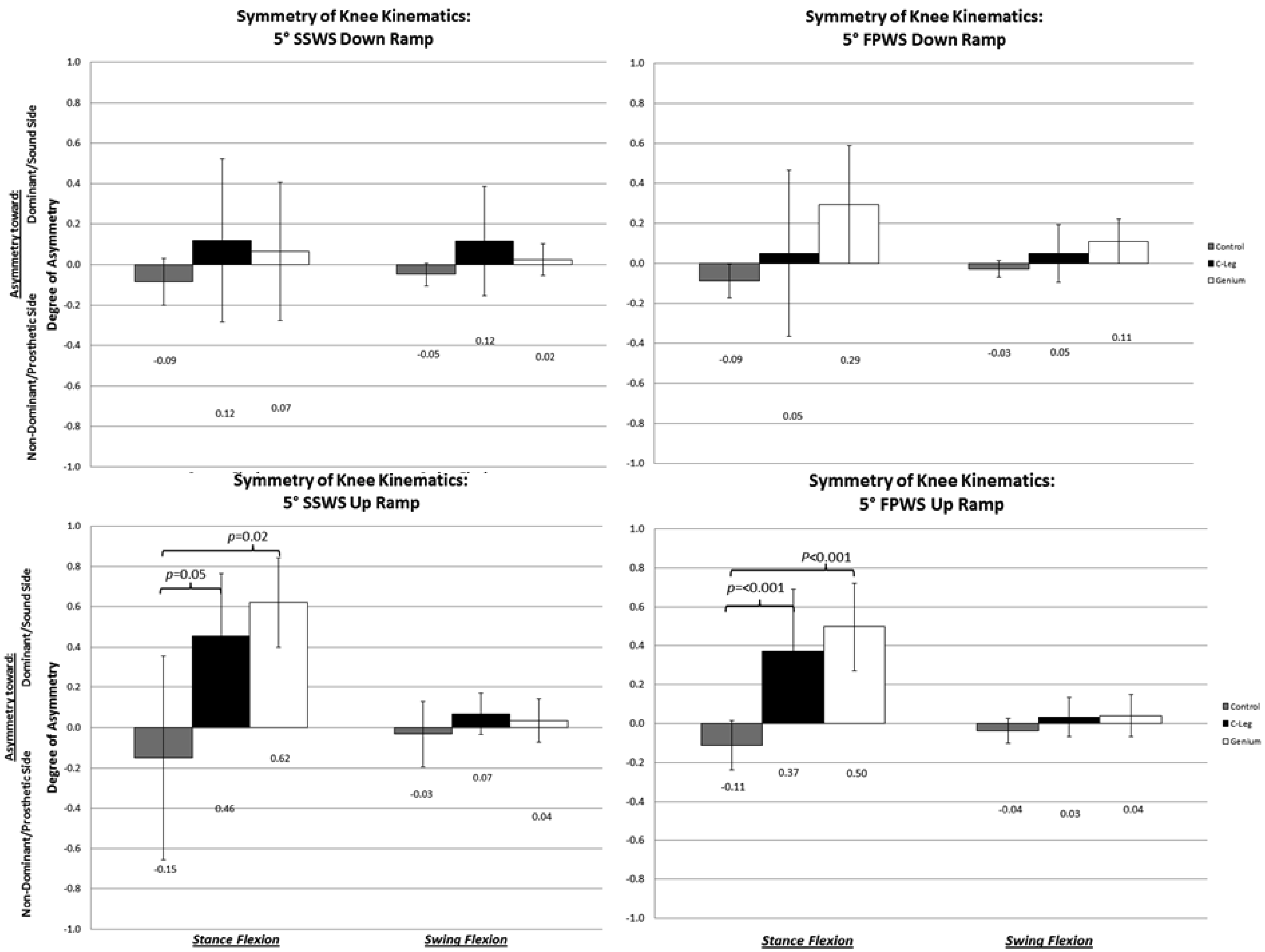

Figure 9.2. Degree of asymmetry on 5 degree ramp.

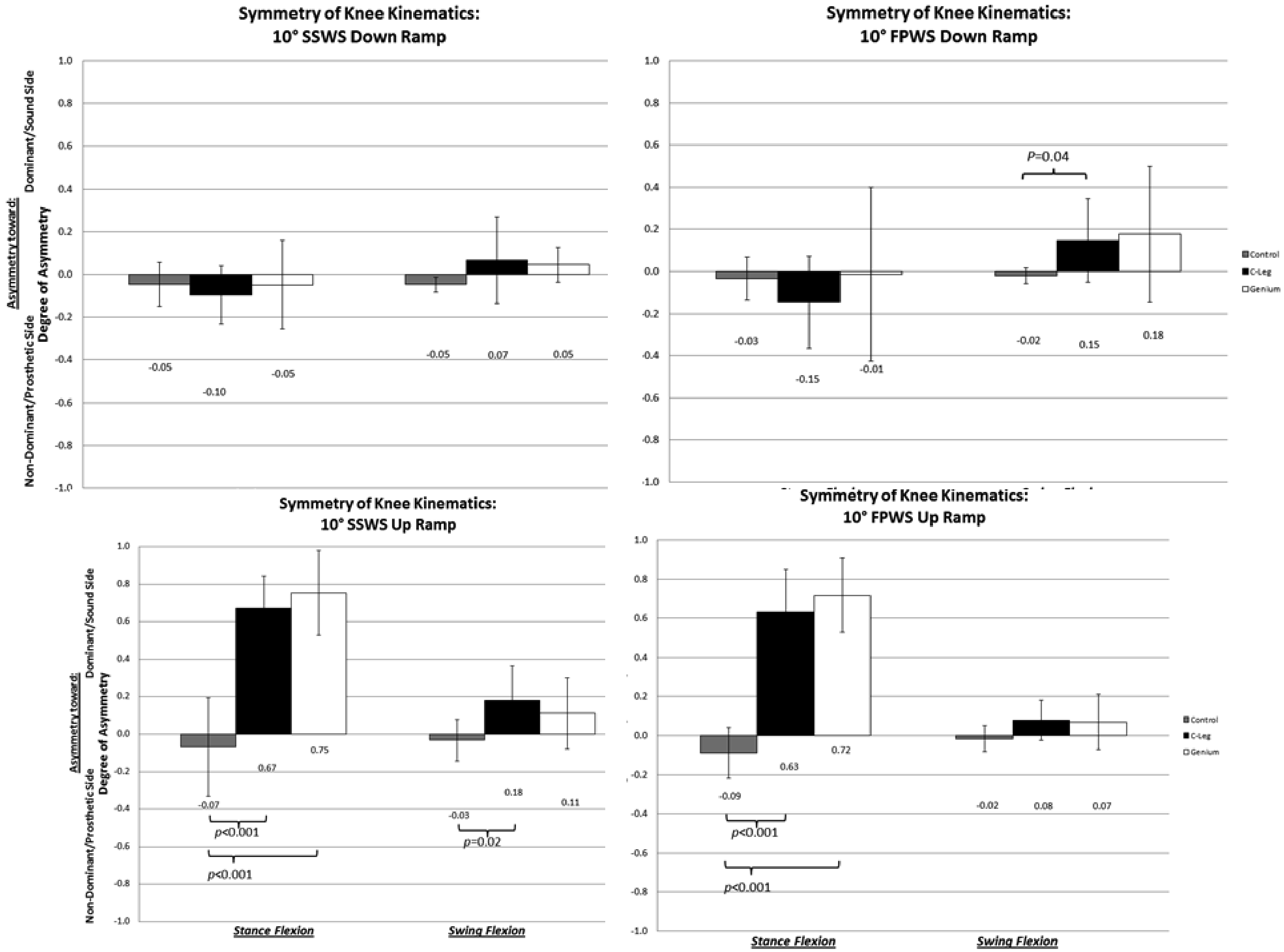

Figure 9.3. Degree of asymmetry on 10 degree ramp.

Timed Walking Tests

With regard to the timed walking tests (TWT), essentially neither knee condition seemed to have an effect on the time to complete a short or medium, distance-based walking test or the associated perceived effort. Two of the four tests were significantly different between the control group and Genium condition. (Table 9.2) This suggests that perhaps longer walking distances, walking that includes stopping, starting, turning and prevailing terrain may be better places to find differences between these two components. Finally, with regard to this battery of TWT's, it appeared that the uneven ground test showed considerable differences between the control group and the amputee group regardless of knee condition. (Figures 9.4-9.7)

Table 9.2. Timed Walking Tests. FPWS is fastest possible walking speed; SSWS is self-selected walking speed. Times are in seconds, RPE is rate of perceived exertion on the Borg 6-20 scale. All values are mean(SD). Significance is set at $p \leq 0.05$ and indicated by an asterisk(*). P values have either a(abnormally distributed data) or n(normally distributed data) to indicate the type of statistical analysis used. See Statistical Analysis in the Protocol for further information.

TWT	Condition						Comparison *p* value					
	C-Leg		Genium		Control		Genium vs. C-Leg		C-Leg vs. Control		Genium vs. Control	
	Time	RPE	Time	RPE	Time	RPE						
6m FPWS	4.1(0.7)	na	4.0(1.0)	na	2.9(0.4)	na	*0.03a	na	*0.04n	na	.009n	na
75m SSWS	65.8(10.0)	9.4(1.9)	64.6(10.1)	9.3(2.2)	54.0(6.9)	10.1(0.3)	0.42n	0.87n	0.13n	0.68n	0.19n	0.07n
75m FPWS	52.9(10.1)	12.1(2.2)	52.9(12.3)	11.9(1.8)	42.4(5.8)	12.8(0.6)	0.47a	0.15a	0.06n	0.22n	0.19n	0.63n
38m FPWS	30.1(7.3)	11.0(2.0)	29.9(7.2)	10.6(2.1)	20.3(1.6)	12.3(1.1)	0.94a	0.43n	0.06n	0.53n	*0.04n	0.19n

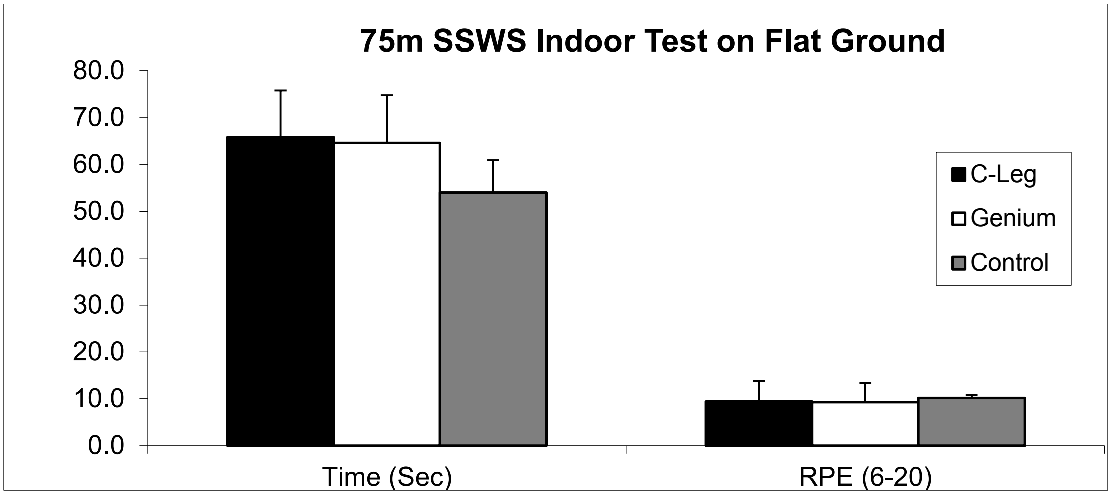

Figure 9.4. Self selected walking speed over 75 meters on flat ground

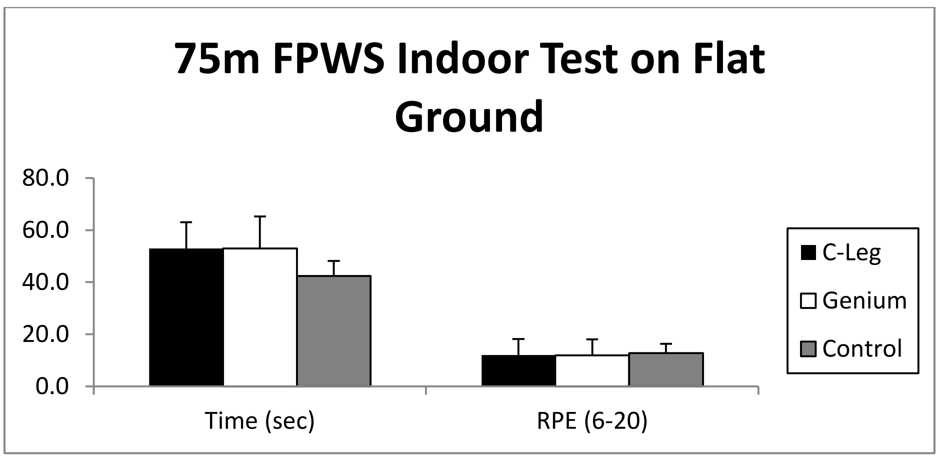

Figure 9.5. Fastest possible walking speed over 75 meters on flat ground

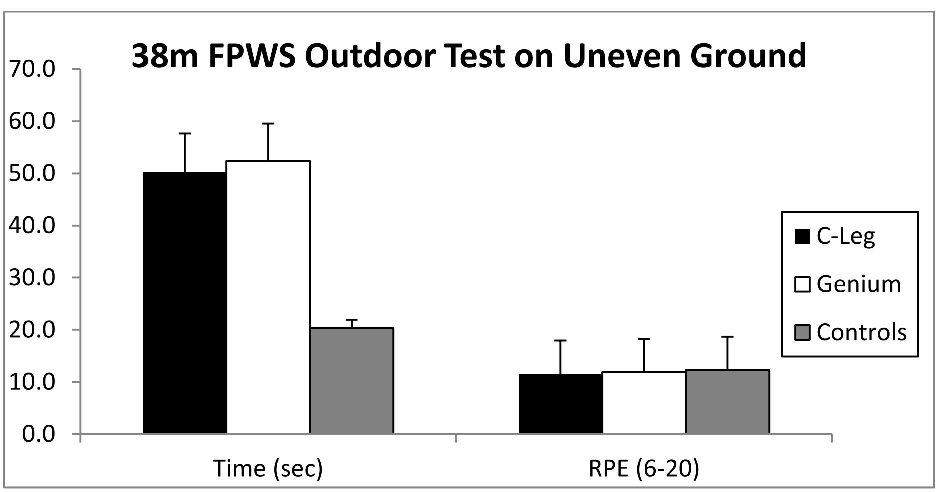

Figure 9.6. Fastest possible walking speed over 38 meters on uneven ground.

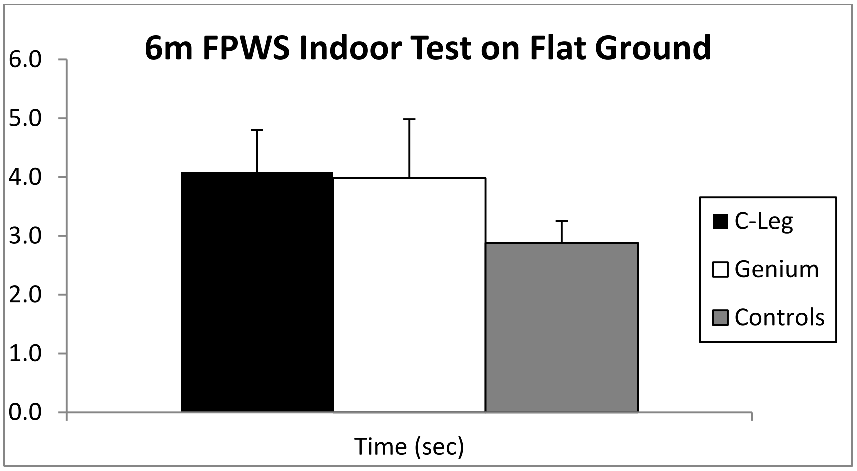

Figure 9.7. Fastest possible walking speed over 6 meters on flat ground.

Continuous Scale Physical Functional Performance Scale-CS PFP-10

Results

The PFP-10 test is a standardized assessment of ten activities of daily living.[2] Upper body function was significantly improved (8.7%, $p \le 0.01$) between knee conditions. (Table 9.3, Figure 9.8) The 8.7% between-knee difference in upper body function was significantly different, as was the 15% difference between the control group and C-Leg performance ($p<0.01$). (Table 9.3, Figure 9.8) In comparing differences in balance activity performance between prostheses and the control group, the 28.5% difference between C-Leg and control reached significance ($p=0.04$). (Table 9.3, Figure 9.8) For the endurance domain, there was a statistically significant ($p=0.04$) difference of 10.3% indicating improvement with Genium use. The difference between the C-Leg and controls was also significant ($p=0.04$) at 30.4%. The PFP-10 cumulative score (PFP) showed a statistically significant ($p=0.03$), 9.1% improvement when using the Genium, over the C-Leg. Compared to the control group, again the C-Leg had a statistically significant (*p*=0.05) score 25.8% lower. (Table 9.3, Figure 9.8) Table 9.4 shows the percent differences per domain and condition or group. The largest percent difference was between the C-Leg condition and control group in the lower body strength domain and the difference was greater than 29%.

Table 9.3. PFP is physical functional performance aggregate score, UBS is upper body strength score, LBS is lower body strength score, UBF is upper body function score, BAL is balance score and END is endurance score. All values are reported as group mean(±SD). Significance is at the $p \leq 0.05$ level and indicated by an asterisk (*).

Domain	Condition			Comparison *p* value		
	C-Leg	Genium	Control	Genium vs. C-Leg	C-Leg vs. Control	Genium vs. Control
PFP	54.2(14.4)	59.6(16.0)	73.0(15.7)	0.03*	0.05*	0.14
UBS	59.4(15.7)	63.5(18.8)	64.3(18.2)	0.80	0.60	0.93
LBS	47.6(15.3)	53.0(17.7)	67.3(17.1)	0.10	0.06	0.14
UBF	65.3(11.2)	71.5(10.3)	76.8(4.3)	0.01*	<0.01*	0.10
BAL	54.7(15.8)	60.4(16.6)	76.5(16.8)	0.07	0.04*	0.10
END	53.4(14.5)	59.5(16.0)	76.7(16.9)	0.04*	0.03*	0.09

Table 9.4. Percent differences between group means presented. The mean(±SD) percent difference is presented in the bottom row. An asterisk (*) indicates which percent differences per domain reached statistical significance.

Domain	% Difference		
	Genium vs. C-Leg	C-Leg vs. Control	Genium vs. Control
PFP	9.1*	25.8*	18.4
UBS	6.5	7.6	1.2
LBS	10.2	29.3	21.2
UBF	8.7*	15.0*	6.9
BAL	9.4	28.5*	21.0
END	10.3*	30.4*	22.4
Mean(SD)	9.0(1.4)	22.7(9.3)	15.2(8.9)

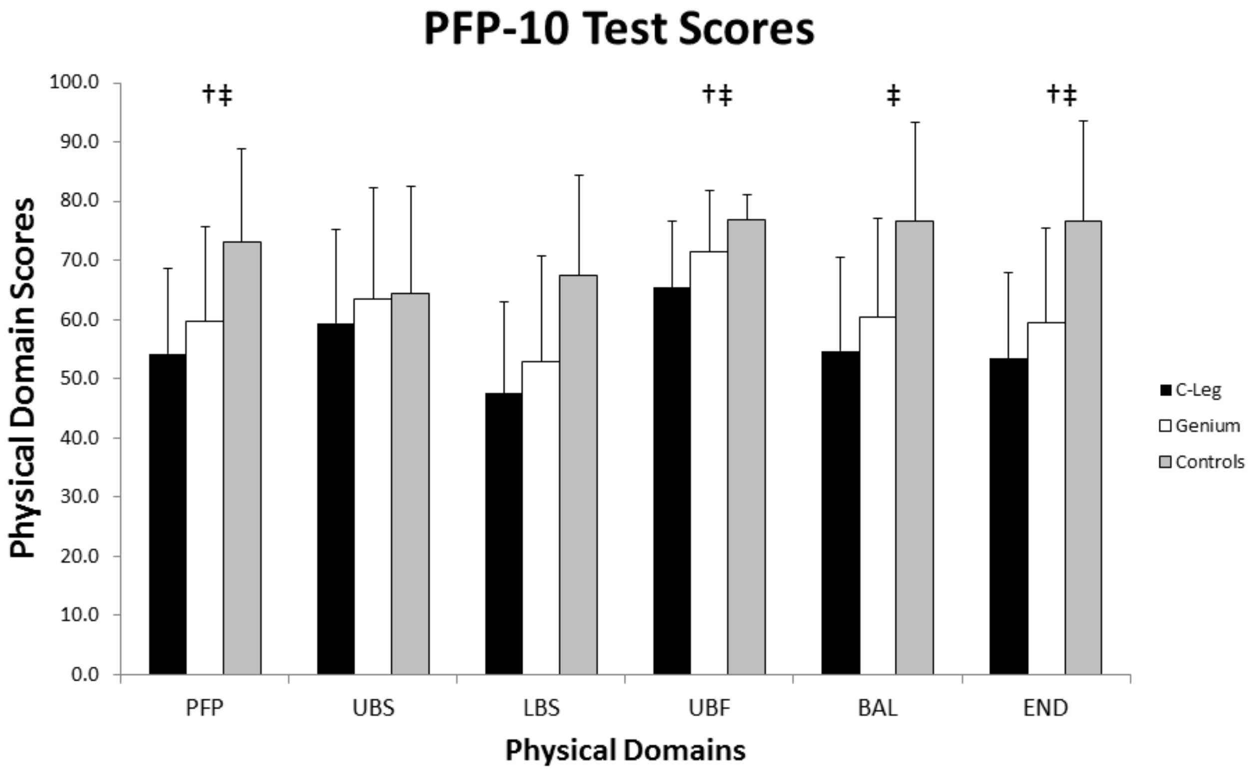

Figure 9.8. PFP-10 Test Scores. The mean difference(±SD) for each of the 5 domain scores and the aggregate score of the PFP assessment. Significant differences ($p \leq 0.05$) between the mean C-Leg and Genium performance scores are indicated by †. Significant differences ($p \leq 0.05$) between the mean C-Leg and Control group performance scores are indicated by ‡.

Discussion

Transfemoral amputation is viewed as a unilateral condition however there are clearly secondary complications to the so-called sound side related to aberrant and compensatory movement[3,4], and asymmetric loading.[5] Asymmetry is a useful measure to assist in understanding side to side differences however variances can be considerably high as large magnitude kinematic data are reduced to a scale of -1.0 to 1.0.[5,6] Biomechanics of functional movements in persons with transfemoral amputation previously utilizing a degree of asymmetry assessment revealed that kinetically, patients prefer to utilize the sound side to a greater extent for loading tasks such as sit to stand.[5] This has clear implications for secondary complications as forces added to the sound side chronically can exceed healthy loading and contribute to degenerative joint complications.[3] In this case, subjects tended to have kinematic preference for the sound knee.

On flat ground, Genium improved stance phase knee flexion symmetry compared to C-Leg but differences failed to reach statistical significance. For swing phase on flat ground, amputees were within 2% of perfect symmetry regardless of walking speed or knee. This is supported by Belleman's et al.'s data showing a more consistent swing phase knee flexion angle.[7]

The inability to demonstrate differences between knee condition on flat ground was apparent in the short and mid-distance, timed walking tests as well. In fact the most remarkable difference in this test series was the difference between amputees and controls on uneven ground (38m). In a recent clinical trial, C-Leg improved 38m uneven terrain performance compared to mechanical knees.[8] There is no comparable difference between knee conditions in these tests. Conversely, in other more diverse functional assessments, differences were observed.

In the amputee mobility predictor for instance, the mean difference between knee conditions was 2.5(out of 47 possible) points. This is 0.9 points less than the reported minimum detectable change however the difference was significant.[1] We observed the two primary items of distinction between knee conditions to be obstacle crossing and stair gait, particularly stair ascent. Stair ascent is featured in two items in the physical functional performance test.

In the PFP-10 test, the smallest between group differences were observed in upper body strength. It is not surprising that some differences are observed as the upper body strength activities are completed while standing and walking (e.g. carrying a loaded pot, carrying groceries). It would be highly unlikely that upper body torque production at a given joint would change during the course of this experiment. However, if a prosthetic knee were providing a more stable platform from which the upper body can function, then it is reasonable to anticipate an increase in functional strength as observed here. Interestingly, this area (UBS) presented the smallest differences between the three groups yet the differences, while not significant, were greater between controls and C-Leg (7.6%) compared with that between controls and Genium (1.2%). Upper body function was also improved with the Genium knee but unlike upper body strength, function was significantly improved (8.7%, $p \leq 0.01$) between knee conditions. As before, the tasks that contribute to the scoring of upper body function are performed in weight bearing. For instance the ability to sweep a floor, complete laundry tasks, etc. seem to be improved if the prosthetic knee is able to readily engage in an intuitive locking mode and readily disengage without concerted mental and physical attempts to do so. Based upon the Genium's sensor configuration which includes axial load data, the Genium is able to engage and disengage a locked standing mode rapidly to facilitate improved standing stability on demand during activity. Contributing to this is the addition of a gyro and accelerometer which provides the ability to detect rearward stepping and provide necessary stability if the toe is loaded with knee extension. This combination of biomechanical factors will trigger free knee flexion for swing phase in the C-Leg knee but the Genium is designed to maintain flexion damping in this case. Therefore, it is likely that following accommodation, there is improved willingness to move multi-directionally in a small space for the tasks performed here. These tasks include sweeping and changing laundry from washing machine to dryer, each requiring rearward stepping functionally while using the arms for manipulation. The next chapter of this document confirms improved multi-directional stepping. The 8.7% between-knee difference in upper body function was significantly different as was the 15% difference between the control group and C-Leg performance ($p<0.01$).

In terms of balance and coordination, there was a 9.4% improvement in tasks incorporating balance with the Genium. Due to considerable variance however, the difference did not reach statistical significance. In comparing differences in balance activity performance between prostheses and the control group, the 21% difference between Genium and controls did not reach significance however the 28.5% difference between C-Leg and control did ($p=0.04$). These tasks include carrying loads, getting up from the floor and considerable positional changes. It is not clear from this more global assessment if 1) the ability for the knee to switch between a collapsible, looser state when clearance is needed yet quickly dampen flexion for stability or 2) confidence upon weight shifting due to locking upon loading enhances the ability to complete tasks that require quick postural changes and limb movements. For instance, the ability to transition from standing to long sitting on the floor then back up to standing requires a rapid postural change. In non-amputees, the knees were observed to flex then extend during this task. In the amputee group, subjects were observed to abduct the amputated hip with an extended knee, lower the body with the sound knee then flex and adduct the involved hip to complete the movement. In only a few instances, was the prosthetic knee flexed during lowering. However, these kinematic observations were outside the scope of the PFP scoring and may be better suited to specific motion analysis of a comparable task. Therefore it remains clear if these few instances played a role in altering the balance domain score. Because the C-Leg requires a considerable toe load and knee extension moment to flex the knee, subjects may be reluctant and find it difficult to take small steps and shift load toward the forefoot. Tasks requiring multiple small steps and forefoot loading may be undertaken more cautiously with C-Leg, leading to lower scores within this and other domains. Kinetic studies will begin to reveal more about toe loading practices in this sample as data becomes available.

Lower body strength is assessed in the PFP-10 by multiple tasks including stair climbing with and without external loads, floor transfers, bending forward multiple times to pick up objects from the floor and more. Lower body strength was not significantly different between groups likely due to the effect of variance. Mean differences were considerable nonetheless. For instance, there was a 10.2% improvement with the Genium relative to C-Leg, 21.2% difference between Genium and control and a 29.3% difference between C-Leg and control. Again, stair ascent and descent were in two of the tasks for LBS. While the Genium does offer the ability to improve stair ascent performance[9], this improvement has not been assessed under a load carriage situation. We observed that when subjects were asked to climb stairs unloaded, reciprocal gait patterns were occasionally utilized with Genium however when loaded and climbing, a typical step-to gait pattern was most commonly adopted. This contributes to some of the Genium's score improvement in this domain but also to the increased variance. Further kinetic study is needed to understand the mechanistic effect of the Genium on stair gait to discern potential differences in stair ambulation patterns and function. For stair descent, it is widely known that the C-Leg offers the ability to descend stairs reciprocally as does the Genium[10]. Again, this has not been studied during load carriage. Further, just because a component offers a potential functional ability, it may not be appropriate for all users.[8] As with stair climbing with a load, anecdotally we observed that a number of subjects chose to descend stairs reciprocally however some did not when loaded regardless of knee. Again such observations are outside the scope of PFP scoring and should be systematically explored using other methods for further clarification.

The distance walked on a six minute walk test, time to complete a grocery carry ambulation task involving stairs and door opening and the perceived exertion for the entire PFP-10 test are the elements included in the endurance domain assessment. Few assessments evaluate the ability to serially assess functional tasks however the PFP-10 does.[2] Additionally, the PFP-10 incorporates a 6 minute walk test which has been used to validate numerous prosthetic functional assessments such as the amputee mobility predictor.[11] Inclusion of the 6 minute walk test provides a highly standardized endurance measure but the PFP-10 also includes the novel load carriage task in a functional context. For the endurance domain, there was a statistically significant (p=0.04) difference of 10.3% indicating improvement with Genium use. The difference between the C-Leg and controls was significant (p=0.04) at 30.4% however the difference between Genium and controls (22.4%) was not statistically significant. This is important because repetitive walking tests that were short and mid-distance completed as part of this protocol showed no difference in perceived exertion or time to complete the tests. Therefore, either the endurance requirement of repetitive walking for 6 minutes or the added load carriage task represent areas where in a more functionally meaningful way, the Genium provides an advantage for the completion of activities of daily living.

In total, the PFP-10 has a cumulative score (PFP). This score takes into account all 5 domains to present an aggregate perspective of a person's functional ability at that point in time. When using the Genium to complete the PFP-10, there was a statistically significant ($p=0.03$), 9.1% improvement over the C-Leg. Compared to the control group, again the C-Leg had a statistically significant ($p=0.05$) score 25.8% lower whereas the Genium's performance was 18.4% different but not significant. To further the collective image of group performance utilizing one knee condition versus the other and also comparing to controls, is the ability to describe performance against the instrument's threshold of independence scores (Figure 9.9) whereby: scores ≥57 reflect likelihood for full independence with activities of daily living, scores ranging from 48 to 56 indicate a risk for some dependency with the completion of activities whereas scores ≤47 indicate the greatest risk for dependence completing activities of daily living. In each domain, the non-amputee control group maintains the highest level of independence which ranges from 100% independence to 80% at risk of dependency. Performance with the Genium revealed superior levels of independence relative to the C-Leg condition with a range of 50 to 90% independence (lower body strength to upper body function respectively). The C-Leg conversely performed with the lowest proportion of independence (proportions of 21 to 73% [LBS to UBF respectively]).

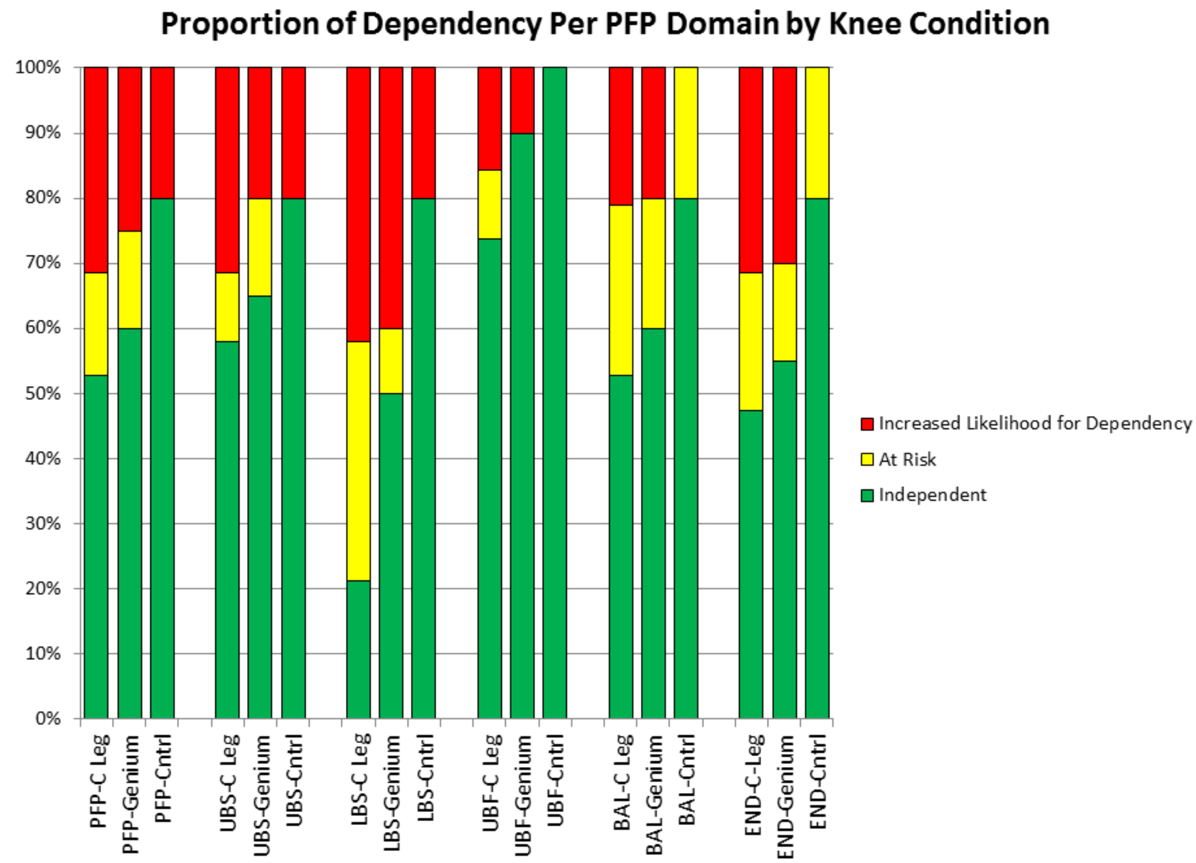

Figure 9.9. Independence with activities of daily living are indicated by PFP scores ≥57 (green color coding). Scores ranging from 48 to 56 (yellow color coding) indicate a risk for some dependency with the completion of activities whereas scores ≤47 indicate the greatest risk for dependence completing activities of daily living. In each domain, the non-amputee control group maintains the highest level of independence which ranges from 100% independence to 80% at risk of dependency. Performance with the Genium revealed superior levels of independence relative to the C-Leg condition with a range of 50 to 90% independence (lower body strength to upper body function respectively). The C-Leg conversely performed with the lowest frequency of independence ranged scores from 21 to 73% (lower body strength to upper body function respectively).

The purpose of this chapter was to report and discuss the results of functional assessments including the amputee mobility predictor, timed walking tests, kinematic analysis of gait and the physical functional performance test. It was the case that one knee was not superior of the other in every test. In more general tests of function however, key differences were noted. The next chapter will report and discuss the results of assessments of safety, balance, and stability.

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Chapter Ten: Results: Safety, Balance, and Stability

Postural Stability

For the percent weight bearing, all subjects relied upon greater heel weight bearing than toe weight bearing within a given foot though within foot (per group) comparisons were not made statistically. Non-amputees relied on significantly (p=0.04) greater heel weight bearing on the dominant side than did the transfemoral amputees. (Table 10.1)

Table 10.1. Postural Stability. The percent of time subjects stood on the respective fore or hindfoot per side of foot during the postural stability test. The level of significance for group comparisons was set at $p \leq 0.05$ and is shown in the right three columns. Significant comparisons are shown with an asterisk (*) and all data comprising this table were normally distributed with the exception of the data for the Genium vs. C-Leg comparison of the forefoot on the sound side.

Postural Stability: % time weight bearing on:	Condition			Comparison *p* value		
	C-Leg	Genium	Control	Genium vs. C-Leg	C-Leg vs. Control	Genium vs. Control
Forefoot Sound/Dom	18.5(16.2)	21.2(18.3)	22.1(20.5)	0.52	0.83	0.44
Hindfoot Sound/Dom	29.6(29.2)	27.0(28.1)	48.8(24.9)	0.75	0.18	*0.04
Forefoot Amp/ Non-Dom	19.4(17.3)	18.8(16.0)	12.3(19.8)	0.98	0.81	0.13
Hindfoot Amp/ Non-Dom	33.3(23.6)	33.0(22.4)	16.7(13.3)	0.90	*0.04	*0.03

Limit of Stability (LOS)

Time to complete the LOS test was not different between the two knee groups. While the TFA subjects required (Genium 17% and C-Leg 19%) more time to complete the test than controls, these differences did not reach statistical significance. (Figure 10.1) The overall directional score was not different between knee conditions however both knee groups were significantly different from the control group. In terms of individual directional scores, review of the radar plot (Figure 10.2) reveals considerable directional impairment between the amputee

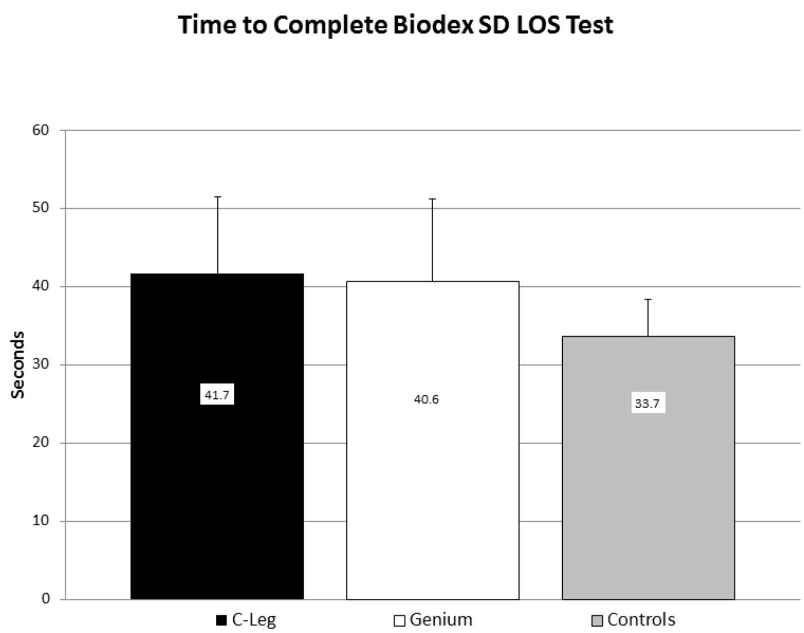

Figure 10.1. Time to complete Biodex SD limits of Stability test. The differences between the knees was not significant, the differences between either knee and the controls also was not significant.

and non-amputee subjects regardless of knee type. Beyond this, there was a significant difference (p=0.01) in the superior control displayed by amputees using the C-Leg in the forward prosthetic direction. While not statistically significant, the Genium knee permitted amputees to have improved control in the backward direction. (Table 10.2)

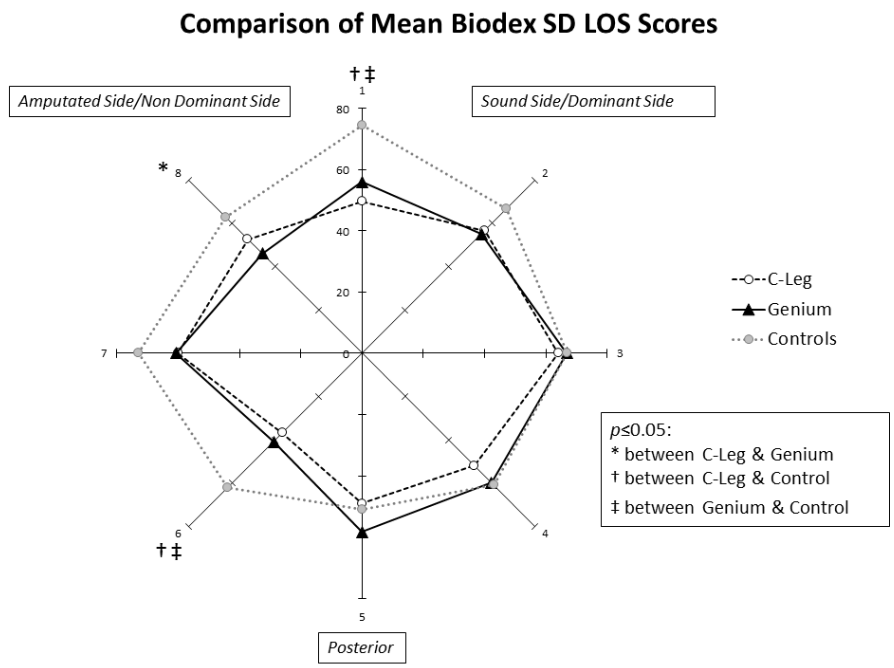

Figure 10.2. Limits of stability radar plot. The Amputated side is plotted on the left, and the sound side is plotted on the right for all subjects regardless of which side they were amputated. This allows for easier visual comparison.

Table 10.2. Limit of stability assessment data. Duration to complete the test, overall stability score and individual directional scores are presented as means(SD). Comparison *p* values are in the right 3 columns. Significance was set at *p*≤0.05 and all data were normally distributed unless noted by an 'a' beside the *p* value. Forward (Fwd), Backward (Bwd), Dominant (Dom), Amp (Amputated).

LOS Time & Directional Scores	**Condition**			**Comparison *p* value**		
	C-Leg	**Genium**	**Control**	**Genium vs. C-Leg**	**C-Leg vs. Control**	**Genium vs. Control**
Time (sec)	41.7(9.7)	40.6(10.6)	33.7(4.7)	0.53	0.31	0.43
Overall LOS	45.1(15.3)	44.5(16.3)	58.9(12.1)	0.69	*0.002	*0.002
Forward	50.1(27.0)	54.7(30.7)	74.6(25.0)	0.18	*0.03	*0.02
Fwd Sound/ Dom	57.6(21.0)	53.0(22.6)	66.7(24.4)	0.21	0.11	0.39
Sound/Dom	66.3(24.2)	65.8(25.6)	66.9(17.9)	0.88	0.39	0.48
Bwd Sound/Dom	52.5(18.2)	58.5(26.3)	60.9(18.0)	0.07	0.16	0.95
Backward	48.5(27.7)	55.7(33.3)	51.1(32.1)	0.13	0.56	0.98n
Bwd Amp/ Non-Dom	37.5(23.8)	41.2(21.7)	61.9(21.7)	0.04a	*<0.001	*<0.001
Amp/ Non-Dom	59.8(24.5)	58.4(25.4)	73.1(21.3)	0.66	0.15	0.28
Fwd Amp/ Non-Dom	52.4(21.4)	45.6(24.3)	62.9(21.4)	*0.01	0.31	*0.03

4 Square Step Test

Mean (SD) times for the 4 square step test were 12.2s(3.3), 11.1s(3.4) and 8.5s(1.8) for the C-Leg, Genium and control groups respectively. Significant differences (*p*≤0.05) were observed between prosthetic knee conditions as well as between each knee condition and the control group.

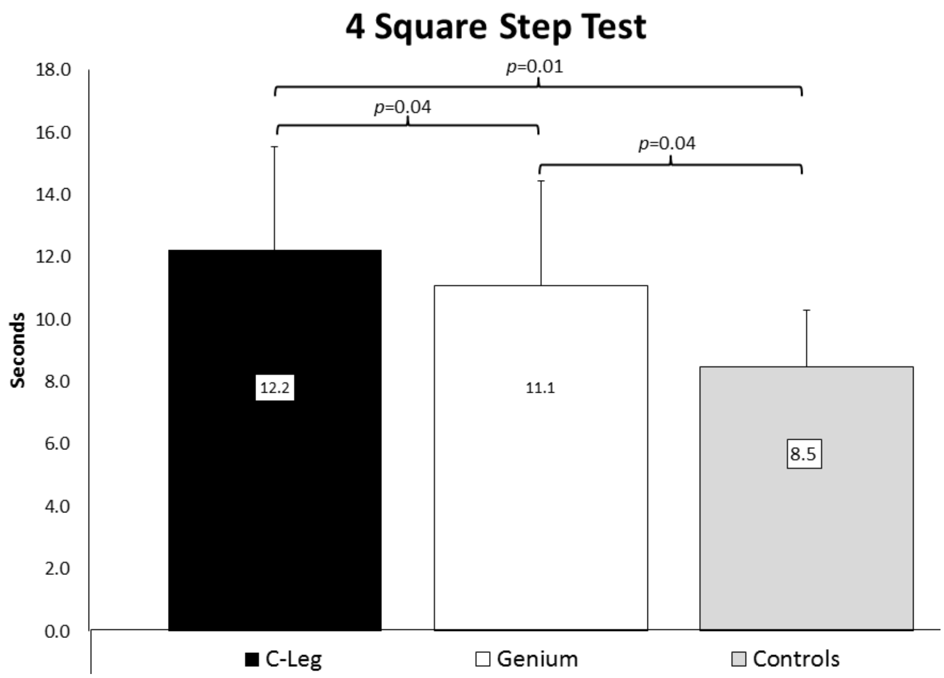

Figure 10.3. The 4 Square step test time in seconds.

2 Minute Declined Ramp Stand

Control subjects were not tested on this assessment as it was intended to assess the perceived effort when using the locked standing mode of the Genium knee compared to how C-Leg users perceive the effort of the task. While using C-Leg, using Borg's rate of perceived exertion (RPE)[1], subjects rated their effort at 8.5(2.6)/20 whereas the Genium resulted in a 13% reduction in effort to 7.4(1.7)/20 however the difference failed to reach statistical significance (p=0.06).

PEQ-A

The PEQ-A did not reveal any statistically significant differences even prior to applying a Bonferroni corrected alpha. Eleven of the fourteen items improved with Genium use. Two items improved in favor of the C-Leg and the number of uncontrolled falls remained unchanged between knee conditions. The PEQ-A is 14 items. All items are visual analog (0-100mm line scored as distance in mm and reported unit-less) except for the 3 items marked by an asterisk(*) which ask subjects to recall the specific number of events. Higher values represent a more positive response. With the exception of the 3 recall items, these data (mean sample responses) were analyzed via non-parametric assessment. A Bonferroni multi-test correction was applied to these data changing the alpha from 0.05 to 0.0036. Notations for data distribution follow *p* values: a- abnormally and n- normally distributed data. Two items (†) improved favoring C-Leg whereas item #7 remained unchanged regardless of knee condition.

Table 10.3. Prosthesis Evaluation Questionnaire-A. Stumbles, Falls, Mental Energy.

Item Topic	**C-Leg**	**Genium**	***p* value**	**% Difference**
1. Mental energy expenditure	27.2	16.4	0.08n	40%
2. Frequency of stumbling	20.1	14.0	0.18n	30%
3. Number of stumbles*	4.9	4.1	0.20a	16%
4. Frequency of semi-controlled falling	6.9	1.5	0.30a	78%
5. Number of semi-controlled falls*	1.8	0.3	0.14a	83%
6. Frequency of uncontrolled falling†	1.9	2.7	0.27a	30%
7. Number of uncontrolled falls*	0.3	0.3	0.22a	0%
8. Confidence while walking	83.2	86.2	0.24n	3%
9. Difficulty multi-tasking while walking	11.6	9.0	0.27a	22%
10. Fear of falling	8.3	5.1	0.09a	39%
11. Frustration with falling	7.3	0.9	0.27a	88%
12. Embarrassment with falling	6.3	3.2	0.13a	49%
13. Fearful of falling without prosthesis	14.2	19.8	0.79a	28%
14. Difficulty with concentration†	8.1	8.8	0.47a	8%

Discussion

In this study, the postural stability assessment was conducted to compare differences in weight bearing while standing and balancing between controls and transfemoral amputees as well as between knee conditions. As discussed in Chapter 8, alignments were set comparably so it was anticipated that weight bearing should also be comparable unless true differences were required to stand safely on the balance platform. There were no differences in the weight bearing distribution that reached statistical significance however there was a slight increase in weight bearing on the C-Leg's forefoot. (Figure 10.4) This is consistent with the C-Leg design which requires a particular stump motor strategy involving considerable toe loading in terminal stance.[2] It is interesting that it did not emerge as significant as we anticipated subjects would have greater confidence having mass over the toe when using a C-Leg. Perhaps this should be studied closer in a dynamic situation to clarify potential motor differences.

The C-Leg requires threshold toe loading (60%) not required by the Genium to initiate knee flexion for swing phase. It is plausible that the directional score improvement toward the forward prosthetic direction is associated with the fact that amputees become acclimated to the force required to initiate knee flexion for swing phase when using the C-Leg. Because the Genium initiates flexion without a comparable load, perhaps amputees learn a new minimized boundary in that direction when not forced to repetitively use it every step. In regard to the posterior directional improvement with Genium, though not significant, the Genium sensor array reportedly improves multi-directional stepping including backward walking. If subjects become accustomed to the ability to step backward, they may develop compensations (i.e. transverse spinal rotations, increased heal loading over the prosthesis, etc.) to improve this particular directional control. Speaking to the differences in directional control more broadly, the radar plot (Figure 10.2) shows a somewhat apparent diminished directional control in most directions between transfemoral amputees and control subjects. The most considerable difference was in the posterior prosthetic direction regardless of knee condition. Posturographic assessment of transfemoral amputees is minimally studied. Kaufman et al. used a different instrument to measure differences between mechanical knee prostheses and the C-Leg in a sensory organization test.[3]

During that assessment, C-Leg improved static balance which agrees with other functional based studies looking at safety of the C-Leg overall. The Biodex SD has been used to study balance associated phenomena in persons with diabetes, arthritis and other neurologic disorders.[4-6] To our knowledge however, this is the first assessment of transfemoral amputees using the Biodex SD to quantify differences in limits of stability. Differences in limits of stability were negligible between knee groups (Figure 10.5) but seem biologically plausible in accordance with component design. Conversely, differences between transfemoral amputees and non-amputees on this test are considerable which is also logical given that transfemoral amputees fall between 1 and 3 times every 60 days.[7]

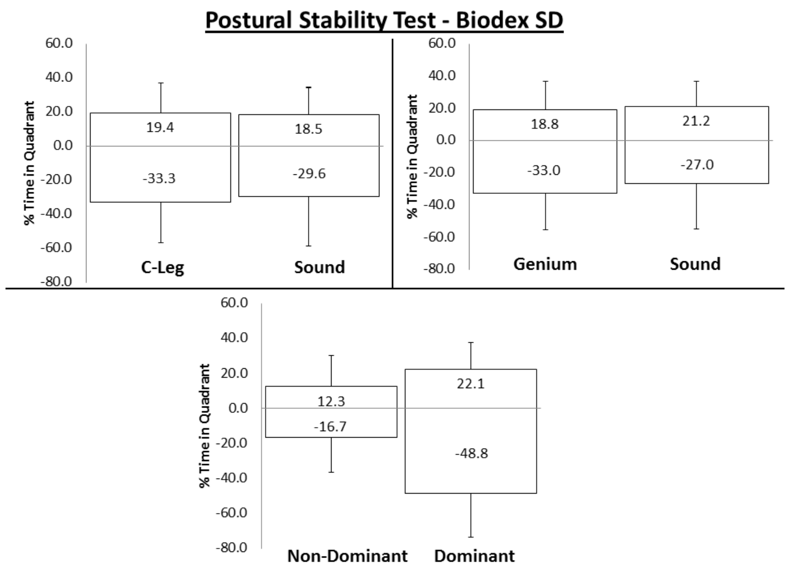

Figure 10.4. Postural Stability test of the C-Leg (upper left), Genium (upper right), and controls (bottom).

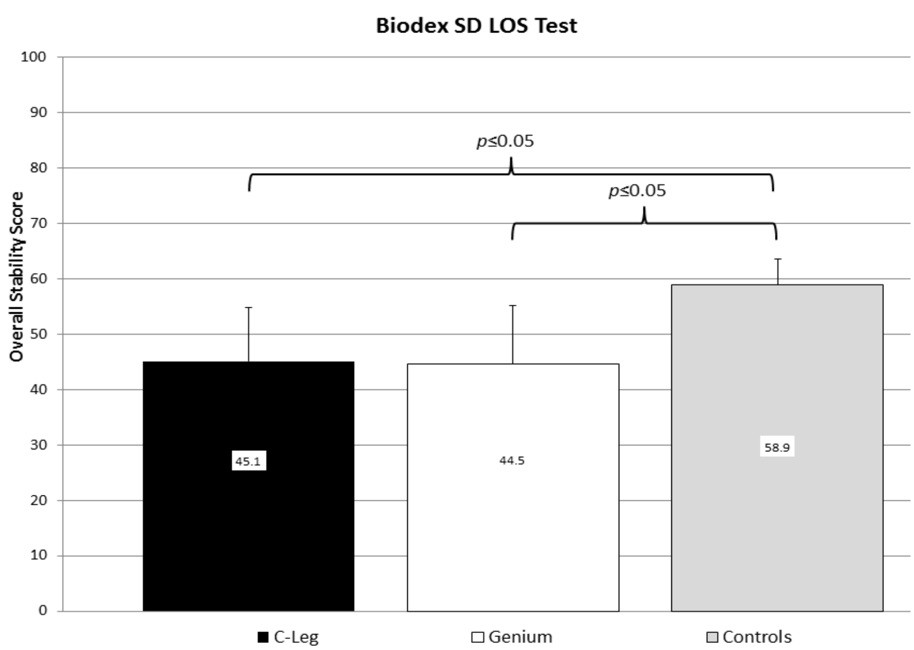

Figure 10.5. Limits of Stability Test, overall stability score.

Regarding multi-directional stepping, the mean duration to complete the Four Step Square Test was decreased with Genium use by 9% compared to C-Leg. Increased ambulatory confidence has been associated with faster or closer to normal walking speeds in the forward direction.[7] This may be true as well for multi-directional stepping whereby increased velocity may result from bolstered confidence. As in the previous chapter of this document, this was evident by improved PFP-10 scores and particularly in tasks requiring multidirectional stepping such as sweeping in a confined space and changing laundry from washing machine to dryer.

The final stability measure in the protocol was the declined ramp stand. This protocol required standing facing down a 7° slope for two minutes. Recently Bellman et al. had a sample of transfemoral amputees perform a similar task.[8] In their study, subjects stood facing down a 10° slope for three minutes while knee moment and weight bearing were recorded. Bellman et al. reported that the Genium's locking feature enabled 47% greater load bearing through the prosthesis when subjects used the Genium compared to C-Leg. Comparably, they reported a 48% increased external sagittal knee flexion moment and substantial reduction in the hip moment necessary to control the knee flexion. Bellman et al. attribute this reduction to the standing feature of the knee which blocks the knee flexion valve permitting increased loading without fear of knee flexion collapse. The fact that the hip moment reduced could have a relationship for our finding of reduced perceived effort in a comparable task. If subjects are able to stand with less muscular effort then it is logical their perceived effort would also be decreased. The perceived effort reported by subjects failed to reach significance. That said, specific training was not offered in regard to the standing feature. Rather, each subject had all Genium features explained to them at initial fitting however this information is voluminous and therefore it is likely that improved performance in this domain may be available if patients are provided specific instruction and practice on multiple occasions.

The Prosthesis Evaluation Questionnaire-A offers the patient the opportunity to self-report their perception about mental energy during ambulation as well as stumbles and falls. Patient perception about performance can considerably enhance objective data and the PEQ-A has been used for this purpose in a recent clinical trial comparing C-Leg with mechanical knee prostheses.[9] It is also important to note that patient recall of events is known to be reliable pending the temporal proximity and saliency of queried events. Recall in this case was at or approximately 3 months (see accommodation data and protocol). It is recognized that stumble and fall events are likely associated with injury and embarrassment and are therefore highly memorable.[7] Kahle et al reported similar numbers of stumbles (3 $\pm$ 4) and falls (1 $\pm$ 2) for subjects wearing a C-Leg in a study comparing the C-Leg to non-microprocessor knees.

At times certain types of measures may have sample variances that are prohibitively high making statistical significance elusive in the absence of a large sample size. Stumbles and falls with high variances have been reported in similar studies for example[7]. However, important clinically significant findings may still be realized in such cases while perhaps not statistically significant[10] For instance, if a study examined the effect of a drug on a terminal cancer and showed a 20% chance of remission but no statistical significance, there is likely value in considering or even using the drug as opposed to having few or no options. A similar comparison can be made in the absolute number of stumbles and falls reported here. While the percent difference between the 2 knees did not show statistical significance, one stumble could lead to a fall, and one fall could lead to serious injury. Stumbles and falls have been reported to be a major fear and reality with TFA.[11]

This chapter reported and discussed results from the safety assessments of the protocol. The next chapter will report and discuss results related to quality of life.

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Chapter Eleven: Results: Measures of Quality of Life and Perceptive Measures

Prosthesis Evaluation Questionnaire

Of the PEQ's seven (7) groups of questions, the following two (2) question groups were selected for this protocol:

1. Group 3: Social and Emotional Aspects of Using a Prosthesis
2. Group 5: Satisfaction with Particular Situations

Sample mean for group 3 showed a non-significant reduction with Genium use whereas the sample mean for group 5 was significantly increased.

PEQ Group	C-Leg	Genium	*p* value
3: Social and Emotional Aspects of Using a Prosthesis	5.9	5.7	0.69
5: Satisfaction with Particular Situations	6.0	6.4	<0.001

The PEQ predominantly uses visual analog data. Resnik et al[1] determined that converting the scoring to a 1 to 7 numeric scale is a more simple and efficient method without sacrificing reliability or validity. The 1-7 scoring method was used in this protocol. Since self-reported quality of life was the topic of interest, groups 3 and 5 were selected from the instrument as the PEQ is validated per section.[2] Group 3 has ten (10) scored items and group 5 has seven (7) scored items. Per knee condition, the entire sample's score per question was averaged. Then, all mean item scores were averaged to comprise the sample mean score for the respective group of questions. This value is reported in the table. A Bonferroni multi-test correction was applied to these data changing the alpha from 0.05 to 0.004. Non-parametric assessment was used as these data represent ordinal scaling and were abnormally distributed.

Discussion

The Prosthesis Evaluation Questionnaire is a valid and reliable instrument that is population specific to persons with lower extremity amputation.[2] Broadly, the PEQ assesses perceived function and quality of life. Validation of the instrument includes items by group[2] and therefore, two specific groups of questions were selected to assess socioemotional and situational satisfaction regarding between-knee differences for this protocol:

1. Group 3: Social and Emotional Aspects of Using a Prosthesis
2. Group 5: Satisfaction with Particular Situations

Questions from group 3 include avoiding stranger's reactions, prosthetic related frustration, effect on relationships, social hindrance and others. The sample mean for this group decreased during Genium use but not significantly. Perhaps the newly added burden of learning to use the new component and for many participants, coming to the study site for training was measurably problematic in the short term. A longer duration follow up may provide additional insight into potential socioemotional burdens related to accommodation and progressively improving proficiency with the new prosthesis. Group 5 items include: satisfaction with gait, the prosthesis, training and importantly an item to rate the present quality of life in general. In this group of questions, Genium use resulted in a highly significant (p<0.001) improvement. We previously reported a “glitz bias”[3] where subjects may answer subjective questions supporting a new technology so it is important to compare such outcomes to objective performance data. Considered in this way, this subjective improvement seems to match objective data. For instance, functional level improved as evident on the AMP and PFP-10 scores; mobility improved in the 4SST. The magnitude of significance may suggest an element of glitz bias as not all functional measures improved. Examples include the timed walking tests and the LOS test. In other clinical trials, the PEQ has been used similarly to corroborate or refute objective performance measures. In all three cases, the subjective PEQ data and objective performance data tend to be in predominant agreement.[3-5]

This chapter reported and discussed quality of life measures. The next and final chapter will provide concluding remarks from the study.

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Chapter Twelve: Conclusion

Strengths and Limitations and Future Work

This study has improved on methods previously used in clinical trials of prosthetic knee components. For instance, previous clinical trials did not randomize knee condition and were subject to an order of effect bias. Similarly, prosthetic feet were poorly reported and not controlled so their effect is unknown. Additionally, functional level has previously been measured only based on clinical judgment as opposed to validated measures. In this study, we randomized allocation, off-site and controlled for prosthetic feet. Additionally, we rigorously documented an a priori accommodation and training plan, reported specific functional training practices as two chapters in this document and tracked accommodation time and training visits of subjects. One additional strength in this protocol is inclusion of a non-amputee control group. This enabled assessment of difference not only between prosthetic knee conditions but also against the control group. We feel methodologic rigor has been elevated in this work and risk of bias minimized. Nevertheless, this study still lacks double blinding. Physical rehabilitation interventions are known to be particularly challenging to blind but this should still be a goal in future studies.[1,2]

Another issue is long term follow up. While a sixty day follow-up is ongoing, a longer-term follow up would be informative but potentially cost-prohibitive. Future work will involve completion of the sixty day follow-up and projections for economic modeling. Advanced statistical analysis will follow as well to dichotomize groups retrospectively as group anthropometrics and other factors permit.

Conclusions

For safety, both C-Leg and Genium seemed to promote static weight bearing beyond the asymmetric values reported in the literature. In terms of limits of stability, TFA’s are clearly impaired, primarily over the amputated side posteriorly however the Genium seems to enable posterior compensations that coincide with multi-directional stepping improvements. Anteriorly, the C-Leg’s toe triggering requirements seem to improve limits of stability but come at the cost of discomfort on ramp ascent. Beyond these observations, the number of stumbles and semi-controlled falls decreased but not significantly so. With regard to safety, it seems that both knee systems represent good options for the community ambulating TFA.

For perceived function, Genium was favored in satisfaction with gait, training and quality of life in general. Such assessment is susceptible to bias and must be balanced with objective measures. That said, functional level clearly improved due to stair function and obstacle crossing. In terms of knee flexion symmetry, differences favored Genium slightly but both knee systems presented problems with ramp ascent. The largest improvements with Genium were seen in the activities of daily living assessment. Here, balance and upper body function surprisingly stood out. Endurance seemed to be improved which was surprising as no isolated short-to-mid distance walking tests were improved. In terms of balance, where posturographic assessment was unable to measure differences, functional contexts did. It seems that the combination of multi-direction stepping with starts and stops and stair ascent are key areas of improvement. Additionally, when using the upper limbs with such movements, function seems to be enhanced with the new sensor array. In conclusion, the sensor array in the Genium knee prosthesis promotes improved function in activities of daily living. Specifically improved in this context were balance, endurance, multi-directional stepping, stair ascent and upper limb function in highly active transfemoral amputees.

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Appendix 1:

Safety, Energy Efficiency, and Cost Efficacy of the C-Leg for Transfemoral Amputees: A Review of the Literature

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Safety, energy efficiency, and cost efficacy of the C-Leg for transfemoral amputees: A review of the literature

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Abstract
The purpose of this paper was to review the literature through a structured literature review and provide a grade of recommendation for patient safety, gait energy efficiency, and cost effectiveness of the C-Leg microprocessor-controlled prosthetic knee for transfemoral amputees. Medline (Ovid) and CINAHL (EBSCO) data bases were searched to identify potentially pertinent studies within the 1995–2009 time range. Studies were screened and sorted. Pertinent studies were rated for methodologic quality and for risk of bias. Following assessment of methodologic quality and bias risk, the level of evidence and a grade of recommendation was determined for each of three categories: Safety, energy efficiency, and cost effectiveness. A total of 18 articles were determined to be pertinent: seven for safety, eight for energy efficiency, and three for cost effectiveness. Methodologic quality was low with a moderate risk of bias in the safety and energy effectiveness categories. Studies in cost effectiveness received high scores for methodologic quality. Though methodologic quality varied across the selected topics, there was sufficient evidence to suggest increased efficacy of the C-Leg in the areas of safety, energy efficiency and cost when compared with other prosthetic knees for transfemoral amputees.

Keywords: *Prosthetics, rehabilitation of prostheses users, levels of evidence, grade of recommendation, microprocessor knee, QALY*

Introduction

Presently there are an estimated 1.6 million persons living with limb loss in the United States.[1] Of these, 86% or approximately 1.3 million, have amputation of the lower extremity.[1] Twenty-six percent of lower extremity amputees, or slightly more than

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357,000 individuals have a transfemoral level amputation.[1] Ninety-five percent of transfemoral amputations (TFA) are attributable to vascular disease. The remaining five percent of TFAs are attributable to trauma, malignancy, and congenital limb deficiencies.[1] There is a higher incidence and prevalence of dysvascular related amputation with advancing age and black individuals have the highest incidence of any particular group.[1,2]

TFAs who achieve successful ambulation are more likely to do so with upper extremity aids and may develop an adapted gait pattern, even while walking on level ground.[3] It is important for amputees to feel stable and safe while walking with their prosthesis. It is also desirable to achieve the maximal functional level possible. Transfemoral amputees use a prosthetic knee for ambulation. Prosthetic knees are generally available with or without microprocessor control. Microprocessor-controlled prosthetic knees (MPK) are commonly equipped with sensors to continuously detect the position, range and forces acting upon the knee throughout the stance and/or swing phases of gait and other activities. Such sensors provide input to the microprocessor so that the knee can appropriately accommodate the particular activity or phase and velocity of gait. This allows virtually instantaneous adaptation to different walking speeds, terrain, and environmental conditions.

The Otto Bock C-Leg (Otto Bock; Duderstadt, Germany) is an MPK that controls stance and swing phase and adjusts to the requirements of the prosthesis wearer at a rate of fifty times per second. The addition of a microprocessor to rapidly regulate stance and swing phase could improve ambulatory functions such as safety and energy efficiency. Such technological advancements usually come at considerable cost to the healthcare system. It is necessary to evaluate such key features of a component and their cost effectiveness. Several studies have evaluated the safety, energy efficiency and cost efficacy of the C-Leg compared to other prosthetic knees. In some studies it has been reported to actually increase the level of function as well as independence.[4,5] The purpose of this literature review was to determine a grade of recommendation regarding safety, energy efficiency during gait and cost effectiveness of the C-leg for TFAs.

Methods

Search strategy

The Medline and CINAHL data bases were searched via the Ovid and EBSCO Host interfaces (respectively) on March 4, 2010. Primary search terms *Microprocessor-Controlled Prosthetic Knees* or *C-Leg* were searched independently and in combination with one of the following secondary search terms: *Safety*, *Falls*, *Stumbles*, *Balance*, *Energy Efficiency*, *or Cost*. Searches were pre-limited using the following criteria: English language, abstract available and peer reviewed (CINAHL only). In Medline, the '*map term to subject heading*' feature was de-selected to eliminate a MeSH heading search. In CINAHL, a default Boolean search was used. A publication date of 1995–2009 was chosen in both databases as the C-Leg was introduced in 1997.[6] A manual search of journals identified by the Rehabilitation Engineering Research Center in Prosthetics and Orthotics' 2006 State of the Science Report[7] and known to the authors as highly relevant in prosthetics research, was also conducted in the event very recent publications or keywords missed important publications in Medline and CINAHL.

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Screening

Resulting references were exported to EndNote (Thompson, CA) bibliographic citation software. Two reviewers independently screened resulting references according to inclusion/exclusion criteria and classified them as either: (i) Pertinent, (ii) not pertinent, or (iii) uncertain pertinence. Full-text articles were reviewed for all citations classified as pertinent or uncertain pertinence. Disagreements regarding citations of uncertain pertinence were resolved by the two reviewers independently reviewing full-text articles then discussing and agreeing on ultimate inclusion/exclusion.

Inclusion criteria:

(1) Must be a comparative study;
(2) Study used objective/quantifiable outcome measures;
(3) C-Leg MPK utilized in one arm of the trial;
(4) Must address one or more of the three key areas of interest: safety, energy efficiency in gait, cost effectiveness.

Exclusion criteria:

(1) Endoprosthetic knee joints (Total knee arthroplasty/replacement);
(2) Editorial, classification or taxonomy papers;
(3) Paper does not address at least one of the three key areas of interest: Safety, energy efficiency in gait, cost effectiveness;
(4) Duplicate publication.

Sorting by topic

Following screening, full-text articles were sorted by the two reviewers for specific pertinence in one or more of the three subtopics (safety, energy efficiency, and cost effectiveness).

Quality assessment

Once pertinent articles were screened and sorted, methodologic quality and risk of bias were independently assessed by the two raters in order to assist with determining the level of evidence to support the three topics of interest. The PEDro Scale was utilized to determine methodologic quality for the safety and energy efficiency topics. The PEDro Scale reportedly has fair to good reliability for application in rehabilitative clinical trials.[8] The scale results in a 0–10 score, with higher scores reflecting higher methodologic quality, based on 11 criteria. The first criterion is not scored. To receive a point in each of the remaining ten criteria, the criteria must be clearly stated in the study resulting in a ‘yes’ answer for presence of that item, and the awarding of one (1) point. If an item is not clearly stated, it receives a ‘no’ answer and receives no point for that criterion. A PEDro score of 6/10 or higher is considered to have high methodologic quality whereas scores lower than 6/10 are considered to have low methodologic quality.[8]

Following the rating of methodologic quality, the SIGN 50[9] assessment forms (three forms) were utilized to: (i) Assess internal validity, (ii) assess degree of bias, and (iii) to extract useful data from the pertinent studies for the safety and energy efficiency topics

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(see Tables 1 and 2). Answers from the checklists are not weighted. The risk of bias is classified as either:

(1) *Low*. All or most of the criteria from the assessment of internal validity are satisfied. Study conclusions would not likely be altered if methods were changed.
(2) *Moderate*. Some of the criteria from the assessment of internal validity are satisfied. Study conclusions would not likely be altered if methods were changed.
(3) *High*. Few or none of the criteria from the assessment of internal validity are satisfied. Study conclusions are likely or very likely to be altered if methods were changed.

To examine methodologic quality for the cost effectiveness topic, the PEDro scale and SIGN 50 assessment forms could not be used. Therefore, we used an internally consistent and validated grading system specifically for the assessment of methodologic quality of health economic evaluations. This grading system, while similar to many checklists, guidelines, and recommendations for economic evaluation and technology appraisal, has several advantages. The grading system is formally validated and can be used to rate economic evaluations on items related to both internal and external validity. A weighted numerical score can be derived to facilitate comparisons and allow users of economic evaluations to discriminate between lower and higher quality evaluations.[10] Sixteen evaluation criteria in this system were ultimately selected based on surveys of 120 international health economists including: Study objectives, design, perspective, data collection, time horizon, discounting, transparency, sensitivity analysis, and incremental analysis. Using weights on each of the 16 criteria a numerical score ranging from 0 (low quality) to 100 (high quality) is obtained. The numerical scores and major evaluation criteria for each economic study are listed in Table 3.

Following assessment of methodologic quality and risk of bias, the level and grade of evidence was determined by using the model designed by the Center for Evidence-Based Medicine.[11]

Analysis

Due to heterogeneity in sample size, methods, accommodation periods, outcome measures and design, meta-analyses were not possible. Effect sizes (Cohen's D)[12] were calculated for all papers with available data using formulas based on independent *t*-tests. It is acknowledged that there is controversy in the use of this method versus a calculation that controls for the dependency of data. Effect sizes are typically larger when dependency of data is considered; limitations though are that more information is needed (for example the correlation coefficient between the data under examination).[12] As the articles reviewed had limited information, we chose to use the calculation based on independent groups, acknowledging that this is a conservative approach.

Results

Following pre-limiting, 45 articles were identified from the database search and three additional articles[5,13,4] from the manual search (Figure 1) for a total of 48 articles. Fourteen duplicate articles were eliminated in EndNote prior to independent screening leaving 34 citations for classification. Sixteen articles were ultimately classified as not pertinent, leaving 18 articles in the review. Of the 18 articles, seven were determined to be pertinent for the safety topic,[4,5,13,15–18] eight were determined to be pertinent for the energy efficiency

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Table I. Safety.

Study	Hafner et al. (2007)	Stevens and Carson (2007)	Kaufman et al. (2007)	Kahle et al. (2008)	Berry et al. (2009)	Blumentritt et al. (2009)	Hafner and Smith (2009)
PEDro score	4	n/a	5	4	3	4	4
Risk of bias	Moderate	n/a	Moderate	Moderate	Moderate	Moderate	Moderate
Effect size	Not enough information	n/a	Not enough information	0.8	Not enough information	Not enough information	0.2–1.4
Study design	Cross-over	Case report	Cross-over	Cross-over	Pre/post test	Repeated measures	Cross-over (re-analysis)
All study outcome measures	Walking tests, PEQ, step count, stumbles/falls, stairs/ramps, preference	Activities Specific balance Confidence scale	Balance, gait biomechanics	Walking tests, stumbles/falls, stairs (MRPP), PEQ, preference	Mixed topic survey	Gait, stumble and fall biomechanics	Walking tests, PEQ, step count, stumbles/falls, stairs/ramps, preference
Measurement method of interest	Questionnaire	Questionnaire	Motor activity and balance tests	Self-report on stumbles and falls	Questionnaire	Biomechanics of situations bearing the risk of falling	Questionnaire
Results of outcome measures of interest with statistical significance†	($p < 0.05$) Reduced frequency: Stumbles (19%), semi-controlled falls (12%), and falls (5%)	Activities Specific balance Confidence scale Balance efficacy increased 30%†	($p < 0.01$) Balance-improved	($p \leq 0.03$) Decreased number of stumbles (59%) and decreased number of falls (64%)	($p < 0.0001$) 2 fall related questions "better": "My overall balance with the prosthesis" (69.8%) "I fall while wearing my prosthesis" (67.2%)	No statistical analysis reported	($p \leq 0.05$) Reduced stumble frequency: K2 (15.8%), K3 (31%) Reduced number of falls: K2 (80%) Reduced falls frequency: K2 (4.5%)
Sample							
Total n	17	1	15	19	368	3	17
Dysvascular PVD and/or DM	1	0	1	7	88	0	1
Trauma	10	1	7	12	185	2	10
Other	6	0	7	0	95	1	6
Age††	48 ± 16 (21–77)	30	42 ± 9 (26–57)	51 ± 19 (22–83)	$55 \pm$ NR (15–85)	25, 42, 43	48 ± 16 (21–77)
Accommodation time on C-Leg	1–33 weeks	9 days. 6-month follow-up.	10–39 weeks	90 days	6–9 months	30 min*	1–33 weeks

†Statistically significant outcomes related to improvement with the C-Leg. Statistical significance and effect size not applicable (n/a) for case studies. ††Mean Age in years $\pm$ SD (not reported [NR]) (Range); unless listed individually. *C-Leg preferred knee.

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Table II. Energy efficiency.

Study	Schmalz et al. (2002)	Perry et al. (2004)	Johansson et al. (2005)	Orendurff et al. (2006)	Chin et al. (2006)	Seymour et al. (2007)	Kaufman et al. (2008)	Highsmith et al. (2009)
PEDro score	5	n/a	6	4	5	3	5	n/a
Risk of bias	Moderate	n/a	Low	Moderate	Moderate	Moderate	Moderate	n/a
Effect size	0.8	n/a	Not enough information	Not enough information	Not enough information	0.9–1.8	Not enough information	n/a
Study design	Pre/post test	Case report	Repeated measures	Cross-over	Pre/post test	Pre/post test	Cross-over	Case report
All study outcome measures	Energy efficiency: Expired gas, heart rate	Energy efficiency: Expired gas, heart rate. Gait biomechanics	Energy efficiency: Expired gas, heart rate. Gait biomechanics	Energy efficiency: Expired gas, heart rate, walking speed	Energy efficiency: Expired gas, heart rate	Energy efficiency: Expired gas, heart rate, obstacle course, walking speed, SF-36	Energy efficiency: Expired gas and doubly labeled water, heart rate	Heart rate, walking speed, Physiological cost index
Speed control method	Treadmill	Over ground/ self-paced	Over ground/ self-paced	Timing lights	Walking meter	Treadmill	Treadmill/free living	Over ground/ Self-paced
Prosthetic alignment method	LASAR posture device	Experienced prosthetist	Experienced prosthetist	Experienced prosthetist	Experienced prosthetist	Not reported	LASAR posture device	Experienced prosthetist
Results of outcome measures of interest with statistical significance†	($p < 0.05$) 6–7% Increased energy efficiency at medium and slow walking speeds	184% Reduction of normal oxygen cost†	None	None	None	($p < 0.05$) Increased energy efficiency @ typical (6.4%) and fast (7%) pace walking	($p \leq 0.04$) Increased energy expenditure: Total daily (8%) Physical activity (6%)	20.2% Reduced post-activity heart rate†
Sample								
Total n	6	1	8	8	4	13	15	1
Dysvascular PVD and/or DM	0	0	2	Not reported	0	0	1	1
Trauma	6	0	3	Not reported	3	Not reported	7	0
Other	0	1	3	Not reported	1	13	7	0
Age††	37 ± 9 (27–53)	≈ 28	44 ± 8 (29–54)	49 ± 10 (NR)	24 ± 8 (NR)	46 ± 13 (30–75)	42 ± 9 (26–57)	82
Accommodation time on C-Leg	Not reported	≈ 8 months	10 h*	3 months	Not reported**	2–44 months***	10–39 weeks	90 days

†Statistically significant outcomes related to improvement with the C-Leg. Statistical significance and effect size not applicable for case studies. ††Mean age in years ± SD (range or not reported [NR]); unless listed individually. *Four subjects routinely used the C-Leg. Remaining four subjects given 10 h to accommodate to the C-Leg. **Chin et al. stated "After changing from the IP to C-Leg, the subjects were allowed to practice walking to familiarize themselves with it." p75. ***C-Leg was preferred knee for all subjects.

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Table III. Cost effectiveness.

Study	Brodtkorb et al. (2008)	Gerzeli et al. (2009)	Seelen et al. (2009)
Grading score (0 = extremely poor, 100 = excellent)	82	91	81
Study setting	Sweden	Italy	The Netherlands
Effect size for total cost and effectiveness	Not enough information	Not enough information	1.3 (utility for new and experiences users) 1.5 (utility for new users only) −0.2 (total costs for new and experienced users) 0.2 (total costs for new users only)
Study design	Observational, cross sectional, Markov modeling (hypothetical cohort)	Observational, cross sectional	Observational, cross sectional
Type of economic evaluation (utility weight if used)	Cost-utility (EuroQol (EQ) Visual Analog Scale)	Cost-utility (EQ-5D)	Cost-consequences (SF-6D)
Study perspective	Healthcare system	Healthcare system and societal	Patient, healthcare system and societal
Comparison	C-Leg versus NMPK	C-Leg versus NMPK	C-Leg versus NMPK
Time horizon	8 Years	5 Years	1 Year
Sensitivity analysis	Probabilistic	1-way on discount rate only	1-way (sub-group analysis)
Incremental analysis performed	Yes	Yes	No
All study outcome measures	Costs (2006 Euros), Quality Adjusted Life Years (QALYs)	Costs (Euros base year not specified), QALYs	Costs (Euros base year not specified), SF-36 scores, QALYs
Results of outcome measures of interest with statistical significance†	No statistical analysis reported	EQ-5D Physical mobility section ($p = 0.045$) EQ-5D Mean utility score 9% increase ($p = 0.007$)	Intervention costs and prosthetics costs ($p = 0.000$), patient/family cost ($p = 0.007$), SF-6D and SF-36 sub scores (range of p values from 0.001–0.071)
Reported incremental ratio (C-leg vs. NMPK)	€3218/QALY (US$ 4560/QALY)	€258/QALY (US$ 870/QALY)	€52864/QALY (US$7 4697/QALY) 1st time users, €65398/QALY (US$ 92407/QALY) all users

(*continued*)

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Table III. (*Continued*).

Study	Brodtkorb et al. (2008)	Gerzeli et al. (2009)		Seelen et al. (2009)	
Sample					
Total *n*	20	100		26*	
		50 C-Leg	50 NMPK	13 C-Leg*	13 NMPK
Dysvascular PVD and/or DM	NR	0	0	1	4
Trauma	NR	49	47	9	7
Other	NR	1	3	3	2
Age††	41 ± 3 (NR)††	46 ± 12 (18–65)	45 ± 12 (18–65)	47 ± 12 (18–65)	47 ± 11 (18–65)
Accommodation time on C-Leg	45 ± 5 months††	> 1 year	n/a	2.4 (± 1.2) years	n/a

NMPK is non-microprocessor knee. †Statistically significant outcomes related to improvement with the C-Leg. ††Standard Error (not reported [NR]). *Sample included one subject with hip disarticulation who utilized a C-Leg.

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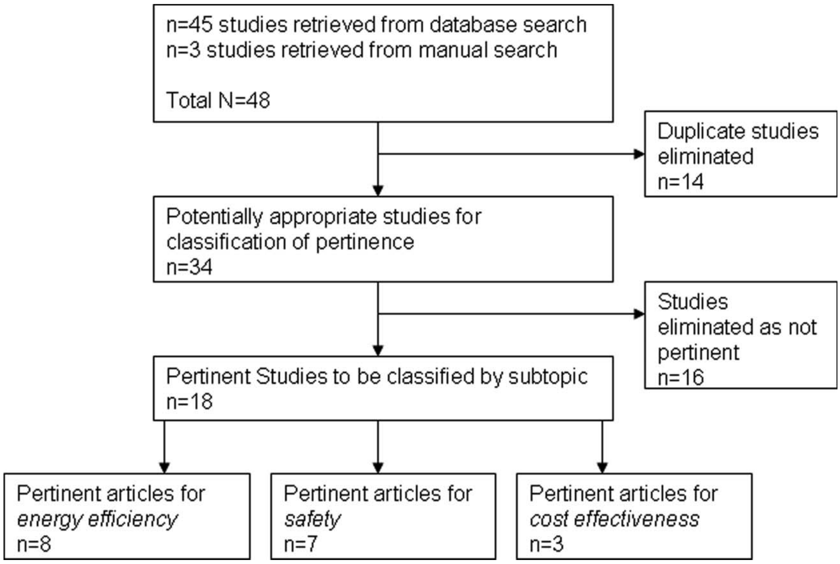

Figure 1. Flowchart showing selection of studies and results.

topic[19–26] and three were determined to be pertinent for the cost effectiveness topic[14,27,28] (see Tables 1–3). The two raters independently achieved identical scoring for methodologic quality and risk of bias so no further statistical analysis was conducted on this.

All seven papers in the safety topic received a PEDro score of $\leq$5/10 (low methodologic quality) and had a moderate risk of bias according to the SIGN 50. There was one case report that could not be scored for methodologic quality and risk of bias. All studies in the safety topic showed an improvement in some safety or surrogate safety measure with use of the C-Leg although statistical analyses were not available for two papers.[13,15] Effect sizes for the safety papers ranged from 0.2–1.4. Cohen[12] described effect sizes as small (0.2), medium (0.5) and large (0.8). Based on that definition, the studies that had enough information to calculate effect sizes showed large effect across the two treatments for all of the significant outcomes with the exception of uncontrolled falls (Cohen's $D = 0.2$). Refer to Table 1 for individual study scores of methodologic quality, risk of bias and effect sizes on the safety topic.

Of the eight papers in the energy efficiency topic only one[24] scored 6/10 on the PEDro scale (high methodologic quality) and had a low risk of bias (SIGN 50) whereas five received a PEDro score of $\leq$5/10 (low methodologic quality) and had a moderate risk of bias. Two[22,26] of these trials reported a statistical improvement in energy efficiency whereas four[19,21,23,24] reported some form of improvement in efficiency or speed that failed to reach significance. The final two papers in this section were case reports, both showing improvements in energy efficiency or a related measure but only minimally contribute to the level of evidence of this section.[20,25] Except for Orendurff et al.[23] and Johansson et al.[24] from the energy efficiency section, all studies in this entire review lacked randomization. All studies in the review lacked blinding. Effect sizes for the energy papers ranged from 0.8–1.8 resulting in large effect sizes with the intervention. The large effect size is only in regard to two of the eight papers[22,26] that reported significance on expired gas treadmill testing between knee conditions and also presented sufficient data to calculate effect size. Refer to Table 2 for individual study scores of methodologic quality, risk of bias and effect sizes on the energy efficiency topic.

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The three studies[14,27,28] in the cost-effectiveness topic scored $\geq$81 out of 100 on Chiou's cost-effectiveness grading system. One study used a cost-consequence economic evaluation and the other two used cost utility. All three studies concluded that the C-Leg was a societally cost-effective prosthetic knee option. Effect sizes for total cost and utilities were calculated for the economic evaluation by Seelen et al., which was the only economic evaluation reporting standard deviations for both total cost and utilities. Effect sizes for utility ranged from 1.3 for both new and experienced prosthetic users to 1.5 for new prosthetic users only. Effect sizes for total cost ranged from -0.2 for both types of users to 0.2 for new users only. Refer to Table 3 for individual study scores of methodologic quality and effect sizes on the cost efficacy topic.

It is important to note that there were no adverse events, safety concerns, detriments to energy efficiency reported in association with use of the C-Leg.

Discussion

Safety: Falls, stumbles & balance

Falls and fear of falling are significant health problems that are of interest to health professionals because they may indicate a decline in function.[29] Miller et al.[30] found that among community-living persons with lower extremity amputation, 52% had fallen in the past 12 months, 49% had a fear of falling, and 65% had low balance confidence scores. The fear of falling is one of the major factors for decreased activity, mobility, and quality of life. For the individual with TFA, selection of the appropriate prosthesis and knee mechanism can restore much of the ambulatory function that has been lost and have an impact on patient safety as it relates to stumbles, falls, balance and balance confidence.

Several studies have evaluated the effect of the C-Leg in safety or surrogate safety related outcomes. Kahle et al.,[4] Hafner et al.,[18] Hafner and Smith[5] observed persons with TFA transitioning from a non-MPK to a C-Leg prosthesis and used either a 60-day recall or self-report instrument (PEQ-A) to collect data on stumbles and falls. Kahle et al. reported a statistically significant reduction in the number of stumble ($p = 0.006$) and fall ($p = 0.03$) events in a sample of subjects with heterogeneous function and etiology. Subjects in this study reported an average reduction (59%) from seven to three stumbles and 64% reduction from three falls to one following accommodation with the C-Leg.[4] Hafner and Smith[5] reanalyzed prior data[18] by dividing their original group into Medicare Functional Classification Levels (MFCL) 2 and 3. In this reanalysis, MFCL 2 users reported a 15.8% ($p = 0.05$) reduction in the frequency of stumbles, a 4.5% reduction ($p = 0.01$) in the frequency of uncontrolled falls, and an 80% reduction ($p = 0.01$) in the number of uncontrolled falls. MFCL 3 users reported a 31% reduction ($p = 0.03$) in the frequency of stumbles.

Balance and balance confidence are believed to be related to and/or associated with falling and risk of falling in persons with TFA.[31,32] Kaufman et al.[17] directly evaluated balance using Dynamic Posturography; specifically the Sensory Organization Test (SOT) following subjects' accommodation with the C-Leg. Investigators reported that use of the C-Leg significantly improved balance performance ($p < 0.01$) as measured by a significantly improved composite score. Stevens and Carson[13] utilized the 16-item Activities-Specific Balance Confidence Scale in a case report where a subject transitioned from a mechanical knee to C-Leg. Following initial fitting of the C-Leg the subject reported a 30% increase in balance confidence. This was unchanged at six month follow-up. Using a 50 question multi topic survey, Berry et al.[16] evaluated balance more subjectively in two items. In these two

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items, ''My overall balance with the prosthesis'' and ''I fall while wearing my prosthesis'' respondents scored 69.8% and 67.2% ''better'' respectively, with use of the C-Leg. Also worthy of mention is that the two items of interest come from two separate sections from Berry et al.'s survey and each section was in total, statistically improved ($p < 0.0001$).[16]

Collapse of the prosthetic knee joint can occur whenever the amputee is suddenly faced with any situation that creates an unanticipated risk of falling. It is during such instances that the safety properties of the prosthetic knee joint are critical if falling and the ensuing risks of injury are to be avoided. Blumentritt et al.[15] performed biomechanical tests in an instrumented gait laboratory to evaluate the safety of the C-Leg. They postulated that three biomechanical factors would be sufficient to assess the clinical safety of prosthetic knees: knee angle, knee moment, and hip moment. Test conditions included: Level ground walking at self-selected velocity, sudden stopping, sidestepping, stepping on an object and tripping by disrupting swing extension. In all conditions tested, the C-Leg never collapsed compared against the non-MPK prostheses, which either collapsed under some or all conditions, and were reportedly ''unsafe''.

Five[4,5,16–18] of these seven studies (Table 1) provide consistent, statistically significant findings of improvements in self-reported reduction in stumble and fall events and improved balance. Additional non-statistically significant improvements support the latter findings and include knee stability in conditions resulting in collapse of other knees and improved balance confidence.[13,15] In total, these seven studies provide a grade ''B'' recommendation[11] that following accommodation with a C-Leg when transitioning from a non-MPK, subjects will recall experiencing a reduction in the number and frequency of stumble and fall events and have improved balance. It must be mentioned that while studies in this section achieved statistically significant improvements, methodologic quality was low and the risk of bias was moderate.

Energy efficiency

Transfemoral amputees are less efficient ambulators and demonstrate a 27–88% increase in energy cost during walking compared with intact individuals.[33,34] Several studies have compared the energy efficiency of walking with the C-Leg to that of other prosthetic knees, and in two pertinent cases, other MPKs.[19,21–26] Using expired gas analysis (Figure 2) and controlled walking conditions, the literature has conflicting results. Several authors have reported an increase in energy efficiency with use of the C-Leg that does not reach statistical significance.[19,21,23,24] Chin et al.'s study included the Intelligent Prosthesis MPK (Blatchford, Hampshire, UK) and reported a non-significant improvement with the C-Leg.[19] Johansson et al. compared the ambulatory energy efficiency of the Rheo knee (Ossur, Reykjavik, Iceland) to the C-Leg and found that the Rheo was more efficient, but the difference also did not reach statistical significance.[24] Contrary to these findings that do not reach statistical significance are study outcomes that do reach significance. Seymour et al. and Schmalz et al. both reported increased energy efficiency with C-Leg compared to non-MPK's at two differing walking speeds: typical ($p = 0.05$) and fast ($p = 0.04$) pace, and medium ($p < 0.05$) and slow ($p < 0.05$), respectively.[22,26]

In two separate case studies comparing non-MPKs to the C-Leg, two unique patient circumstances were presented. These reports described setting activity intensity in a geriatric patient and quantifying rate of oxygen consumption in a bilateral TFA patient. Highsmith et al.[20] utilized a practical clinical assessment of heart rate to determine the efficacy of a rehabilitation program that included the C-Leg. Following the program the geriatric patient experienced a reduction in heart rate more conducive to daily activity. Perry

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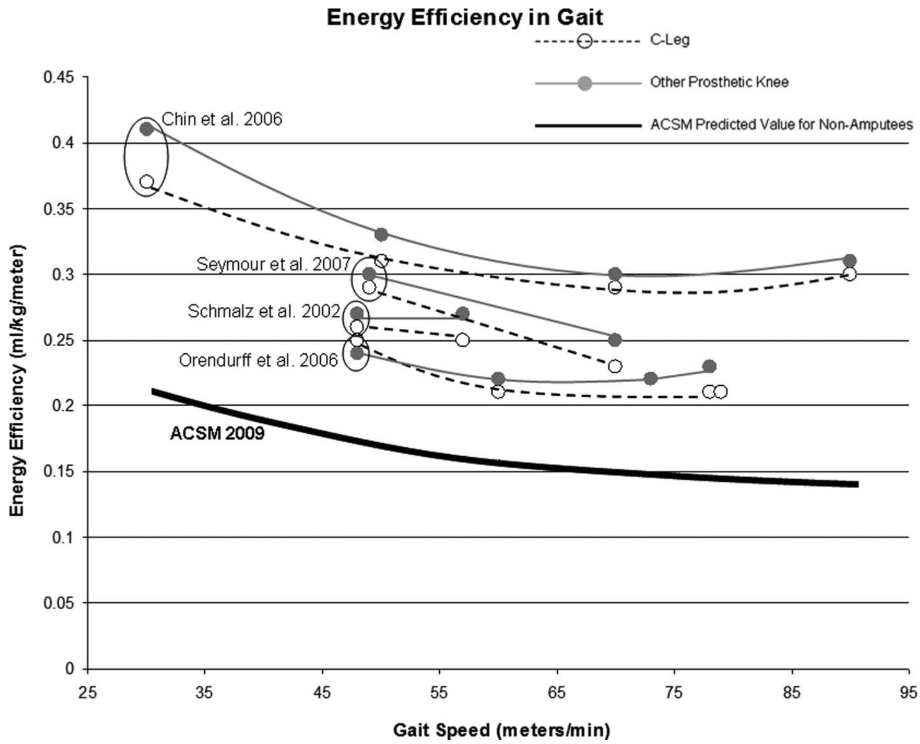

Figure 2. Energy efficiency plotted as a function of gait speed for studies providing the necessary data for graphing. C-Leg is plotted as dashed lines with open circles whereas 'other' prosthetic knees are plotted as solid grey lines and circles. For reference, energy efficiency of able-bodied non-amputee ambulation, as defined by the American College of Sports Medicine prediction equation, is plotted as the solid black line.

et al.[25] also reported favorable outcomes regarding reduced oxygen consumption. Their subject with bilateral TFA was able to walk farther, faster, and with a lower oxygen cost compared with Mauch knees (Ossur, Reykjavik, Iceland) and stubby prostheses.

Seven of the eight studies in this section (Table 2) consistently showed increased energy efficiency while walking with the C-Leg compared to other knees.[20–26] However, only two reached statistical significance.[22,26] Two[23,25] of the four studies that could not demonstrate statistical significance did show an increased self selected walking speed, consistent with Kahle et al.[4] as well as increased total daily energy expenditure associated with increased physical activity.[21] Johansson et al.'s study was the only one in this section with high methodologic quality and a low risk of bias.[24] Using analysis of expired gas, in aggregate, seven of these studies provide statistically inconsistent evidence that the C-Leg improves energy efficiency while walking.[19,21–26] Additionally, one case report supports the finding of improved efficiency using measures of heart rate.[20] Because of the inability to consistently demonstrate a statistically significant increase in energy efficiency, these eight studies provide a grade "D" recommendation[11] in favor of using the C-Leg to increase energy efficiency during gait.

However, energy efficiency during gait does not predict activity of amputees during daily living. In order to determine amputee activity in their free-living environment, Kaufman et al.[21] measured total daily energy expenditure using the doubly labeled water method. This is the most accurate and robust method available to estimate energy expenditure in

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free-living conditions.[35,36] There was a statistically significant increase of 6% ($p = 0.02$) in the portion of total daily energy expenditure attributed to physical activity. This increased energy expenditure represented more physical movement rather than increased effort to walk because controlled condition energy efficiency while walking was found to be statistically equivalent in several studies.[21,23,24] Kaufman's conclusion that the C-Leg enables a free living activity increase is in contradiction to studies with step count which do not show increased activity.[18,37] Kaufman explained that the discrepancy is due to the fact that step counts do not reflect different metabolic requirements associated with changes in walking elevation or walking speed changes. This is an area that needs further exploration, and is a potential topic area for future review.

Cost effectiveness

The economic evaluations graded in this review were based in Europe (Sweden, Italy, The Netherlands) and each study evaluated cost and effectiveness from their respective healthcare system. All economic studies also evaluated cost and effectiveness from the societal perspective including productivity losses and patient/caretaker costs with the exception of Brodtkorb et al.[28] While each study reported some measure of utility, only Seelen et al. was classified as a cost-consequences study as no cost-utility ratio was reported. Even though Seelen et al.[14] did not report incremental cost-utility ratios of C-Leg vs. the comparator, the implied societal incremental cost-utility ratio for the Seelen et al.[14] study can be calculated based upon the reported cost and SF-6D values. The ratio of incremental cost to incremental utility in Seelen et al. is €52864/QALY (US$ 74697/QALY) and €65398 (US$ 92407) for first-time prosthesis users and repeat and first-time users combined. These results suggest that depending upon the distribution of new prosthetic users and previous prosthetic users in the eligible population the cost will vary and hence the cost-effectiveness of the C-Leg.

All of the studies reporting societal cost-effectiveness data found that C-Leg is the dominant prosthesis strategy providing lower societal cost and a positive QALY gain from C-Leg adoption. Brodtkorb et al.[28] reports a health system perspective incremental ratio of €3218/QALY (US$ 4560), falling well within standard cost-effectiveness thresholds. Given the negative societal incremental cost-utility ratios and the higher cost of the C-Leg, cost saving in these studies must be accomplished via higher productivity loss, patient/family caretaker costs, and household assistance costs associated with non-electronic prostheses. Gerzeli et al.[27] report productivity losses using the human capital approach as being over 40% higher for the mechanical knee group. Seelen et al.[14] also find lower productivity cost for the C-Leg group but also higher housekeeping assistance cost associated with the non-electronic knee joint group. In total, these three studies provide a grade "B" recommendation[11] that provision of a C-Leg is cost effective from a societal perspective and provides a positive QALY gain. Further research on differences in the duration of time to employment and on housekeeping assistance requirements during rehabilitation needs to be conducted to determine if these cost-effectiveness results are robust.

Several limitations regarding these studies and the grading system should be noted. First given the limited number of economic evaluations caution should be exercised in interpretation of the incremental cost-utility ratios. While sensitivity analysis was performed in all of the studies reviewed, the studies reporting cost saving from the societal perspective did not perform sensitivity analysis on those costs most likely to change the decision rule if varied, namely productivity, family/patient, and housekeeping assistance costs. In some cases these cost differences were insignificant and this should be examined by careful

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sensitivity analysis of these parameters. Relatively sophisticated sensitivity analysis was performed by Brodtkorb et al.[28] but they did not report societal costs and the study was penalized in the grading system by relying upon expert opinion for key parameters in the model. Secondly all of the current economic studies on C-Leg are set in countries within healthcare systems that vary from country to country. The differences in the structural characteristics of each country's healthcare system make the comparability of the results tenuous. Further studies will need to be performed in different country settings on the cost-effectiveness of the C-Leg. Finally there are some limitations to the grading system used to score the economic evaluations. While the system is flexible with regard to the variety of evaluations one finds in economic studies of new medical technologies, the scoring system is less able to distinguish quality among studies that score in the good to excellent range.[10] Each study is ranked dichotomously on each of the 16 criteria but each study reviewed performed at differing levels of quality on key criteria including transparency, sensitivity analysis, data quality, and conclusions. Each study clearly had strengths and weaknesses but all studies included key elements necessary for a sound economic evaluation.

Study limitations

This review of the literature is limited in that it is not fully inclusive of all studied aspects of the C-Leg as compared to other knees. While conducting this review the following areas emerged as future potential literature review topics but were classified as ''not pertinent'' for our a priori areas of interest: Perceived function (i.e., the Prosthesis Evaluation Questionnaire, patient preference and body image) and biomechanical measures (i.e., gait on flat ground, stairs and ramps). Additionally, amputees of dysvascular etiology were not represented at levels commensurate with estimates from epidemiologic studies,[1,2] which limits generalizability of results to this sub-group. Finally, it was observed that numerous variables were not controlled or standardized across studies. Examples include functional level and its rating, accommodation time, control knees, methodologies and selection of outcome measures. This variability across studies prevents the ability to conduct meta-analyses.

Conclusion

There was sufficient evidence to suggest increased efficacy of the C-Leg in the areas of safety, energy efficiency and cost when compared with other prosthetic knees for transfemoral amputees. Regarding safety, available evidence supports a grade ''B'' recommendation that following accommodation with a C-Leg, users will experience a reduction in stumble and fall events and have improved balance. Use of the C-Leg for the purpose of improving energy efficiency is supported by a grade ''D'' recommendation. However, research has shown that amputees spontaneously increase their physical activity in the free-living environment when using the C-Leg compared to a non-microprocessor controlled knee. So, energy efficiency may not be of primary relevance. Finally, evidence supports a grade ''B'' recommendation that the C-Leg is cost effective and worth funding. Based on standardized review criteria, methodologic quality could be improved and the risk of bias minimized with improved study design, decreased attrition, and use of double blinding for microprocessor-controlled knee prosthetic studies. While these are worthwhile goals, the practicality of some of these methodological changes in prosthetic research is currently unrealistic.[38,39] Specifically, patients recognize differing prosthetic components and the different prosthetic knees need to be aligned differently, which makes it unrealistic to

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conduct double-blind studies.[38] So, given these constraints, the grades of recommendations demonstrate that the C-Leg is a clinically significant improvement for transfemoral amputees.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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Appendix 2:

Prosthetics Evaluation Questionnaire A (PEQ-A)

PEQ-A

1. Over the past 4 weeks, how much mental energy was required to walk with your prosthesis?

   Minimal Mental Energy — Maximal Mental Energy

2. Over the past 4 weeks, how often have you "stumbled" while wearing your prosthesis?

   Never Stumbled — Frequently Stumbled

3. Over the past 4 weeks, please estimate the *number* of stumbles you have had?

   I stumbled ________ times in the last 4 weeks.

4. Over the past 4 weeks, how often have you had a "semi-controlled" fall?

   Never — Extremely Often

5. Over the past 4 weeks please estimate the *number* of semi-controlled falls you have had?

   I experienced ________ semi-controlled falls in the last 4 weeks.

6. Over the past 4 weeks, how often have you had an "uncontrolled fall"?

   Never — Extremely Often

7. Over the past 4 weeks please estimate the *number* of uncontrolled falls you have had?

   I experienced _________ uncontrolled falls in the last 4 weeks.

8. Over the past 4 weeks, how confident have you felt while walking on your prosthesis?

Not Confident At All — Extremely Confident

9. Over the past 4 weeks, how difficult has it been to complete a task while walking such as talking or reading?

Not Difficult At All — Extremely Difficult

10. Over the past 4 weeks, how often has your fear of falling kept you from performing activities that you would normally do?

Never — Extremely Often

11. Over the past 4 weeks, how frustrated have you been with the amount of falls you have taken?

Not Frustrated At All — Extremely Frustrated

12. Over the past 4 weeks, how embarrassed have you been when you fall?

Not Embarrassed At All — Extremely Embarrassed

13. Over the past 4 weeks, how fearful have you been about falling without your prosthesis?

Not Fearful At All — Extremely Fearful

14. Over the past 4 weeks how often have you felt it was difficult to concentrate on anything other than walking?

Never Extremely Often

Appendix 3:

A Method for Training Step-over-Step Stair Descent Gait with Stance Yielding Prosthetic Knees: A Technical Note

A Method for Training Step-Over-Step Stair Descent Gait With Stance Yielding Prosthetic Knees: A Technical Note

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ABSTRACT

Limited information is available concerning stair descent training for transfemoral amputees using prosthetic knees. Literature describing stair descent training techniques are predominantly available for the step-to-step stair descent method. A thoroughly descriptive technique for training prosthetic knee users to reciprocally descend stairs, using a step-over-step pattern is not available. The purpose of this technical note is to describe a procedure for training stance-yielding prosthetic knee users how to descend stairs using a reciprocal, step-over-step pattern. The technique describes stair setup, safety considerations including hand railing, use of a gait belt, guarding techniques and a one versus two therapist technique. Nineteen subjects were initially trained in this technique, and all subjects demonstrated the ability to reciprocally descend stairs after training. Reciprocal step-over-step stair descent is not appropriate for all transfemoral amputees; however, we recommend considering the supervised, therapeutic application of this technique for all transfemoral amputees using stance yielding prosthetic knees. We suggest that practicing this technique might improve a prosthetic knee user's overall functional performance such as their ability to utilize stumble recovery during a missed step, to transition more symmetrically from stand to sit and to utilize knee flexion during the loading response of gait. (*J Prosthet Orthot*. 2012;24:10–15.)

KEY INDEXING TERMS: C-Leg, Mauch SNS, microprocessor knee, physical therapy, reciprocal gait, rehabilitation, transfemoral amputee

Information regarding stair descent performance using prosthetic knees is available in terms of outcome data and biomechanical comparisons.[1,2] Literature describing training techniques for stair descent is also available in pathologic populations; however, only the nonreciprocal, step-to-step method is described.[3] Another common name for the nonreciprocal, step-to-step pattern is the tap-step pattern,[4] and clinicians commonly relate this to patients with the command "down with the bad" when referring to leading stair descent by stepping down with the involved leg.[5] Literature detailing a technique for training a prosthetic knee user to perform the reciprocal step-over-step stair descent technique is very limited. The step-over-step method of stair descent has been a viable option for transfemoral amputees since the introduction of the Mauch Swing and Stance (SNS) knee unit in 1968.[6,7] A Mauch knee patient instructional manual[8] pictorially demonstrates two methods of step-over-step stair descent and recommends decreasing stance resistance if the user feels they are "waiting for the prosthetic knee to bend." Because a thorough technical description is lacking, the purpose of this technical note is to describe a procedure for training a stance yielding prosthetic knee user how to descend stairs using a reciprocal, step-over-step method.

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TECHNIQUE

STAIR CASE

The first safety consideration is the stair design. Initial training with an inexperienced amputee may best be conducted on a smaller therapy stair set. Such training stairs are ideal as they incorporate bilateral handrails, are routinely finished with high-friction grip tape on the stair tread, and are commonly only three to five steps in height, which can minimize anxiety regarding ultimate height (Figure 1).

GUARDING

Standard practice is that the primary therapist guards from a position between the ground and the patient.[3] In addition, although the technique can be administered with one therapist, the authors' experience is that having an additional person guarding from above/behind assures the patient is closely watched and protected while standing in this precarious position. In addition, it is recommended that the person guarding from above/behind the patient hold onto a standard gait belt appropriately applied to the patient's waist.[3] (Figure 2)

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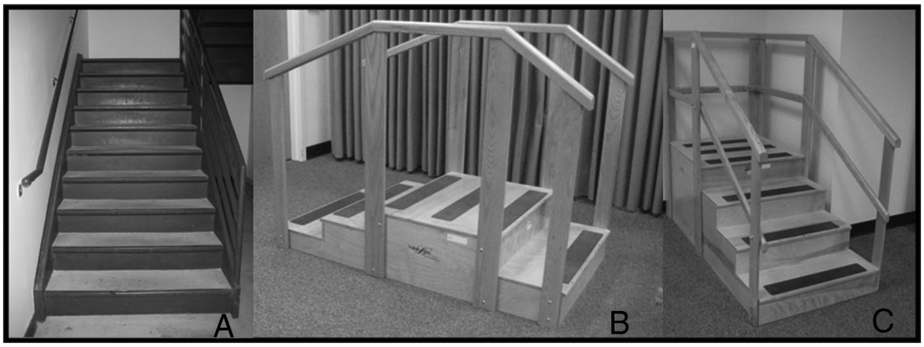

Figure 1. If therapy stairs (B and C) are not available and a permanent building stair case (A) is considered as an alternative setting, it is recommended to only use the first few steps on the lower end of the structure.

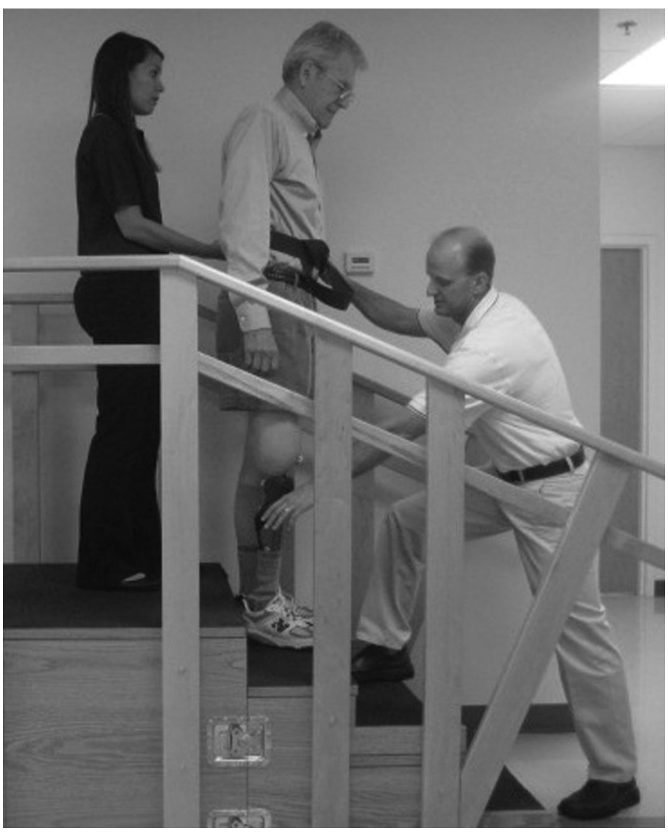

Figure 2. It is recommended to have two therapists available to guard the patient because this ensures that the patient is closely watched and protected. The lead therapist would guard the patient by standing below them on the staircase, and the second therapist would stand above the patient on the staircase and hold onto the patient's gait belt.

HANDRAILS

Handrails, although not necessary for all persons, can be beneficial in terms of security.[9–11] Therapy stair cases are routinely equipped with bilateral handrails that bolster patient confidence. If structurally permanent building staircases are utilized, bilateral railing may not be within reach. In such cases, it is recommended that the patient initially utilize the handrail opposite the prosthesis to mirror assistive device training, but eventually practice using either side.[3] Still in other situations (i.e., outdoor stairs, stadium bleachers, grandstands, movie theatres), no railing may be available, and in these cases, lower skilled ambulators may be able to practice with their assistive device or by holding onto the shoulder of a person walking in front of them. Advanced users may be able to achieve stair descent without the use of a railing; however, both of the latter subjects are beyond the scope of this technical note.

Handrails can be a hindrance in some cases.[9–11] For instance, the patient may apply excess load through the upper limbs, thereby decreasing lower limb load. This can potentially create reliance on upper limb support that can be difficult to minimize long-term or create additional friction at the hand/rail interface that must be overcome before advancing forward.[11]

KNEE GUARDING

The primary therapist guards with an open palm just distal to the knee axis. The fingers are extended as opposed to flexed, preventing their placement on the posterior aspect of the knee (Figure 3) in the event of knee collapse, which could potentially injure the fingers. This position enables the therapist to guard against rapid prosthetic knee collapse into flexion by simply pushing the prosthetic shank posteriorly, extending the knee. This position is only an option when two persons are available to train the patient. If only one person is able to train the patient, the therapist will guard and simultaneously train from the front, and the prosthetic shank will be blocked by the therapist's opposing leg (Figure 4).

INITIAL PATIENT POSITION

Using the tap-step pattern ("up with the good," also known as the step-to-step pattern), the patient climbs two or three steps then turns around to prepare for descent training. With the primary therapist guarding from below and assisting practitioner positioned above/behind, the patient steps forward into the initial position. The initial position places the midfoot of the prosthetic foot at the step's leading edge (Figure 5). This minimizes the risk of toe loading, which is

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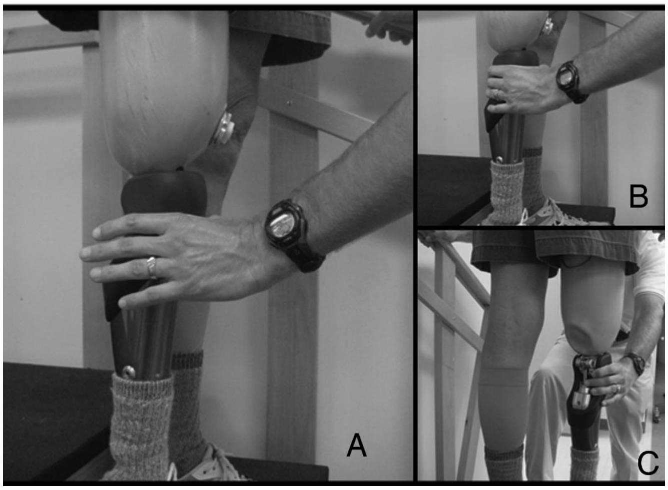

Figure 3. A, Correct guarding: the primary therapist guards with an open palm just distal to the knee axis and keeps his or her fingers extended. This prevents potential injury to the fingers in the event of knee collapse. B and C, Incorrect guarding: the therapist should not flex his or her fingers and contact the posterior aspect of the knee, as this could potentially injure the therapist's fingers in the event of knee collapse.

necessary to trigger the prosthetic knee's swing phase release. This foot placement permits the prosthetic knee's stance control to manage knee stability, minimizing the risk of knee collapse during step descent.

INITIAL PRACTICE

Once initially positioned, the primary therapist provides a visual cue (hand target) for the patient to contact with the toes (or limb end point)[12] of the sound limb (Figure 6). The hand target must be positioned far enough in front of the patient to permit the sound side heel to adequately clear the step. Similarly, the hand target must be in the correct vertical position, such that the toe can contact it without the patient having to flex a joint to reach it comfortably. Contacting the sound-side toe to the therapist's hand target is important to establish kinesthetic memory of all joints[12,13] relative to the body's orientation when performing stair-descent. In addition, reaching out the sound foot to touch the hand target while standing on the prosthetic limb at the step's edge promotes increased weightbearing in the socket and balance on the prosthetic side in preparation for descent. It should be noted that this position is considered precarious by many patients and may require multiple repetitions or multiple practice sessions to accomplish because of the need for coaching, practice, and reassurance. When the patient is confidently able to step out and reach the hand target with precision, they are ready to proceed to step descent practice.

STEPPING DOWN LEADING WITH SOUND LIMB

Using the instructions above in "*Initial Practice*," the patient places his sound foot out in preparation for stepping

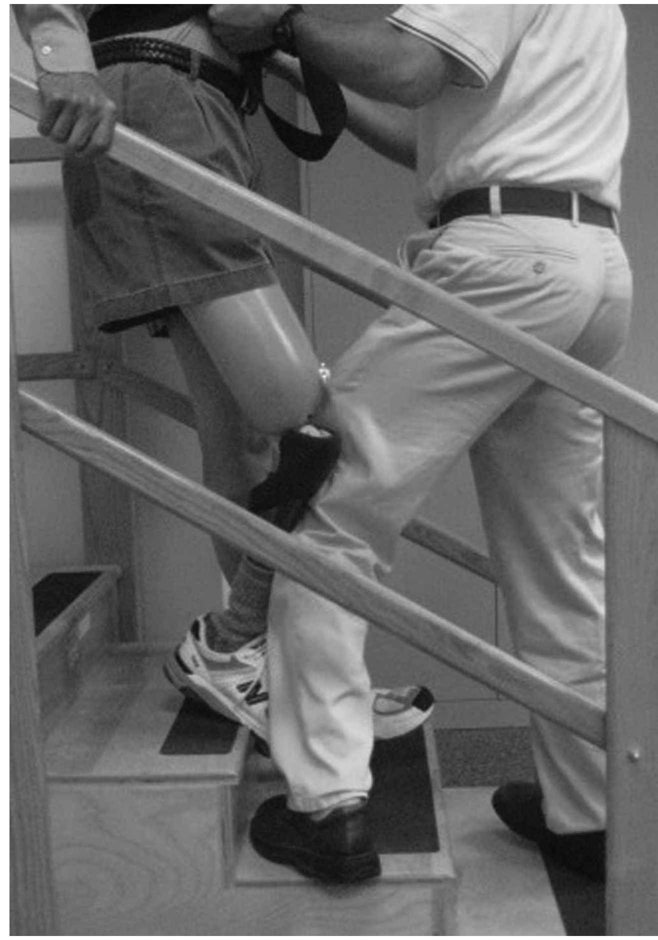

Figure 4. If there is only one therapist available to guard the patient, the therapist will guard the patient and simultaneously train him or her from the front, and the therapist will use his or her leg to block the prosthetic shank.

Figure 5. The initial position is to place the midfoot of the prosthetic foot at the leading edge of the step.

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Figure 6. While continuing to guard the prosthetic knee, the therapist's opposite hand is presented as an end effector target for the patient's sound side foot. The hand target provides a visual cue for the patient to assist in positioning the entire lower limb appropriately in preparation for descent controlled by the prosthetic knee. In this position, the patient can develop a kinesthetic awareness for where the joints should be positioned for descent.

(or step descent practice). Once the sound foot contacts the hand target, the therapist lightly grips the lateral aspects of the sound forefoot and shows the patient visually that the heel need only descend approximately 6 to 8 inches (15.2–20.3 cm). The therapist informs the patient that to place the sound heel on the lower step, the prosthetic knee must be slowly flexed. Allow the patient to return the sound foot to the step while the therapist explains that the patient is quite likely contracting the hip extensors of the residual limb to maintain prosthetic knee extension as he stands on the stairs at rest. In other words, the patient is pulling his residual limb into hip extension against the posterior wall of the prosthetic socket. The therapist can tap on the anterior socket wall and explain that either 1) force must be applied to the anterior socket wall or 2) the force being applied on the posterior socket wall must be decreased to flex the prosthetic knee for stair descent.

With this explanation completed, provide the hand target once again, for the sound side foot. Once the foot contacts the target, instruct the patient to push on the anterior socket wall (or release force on the posterior wall) to step down. Once this has been accomplished successfully and if repetition is desired, have the patient reset his sound foot on the step and repeat as necessary until mastered.

STEPPING DOWN LEADING WITH PROSTHETIC LIMB

Once the patient is able to descend leading with the sound limb and the sound limb is bearing the patient's weight, the next component is to descend leading with the prosthetic limb. This is the most common stair descent technique for patients and fits with the very typical "down with the bad" instruction. Although not likely needed, the same hand target practice can be used for this portion as well.

RECIPROCAL, STEP-OVER-STEP DESCENT—PUTTING IT ALL TOGETHER

At this point, the patient has mastered descent with both limbs individually and is ready to practice the reciprocating, step-over-step pattern descent. Start the patient three to five steps up from the floor in the initial position. The first time the patient attempts this whole skill pattern, it is recommended that the two therapist method of guarding be utilized. With the guarding and safety considerations in place, begin with the hand target for the sound side, so the patient descends leading with the sound limb first. Once the patient steps down leading with the sound limb, he should immediately be instructed to step down over the step the sound limb is on with the prosthetic limb and repeat this reciprocal, step-over-step pattern. Practice and cue as necessary.

ADDITIONAL CONSIDERATIONS

Once reciprocal stair descent is mastered on a smaller therapy set of stairs, other factors should be considered and introduced given each patient's unique functional needs. A metronome[14] can be utilized, for example, to alter or solidify the stepping rate. Depending on the patient's stability needs, guarding can potentially be progressively decreased from two to one therapist and eventually to decreasing levels of assistance. The staircases practiced on should be altered to introduce variance in terms of step size, environmental distraction, hand railing availability, lighting, and climate conditions.

DISCUSSION

The purpose of this technical note is to introduce a technique to train stance yielding prosthetic knee users how to walk reciprocally down stairs. As a part of a clinical trial, utilizing this technique, we trained 19 transfemoral amputees to descend stairs reciprocally. We measured their stair descent ability and confirmed that after training, all were able to demonstrate reciprocal stair descent.[2] We also indicated that this may not be appropriate for everyone to practice on a daily basis as a part of their routine ambulatory activities.

The knee moment reported (normalized to height and weight: N/kg) for reciprocal stair descent in transfemoral amputees using stance yielding knees is higher than that reported for stumble recovery, sitting down from standing, and knee flexion in the loading response of gait.[1,15–17] (Table 1) We suggest that it is important to consider training all transfemoral amputees using stance yielding knees in reciprocal stair descent as it potentially has functional carry over and motor learning in other functional activities. Other such activities that rely on stance control include stumble recovery, sitting down from standing, and

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Table 1. Sagittal plane prosthetic knee moments for activities requiring stance yielding

Study	Schmalz et al.[1]	Blumentritt et al.[15]	Highsmith et al.[16]	Segal et al.[17]
Activity	Reciprocal stair descent	Stumble recovery	Stand to sit	Stance flexion
Reported knee moment	-1.52 N · m/kg	≈ 0 to -50 N · m[a]	-0.05 N/kg	0.142 N · m
Sample's mean height (m)	1.82	1.75	1.76	1.73
Sample's mean mass (kg)	83	75	81	80
Normalized knee moment (N/kg)[b]	0.87	≈0 to 0.39[a]	0.05	0.001

Knee moments are those reported for C-Leg only.
[a] Specific values not reported by Blumentritt et al. Range of values estimated from 1) stumble recovery knee moment activated while stepping onto a variety of velocity, surface, and object conditions and 2) data that are represented graphically in this article.
[b] Knee moment reported in the respective manuscripts normalized by reported sample's average body height and weight to provide a relative comparison across activities. Absolute values are depicted to compare moment magnitude irrespective of authors' chosen sign convention.

knee flexion in the loading response of gait. In addition, these tasks are included in the initial set up and adjustment of a C-Leg.[18,19] For instance, at the initial C-Leg fitting and setup, one of the first tasks is to have a patient sit in a chair repeatedly until patient and prosthetist are satisfied with sitting resistance. The user should be satisfied and confident with the resistance, such that they are willing and able to apply as much load into the prosthesis as possible, thereby unloading the uninvolved side and maximizing kinetic symmetry while transitioning from stand to sit.[16]

CONCLUSION

With emphases on patient outcomes becoming the norm and the functional capabilities of prosthetic componentry expanding, the role of physical rehabilitation to assure mastery of device function is increasing. The presence of detailed rehabilitation techniques in the literature is limited. This technical note presents a strategy for training the transfemoral amputee how to utilize the reciprocal stair descent capability of stance yielding knees and offers considerations to expand for individualized functional needs. The technique is associated with positive clinical outcomes data, but the task of reciprocal stair descent is probably not appropriate for all transfemoral amputees utilizing stance yielding prosthetic knee mechanisms. Whether or not a patient ever utilizes the technique in daily life, training such patients with a comparable technique, at least therapeutically, may have functional significance in other daily activities such as stumble recovery during a missed step, in moving from stand to sit, and during the loading response of gait.

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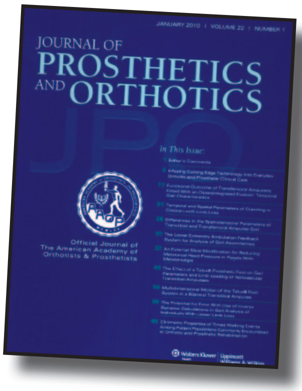

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