Function and Body Image Levels in Individuals with Transfemoral Amputations Using the C-Leg®

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FUNCTION AND BODY IMAGE LEVELS IN INDIVIDUALS WITH TRANSFEMORAL AMPUTATIONS USING THE C-LEG®

A Scholarly Project

by

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of the

University of North Dakota

for the degree of

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And most importantly, I would like to thank George and Val Rae Swanson, my parents who have been my inspiration behind each and every project throughout my life, and instilled insight, motivation, and values in me that I will treasure always.
Purpose: It was purposed that individuals using the Otto Bock C-Leg®, a microprocessor controlled prosthetic knee joint, may experience an enhanced level of functional independence. Secondly, it was hypothesized that with increased functional abilities and independence from using the C-Leg® comes a positive body image.

Methods: Following IRB approval, a purposive sampling method was used to recruit 8 adult volunteers from a regional rehabilitation hospital. Inclusion criteria for participants in this study included individuals who had a transfemoral amputation, were currently using the C-Leg®, were over the age of 18 years, and without cognitive limitations. Subjects were asked to complete a series of three surveys: the Reintegration to Normal Living Index (RNL), the Situational Inventory of Body-Image Dysphoria (SIBID), and the C-Leg® Function & Body Image Survey (CFBIS). Survey questions pertained to personal satisfaction with the C-Leg®, functional independence, role performance, and body image.

Results: Response categories of functional role performance and body satisfaction were correlated to test the hypotheses. A Spearman’s rho of -.434 was calculated, showing a fair but not statistically significant relationship. Significant relationships were found between functional role performance and social integration ($r_s=.743$), self-efficacy ($r_s=.863$), personal relationships/sexuality ($r_s=.711$), and psychological distress ($r_s=-.772$). This relationship was supported by responses from the CFBIS indicating that the C-Leg® expands a client’s level of function, self-esteem, and motivation.

Conclusions: There was a fair correlation between functional role performance and body satisfaction in individuals using the Otto Bock C-Leg®. Individuals using the C-Leg® were found to exhibit patterns of improvement regarding improved lifestyle, activity performance, motivation, and self-confidence. The most common improvements in activity performance were found with walking, walking up and down stairs, participating in sports (i.e. basketball, hiking, and skating), work/employment activities, and decreased fatigue due to low requirement of energy expenditure. Body image was found to be
improved due to the fact that individuals were able to walk with a more natural gait, and also felt more secure in public places because of the stability the C-Leg® offers.
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CHAPTER I
INTRODUCTION

Introduction

Amputation is a life-changing event that can happen to anyone. In fact, “there are approximately 400,000 people with amputations in the United States, with between 43,000 and 50,000 amputations performed annually. Ninety percent of these amputations are of the lower limbs” (Wetterhahn 2002, p. 195). Amputation can be defined as “the surgical removal of all or part of a limb due to disease or injury” (Hanger, 2001). “Amputation is a triple insult that results in loss of function, body image, and sensation” (Pandian, 1999, p. 97). Amputation will be defined and discussed in greater depth in Chapter II. In the following paragraphs, functional limitations that are common to persons post lower extremity amputation will be presented.

Loss of function results in the inability to successfully participate in family, social, vocational, and/or sexual roles. The person may have difficulty with various activities of daily living, such as dressing, transferring, and other activities that require balance or weight shift (Reed, 2001). Those with transfemoral amputations will need to learn to perform these activities differently because the dynamics of the body have changed due to the amputation. Other tasks that may be difficult include specific work or homemaking tasks that require balance and mobility. The person may also be unable to engage in leisure activities unless the right modifications (personal or environmental) are made.
Loss of sensation results in many sensorimotor issues. The individual has lost push-off force using the great toe. The center of gravity is changed in relation to loss of body mass. This in turn affects balance and righting reactions. The individual may have difficulty accommodating to uneven ground or surfaces. Other possible issues include limited power and mechanical leverage, hyperesthesias, and deconditioning of the body. Increased energy expenditure while walking is also an issue because fatigue develops at a much faster rate after the amputation. When all combined, these sensory losses can make it complicated to regain a functional gait.

Loss of body image often has an impact upon one’s self-esteem. Body image can be defined as “a person’s concept of his or her physical appearance. The mental presentation, which may be realistic or unrealistic, that is constructed from self-observation, the reactions of others, and a complex interaction of attitudes, emotions, memories, fantasies, and experiences, both conscious and unconscious; the degree of worth and competence one attributes to oneself” (Como, 2002, p. 223). Losing a limb may cause the inability to clearly recognize one’s personal body characteristics. Living without a limb requires learning to live an entirely new lifestyle, one much different from the “normal” population. For example, every day activities may be performed differently, clothes may have to be modified, and gait may be noticeably unbalanced. These changes may foster a feeling of incompetence for the individual. This lifestyle has the potential to separate oneself from society as “different”, causing the decline in self-esteem. Additional aspects of body image will be defined and discussed in Chapter II.

Psychosocial issues are considered components of the loss of body image, such as the individual having hostile feelings toward the one self or the medical team. They may
also feel depressed as they mourn the loss of the limb. Common recurrent thoughts are “why me?” (Reed, 2001). Some individuals feel they constantly have to “prove” they can do things, resulting in additional stress. These psychosocial issues can all take a toll on the mental part of one’s body image.

Function, sensation, and body image are three areas that must be addressed by the medical rehabilitation team. Physicians, prosthetists, physical therapists, occupational therapists, and nurses all play an important role on the team. This study has been done from an occupational therapy perspective. Occupational therapy focuses on gaining as much functional independence as possible in roles of self-care, work, and leisure, both mentally and physically. The individual with a transfemoral amputation who wants to live a highly active, physically demanding lifestyle creates a role unique to all three areas of function, sensation, and body image, requiring specialized intervention. This specialized intervention involves teaching individuals to live a new lifestyle with a prosthesis.

**Occupational Functioning Model**

Occupational therapy can be defined as “a health rehabilitation profession designed to help people of all ages with physical, developmental, social, or emotional deficits regain and build skills that are important for functional independence, health and well-being” (Como, 2002). “The goal of occupational therapy is the development of competence, which promotes a sense of self-efficacy and self-esteem. Competence refers to effective interaction with the physical and social environments.” One main model of practice that guides an occupational therapist in data gathering, interpretation, and treatment planning
is the Occupational Functioning Model (OFM). The OFM is comprised of six main propositions (Trombly, 2002):

1. To engage satisfactorily in a life role, a person must be able to do the tasks that, in his or her opinion, make up that role.

2. Tasks are composed of activities, which are smaller units of behavior.

3. To be able to do a given activity, one has to have certain sensorimotor, cognitive, perceptual, emotional, and social abilities.

4. Abilities are developed from capacities that the person has gained through learning or maturation.

5. These developed capacities depend on first-level capacities that derive from a person’s genetic endowment or spared organic substrate.

6. Personal, social, cultural, and physical contexts and environments surround and influence the life and occupational functioning of an individual.

   One main assumption of the OFM is that people strive to achieve feelings of satisfaction, defined as having a sense of self-efficacy and self-esteem. Levels of self-esteem depend on confidence that they can make desired things happen, and the sense that others will appreciate and recognize their competence. Self-efficacy focuses on people’s beliefs in their performance capabilities in regard to specific tasks. These two qualities originate from being in charge of one’s own life and being competent in one’s life roles. The sense of competence allows people to believe in their own control rather than being controlled by the social or physical environments. This competency can lead to higher levels of independence and satisfaction.
Another assumption of the OFM is that the ability to carry out one’s roles and activities of life depends on basic abilities and capacities such as strength, perception, and sequencing abilities. Roles are defined as “socially expected behavior patterns associated with an individual’s status in a particular society” (Trombly, 2002, p.5).

The OFM divides roles into three functional areas of self-maintenance, self-advancement, and self-enhancement. Self-maintenance roles include those associated with the development and maintenance of the self, such as family and home. Examples include person, grandparent, son, homemaker, and exerciser. Self-advancement roles take place in the productive community setting, such as worker, student, intern, investor, and voter. Self-enhancement roles add to the sense of accomplishment and enjoyment in leisure areas. Examples include friend, club member, golfer, and pianist.

North American culture places a high value on the role of an independent person. Many capacities contribute to development of a single ability, while many abilities are required to successfully complete an activity. These capacities have a phenomenon of plasticity, which is “when one capacity or ability is impaired, occupational dysfunction does not automatically occur” (Trombly, 2002, p.3). Other abilities may adjust to allow accomplishment of the activity. To achieve master competency, functional and meaningful activities are practiced using assistive technology (such as the C-Leg®), adaptive methods, or adapted environment to facilitate performance. These activities rely on basic abilities. An ability is “a general trait, such as muscle strength or certain actions that individuals bring with them when they begin to learn a new task” (Trombly, 2002, p. 8). Examples of motor and process abilities include stabilizing, positioning, walking, and transporting.
One final assumption of the OFM is that satisfactory occupational functioning occurs only within environmental and contextual constraints particular to the individual. Environment is defined as “the complex of external factors, circumstances, objects, and social and cultural beliefs and practices that influence the life of an individual” (Trombly, 2002, p.9). Context is defined as encompassing “all that surrounds and influences any aspect of human functioning-physical environment as well as social, personal, and cultural contexts” (Trombly, 2002, p.9). According to Section 902 of the American Disability Act, a person is considered to have a disability when they have (http://www.eeoc.gov):

(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual;

(B) a record of such an impairment; or

(C) being regarded as having such an impairment.

The OFM is a useful model to use when designing rehabilitative intervention for individuals with transfemoral amputations. Treatment following the OFM is based on its hierarchical organization, indicating that higher-level occupational functioning is created on a solid base of abilities and capacities. One such capacity is body image.

**Otto-Bock C-Leg®**

The Otto-Bock C-Leg® is today’s most current innovation in the world of prosthetics for highly active transfemoral amputees. It is a microprocessor controlled knee joint that features on-board sensor technology that reads and adapts to every move an individual makes, measuring angles and movements 50 times per second. Although the Otto-Bock C-Leg® research will be presented in Chapter II, it may be stated that there is currently a
lack of research with this new product, as well as a lack of recorded client satisfaction with its use. If the outcome satisfaction of the C-Leg, regarding function and body image, was better understood, it is possible more individuals with transfemoral amputations could benefit physically and psychologically. While assessing the individual’s roles and abilities, occupational therapists could determine if the C-Leg may be an appropriate match for each client’s highest level of participation.

**Research Question**

The purpose of this study is to discover a connection of high levels of both personal satisfaction with the C-Leg and functional abilities to a positive body image. The main research question is “What is the incidence of an enhanced level of functional independence and a positive body image among individuals using the C-Leg®?” This information will be gathered through a series of surveys answered by individuals using the C-Leg®. Chapter II will explore relevant research and literature written on amputation, gait, prosthetic knee mechanisms, the Otto-Bock C-Leg®, and body image.
CHAPTER II
REVIEW OF LITERATURE

Introduction

This chapter takes an in depth look at existing literature and research pertaining to five main aspects of this research study. First the main causes and different levels of amputation will be identified. Then the normal gait cycle will be analyzed and broken down into eight phases, including muscle actions and range of motion for each phase. Next a detailed review of prosthetic knee mechanisms will identify different types of units, including advantages and functional limitations for each type. This review will be followed by research studies and terminology associated specifically with the Otto-Bock C-Leg® since this research study is focused on this particular knee unit. Finally, body image will be defined, the connection of body image to functional activity will be explored, and the variable of self-confidence will be discussed.

Amputation

The two most common causes of major amputation are peripheral arterial occlusive disease (PAOD) and infection secondary to diabetic foot ulceration, followed by trauma, malignancy, and congenital malformations (Gibson, 2001). Upper limbs are rarely affected by PAOD or diabetic ulceration, which is why lower limb amputation is performed far more frequently. The main symptom of PAOD is pain on walking due to arterial insufficiency, otherwise known as intermittent claudication. Diabetic foot ulceration can exist along with PAOD or by itself. Sepsis (infection), arteriopathy and denervation (diabetic neuropathy) are the three main contributing factors. Neuropathy
results in loss of sensation of the foot, causing the client to be unaware of an ulcer that progresses through various stages of severity.

Deciding to amputate can be a difficult decision for physicians as well as the client. A challenge the healthcare team faces is to educate the client that amputation will be a gain instead of a loss, as removing a diseased limb will restore function. It is important, however, to not promise the client a positive prognosis if it is unrealistic.

When determining the level of amputation, the physician must consider primary wound healing and maximizing the client’s function. For example, a transfemoral amputation will heal most quickly, but will jeopardize the client’s chances of walking due to the loss of the knee.

There are 9 classified levels of amputation of the lower extremity (Reed, 2001). A partial foot (Chopart) amputation is done through the foot, retaining the calcaneus and talus. A Syme’s (ankle disarticulation) amputation is done through the ankle with the heal pad attached to the distal end to aid in weight bearing. A knee disarticulation is done through the knee joint. A below-the-knee amputation (BKA), or transtibial amputation, is done through the tibia and fibula. The residual limb must extend 11-12 cm below the patella to be considered a standard BKA. Any length shorter than this is considered a short BKA.

An above-the-knee amputation (AKA), or transfemoral amputation, is done through the femur. The residual limb must extend 22-28 cm below the tip of the greater trochanter to be considered a standard AKA. Any length shorter than this is considered a short AKA (Gibson, 2001). A hip disarticulation separates the femur from the acetabulum. Finally, a hemipelvectomy (or hindquarter) is the removal of the lower
extremity along with half of the pelvis. Regardless of what level of amputation an individual undergoes, there will be an alteration in their gait cycle.

**Gait**

Gait can be defined as the manner or style of walking, including rhythm, cadence, and speed (Mosby, 2001). One complete gait cycle is considered to be the time from heel strike to the next ipsilateral heel strike (Rancho Los Amigos, 2001). This cycle can be divided into stance and swing phases.

The swing phase of the gait cycle begins as soon as the toe of one extremity leaves the ground, and ends just prior to when the heel of the same extremity strikes the ground. There is no contact between the extremity and the ground at any time. This phase makes up approximately 38% of a complete gait cycle. The stance phase makes up the other 62% of the cycle. This is the period in which some portion of the foot is in contact with the ground, beginning as the heel makes contact with the ground and ending when the toe lifts (Norkin, p. 450).

These two phases can be subdivided into the eight phases of gait. The normal gait summary table (Appendix A) identifies each phase, and describes the position of each joint and the major muscles in action. Critical events are also listed, which are motions or positions that contribute to the accomplishment of the functional tasks (Rancho, 2001). “Selection of the optimal prosthetic knee mechanism is one critical element in prosthetic rehabilitation of the person with a limb amputated at a higher level” (Michael, 1999).

**Knee Mechanisms**

In today’s world of technology and medical advancements, many different options are available when a prosthetist fits a prosthesis. The three main components to
assess in a transfemoral prosthesis include the socket (i.e., portion of prosthesis that fits over the residual limb), the knee joint, and the foot (Marks & Michael, 2001). Selecting the preeminent knee mechanism is the most critical component of the rehabilitation process because of its importance to gait and functional mobility, and eventually participation in life activities.

Michael did an extensive review of modern prosthetic knee mechanisms in 1999 to show all available options, and also candidate criteria required to be considered for each different option. There are 2 main categories of knee mechanisms: mechanically controlled and microprocessor controlled. “These groups can then be subdivided according to the complexity of the stance stability and swing phase control provided” (Michael, 1999, p. 39).

Many variations of mechanically controlled knee devices are still available. Single axis joints are one type that bend freely, but offer no swing phase control. Hence, these are rarely still used. Some single axis units offer an adjustable friction cell, or “stance control”. This is a device with an adjustable brake mechanism, which presses with fixed force against the knee axle. This provides dampening of swing phase motion, adding stability to the knee unit. “There is a spring loaded extension assist to limit heel rise and to propel the shin into full extension before heel strike” (Michael, 1999, p. 40). However, “the amputee has to stop and bend down to turn a knob on the prosthesis each time his cadence changes” (Kirker, Keymer, Talbot, and Lachmann, 1996, p. 268). Considering other advancements in the prosthetic field, this knee unit is used only if follow-up care will be difficult or impossible (i.e. the client lives two hours away).
In addition, there are two functional limitations to the single axis knee units. One is that it should only be used to walk on flat, smooth surfaces. “The knee will buckle if the net ground reaction force passes anterior to the knee center” (Michael, 1999, p. 40). This shift of forces may take place if the patient walks outdoors or on stairs frequently. The other limitation is that it will only swing at one fixed cadence of gait. There is a delayed swing phase, which indicates only those who do not change their rhythm or speed of walking should be using this unit. If an individual were to walk faster than normal or try a flight of stairs at a faster pace, the knee could buckle and cause a fall.

Fluid swing phase units are another type of mechanically controlled knee mechanism in lower extremity prosthetics. “If the patient with an amputated limb is expected to vary their walking speed, then mechanical swing control devices will be insufficient and fluid control should be considered” (Michael, 1999, p. 45). There are two main types: hydraulic (fluid filled) and pneumatic (air filled). Hydraulic units are controlled by fluid flow restriction. The fluid in the joint is usually silicone oil. The higher the activity level of the joint is, the higher the turbulence of the fluid will be. The restriction of fluid creates a high damping force that adds control to the shin. This unit is frequently used because it can overcome the single axis friction design limitations discussed earlier. A limitation of the hydraulic unit is that the more complex these units are designed, the heavier and more expensive they become. Despite these facts, this is one of the most common knee joints used today. It absorbs shock, reduces the rise in center of gravity, and more closely simulates normal gait kinematics.

Pneumatic units are controlled by airflow in the joint. The primary advantage of this joint is that it is unaffected by change in environmental temperatures. This is
especially helpful for those individuals living in areas of extreme or frequently changing climates. However, it is recommended only for slow to moderate cadence walkers because vigorous ambulators may be able to out walk this unit (Michael, 1999).

Polycentric units are yet another type of mechanical knee component. “Polycentric mechanical units have many clinical and biomechanical advantages over the more basic designs, which accounts for their increasing use worldwide” (Michael, 1999, p. 41). This unit has four points of rotation, each connected by a linkage bar, thus optimizing both stance and swing phases. It also improves the sitting appearance of the knee when flexed at 90°. The point at which a polycentric knee appears to be bending at a given moment is referred to as its instant center of rotation (ICR). If the patient flexes a few degrees, the ICR moves anterior to the ground reaction force causing almost effortless knee flexion. The ease of flexion combined with stance stability makes the polycentric unit a common choice. Compared to a single axis, the polycentric unit can offer additional swing phase advantages, including toe clearance. This prevents catching the toe on the ground right before stance contact, which makes for less chance of falling. Overall, there are many options to choose from when looking at mechanically controlled prosthetic knee mechanisms. Price range and convenient maintenance of components are key advantages to the mechanical units.

Microprocessor controlled units were introduced around 1990. There are two pneumatic knee prostheses controlled by microprocessors available: the Endolite Intelligent Prosthesis Plus (IP), and the Seattle Limb Systems Power Knee (Michael, 1999). Both use a single onboard sensor to detect when the knee is in full extension and adjust a pneumatic swing control cylinder accordingly. The microprocessor control can
overcome the limitations of mechanical devices, specifically allowing for symmetrical
gait. The computer adjusts the pneumatic resistance of these knees. This optimizes the
adjustment for a broad range of gait speeds from very slow to very fast.

A case study was done to compare the IP to pneumatic swing prostheses. An
individual with a transfemoral amputation walked at three different speeds: slow,
comfortable, and fast. Results showed relatively large variations in cadences, with the IP
demonstrating a more consistent pace and contributing to a variation in energy
expenditure (Taylor, 1996). Thus, the microprocessor-controlled unit demonstrated its
ability to provide a significantly more consistent gait than the pneumatic unit.

Alignment is also optimized by the IP computer’s ability to apply any needed
changes according to the pace of ambulation the amputee chooses. Alignment is
important throughout the entire prosthesis. If the knee is misaligned from the socket, the
residual limb will be misaligned causing a painful torque on the hip. A secondary clinical
benefit from the microprocessor is that the patient perceives the knee as more consistent,
and therefore develops more confidence in the prosthesis. “Case studies are now
showing that less energy is used while walking with a microprocessor controlled knee
because less effort is needed to control the swing phase timing of the prosthesis”
(Michael, 1999, p. 43).

*Otto Bock C-Leg®*

A more advanced computer controlled knee mechanism has recently been released
called the C-Leg® from the company Otto Bock Health Care. “Otto Bock’s highest
priority when developing the C-Leg® was to provide optimal stability during the gait
cycle” (Otto Bock, 2004, p. 2). “This knee joint uses a hydraulic cylinder to provide
superior swing phase responsiveness, along with variable hydraulic stance phase control” (Michael, 1999, p. 43). It is a single-axis knee utilizing six independent parameters that are externally adjustable with any Windows computer (Otto Bock Industry, n.d.).

The reason this design is so unique is because it uses multiple sensors that are integrated into the prosthetic shin structure to gather and calculate biomechanical data. Such data includes the amount of vertical loading on the foot, the sagittal plane ankle moment, and the position, direction, and angular acceleration of the knee joint. These elements are sampled fifty times per second, allowing the computer to readjust the knee accordingly. This data is used to determine “when it is safe and efficient to move out of stance phase, allowing for the free swing of the leg while being supported on the other limb” (Otto Bock, 2004, p. 2). The C-Leg® uses a software gait analysis algorithm to optimize hydraulic stance and swing control resistances up to sixty times within a typical 1.2-second gait cycle (Michael, 1999). This analysis of input components, data analysis, and stance stability resistance is termed “Real Time Gait Analysis”, or RTGA (Otto Bock, n.d). Because the normal gait cycle is only 1.2 seconds, microprocessor must work in “real time” in order for the knee to have optimal coordination of stance resistance, swing, extension dampening and swing dampening. An understanding of other microprocessor controlled knee units is necessary to recognize why “real time” is unique. Other knees, such as the IP, control swing phase resistance with a pneumatic cylinder that has five pre-set valve positions. This means these knees can only offer five levels of resistance. The microprocessor measures the passage of time from toe-off to heel-strike. This time is compared to one of only three settings (“slow walk”, “medium walk”, and
“fast walk”). When clients are fit with this type of knee, they are asked to walk at a slow, medium, and fast pace. These rates are then recorded on the microprocessor. The cadence cycle times are averaged and compared to one of the “slow”, “medium”, or “fast” recorded gait rates, and is then matched with one of them. Therefore, an exact setting cannot be chosen. The other drawback is that this limiting process takes approximately 3.6 seconds, which is three times the amount of time a normal 1.2 second gait cycle takes (Otto Bock, n.d.).

Improved energy expenditure is another advantage of the C-Leg®. A study was done by the Otto Bock Orthopedic Industry (Schmalz, n.d.). They recruited six experienced people with transfemoral amputations to compare the physiological cost of both a conventional hydraulic controlled single axis knee joint and the C-Leg® during three treadmill walking trials of fifteen minutes each. “Energy expenditure was measured using expiratory volumes and oxygen and carbon dioxide concentration levels, which determine oxygen consumption, carbon dioxide emission, and the respiration quotient” (Schmalz, n.d., p.1). Results showed the C-Leg® adapted swing phase resistance to walking speed for a wider range of cadences than the hydraulic joint did. These findings are significant in that it was proven that the C-Leg® can allow users to walk on a wide variety of terrain with ease as shown by the decreased energy expenditure.

In a related study by Kastner, ten persons with unilateral above-the-knee amputations were recruited to participate in four gait analysis trials walking on uphill, downhill and flat treadmill settings. Times and pulse rates were recorded during their thousand-meter walk on the treadmill. Results showed that the C-Leg® offers a harmonic gait over a larger range of speeds, meaning there were significantly lower
flexion speeds at the beginning of swing phase (Kastner, 2002). This caused the prosthesis to swing more calmly. The limitation of this study is that the Participants all had extensive experience with amputation, and were therefore, “good walkers”. These results may not apply to a person with a recent amputation.

Although the new C-Leg® prosthesis is bringing new hope to the world of prosthetics, not everyone is fit for this type of unit. Prescription restrictions, along with the individual’s goals and capabilities, should be taken into careful consideration before recommending a C-Leg®. Criteria that an individual must meet in order to use the C-Leg® include (Hanger Prosthetics & Orthotics, 2002):

1. Patients with adequate cardiovascular reserve and cognitive learning ability to master the higher level of technology and to allow for faster than normal walking speed.
2. The patient must demonstrate the ability to ambulate at a faster than baseline rate using a standard prosthetic application with a swing and stance control knee.
3. Demonstrated patient need for long distance ambulation at variable rates (greater than 400 yards) on a daily basis. Use of the limb in the home or for basic community ambulation is not sufficient to justify provision of the computerized limb over standard limb applications.
4. Demonstrated patient need for regular ambulation on uneven terrain or for regular use on stairs. Use of the limb for limited stair climbing in the home or employment environment is not sufficient evidence for prescription of this device over standard prosthetic application.

So how does amputation, the knowledge of prosthetic knee mechanisms, physical activity via gait, and body image all relate back to occupational therapy? Occupational therapy tends to focus on the same target goal as every prosthetic design (especially the microprocessor controlled units) aims for – energy conservation. “Efforts are continuously being made to develop artificial knee mechanisms that alleviate patient discomfort, increase stability, reduce loads transferred to the sound leg and vertebral
column, and reduce the energy consumption during gait” (Buckley, 1997, p. 330).

“Walking with an artificial limb takes considerably more energy than walking normally—up to 30 per cent more for a single BKA and up to 100 per cent more for an AKA” (Gibson, 2001, p.51). Improved energy expenditure is another advantage of the C-Leg®. Otto Bock, n.d., p. 2) explain three reasons why this is true:

1. Superior swing phase control characteristics of the C-Leg appear to reduce the amount of excess effort the individual must expend to walk a given distance.

2. The enhanced stance phase control, combined with the superior swing functioning, increases the individual’s confidence in the prosthesis. New wearers typically comment that they have increased their activity level and range of activities “because the C-Leg makes it possible to do more things safely and comfortably”.

3. Since studies have clearly shown that individuals with amputations are Participant to an increased risk for heart disease due to their more sedentary lifestyle, technology which allows them to increase their activity level significantly may diminish this morbidity and mortality.

Body Image

Hanger, Inc. (2001, p. 37) defines body image as “awareness and perception of one’s body related to both appearance and function”. We live in a society that focuses on body image. Extreme measures from plastic surgeries to gastric bypasses are performed every day because people want to improve their looks. In fact, according to the American Society of Plastic Surgeons 6.6 million people had cosmetic plastic surgery in
Body image is an important part of self-concept. When an individual has an amputation, their figure is altered. This disfigurement can have a negative impact on their body image, as well as motivation to participate in social or physical roles.

Wetterhahn conducted a nonrandomized survey study with 56 people with lower extremity amputations to determine if a relationship existed between body image and level of participation in physical activity and sports. Results showed a positive relationship between regular participation in physical activity and body image. Increased levels of physical activity and function in life lead to an increased self-esteem, and a more intact body image. Everyday roles in life can be carried out with maximized function of the body, which is largely achieved through physical capacity.

“For amputees, physical activity improves proprioception in limbs and increases proficiency in the use of prosthetic devices. With greater agility and coordination, individuals with amputations have increased confidence and a better sense of their own physical control” (Wetterhahn, 2002, p. 196).

In every area of self-care, work, and leisure there is some type of physical activity needed. Whether it is walking or sprinting, technology has given individuals with transfemoral amputations the ability to perform. It is important to understand which prosthesis will be best fit the individual’s lifestyle and activity level to accommodate their active roles in life. “For amputees, physical activity improves proprioception in limbs and increases proficiency in the use of prosthetic devices. With greater agility and coordination, individuals with amputations have increased self-confidence and a better sense of their own physical control” (Wetterhahn, 2002, p. 196). This concept relates back to the Occupational Functioning Model, the main model this study follows. “To
engage satisfactorily in a life role, a person must be able to do the tasks that, in his or her opinion, make up that role” (Trombly, 2002). If individuals are able to fulfill these roles, this sense of physical control may come more easily.

Incorporating daily functional activities into the prosthetic training process helps facilitate weight shift on and off the prosthesis in various body positions (Pandian, 1999). After basic walking is achieved, community reintegration (i.e. driving, public transportation), recreational activities, and vocational rehabilitation should be addressed to enhance overall daily function. A home evaluation is critical, including looking at specifically stairs or other barriers and the bathroom arrangement. Vocational evaluation and discussion of any future work adaptations should also be considered. Appreciating the client’s preoperative lifestyle will help facilitate appropriate initial prosthetic prescription, and also in designing a suitable rehabilitation program for the individual. Using this holistic approach offers the client the most effective means for successful reintegration into their previous lifestyle.

Summary

The C-Leg® has opened new doors for people with transfemoral amputations who wish to participate in roles requiring high levels of physical activity. “Correlations between amputation, body image, and other variables have rarely been investigated” (Wetterhahn, 2002, p. 195). Hopefully more research is done in this area, especially regarding current technological advancements such as the new C-Leg®. Research is the first step in gaining an understanding of the potential the C-Leg® has to provide individuals with transfemoral amputations with the most independent lifestyle possible.
Most studies to date, such as those done by Kastner and Schmaltz, have been done using treadmill trials. A large percentage of ambulation in every-day life is spent maneuvering around objects, walking on uneven terrain, changing speed, sitting down and standing up, rather than steady level walking as on the treadmill (Taylor, 1996). While the treadmill trials are able to assess energy expenditure and oxygen consumption while walking and/or running, function is overlooked. There is a gap in current C-Leg® research relating to functional activity performance.

In this study, instruments were used to gather responses about these practical conditions individuals may experience, and therefore a more accurate assessment can possibly be made regarding increased function with the C-Leg®. The next chapter will describe the methodology associated with this research study conducted to explore individual’s performance of life’s roles while using the C-Leg®.
CHAPTER III

METHODOLOGY

The purpose of this survey study was to determine if people who use the C-Leg® are able to fulfill their roles in life with an improved level of function and a positive body image. The C-Leg® is a microprocessor-controlled prosthetic knee joint that has recently been introduced into the world of lower extremity prosthetics by Otto Bock Health Care. In this study, individuals using the C-Leg® were asked questions pertaining to overall daily function and body image. Data were obtained through the use of three surveys completed by eight Participants who are outpatients in an acute rehabilitation hospital in the Midwestern United States.

Hypotheses

This study was designed to test the following hypotheses. It was purposed that individuals using the C-Leg® may experience an enhanced level of functional independence. Secondly, it is hypothesized that with increased functional abilities and independence from using the C-Leg® comes a positive body image.

Design of the Study

Data were obtained by each participant completing three surveys. This pilot study took place in North Dakota during the time of January 1, 2004, to April 24, 2004, in an orthotics and prosthetics department of a Midwestern acute rehabilitation hospital. A certified prosthetist (CP) was asked to recruit eight clients, and to provide a schedule of appointments for all Participants. Surveys were distributed either before or after their regularly scheduled appointment. The principal investigator was present at each
appointment, explained the research, reviewed the informed consent form, and distributed the surveys to all Participants. All surveys took approximately 20 minutes total to complete. Participants were informed that no compensation was to be provided for completing these surveys.

Selection of Sample

In North Dakota, there has been 30 C-Legs® issued to date. Inclusion criteria for participants in this study included individuals who had a transfemoral amputation, were currently using the C-Leg®, were over the age of 18 years, and without cognitive limitations. Individuals over the age of 18 were selected in order to document increased function in a variety of life roles, most of which are not filled until after the age of 18. No Participants having any cognitive impairment were selected because of the potential hindrance to informed consent and understanding of their involvement in this research. Eight individuals who met these predefined criteria were deliberately recruited by a C.P. employed by the hospital; therefore this research involved a purposive sampling method (DePoy, 2000).

Data Collection

Three surveys were the only tools used to gather information in this study, and were distributed to eight Participants recruited from a regional hospital. Permission to conduct this study was granted prior to study inception from the joint Institutional Review Board (IRB) process between the University of North Dakota and the regional hospital. Participant confidentiality was maintained by using a coded number system with the surveys. Participants completed informed consent forms that explained all risks and
benefits of the study. This consent form can be found in Appendix B. All completed consent forms and surveys were stored according to IRB-approved procedures.

Instrumentation

Participants were asked to complete a series of three surveys. Survey questions pertained to personal satisfaction with the C-Leg®, functional independence, role performance, and body image. These surveys are included within Appendices C-E.

Reintegration to Normal Living Index (RNL)

The first survey distributed was the 11-item Reintegration to Normal Living Index (RNL) constructed by Wood-Dauphinee, Opzoomer, Williams, Marchand, and Spitzer in 1988 (Appendix C). The RNL asked how the Participant manages activities, roles, and relationships on a day-to-day basis, as the writers acknowledged, “to function independently patients must be able to participate in a broad range of activities” (Wood-Dauphinee et al., 1988, p.583). Participants responded by marking a 10 centimeter visual analogue scale (VAS) that ranged from “does not describe my situation” to “fully describes my situation”.

Content validity was investigated by determining which components of living made up the construct “reintegration” since “it is comprised of attributes that sometimes cannot be observed directly” (Wood-Dauphinee, et al., 1988, p. 584). However there are types of behaviors and attitudes that promote a conclusion that an individual has reintegrated. These behaviors and attitudes were studied. Pertinent literature was reviewed first. Two questionnaires were constructed for expert panel respondents to provide information regarding activities, roles, and relationships to be resumed and the hardships to be overcome by an individual before “reintegration” was complete. After receiving three
advisory panels’ approval and a final questionnaire was completed, the concept of reintegration was refined. Results of the questionnaires implied that the realms most closely related to reintegration to normal living patterns after disease or trauma are indoor, community, and distant mobility, self-care, daily activity, recreational and social activities, general coping skills, family roles, personal relationships, and presentation of self to others. Responses also purposed that “reintegration means the ability to function, to do what one wants to do or feels one has to do, not that one must be free of symptoms or even disability” (Wood-Dauphinee et al, 1988, p. 585).

Internal consistency analyses were performed on a sample of 80 clients from acute-care hospitals and one rehabilitation center. Overall Cronbach’s Alpha was reported at .904. Only one item about the comfort with which self-care needs were met was reported low at .39.

The RNL Index demonstrates adequate Interrater reliability and high internal consistency, as well as content validity. It is unique in the fact that it is concerned with issues of living rather than medical outcomes, and incorporates client perceptions. It is responsive to changes in the clinical status of clients, especially when considering the subscales of Daily Living and Perceptions of Self are considered. When considering criterion validity, the index is to some extent related to work and disease status. Construct validity is demonstrated to a moderate degree and/or statistically significant when assessed against the Quality of Life (QL) Index and the Structure of Psychologic Well-Being. “The RNL index appears to assess global function and measures both the clients’ perceptions of their own capabilities and objective indicators of physical, social and psychological performance” (Wood-Dauphinee et al., 1988, p. 583).
Situational Inventory of Body-Image Dysphoria (SIBID)

The second survey used was the Situational Inventory of Body-Image Dysphoria (SIBID) constructed by T.F. Cash in 2000. The SIBID is a multidimensional body-image assessment of people’s negative body-image emotions in every-day situations and experiences that are derived from their attitudes about their physical experience (see Appendix D). It is also a valid tool to assess therapeutic change. Participants were asked how often they experience negative about themselves in 50 specific situations. They were given a 5-point Likert Scale with the values ranging from 0 = never to 4 = almost always. The SIBID is unique in the fact that it captures the emotional experience within situations involving body exposure, social scrutiny, social comparisons, wearing certain clothing, looking in the mirror, eating, weighing, and exercising (Cash, 2000).

The SIBID has excellent internal consistency for both sexes and is also acceptably stable over a 1-month interval (Cash, 2000). “Regardless of the number of extracted factors, the first emergent component accounted for considerable variance followed by very minor components whose items did not load uniquely on that factor. Thus, the SIBID is best regarded as a unidimensional measure yielding a single composite mean score” (Cash, 2000, p. 3). The normative data reported by Cash (2000) shows a significant gender difference in body-image dysphoria, with women reporting having experienced body-image distress more frequently than men.

Initial studies show that the SIBID has a consistent pattern of moderately high correlations with other standardized measures of body image for men and women. The SIBID was positively and significantly correlated with the Beck Depression Inventory
(r = .53), the Fear of Negative Social Evaluation Scale (r = .61), and negatively correlated
with social self-esteem on the Texas Social Behavior Inventory (r = -.50) (ps < .001).

Regarding discriminant validity, Cash (2000) examined the correlation of the SIBID
with the short form of the Social Desirability Scale. Modest negative correlations were
observed (r = -.28) for women and (r = -.22) for men. Through partial correlational
analysis, it was revealed that the associations of the SIBID with other body-image indices
and with psychosocial adjustment were slight but insignificantly affected by shared
variation due to socially desirable responding (Cash, 2000).

Cash tested his model of negative body-image emotions as cognitively mediated and
reinforced by behavioral avoidance (Cash, 2000, p. 5). Predictability of SIBID scores
from selected cognitive-behavioral variables were examined through a regression
analysis. Results showed that women with greater body image dysphoria engage in more
behavioral avoidance, are more appearance invested, hold physical ideals that they
perceive themselves to be more discrepant, have stronger public self-focus of attention,
and are heavier in body mass (R = 0.80, p<.001). Other studies have also confirmed that
the SIBID is a predictable function of both body-image evaluations and investment in
appearance. These results support this framework and the validity of the SIBID.

A recent (2000) unpublished study of body image coping, Cash and Flemming found
that men and women who reported more frequent body image dysphoria on the SIBID
also reported more frequent cognitive and behavioral efforts to cope with such emotions.
The two body image coping strategies of avoidance/immersion and appearance
modification were strongly related to the SIBID scores (for men r_s = .75 and .59
respectively; for women r_s = .74 and .72, respectively). Correlations were much lower
between the SIBID and rational coping strategies ($r_s<.30$). “These findings may reflect the relative ineffectiveness of the first two strategies relative to the third in the regulation of negative body image affect” (Cash, 2000, p.5).

To conclude the validity of the SIBID, Cash looked at its responsiveness to interventions. “Four investigations of the efficacy of cognitive-behavioral body-image therapy included the SIBID as an outcome measure. Each study confirmed the responsiveness of the SIBID to treatment, evinced by significant reductions in the SIBID scores” (Cash, 2000, p.5).

*C-Leg® Function and Body Image Survey (CFBIS)*

The third survey was designed by the researcher entitled the C-Leg® Function and Body Image Survey (CFBIS). The CFBIS asked 6 open-ended questions regarding personal thoughts and opinions about the C-Leg® and the individual’s current functional abilities. The protocol can be found in Appendix E, and responses can be found in Appendix F.

An open-ended design was chosen for this survey to try to capture thoughts and feelings from Participants that may have been missed with the other two structured surveys. Highly sensitive issues, such as self-evaluation of function and body image after an amputation, can be investigated through these questions in further detail than, for example, using a Likert scale alone which can limit a participant’s responses. Also, issues that are most important to the individual can be discovered through open-ended questions instead of restricting them to issues the researcher may deem most relevant. “The meaning of the questions to the Participant can be identified” (DePoy, 2000, p. 191).
Of course there are limitations to open-ended questions as well. Individuals may not want to directly address sensitive issues in their own thoughts and/or feelings. It may be easier for them if there are choices presented. Also, time becomes a factor for both the Participant and the researcher. Open-ended questions take more time to complete than, for example, simply circling a choice from a list. Extensive time is also required by the researcher to analyze these responses, which cannot be readily compared across groups (DePoy, 2000). Despite these limitations, it was in the researcher’s opinion that when considering the research purpose, phenomena being studied, and the study population, an open-ended survey was a necessary complement to the other two standardized surveys.

Analysis

Descriptive analysis was conducted to provide frequencies, percentages, and nonparametric correlational analysis. Statistical results were computed using SPSS. Open-ended questions were analyzed descriptively for content and frequency. These results were entered into summary tables to allow for investigation for any existing patterns correlations among Participant responses. The RNL and the SIBID (the two standardized tools used) were compared and correlated using integrated response categories to increase content validity. This was done by assigning all questions from both surveys into seven common categories. Participant responses were averaged in each of the categories. If the average from both surveys were similar, a correlation was determined in the specific category.

The first category used in analysis was social integration. Integration is defined as the organization of organic, psychologic, and social traits and tendencies of an individual into a harmonious whole (Wood-Dauphinee, 1988). The social component of integration is
emphasized in this category for successful reintegration into life after an injury. The second category was *body satisfaction*. “Body image is a multifaceted psychological construct that includes the subjective attitudinal and perceptual experiences of one’s body, particularly its appearance” (Cash, 2000, p. 1). This aspect also correlates with the self-efficacy and self-esteem constructs used in the OFM, the underlying theory of this study. The third category was *functional role performance*. Functional status can be defined as the normal or characteristic performance of an individual, therefore including physical, mental, emotional, and social dimensions reflecting both a behavioral and a subjective interpretation of performance (Wood-Dauphinee, 1988). “Roles are socially expected behavior patterns associated with an individual’s status in a particular society” (Trombly, 2002, p. 5). Competence in these roles is highlighted in the OFM.

The fourth category was *self-efficacy*, which refers to people’s beliefs in their performance capabilities with respect to a specific task. It does not concern the task itself, but rather the judgments of what one can do with the skills. It is also the individual’s judgment of how effective his or her responses to cope with a given problem will be (Trombly, 2002, p. 5). Self-efficacy is the pinnacle of the OFM hierarchical paradigm.

The fifth category was *social scrutiny*, which is a situational and contextual event that contributes to the intensity and frequency of dysphoric body-image emotions (Cash, 2000). Social scrutiny can have a possible effect on role performance and body image. The sixth category was *personal* relationships, which are ties with relatives, significant others and/or friends (Wood-Dauphinee, 1988). The seventh and final category used was *psychological distress*, which refers to a feeling regarding self-perception of appearance.
and/or functional abilities that may interfere with reintegration and body image (Cash, 2000).

Summary

The methodology of the study was presented in Chapter III. A summary of the design with its sample and hypotheses were also provided. Instruments used were profiled and analysis methods were delineated. These topics will be reconsidered with a discussion of the survey results in the imminent Chapter IV.
CHAPTER IV
RESULTS

A purposive sample of 8 men with transfemoral amputations using the C-Leg® participated in the study. The mean length of time of C-Leg® use was approximately one year and nine months. The following information provides a summary of descriptive information gained from 3 surveys administered to the 8 participants.

C-Leg® Function and Body Image Survey (CFBIS)

The CFBIS is a survey developed by the author for the purposes of gathering information directly related to the C-Leg®, and can be found in Appendix D. Results of the CFBIS were determined through descriptive analysis. Complete participant responses were placed in summary tables (Appendix E). These responses were analyzed for any patterns that existed.

There were two Participants who had just started using the C-Leg® who answered in much less detail, if at all to the questions on the CFBIS. Because they had only been using the C-Leg® for a short period of time (i.e. 3 weeks), they stated they have not noticed any significant differences in their lives yet, but were optimistic about the future. Due to this inexperience, they felt they were unable to answer all the questions accurately.

There were 3 overall patterns found when analyzing responses from the CFBIS: lifestyle performance, activity performance, and self-confidence. The most common answer for major life improvements given was walking. Walking faster, on uneven
terrain, and up and down stairs were frequently emphasized as an explanation for improved lifestyle performance.

Another common response for life improvement was motivation. Participants illustrated this motivation in two connotations; endurance and ability. From an endurance perspective, motivation was described as having more energy for activities, particularly sports. One participant discussed how he could be around people longer because he “doesn’t wear out”. When looking at performance capacity, motivation was described as having motivation to do new things. One Participant described this as feeling as though “the chains are gone!”. Another Participant gave an all-encompassing response of “The C-Leg® has improved my whole life”.

Patterns also emerged when looking at activity performance. Feelings of safety and security were brought up frequently (50.0%). Three participants expressed they feel much safer because they will not fall down as easily when walking with the C-Leg® compared to their previous prosthetic knee. Other participants said they were able to perform work activities better, such as mechanical work on cars and machinery. Another safety issue discussed by a participant was that because the knee bends more naturally, sitting down is much easier. Finally, one participant stated his activities of daily living can be done safer in general due to the C-Leg®.

Sports were also a recurrent response regarding activity performance (37.5%). Specific sports mentioned were: basketball, hiking, skating, golf, and dancing.

Finally, the third pattern that surfaced when examining responses was self-confidence. Two common variations of this theme existed; sensorimotor confidence and social confidence. Physically, participants conveyed their perceptions of feeling more confident
in connection with the safety issues discussed earlier. One participant mentioned he has a more natural step that gives him more control, which he says is why he does not fall down as much anymore. Another participant said he likes that the C-Leg® is lightweight because he becomes less fatigued. Finally, another participant pointed out he is able to walk with less of a limp.

Social confidence was expressed through various responses. An example was given that the Participant feels more “normal” in society because of a more normal looking gait. Another similar response given by another Participant was that his steps are more normal looking because the leg does not look so stiff and straight. Participants also discussed feeling more socially self-assured because of less falls in public. Finally, one Participant expressed his social confidence with the response “I’m proud to show off this leg to huge audiences of students”.

In summary, the results of the CFBIS show positive improvements in many of the participants’ lives. Specific areas of improvement found were: improved lifestyle, including endurance, ability, and motivation; activity performance, including safety and security; and self-confidence, including feelings of sensorimotor performance and social confidence.

Reintegration to Normal Living Index (RNL) & Situational Inventory of Body Image Dysphoria (SIBID)

This study was designed to investigate two hypotheses. It was purposed that individuals using the C-Leg® may experience an enhanced level of functional independence. Secondly, it was hypothesized that with increased functional abilities and independence from using the C-Leg® comes a positive body image.
Response categories of functional role performance from the RNL and body satisfaction on the SIBID were correlated to test hypothesis two. A Spearman’s rho of -.434 was calculated, showing a fair, but not statistically significant, relationship ($p=.141$).

To address the hypotheses, frequencies, percentages, and nonparametric correlations via Spearman’s rho were used to analyze results of the RNL and the SIBID, and were computed for each individual response category of both instruments. There were three response categories common to both of the instruments, including social integration, functional role performance, and personal relationships/sexuality. These three response categories within the RNL and SIBID were analyzed to answer hypothesis one regarding individuals using the C-Leg® and their enhanced level of functional independence.

In the social integration category, 50.0% of participants (n=8) responded with an answer of 10 of 10 (mean = 8.63, s.d. = 1.87) on the RNL saying they felt completely reintegrated into their social integration roles. The remaining participants’ answers ranged from 5.5 to 9 on a scale of 0 to 10. In the same category on the SIBID, 75.0% of participants responded with answers of zero or one on a scale of 0 to 4 (mean = .98, s.d. = .73), indicating they “never” to “sometimes” experience negative feelings about themselves in social activities. When correlated, a Spearman’s rho of -.253 was calculated ($p=.272$), demonstrating little relationship which is not statistically significant between the two instruments. This relationship was supported by the social self-confidence pattern discovered in the CFBIS analysis.

In the functional role performance category, 37.5% of participants responded with a 10 of 10 (mean = 7.47, s.d. = 2.54) on the RNL, saying the felt completely reintegrated
into the roles in their lives. The remaining participants’ answers ranged from 4.0 to 8.25 on a scale of 0 to 10. In the same category on the SIBID, 75.0% of participants responded with an answer of zero or one (mean = .83, s.d. = .59), saying they “never” to “sometimes” feel negative about themselves when fulfilling their life roles. When correlated, a Spearman’s rho of -.448 was calculated, which shows a fair, but not a statistically significant relationship (p=.133) between the two instruments. This relationship was supported by the improved lifestyle and activity performance patterns discovered in the CFBIS analysis.

In the third category, personal relationships/sexuality, 75.0% of participants answered with a 10 of 10 (mean = 8.50, s.d. = 3.21), saying they felt completely reintegrated into their relationships in their lives. The remaining participants’ answers between 1 and 7 on a scale of 1 to 10. In the same category on the SIBID, 87.5% of participants answered zero or one (mean = .55, s.d. = .61), interpreted to mean that they “never” to “sometimes” feel negative about themselves in their personal relationships. When correlated, a Spearman’s rho of -.523 was calculated, showing a fair, but not a statistically significant relationship (p=.092) between the two instruments. This relationship was supported by the self-confidence and motivation patterns discovered in the CFBIS analysis. This relationship was also supported by responses given to open-ended question number 43 on the SIBID, of which 87.5% of participants said they feel negative about themselves “never” to “sometimes” when with a certain person. A summary of these responses can be found in Appendix G.

Functional role performance on the RNL was correlated with the remaining six response categories of the SIBID. Significant relationships reported using Spearman’s
rho coefficients were found with social integration (.743, $p=.017$), self-efficacy (.863, $p=.003$), personal relationships (.711, $p=.024$), and psychological distress ($-.772$, $p=.012$). There was a fair relationship between functional role performance and eating and weight (.420, $p=.150$) and close to no relationship with social scrutiny (.032, $p=.470$).

Although not directly related to the main hypotheses, frequencies and percentages were run on the other occupational therapy-related variables. On the RNL, self-efficacy results show that 62.5% of participants answered with a 9 or 10 on the scale of 1 to 10 (mean = 8.47, s.d. = 1.73), indicating they feel completely reintegrated considering their self-perceptions of skill and activity performance. On the SIBID, body satisfaction results show that individuals “never” to “sometimes” experience negative feelings (mean = .75, s.d.=.53). On the SIBID, social scrutiny results show that individuals “never” to “sometimes” experience negative feelings (mean = .84, s.d. = .39). Finally, on the SIBID eating and weight results show that individuals “never” to “sometimes” experience negative feelings (mean=.58, s.d.=.44).

Summary

This study investigated two hypotheses. The research question “Do persons using the C-Leg® experience increased functional independence?” was posed in hypothesis one. In general, a range of responses from a low of 37.5% to a high of 75.0% on the RNL and the SIBID indicates that participants experience reintegrated functional role performance. In the CFBIS results, this finding is substantiated by comments regarding improved lifestyle, including endurance, ability, and motivation; activity performance, including safety and security; and self-confidence, including feelings of sensorimotor performance and social confidence.
The research question “Does a positive body image come with increased functional independence?” was posed in hypothesis two. A fair relationship was reported between functional role performance on the RNL and body satisfaction on the SIBID.

The CFBIS served to correlate results of the RNL and SIBID directly to the C-Leg®. Correlations between other response categories with functional role performance were described, including four of which were significant. Conclusions, limitations, and areas for further research will be discussed in the upcoming Chapter V.
When reflecting on studies previously mentioned in the literature review, this study has points of agreement and departure. There are similarities specifically with the study done by Wetterhahn (2002). Results of her study showed a positive relationship between regular participation in physical activity and body image. Increased levels of physical activity and function in life lead to an increased self-esteem, and a more intact body image. Everyday roles in life can be carried out with maximized function of the body, which is largely achieved through physical capacity. “For amputees, physical activity improves proprioception in limbs and increases proficiency in the use of prosthetic devices. With greater agility and coordination, individuals with amputations have increased confidence and a better sense of their own physical control” (Wetterhahn, 2002, p. 196).

The responses from the CFBIS coincide with her findings in that patterns of social and physical confidence are connected with gaining function from the C-Leg®. The departure with this study and Wetterhahn’s is that participants in this study claim that they do not necessarily gain new functional ability, but rather expand on what they had with the knee joint they used prior to the C-Leg®. This was substantiated specifically by responses to question number five on the CFBIS.
Limitations

There are three main limitations of this study. First, the sample of 8 participants that participated in this study is considered to be small. Although the C-Leg® is still rather new, according to Paul Edman, CP there have been 29 C-Legs® issued in North Dakota, and 4,621 issued in the U.S (personal communication, April 5, 2004). Therefore, a larger sample could be accessed, and would be helpful in identifying trends.

This leads into the second limitation of participants having only used the C-Leg® for a short period of time. It would be helpful to get not only a larger sample, but also a sample that is comprised of individuals who have used the C-Leg® for at least one year.

Finally, body image is a nebulous concept that can be defined in many different ways among different people. Therefore, quantifying and measuring this concept is quite difficult, especially with a standardized tool.

Recommendations

For future research regarding this topic, it is recommended that an experimental design be used. Two groups of individuals nationwide from randomly selected regions of the U.S. (one using the C-Leg® and one using a different knee joint) could be used to gain a better understanding of whether or not results are specifically due to the C-Leg® or other external factors. Also, two groups could be compared by new users and the other more experienced users.

Using different instrumentation may be conducive to more accurate results. A tool that is functionally sensitive concerning body image would serve to do this. The SIBID incorporates daily function regarding negative emotions, however is not intended to measure level of function. The RNL serves as a global assessment of function, and is not
intended to measure body image perceptions. There is a need for such an instrument to be developed to fully encompass both of these variables.

Due to body image being such an abstract concept, it is difficult to use a standardized tool for measurement. For future research, it is recommended that interviewing be a main method of data gathering to allow participants to express their thoughts and feelings openly, and to not restrict them to a number representation on a survey.

Interpretations

As the primary researcher, I feel that, although not statistically significant, the fair relationship found between functional role performance and body satisfaction was intensely supported by the responses from the CFBIS. The primary intent of the CFBIS was to bridge the gap between the RNL and the SIBID, and to gather information specific to the C-Leg®. Results contribute to the field of occupational therapy in that there is a realistic need for therapy specific to individual roles after having an amputation. This study contributed to the knowledge base of occupational therapy by providing a better perspective on what individuals with amputations need from the field, and how their participation in life roles dramatically changes. Results coincide with the OFM assumptions that to engage satisfactorily in a life role, a person must be able to do the tasks that, in his or her opinion, make up that role, and that personal, social, and physical contexts and environments surround and influence the life and occupational functioning of an individual. The C-Leg® appears to be able to provide an expanded level of functioning, which allows for better role fulfillment for clients.

For the field of prosthetics, this study shows an all-around satisfaction with the C-Leg®. This shows prosthetists that they are providing assistive technology to clients that
is satisfactory to their clients, and that the C-Leg® provides performance beyond the “minimums” of life.
REFERENCES:


Otto Bock Healthcare.


**Appendix A**

*NA:* No muscle activity

<table>
<thead>
<tr>
<th>Event</th>
<th>DEFINITION</th>
<th>HIP</th>
<th>KNEE</th>
<th>ANKLE</th>
<th>CRITICAL EVENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weight Acceptance</strong></td>
<td>Weight is rapidly loaded onto outstretched limb.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Forward progression</em></td>
<td></td>
<td>20º flexion; extensors</td>
<td>5º flexion; quadriceps</td>
<td>NA; pretibials</td>
<td>Heel first contact.</td>
</tr>
<tr>
<td><em>Stability</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Shock Absorption</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Initial Contact</td>
<td>Foot strikes ground.</td>
<td>20º flexion; extensors</td>
<td>5º flexion; quadriceps</td>
<td>0º; pretibials</td>
<td></td>
</tr>
<tr>
<td>2. Loading Response</td>
<td>Shock absorbed as forward momentum is preserved. Foot-flat position is</td>
<td>20º flexion; extensors &amp; abductors</td>
<td>15º flexion; quadriceps</td>
<td>5º plantar flexion; pretibials</td>
<td>Hip stability; controlled knee flexion and ankle plantar flexion.</td>
</tr>
<tr>
<td></td>
<td>achieved.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Single Limb Support</strong></td>
<td>Weight is transferred onto metatarsal heads and heel comes off the ground.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Stability</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Forward Progression</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Mid Stance</td>
<td>Body progresses over foot in a controlled manner. Contralateral swing limb</td>
<td>0º; abductors</td>
<td>5º flexion; quadriceps, then NA.</td>
<td>5º dorsi flexion; calf</td>
<td>Controlled tibial advancement.</td>
</tr>
<tr>
<td></td>
<td>provides momentum.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Terminal Stance</td>
<td>Body progresses past forefoot.</td>
<td>20º hyperextension; NA.</td>
<td>5º flexion NA</td>
<td>10º dorsi flexion; calf</td>
<td>Controlled ankle dorsiflexion with heel rise; trailing limb.</td>
</tr>
<tr>
<td><strong>Swing Limb Advancement</strong></td>
<td>Limb is unloaded and foot comes of the ground.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Foot clearance</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Limb advancement</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Pre-Swing</td>
<td>Forefoot on floor. Knee rapidly flexes while weight shifts to other limb.</td>
<td>10º hyperextension; adductors</td>
<td>40º flexion; NA</td>
<td>15º plantar flexion; NA</td>
<td>Passive knee flexion to 40º; ankle plantar flexion.</td>
</tr>
<tr>
<td>6. Initial Swing</td>
<td>Thigh advances; knee continues to flex and foot clears ground.</td>
<td>15º flexion; flexors</td>
<td>60º flexion; flexors</td>
<td>5º plantar flexion; pretibials</td>
<td>Hip flexion to 15º; Knee flexion to 60º.</td>
</tr>
<tr>
<td>7. Mid Swing</td>
<td>Thigh continues to advance as knee begins extension. Foot clearance is maintained. 25° flexion; flexors initially, then hamstrings 25° flexion; flexors 0°; pretibials</td>
<td>Further hip flexion to 25° and ankle dorsiflexion to 0°.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>----------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Terminal Swing</td>
<td>Leg reaches out to achieve step length. 20° flexion hamstrings 5° flexion; quadriceps 0°; pretibials</td>
<td>Knee extension to neutral (possibly 5° flexion).</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix B

UNIVERSITY OF NORTH DAKOTA
DEPARTMENT OF OCCUPATIONAL THERAPY
SCHOLARLY PROJECT RESEARCH

Title: “Function & Body Image Levels in Individuals with Transfemoral Amputations Using the C-Leg®.

Study Directors: Erica Swanson, O.T.S. Jan Stube, PhD, OTR
1021 Jennifer Dr. UND OT Dept.
Washburn, ND 58577 PO Box 7126
(701)-739-0401 Grand Forks, ND 58202-7126
(701)-777-3099

*This consent form may contain words that are new to you. If you read any words that are not clear to you, please ask the person who gave you this form to explain them to you.

My name is Erica Swanson and I am currently completing my Master’s Degree in Occupational Therapy at UND. You are being asked to take part in a research study assessing function and body image levels. You have been chosen because you are currently using the C-Leg®. The purpose of this research is to find out if the C-Leg® has enhanced your level of function in every day activities and in physical activity, and enhanced your body image.

If you agree to take part in this research study, you will be asked to complete three surveys. It will take approximately 20 minutes to complete all three surveys, and they will be completed here in the Altru O&P Dept. You will be asked questions regarding personal satisfaction with the C-Leg®, functional independence, role performance, self-confidence, and body image.

There is a possibility that answering these questions may cause you to think about feelings that make you sad, anxious, frustrated, or upset. If at any time you feel discomfort you may withdraw from the study without penalty by simply turning in your surveys to the researcher who will be present outside the room. Incomplete surveys will result in termination from the study, with absolutely no consequences to you.

There is no promise that you will receive any benefit from taking part in this study. However, possible benefits include contributing to the fields of occupational therapy and prosthetics, other individuals with transfemoral amputations, and Altru Rehabilitation Hospital. Because the C-Leg® is new to the field of prosthetics, there is a lack of research concerning its performance and client satisfaction. Your honest opinions and responses will help more professionals understand the C-Leg’s® ability to enhance quality of life.

Your records will be kept private and will not be released without your consent except as required by law. All data will be stored in locked file cabinets. Your signed consent form will be stored in a cabinet separate from the data. Only the researcher, her faculty supervisor, and people who audit IRB procedures will have access to the research data. Paul Edman, CP, will have access to this consent form. All data will be shredded after three years. Your identity will be kept confidential by coding each survey with a number. Your name will never be used in the presentation of these research findings, and your medical records will not be accessed.
If you have any questions about the research now or during the study contact Erica Swanson at (701)-739-0401 or Jan Stube at (701)-777-3099. If you have any questions regarding your rights as a research subject, you may contact the Office of Research & Program Development at the University of North Dakota at (701)-777-4279.

**STATEMENT OF CONSENT:**

*I have read the above description of this research study. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will also be answered by a member of the research team. I voluntarily agree to take part in this study, and may withdraw at any time. I understand I will receive a copy of this consent form, and a data summary sheet upon completion of the study to inform me of the results. I understand that my medical records and study records are confidential. However, representatives of the study sponsor, the U.S. Food and Drug Administration (FDA), or the Institutional Review Board (IRB) may need to inspect my medical and/or study records. By signing this consent, I am allowing this inspection.*

___________________________________
Printed name of subject                 date

___________________________________
Subject’s Signature                        date
Appendix E

UNIVERSITY OF NORTH DAKOTA
OCCUPATIONAL THERAPY RESEARCH

C-Leg: Function & Body Image Survey

1. How long have you used the C-Leg®?

_________________________________________________________________________________

2. What do you think, if any, the biggest improvement in your life has been since you began using the C-Leg®?

_________________________________________________________________________________

_________________________________________________________________________________

3. What activities are you able to perform better, if any, due to using the C-Leg®?

_________________________________________________________________________________

_________________________________________________________________________________

4. How has your self-confidence level changed, if at all, since you began using the C-Leg®? (i.e. physically, socially, etc.)

_________________________________________________________________________________

_________________________________________________________________________________

5. Are there any activities you can do now that you were not able to do before using the C-Leg®?

_________________________________________________________________________________

_________________________________________________________________________________

6. Are there any comments regarding your current level of function and/or body image you would like to add that you feel may contribute to this research study?

_________________________________________________________________________________

_________________________________________________________________________________

Thank you for participating!
Appendix F

CFBIS Questionnaire

Results Summary

1. How long have you used the C-Leg®?

<table>
<thead>
<tr>
<th>Subject</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 months</td>
</tr>
<tr>
<td>2</td>
<td>2.5 years</td>
</tr>
<tr>
<td>3</td>
<td>3-4 years</td>
</tr>
<tr>
<td>4</td>
<td>3 weeks</td>
</tr>
<tr>
<td>5</td>
<td>22 months</td>
</tr>
<tr>
<td>6</td>
<td>1 year</td>
</tr>
<tr>
<td>7</td>
<td>2.5 years</td>
</tr>
<tr>
<td>8</td>
<td>2.5 years</td>
</tr>
<tr>
<td>Average</td>
<td>21 months (1 year, 9 months)</td>
</tr>
</tbody>
</table>

2. What do you think, if any, the biggest improvement in your life has been since you began using the C-Leg®?

<table>
<thead>
<tr>
<th>Subject</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I can walk faster; it swings better</td>
</tr>
<tr>
<td>2</td>
<td>Mobility, energy, sports</td>
</tr>
<tr>
<td>3</td>
<td>Not falling down so much more control of steps – more natural step</td>
</tr>
<tr>
<td>4</td>
<td>Sitting down in chair is less work</td>
</tr>
<tr>
<td>5</td>
<td>Motivation, ability to do new things, the chains are gone!</td>
</tr>
<tr>
<td>6</td>
<td>More energy, safety from falls (old leg the knee would buckle and down I’d go); light weight</td>
</tr>
<tr>
<td>7</td>
<td>Am less likely to fall</td>
</tr>
<tr>
<td>8</td>
<td>The C-Leg is easier to walk in. Your back, other leg doesn’t tire out so fast.</td>
</tr>
</tbody>
</table>

3. What activities, if any, are you able to perform better due to using the C-Leg®?

<table>
<thead>
<tr>
<th>Subject</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Same as with previous leg</td>
</tr>
<tr>
<td>2</td>
<td>Walking, stairs, golf, skating</td>
</tr>
<tr>
<td>3</td>
<td>Walking on uneven surfaces – sitting down (knee bends more naturally)</td>
</tr>
<tr>
<td>4</td>
<td>Going down stairs</td>
</tr>
</tbody>
</table>
5. Walking, going up and down stairs, mechanical activities.
6. Walking, stairs
7. Walking
8. Hiking, ramps at work. Stairs a lot better.

4. How has your self-confidence level changed, if at all, since you began using the C-leg®? (i.e. physically, socially, etc.)

<table>
<thead>
<tr>
<th>Subject</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>Socially – more confident</td>
</tr>
<tr>
<td>3</td>
<td>My steps are more normal looking – leg doesn’t look so stiff and straight</td>
</tr>
<tr>
<td>4</td>
<td>No, not yet</td>
</tr>
<tr>
<td>5</td>
<td>Self confidence has really improved due to easier motivation.</td>
</tr>
<tr>
<td>6</td>
<td>Increased, due to the security of the leg i.e. no falls in public</td>
</tr>
<tr>
<td>7</td>
<td>No</td>
</tr>
<tr>
<td>8</td>
<td>A lot, once you adapt to the C-Leg you don’t stumble or fall as much. More sure of yourself.</td>
</tr>
</tbody>
</table>

5. Are there any activities you can do now that you were not able to do before using the C-Leg®?

<table>
<thead>
<tr>
<th>Subject</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>Skating, walking up and down hills</td>
</tr>
<tr>
<td>3</td>
<td>No, not really</td>
</tr>
<tr>
<td>4</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>More walking, walking downhill, play basketball, dancing</td>
</tr>
<tr>
<td>6</td>
<td>Not so much more, but I can do activities safer.</td>
</tr>
<tr>
<td>7</td>
<td>No</td>
</tr>
<tr>
<td>8</td>
<td>Not really; you’re able to walk longer, and can be with people longer because you don’t have to take your leg off because you wore out.</td>
</tr>
</tbody>
</table>

6. Are there any comments regarding your current level of function an/or body image you would like to add that you feel may contribute to this research study?

<table>
<thead>
<tr>
<th>Subject</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I’m still in the learning phase with the “C-Leg”. I am optimistic about the future.</td>
</tr>
<tr>
<td>2</td>
<td>Able to walk with less of a limp (more natural)</td>
</tr>
<tr>
<td>3</td>
<td>Wearing my prosthetic makes me look like everyone else.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>4</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>The C-Leg has improved my whole life.</td>
</tr>
<tr>
<td>6</td>
<td>I’m proud to show off this leg to huge audiences of students.</td>
</tr>
<tr>
<td>7</td>
<td>Therapy is very helpful</td>
</tr>
<tr>
<td>8</td>
<td>I am always interested in new technology concerning the C-Leg. Anything that will help a person to adapt to a more normal life is a plus.</td>
</tr>
</tbody>
</table>
RNL/SIBID RESPONSE CATEGORIES

1. **Social Integration**: Integration is defined as the organization of organic, psychologic, and social traits and tendencies of an individual into a harmonious whole (Wood-Dauphinee, 1988).

   **RNL**: #10 – In general, I am comfortable with myself when I am in the company of others.
   **SIBID**: How often are negative feelings experienced when:
   - #1 – At social gatherings where I know few people
   - #3 – When I am the focus of social attention
   - #5 – When I am with attractive persons of my sex
   - #6 – When I am with attractive persons of the other sex
   - #16 – If I’m dressed differently than others at a social event
   - #42 – When I am with people who are talking about weight or dieting

2. **Body Satisfaction**: “Body image is a multifaceted psychological construct that includes the subjective attitudinal and perceptual experiences of one’s body, particularly its appearance” (Cash, 2000, 1).

   **RNL**: #4 – I am comfortable with how my self-care needs (dressing, feeding, toileting, bathing) are met. (Adaptive equipment, supervision, and/or assistance may be used).
   **SIBID**: How often are negative feelings experienced when:
   - #2 – When I look at myself in the mirror
   - #4 – When people see me before I’ve “fixed up”
   - #7 – When someone looks at parts of my appearance that I dislike
   - #8 – When I look at my nude body in the mirror
   - #9 – When I am trying on new clothes at the store
   - #11 – After I have eaten a full meal
   - #12 – When people can see me from certain angles
   - #13 – When I am wearing certain “revealing” clothes
   - #20 – If my friend or partner doesn’t notice when I’m “fixed-up”
   - #22 – When the topic of conversation pertains to physical appearance
   - #28 – When I see myself in a photograph or videotape
   - #33 – After I get a new haircut or hairstyle
   - #36 – When I am not wearing any make-up
   - #39 – When I have my photograph taken
   - #40 – If my hair isn’t fixed just right
3. **Functional Role Performance:** Functional status can be defined as the normal or characteristic performance of an individual, therefore including physical, mental, emotional, and social dimensions reflecting both a behavioral and a subjective interpretation of performance (Wood-Dauphinee, 1988). “Roles are socially expected behavior patterns associated with an individual’s status in a particular society” (Trombly, 2002, 5).

**RNL:** #3 - I am able to take trips out of town as I feel are necessary
#5 – I spend most of my days occupied in a work activity that is necessary or important to me. (Work activity could be paid employment, housework, volunteer work, school, etc.) (Adaptive equipment, supervision, and/or assistance may be used).
#6 – I am able to participate in recreational activities (hobbies, crafts, sports, reading, television, games, computers, etc.) as I want to. (Adaptive equipment, supervision, and/or assistance may be used).
#8 – I assume a role in my family which meets my needs and those of other family members. (Family means people with whom you live and/or relatives with whom you don’t live but see on a regular basis).

**SIBID:** How often are negative feelings experienced when:
#10 – When I am exercising
#24 – When I haven’t exercised as much as usual
#44 – At particular times of the day or evening
#45 – During particular times of the month
#46 – During particular seasons of the year
#47 – During certain recreational activities
#48 – When I eat certain foods

4. **Self-efficacy:** Refers to people’s beliefs in their performance capabilities with respect to a specific task. It does not concern the task itself, but rather the judgments of what one can do with the skills. It is also the individual’s judgment of how effective his or her responses to cope with a given problem will be (Trombly, 2002, 5-6).

**RNL:** #1 – I move around my living quarters as I feel is necessary (Wheelchairs, other equipment or resources may be used).
#2 – I move around my community as I feel is necessary (Wheelchairs, other equipment or resources may be used).

**SIBID:** How often are negative feelings experienced when:
#14 – When I see attractive people on television or in magazines
#17 – When I get on the scale to weigh
#26 – When my clothes don’t fit just right