THE STRONGEST PREDICTORS OF LENGTH OF STAY AND PROSTHETIC FITTING FOR PEOPLE WITH LOWER LIMB AMPUTATIONS

by © Michael Chislett

A thesis submitted to the School of Graduate Studies

in partial fulfillment of the requirements for the degree of

Master of Science in Medicine (Clinical Epidemiology), Faculty of Medicine

Memorial University of Newfoundland

October 2020

St. John's, Newfoundland and Labrador

ABSTRACT

Title: The Strongest Predictors of Length of Stay and Prosthetic Fitting for People with Lower Limb Amputations.

Objective: To identify the strongest predictors of rehabilitation length of stay and prosthetic fitting success for lower limb amputees.

Design: Retrospective analysis of clinically collected cohort.

Setting: Canadian inpatient rehabilitation facility.

Participants: Consecutive lower limb amputees admitted for prosthetic fitting from 2010-2017 (N = 103; mean age 65.3 ± 10.6 years).

Interventions: Not applicable.

Main Outcome Measures: Predictor variables included the Lower Limb Amputee Measurement Scale (LLAMS), which is a 31-question tool to predict length of stay with indicators in medical, cognitive, social, physical, activities of daily living, and other subsections; admission Functional Independence Measure (FIM®); level of amputation (below-knee or above-knee); age; sex; and time from surgery to admission. Length of stay was measured as days from admission to discharge. Successful prosthetic fitting was defined as ability to use a prosthesis on discharge.

Results: The mean length of stay was 63.6 (± 33.3) days and 21.4% of patients failed prosthetic fitting. Higher LLAMS, lower FIM®, and above-knee amputation significantly predicted longer length of stay ($p < 0.001$, $R^2 = 0.36$). Age, sex, and time from surgery did not significantly predict length of stay or prosthetic fitting. Higher LLAMS significantly ($p = 0.032$) predicted unsuccessful prosthetic fitting. A revised LLAMS, including the strongest predictors of length of stay increased the R^2 of the model from 0.36 to 0.51. A revised LLAMS, including the strongest predictors of prosthetic fitting increased the R^2 of the model from 0.15 to 0.32.

Conclusions: The LLAMS, admission FIM®, and level of amputation can be used to predict length of stay in people with lower limb amputations admitted for prosthetic fitting. Within the LLAMS, history of cognitive impairment/psychiatric illness, clinical judgement, and living alone were the strongest predictors of increased length of stay. Functional tasks and skin condition indicators were the strongest predictors of successful fitting. Shortening the tool to five items increased the predictive ability of the LLAMS.

Key words: amputation, amputees, prostheses, length of stay, rehabilitation

ACKNOWLEDGEMENTS

Completing this degree has allowed me to gain a better theoretical understanding of clinical research methods and to gain practical experience in completing clinical research. These skills will benefit me moving forward in my career to analyze problems and I hope to continue completing research relevant to rehabilitation disciplines.

I would like to acknowledge the support of my supervisory committee, Dr. Michelle Ploughman, Dr. Holly Etchegary, and Dr. Jason McCarthy. Dr. Ploughman, in particular, has supported my interest in research long before I started this degree program and has continued to be a mentor throughout the completion of the degree requirements. Completing this degree while balancing a full-time career, volunteer and family commitments has not been easy, but it has been made possible by Dr. Ploughman's consistent guidance and understanding.

I would also like to thank the other students and staff of the Recovery and Performance Laboratory and my colleagues in Eastern Health for their support.

Lastly, I would like to acknowledge this research was funded by a grant from the Health Care Foundation.

TABLE OF CONTENTS

Contents

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS AND SYMBOLS

LLA	Lower limb amputation
DM	Diabetes mellitus
LOS	Length of stay
LLAMS	Lower limb amputee measurement scale
FIM®	Functional independence measure
ADL	Activities of daily living
AKA	Above-knee amputation
BKA	Below-knee amputation
SD	Standard Deviation
CI	Confidence Interval
±	Plus or minus
%	Percentage
=	Equal
<	Less than
>	Greater than

LIST OF APPENDICES

CHAPTER ONE

Overview

Having a lower limb amputation (LLA) is a life changing event that requires a considerable amount of adjustment and rehabilitation. Amputation of a limb occurs when medical or surgical attempts to save the limb have failed. LLA can be the result of a traumatic accident, cancer, complications of diabetes, poor circulation or other medical reasons[1]. In Canada, most amputations occur as a result of diabetes and vascular disease[2]. Amputation of the lower limb can severely limit a person's ability to walk independently, particularly if they are elderly or have other medical issues[3]. People who have an amputation of the leg, either above or below the knee can be fit with an artificial limb. There are various types of artificial limbs (prostheses) that can be used depending on the level of amputation and the activity level of the person[4]. Regardless of the type of prosthesis, being fit with a prosthesis is a process that requires a period of rehabilitation[5]. Fitting with a prosthetic limb contributes to improved quality of life and mobility for people with LLA[6].

In Canada, the age-adjusted incidence of LLA between 2006 and 2012 was 23 per 100,000; in the province of Newfoundland and Labrador, the incidence was much higher than the national rate at 38 per 100,000, which may be due to high rates of obesity and diabetes in this province[2]. People with diabetes were 29 times more likely to have a LLA compared to people without diabetes[2]. It is imperative that the health care system has effective processes to manage people with LLA, and rehabilitation with the prescription of a prosthesis is one of these strategies.

While prosthetic limbs have benefits, it takes more energy to walk with a prosthesis than with it does to walk with two intact limbs[7]. As well, there are risks of complications such as falls. A person with a prosthetic limb does not have the sensation to detect fall risks, such as wet floors or uneven surfaces, and impaired balance or strength makes preventing these falls more difficult[8]. Continued use of a prosthesis requires ongoing monitoring and devices often require maintenance and refitting because the size and shape of the residual limb tends to change over time and prosthetic components need replacement from wear and tear[4]. In some jurisdictions (including Newfoundland and Labrador), prosthetic devices are not covered by a government health plan so people are responsible for the costs of the initial prosthesis and ongoing maintenance. Therefore, clients must consider the financial cost of prosthetic fitting against the potential benefits.

In Canada, up to 36% of people with LLA are admitted to an inpatient rehabilitation facility to work with the interdisciplinary team to gain independence and/or learn how to use a prosthesis[9]. When patients are admitted to a rehabilitation facility to receive a prosthesis, it is important to be able to predict their length of stay and whether the prosthetic fitting will be successful. This gives the patient and their family a better understanding of how long the process will take and allows the interdisciplinary team to plan for the patient's care needs. Keeping a rehabilitation stay as short as possible is important for the client, to help them return home expeditiously, and for the health care system, to be as efficient as possible. Efficient inpatient bed utilization prevents long wait times for admission to inpatient rehabilitation facilities.

Some people with LLA are not able to be fit with a prosthesis. Each case requires a clinical decision to be made by a physician and/or interdisciplinary team based on the patient's motivation and medical status, in consultation with the patient and family. There are no universal criteria that make someone a suitable candidate for a prosthesis[10, 11]. If we are better able to identify factors associated with successfully completing rehabilitation for fitting with a prosthesis, clinicians and patients involved in these decisions will have more evidence available to inform them and help them justify their decisions.

There are few tools available to objectively predict how long a stay a patient will require if admitted to an inpatient rehabilitation facility, or the likelihood of a successful prosthetic fitting. The objective of this thesis was to understand how well available variables were able to predict length of stay and successful prosthetic fitting in a sample of people with LLA receiving rehabilitation at an inpatient rehabilitation facility.

Chapter One will review the epidemiology of LLA, impacts of LLA on people who undergo this procedure, prosthetic rehabilitation, and the objectives for this thesis. Written as a manuscript, Chapter Two will provide a brief review of the literature, details of the methods used to conduct this study, presentation of findings, and a brief discussion addressing the main findings. Chapter Three will discuss, in more detail, the significance and implications of the results of this study. The discussion will show how the results add to the body of literature in this area, particularly in relation to identifying suitable candidates for inpatient prosthetic rehabilitation and predicting the required length of stay. Finally, the study limitations will be discussed and suggestions for future research in this area will be explored.

1.1 Epidemiology of Lower Limb Amputation

1.1.1 What is Lower Limb Amputation?

LLA is a necessary surgical procedure to remove a diseased, ischemic, mangled, or nonfunctional part of a leg or foot[12]. LLA can be classified as either major or minor. Minor amputations include amputations of toes or the foot up to the level of the ankle; amputations at a level above the ankle are considered major amputations[13]. The most common levels of LLA in Canada between 2006 and 2012 were transtibial (31%), foot (28%), transfemoral (24%) and toe (15%) [2]. The surgeries may be planned or unplanned depending on the cause. Most surgeries are completed by vascular surgeons, orthopedic surgeons, and general surgeons[9].

1.1.2 Incidence and Prevalence of Lower Limb Amputation

Estimating the incidence or prevalence of LLA is a difficult task due to limited databases, differences in methods of documenting LLA, and variation in methods used for studies attempting to estimate incidence rates[1, 2, 14, 15]. Estimates of LLA incidence vary widely between countries[15]. Rates for LLA have been reported ranging from 46 to 9600 per 100,000 in people with diabetes and from five to 31 per 100,000 in the total population[15]. Rates when only major LLAs were included ranged from six to 600 per 100,000 in people with diabetes and four to 68 per 100,000 in total populations[15]. A 2017 study by Imam et al.[2] endeavored to identify the age-adjusted incidence of LLA in Canada. This study included all LLA (major and minor) in all Canadian provinces from the year 2006 to 2012. The overall age-adjusted rate was calculated to be 23 per 100,000[2]. The incidence of LLA in Canada rate was much lower than the rate of some other disabling conditions such as stroke (297 per 100,000 in 2012/13)[16] that also require rehabilitation. Rates were lowest in British Columbia (20) and Quebec (20) and highest in Newfoundland and Labrador (38)[2]. The rate for Newfoundland and Labrador was much higher than the rates of British Columbia and Quebec and appears to be related to higher rates of obesity and diabetes in this province[2]. From 2006 to 2011, the rates of LLA declined, consistent with worldwide trends[2, 15]. While incidence rates were decreasing, the overall number of LLAs continued to rise related to increasing population size, particularly in the older segment of the population[2, 14, 15]. The prevalence of people living with limb loss in the United States is projected to increase from 1.6 million in 2005 to 3.6 million by 2050, which is attributed to the aging population and the associated increased number of people living with conditions such as diabetes[14]. Given the rising number of diabetes-related amputations in Canada[2], it is reasonable to expect a similar increase in prevalence in this country.

It is important to use age-adjusted rates for incidence of LLA because age-related differences exist for people with LLA. Imam et al. found that 55% of LLAs occurred in people aged 50-74, compared to 31% in people 75 years old or older and 14% in people 49 years old and younger[2]. In another Canadian study, the average age of people undergoing LLA was 65±12 years[9]. Sex differences also exist amongst people undergoing LLA. LLA occurs much more commonly in males than in females. Imam et al. found that 69% of people undergoing LLA in Canada were male[2]. Rates from other countries confirm that males are at higher risk of LLA, both from diabetes/vascular-related causes and from traumatic causes[15]. The difference in rates between males and females is not well-explained, but in terms of traumatic amputations, the peak occurs among males between the ages of 20-29, which could be related to engaging in higher risk occupations and motor vehicle accidents[13].

Ethnicity and race appear to play a role in rates of LLA. Rates of LLA in the United States are highest amongst people of African or Hispanic descent and Native Americans[13]. Higher rates of diabetes, sociodemographic factors and disparities in access to healthcare in these groups may account for some of these differences[13, 17]. Similar findings exist for indigenous people in Canada. First Nations people in Ontario with peripheral arterial disease were three to five times more likely than other Ontario residents with peripheral arterial disease to undergo

LLA, despite similar rates of revascularization procedures [18]. The higher incidence of LLA in First Nations people was even more evident in those 44 years of age and younger, who were six times more likely than other Ontario residents in this age group to have a LLA[18]. The authors proposed that the disproportionate rate of LLA amongst First Nations people may be due to more limited access to healthcare and delayed diagnosis of peripheral arterial disease in First Nations groups, necessitating LLA at a higher rate[18]. Furthermore, another study reported that Aboriginal Canadians with diabetes and end-stage renal disease had less knowledge regarding diet, foot care and footwear recommendations which was attributed to greater financial hardship, insufficient family support, and experiencing a language barrier [19]. More research is needed to understand the factors underlying these inequalities and develop effective strategies to decrease rates of LLA amongst vulnerable populations.

1.1.3 Etiology of Lower Limb Amputation

The main cause of LLA in Western countries is complications of diabetes[2]. Other causes include vascular disease, infections, trauma, cancer, and congenital amputations. In some cases, there may be several factors contributing to the need for LLA and a single cause may not be easily identified. For example, rates of amputation due to diabetes have been decreasing, though rates amongst people with diabetes who have greater than three comorbidities and end-stage renal disease have been increasing[17]. Therefore, LLA may be more dependent on the interplay of multiple diseases processes rather than a single cause[13]. Nonetheless, researchers in Canada have reported the most common causes of LLA based on the primary diagnosis in health records. Imam et al. reviewed 44,430 hospitalizations for LLA (major and minor) that were included in the Canadian Institute for Health Information’s database between 2006 and 2012[2]. Hospital admission diagnoses codes were used to identify the primary causes of LLA. Five codes were identified, including diabetes, vascular/infections, trauma, cancer, and congenital. The percentage of LLA due to each of the causes is presented below in Figure 1.1.

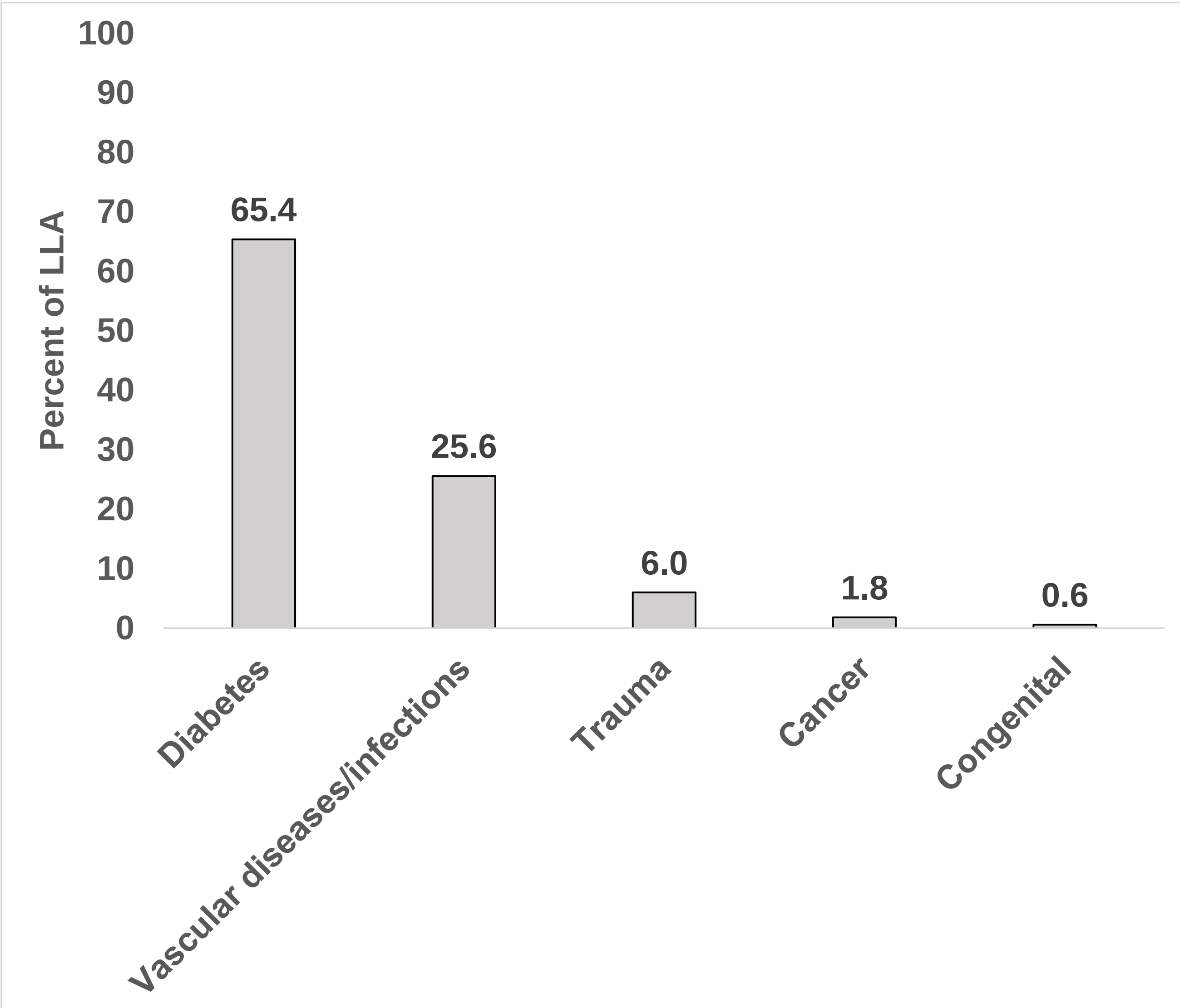

Figure 1. 1 Primary causes of Lower Limb Amputation in Canada

This is an original figure created for this thesis, based on data reported by Imam et al.[2]

1.1.3.1 Diabetes Mellitus is a main cause of Lower Limb Amputation

Diabetes is the most responsible cause of LLA in Canada, accounting for 65% of all LLAs between 2006 and 2012[2]. Although the mechanism by which diabetes leads to LLA is multifactorial, the main way is due to the development of diabetic foot ulcers[20]. Up to 25% of people with diabetes will develop a foot ulcer in their lifetime[21]. Diabetic foot ulcers develop as a complication of consistently high glycemic states, which cause damage to sensory, motor, and autonomic nerve cells. These neuropathies lead to decreased protective sensations and altered motor patterns and gait. These factors combine to make people more susceptible to increased pressure, minor trauma, and deformities of their feet. The ulcers that develop as a result of these mechanisms do not always heal. People with diabetes are also prone to infection and slow healing, particularly when they have peripheral arterial disease[22]. When foot ulcers do not heal, the risk of LLA is increased. As many as 85% of non-traumatic LLAs are preceded by a foot ulcer[20].

Another common complication of diabetes is the development of peripheral arterial disease. Peripheral arterial disease refers to the narrowing or blockage of peripheral arteries, most commonly in the lower extremities. Diabetes is considered a major risk factor for peripheral arterial disease[23]. As little as a 1% increase in HbA1c (a marker of average blood glucose levels over a three-month period) has been associated with an over 20% increase in the development of peripheral arterial disease, within four-five years[24]. Peripheral arterial disease in people with diabetes progresses more rapidly and is more diffuse than in people without diabetes[23]. The pathway by which diabetes predisposes people to peripheral arterial disease is complex. Essentially, the pathophysiological state created by diabetes accelerates the processes by which atherosclerosis and atherothrombosis lead to clinically significant peripheral arterial disease[23].

1.1.3.2 Vascular Disease as a cause of Lower Limb Amputation

Vascular disease accounts for a large proportion of the need for LLA in North America[25]. Peripheral arterial disease has a prevalence of 3% to 10% in the general population and as high as 15% to 20% in people greater than 70 years old[26]. It is also more common in smokers and people with diabetes[26]. Once a person develops peripheral arterial disease, they are at an increased risk of requiring a LLA. Approximately 5% of people with symptomatic peripheral arterial disease will have a LLA within five years[27]. Peripheral arterial disease can be the primary cause of amputation or may contribute to amputation in combination with other risk factors. Peripheral arterial disease as a primary cause occurs as part of the disease progression. Initially the disease is managed medically. When distal lower extremity circulation becomes impaired enough to be classified as critical limb ischemia, surgical intervention is typically required. Critical limb ischemia is associated with impaired quality of life, high morbidity and mortality[28]. As many as 67% of people with critical limb ischemia will require a LLA within four years[29]. Additionally, mortality rates for people with critical limb ischemia have been reported as high as 20% within six months of diagnosis and 50% within five years[28]. These rates are higher than for any other occlusive cardiovascular disease, including symptomatic coronary artery disease[28]. Open bypass surgery or endovascular procedures seek to improve distal circulation by bypassing occluded vessels or reducing/removing occlusions. When these procedures fail and/or the disease progresses, amputation may be necessary to reduce pain and prevent more severe outcomes such as death[27].

Peripheral arterial disease can also contribute to LLA in conjunction with other primary causes. A person with a diabetic foot ulcer who also has peripheral arterial disease will have less ability to heal, higher rates of major LLA and higher rates of mortality[22]. Because diabetes and peripheral arterial disease are so closely associated, it is often difficult to isolate one from the other as the primary cause of LLA[2]. The decreased peripheral circulation from peripheral arterial disease can also limit healing for wounds with other etiologies, such as traumatic injury of the lower limb, increasing the risk of failed healing and the need for LLA[30].

1.1.3.3 Infections can lead to Lower Limb Amputation

There are several kinds of infections that may lead to LLA. One such type of infection is osteomyelitis. Osteomyelitis refers to inflammation of the bone, most commonly caused by bacterial infections. It can result from infections associated with diabetic foot ulcers but can also occur in conjunction with a traumatic injury such as an open fracture, as a complication of surgery[31]. Osteomyelitis may be treated medically, by optimizing the person's physiological state and administering antibiotics, or surgically, to prevent the spread of infection and avoid major amputation[31]. Lam et al. showed that with a limb salvage protocol for chronic osteomyelitis all but five of 67 patients were able to avoid amputation[32].

There are rare but serious infections that may lead to LLA. Necrotizing fasciitis of the lower extremity is a serious bacterial infection that often requires surgery and can occur in people with or without diabetes[33], though people with diabetes are more likely to require LLA[34].

A recent study reporting on cases of necrotizing fasciitis found that 13% required an above-knee amputation[34]. Fortunately, necrotizing fasciitis is rare, occurring globally at a rate of 0.4 per 100,000 per year[34].

Sepsis is another rare but serious condition, which may result in LLA. Sepsis is defined as life threatening organ dysfunction caused by a dysregulated response to host infection[35]. As part of the disease process, clots may form in peripheral blood vessels, limiting perfusion to the arms, legs, hands and feet. If blood flow cannot be restored to the affected limbs amputation may be necessary.

1.1.3.4 Traumatic causes of Lower Limb Amputation

The incidence of amputation due to trauma varies in different regions. In the United States, trauma accounts for 16% of all amputations and 45% of the prevalent cases of amputation[14]. Traumatic amputations more commonly affect the upper limbs than the lower limbs[13]. The worldwide incidence of traumatic LLA is difficult to obtain because many countries do not keep accurate records. LLA due to trauma can result from military conflicts affecting soldiers and/or civilians. In the United States, there were 6000 amputations to soldiers in the Vietnam War and 1715 amputations from operations in Iraq and Afghanistan, 23% of which included more than one limb[13].

Traumatic LLA can also occur from workplace injuries, motor vehicle accidents, and various other accidents[13]. Rates of these types of injuries have been decreasing due to improved safety standards and the advancement of limb salvage procedures[13]. Traumatic amputations affect a younger population, with over two-thirds occurring in adolescents and adults younger than 45 years old[36]. The most common cause of amputation (upper and lower extremity combined) in children is lawnmower related accidents[37]. To prevent these amputations, education campaigns directed towards children and parents, should be seasonal, i.e. beginning in March or April to prevent lawnmower accidents and spring and early fall to prevent other farming-related injuries[37].

1.1.3.5 Cancer causing Lower Limb Amputation

LLA due to cancer in the United States is rare, occurring at a rate less than one-one hundredth the rate of LLA from vascular diseases[13]. LLA due to cancer can occur due to metastatic progression of the disease or as a primary malignancy affecting the bone. Primary bone cancer is uncommon, accounting for only 0.2% of all carcinomas[1]. The three most common malignancies of bone are osteosarcoma (affecting the long bones), chondrosarcoma (affecting joints), and Ewing sarcoma (affecting the axial skeleton). Amputation due to primary cancer is most commonly due to osteosarcoma, but the current amputation rate for this disease is less than 1%[1]. These cancers occur most commonly in children and young adults[1]. Advances in detection and treatment mean that few of these primary bone malignancies result in the need for LLA[1].

1.1.3.6 Congenital Amputations

Congenital amputation occurs when people are born without a limb, or part of a limb. This results from intrauterine growth inhibition or destruction of normal embryonic tissues[1]. The exact etiology is unclear but potential causes include: exposure to chemical agents or drugs, fetal position or constriction, endocrine disorders, exposure to radiation, immune reactions, occult infections and other diseases, single-gene disorders, chromosomal disorders, and other syndromes of unknown cause[1]. Congenital amputation is rare, occurring in approximately two to seven per 10,000 live births worldwide[38], and tends to affect the upper limbs more than the lower limbs[13]. Congenital amputations accounted for 0.6% of LLA in Canada between 2006 and 2012[2].

1.2 Impacts of Lower Limb Amputation

LLA impacts the healthcare system and people with LLA greatly. While healthcare costs associated with LLA are high, for people living with LLA, the impact goes well beyond financial cost. LLA impacts many areas of a person's life, including their mobility, functional independence, health-related quality of life, pain levels, body image, mood, and life expectancy.

1.2.1 Changes to Mobility and Function after Lower Limb Amputation

One of the most obvious impacts of LLA is the loss of mobility. A survey of the most common concepts described by people with LLA across six different countries (Austria, Australia, China, Germany, and the United States) revealed that most people experience problems in the International Classification of Functioning, Disability and Health domain of activities and participation[39]. Specifically, people described difficulty moving around inside and outside their home and with recreation and leisure activities[39]. This is not surprising, given that people awake from surgery and must immediately face the new reality of attempting to mobilize with part of a limb removed. As with any surgery, there is a gradual increase in mobility that occurs as the person recovers, but unlike with other procedures, people with LLA continue to face the challenge to mobility imparted by the loss of a limb. One such challenge is impaired balance, which has been associated with poor mobility outcomes for people with LLA[10, 40]. People with LLA may use gait aids such as crutches, walkers, or canes to compensate for the loss of their limb and may eventually receive a prosthetic limb. However, walking with a prosthetic limb requires greater energy expenditure than that of walking with two intact limbs. Walking with a prosthesis requires more oxygen consumption than walking with intact limbs at a given walking speed[41]. These extra energy costs mean that people with LLA, even after being successfully fit with a prosthesis, must work harder to move around their everyday environments. To compensate for these high energy demands, people with LLA, particularly those with an above-knee amputation, tend to walk at a slower pace or limit their walking altogether[42, 43].

Regardless of whether they use gait aids or prosthetic limbs, mobility remains very limited for most people with LLA. Czerniecki et al. followed a cohort of 72 people having a major LLA due to vascular disease or diabetes at a Veteran's facility in the United States and found that at 12-months follow-up only 33% had achieved mobility success, defined as being at a mobility level the same or higher than their pre-surgery level[44]. A retrospective cohort study of 169 people with LLA in Spain observed that 88% were able to ambulate greater than 45 metres with a prosthesis by discharge from rehabilitation services[45], but this too is a low bar which does not indicate a high level of mobility. Fortington et al. conducted a review of studies reporting mobility outcomes for people older than 60 years with LLA. Consolidated evidence from these studies confirmed that between 18% and 39% of people with LLA achieved a mobility level equivalent to independent prosthetic walking; this increased to 50% to 70% for studies examining patient groups who were pre-selected as suitable for admission to a rehabilitation or prosthetic centre[46]. However, despite such promising outcomes, they noted that only 20% were able to maintain household prosthetic walking in the long-term[46]. Being able to move about safely at home and in the community is an important indicator of successful fitting. Davies et al. analyzed a sample of 281 people with LLA referred to an outpatient based amputee rehabilitation program in the United Kingdom, finding that 66% of transtibial and 50% of transfemoral amputees achieved household ambulation at one year post amputation and that 54% of transtibial and 29% of transfemoral amputees achieved community ambulation (defined as being able to independently walk outside, with or without a gait aid) in the same timeframe[47]. Clearly, there are lasting mobility deficits for people with LLA and as such, they remain limited in mobility long after they have recovered from their surgery.

Limitations in ability to mobilize translate to overall decreased activity levels. People with LLA tend to walk at slower walking speeds to compensate for the increased energy expenditure required[7] and this can lead to them being less active. Studies of activity levels amongst people with LLA, based on steps/day, revealed averages of between 1450 and 3063 steps per day for people with unilateral LLA[43, 48-51]. These studies raise concern for the overall activity levels of people with LLA when we consider that the threshold for being considered sedentary is less than 2500 steps per day and the average for nondisabled adults is between 3000 and 7500 steps per day[43].

People with LLA admitted for rehabilitation identify achieving independence in self-care as one of their most important goals[52]. However, in a study examining short-term functional outcomes in a sample of 105 people with LLA in a hospital in Denmark, patients demonstrated dependence in activities of daily living. The study used the Barthel Index, a measure of activities of daily living addressing ten domains (personal hygiene, bathing, eating, toileting, dressing, bowel control, bladder control, ambulation or wheelchair use, bed to chair transfers and stair climbing), each on a five-point scale with higher scores indicating greater independence[53]. The mean Barthel Index score decreased from 85, one month pre-surgery, to 59, three weeks post-surgery and 41% of patients still required assistance to transfer from bed to chair [53]. This loss in function was greater in patients who were older or were delayed in receiving physiotherapy[53]. In a prospective cohort study of 144 people with LLA due to vascular disease admitted to an inpatient rehabilitation facility in Italy, the average admission Barthel Index score was 63[54], suggesting that patients still required assistance for activities of daily living even more than three months after surgery.

In a similar fashion as the Barthel Index, the Functional Independence Measure (FIM®) rates the level of dependence in activities of daily living and is commonly used throughout rehabilitation centers in North America[9]. Scored by trained raters who are health care professionals, the FIM® addresses function across 18-domains (Table 1.1). Each item is scored on a seven-point scale with higher scores indicating greater independence, therefore total FIM® scores range from 18 (complete dependence) to 126 (complete independence)[55]. The FIM® can be subdivided into 13 motor function items to give a motor subscore (scores 13 to 91) and five cognitive items to give a cognitive subscore (scores five to 35) and has been validated in people with LLA[56, 57].

Table 1. 1 The Functional Independence Measure®

Functional Independence Measure (FIM®)	
Motor subscore	Scoring:
1. Eating 2. Grooming 3. Bathing 4. Dressing-upper body 5. Dressing-lower body 6. Toileting 7. Bladder management 8. Bowel management 9. Transfers bed to chair or wheelchair 10. Transfers to toilet 11. Transfers to tub or shower 12. Locomotion walking or wheelchair 13. Locomotion stairs	1 = Total assist needed 2 = Maximal assist (can perform 25 percent of the task) 3 = Moderate assist (can perform 50 percent of the task) 4 = Minimal assist (can perform 75 percent of the task) 5 = Supervision needed 6 = Modified independence (may use an assistive device) 7 = Independence
Cognitive subscore	
14. Comprehension 15. Expression 16. Social interaction 17. Problem solving 18. Memory	

FIM® scores help to group patients in order to plan for rehabilitative and community-based care. For instance, Hershkovitz et al. prospectively followed a cohort of 117 people with LLA admitted to a rehabilitation facility in Israel for rehabilitation and assessment for prosthetic fitting[58]. The average admission FIM® for this population was 74 for those who went on to receive a prosthesis and 50 for those who used a wheelchair as their primary means of locomotion[58]. On admission to inpatient rehabilitation, most people required at least minimal assistance with basic activities of daily living and the degree of assistance was at least partially linked to whether a person was considered a prosthetic candidate or not. However, by discharge from inpatient rehabilitation the average FIM® scores had improved to 91 for people fit with a prosthesis, while those unsuitable for a prosthesis showed only minimal improvement[58]. Whether FIM® can be used for the purpose of predicting successful fitting is not clear. An evaluation of 1502 people with LLA admitted to rehabilitation facilities in the United States demonstrated that admission FIM® scores were in a similar range with the median being between 69 and 81[59] depending on whether they received early or late admission to rehabilitation.

Since FIM® is used in both Canada and the US, we are able to examine how the health care systems may differ in terms of the care of people with LLA. Leung et al. conducted a study on 41 people with LLA consecutively admitted to an inpatient rehabilitation facility in Canada for pre-prosthetic or prosthetic rehabilitation. The average admission total FIM® score in this sample was 107 and motor subscore was 72, indicating near independence with basic activities of daily living and suggesting that this sample of Canadian patients were on average 26 points higher than samples previously reported in the United States[60]. Similarly, the average admission FIM® score for people with LLA admitted to inpatient rehabilitation facility in Canada between 2006 and 2012 (n = 2902) was 92±17 and the average discharge FIM® score was 107±15[25].

Although the 15-point score change is substantial, the FIM® scores are high suggesting that people who were admitted to a rehabilitation hospital were independent in many activities of daily living even before they were fit with a prosthesis. It is also possible that the higher scores reflect a screening process that may pre-select people with higher levels of function who are deemed more likely to succeed in prosthetic fitting[61]. Additionally, some authors suggest that FIM® has a ceiling effect for people with LLA and does not capture the full extent of tasks required to be independent with a prosthesis (e.g., donning the prosthesis, caring for the residual limb etc.)[60]. Higher admission FIM® scores, suggesting relative independence in activities of daily living, could also reflect a longer time from surgery to admission, which could afford more opportunity for patients to gain independence in the home. Some data in Canada supports that more people who undergo a LLA are discharged home from acute care rather than directly to an inpatient rehabilitation facility[61]. People with LLA are typically discharged from acute care, if possible, and only transferred directly to an inpatient rehabilitation facility if they require further rehabilitation to achieve a level of function that will allow them to return home. Regardless, these results suggest that people with LLA regain independence in basic activities of daily living as measured by the FIM® after rehabilitation but are not fully independent. Whether admission FIM® can be used to predict successful prosthetic outcomes is not known.

Few studies have reported whether the initial functional gains of rehabilitation are sustained after discharge. Arneja et al. completed a study in Manitoba, Canada that included a comparison of discharge and follow-up FIM® scores between people with major LLA due to peripheral arterial disease who had a comorbidity of end-stage renal disease and matched (for age, sex, and amputation etiology) people with major LLA without end-stage renal disease[62]. They found that the average discharge FIM® score (108 for the renal disease group, 112 for the control group) remained stable at follow-up (104 for the renal disease group, 111 for the control group), an average of 14 months after discharge[62]. Gains in function during the rehabilitation phase were maintained in this sample of people with LLA. However, it is important to note that neither group showed further improvement at follow-up. We might expect that the level of function would improve with time. This finding may indicate a need for interventions to improve function after inpatient rehabilitation or may be due a ceiling effect for the FIM® in this population.

1.2.2 Quality of Life after Lower Limb Amputation

The World Health Organization defines quality of life as *"an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment"*[63].

Defining and measuring quality of life has challenges in people with LLA. General measures of quality of life, such as the Medical Outcomes Study 36-Item Short-Form Health Survey, Euroqol 5-Dimension scale, and the World Health Organization Quality of Life scale are applicable to broad populations and provide normative values but can be less sensitive to change and fail to take into account issues specific to people with LLA. There are few LLA specific measures and those that exist are prone to the problems of condition-specific measures in that they do not allow for comparison to healthy populations, or other conditions, and may be so specific that they omit important domains. Only about 14% of outcome measures used in studies involving people with

LLA are condition specific[64]. The Prosthesis Evaluation Questionnaire measures prosthetic use and satisfaction as well as measures of social interaction and well-being but is specific to people currently using a prosthesis[65]. Similarly, the Trinity Amputation and Prosthesis Experiences Scales measures psychosocial adjustment, activity restrictions and prosthetic satisfaction, and is again, specific to people currently using a prosthesis[66].

Suckow et al. conducted a qualitative study to better understand determinants of quality of life in 26 people with LLA due to critical limb ischemia. They conducted focus groups in four regions of the United States with people who were three to 27 years post amputation. The participants identified that the most common determinants of quality of life were impaired mobility (e.g., difficulty with walking up ramps and stair climbing), pain, disease progression in the contralateral limb, and depression/frustration[67]. In this sample, 68% of people had a prosthesis, but 83% reported using a wheelchair more than half of the time. Despite frequently using a wheelchair, they unanimously agreed that using a prosthesis improved their quality of life[67]. Additionally, 27% of participants reported wishing they had received a LLA sooner, and 71% wished they had met with a prosthetist earlier and had more time in rehabilitation[67]. Pain issues were common; 81% reported having phantom pain or sensations but stated that this pain was preferred to the ischemic pain they experienced pre-operatively[67]. Mood disturbances were also prevalent: 54% of participants reported depression impacting quality of life, which they attributed to feeling isolated to their homes, lacking independence, and limited social support[67]. Sexual function and return to work were reported as determinants of quality of life by a smaller portion of participants; 65% were unemployed prior to their amputation[67]. This enlightening study detailed the specific concerns of people with LLA, information that is typically disregarded in more generic measures of quality of life. Of particular interest is this tradeoff between mobility and pain after LLA. In people with critical limb ischemia, LLA leads to greater mobility impairment but also reduced ischemic pain. As well, the suggestion by participants that they wished they had more time in rehabilitation indicates that rehabilitation programs in the United States may be shorter in duration than is required to meet the needs of people with LLA.

When we consider studies on quality of life there are conflicting results, which may be related to the issues outlined above with the difficulty in measuring quality of life in this population. Zidarov et al. conducted a study of quality of life amongst people with LLA (n = 19) undergoing inpatient rehabilitation in Montreal, Canada. They measured general quality of life using the Subjective Quality of Life Profile and amputation specific measures, including the Prosthesis Evaluation Questionnaire and Amputee Body Image Scale. These measures, taken at admission to inpatient rehabilitation (an average of 77 days after LLA), discharge and on 3-month follow-up, showed relatively good quality of life outcomes. The overall quality of life scores were higher than normative values for healthy populations at admission, discharge and follow-up[52]. Items related to independence, physical abilities, dependence on family and sexual satisfaction were rated lower than healthy populations[52]. Scores on the Prosthesis Evaluation Questionnaire were relatively high as well, with an average score of 7.4/10 on discharge and 7.0/10 at follow-up[52]. Body image scores were considered low, indicating absence of body image disturbances at all three time points. People with transfemoral amputation had significantly worse body image scores than people with transtibial amputations. The authors explained that these positive outcomes could be related to the short timeframe of the study (three months) and that having a LLA may have relieved some physical and psychological suffering in this sample[52].

In a study extending beyond the initial rehabilitation period, Fortington et al. examined quality of life in a sample of 82 people with LLA in the Netherlands in the first 18 months after their first major LLA due to vascular disease, diabetes, or infection. They measured general quality of life using the Research and Development Corporation Measure of Quality of Life, which measures quality of life across seven domains (physical functioning, social functioning, vitality, pain, perceived change in health, mental health, and general health)[68]. They measured this outcome at the time of LLA, six months, and 18 months after surgery and found a significant increase in quality of life from each time point to the next in five of the seven domains (all except general health and mental health, which remained unchanged), with most of the improvement in the first six months[68]. While quality of life increased over time for people with LLA, it remained lower than that of healthy populations. At 18 months after surgery, participants had significantly worse quality of life in the physical functioning, social functioning, and pain domains but no significant difference in mental health, vitality, and general health domain, and significantly better scores in perceived change in health compared to healthy populations[68]. Physical function was significantly affected by age and level of amputation, with older people and those with above-knee amputation having lower physical function scores[68]. Ability to walk, regardless of distance, significantly improved social functioning[68].

A systematic review of quality of life that included 26 studies reported that quality of life was generally poor among people with LLA compared to the general population or to controls [69]. Despite heterogeneity with respect to populations included (in terms of etiology of LLA and time since surgery), methodology and outcome measures, they concluded that impaired physical functioning adversely affected quality of life, particularly in people with LLA due to vascular disease[69]. Other variables noted to negatively affect quality of life were older age, lower education level, gender (quality of life was lower in females), presence of phantom and residual limb pain, depression, lower level of independence in activities of daily living, sexual dissatisfaction, and lower social acceptance and functioning[69].

A more recent systematic review focused on only people with LLA due to vascular disease to determine factors affecting quality of life specific to this population. After analyzing the 12 included studies, they concluded that quality of life in this population is affected the most by ability to walk with a prosthesis[6]. Factors noted to negatively affect quality of life were age greater than 65 years, being male, having diabetes, and less family support. Quality of life was generally higher in people with transtibial amputation compared to transfemoral amputation and in people who could live in their own home rather than in a care home, as long as they were able to leave their home[6]. Based on these findings, the authors advocated that rehabilitation should focus on modifiable factors, particularly mobility[6].

1.2.3 Pain and its impact on living with Lower Limb Amputation

As with any surgical procedure, it is expected that people having a LLA will experience pain in the post-operative period. People with LLA typically experience three types of pain phenomena: (1) residual limb pain, defined as pain at the site of the amputation or in some part of the remaining part of the amputated limb; (2) phantom limb sensations, defined as any sensation in the absent part of the limb except pain; (3) phantom limb pain, painful sensations referred to the absent part of the limb[70]. These sensations can persist for varying degrees of time and at varying intensities. Gallagher et al. identified that 48% of a sample of people with LLA in Ireland had residual limb pain and 69% experienced phantom limb pain[71]. Though fewer people reported residual limb pain, residual limb pain was reported to be more intense, experienced for longer durations and had a greater impact on daily functioning[71]. Ehde et al. had a similar finding in a survey of 255 community dwelling people with LLA, who were all greater than six months post-surgery. They reported that 79% of respondents experienced phantom sensations (described as tingling, itching, feeling missing feet or toes), 72% experienced phantom limb pain (described as sharp, tingling, shooting, stabbing, throbbing, and aching), and 72% experienced residual limb pain (described as aching, sharp, throbbing, hot-burning, tingling, and shocking)[72]. Pain was also experienced in other locations with back pain being the most common[72]. High rates of pain were also reported by ambulatory people with LLA, with 56% experienced residual limb pain and 48% experienced back pain[73]. Fortunately, evidence shows that most residual limb pain can be attributed to the fit of the prosthesis and can be improved with prosthetic adjustments; phantom pain usually is greatest post-surgery and diminishes over time[74]. A staged approach to pain management is advocated, that relies on gaining an understanding of the potential causes of the pain, then starting with the least invasive approaches before moving to more invasive approaches or the use of narcotics[74]. Still, pain can be a persistent issue after LLA that requires the attention of rehabilitation professionals to minimize its impact on people with LLA.

1.2.4 Body image disturbances after Lower Limb Amputation

Body image is described as a mental perception that a person creates about themselves, which is influenced by internal perceptions, social interactions, and external surroundings[75]. It is easy to imagine that a person with LLA will have an altered body image given that that have lost a portion of a limb. Even though Zidarov et al. found that body image disturbance was fairly low for people with LLA up to three months after surgery, they did note that body image disturbance was higher for people with a transfemoral amputation. The greater degree of body image disturbance in people with a transfemoral amputation could be related to the fact that this higher level of amputation results in greater tissue loss, including the loss of the knee joint, which may be more observable to others. Holzer et al. assessed body image using the Multidimensional Body-Self Relations Questionnaire in a sample of people with major LLA admitted to an inpatient rehabilitation facility in Germany within six months of their surgery. In this sample, people with LLA had greater body image disturbance compared to controls[76]. Woods et al. studied the relationship between sexual functioning, body image, mood, and anxiety in a sample of 49 people with LLA in Ireland. About one-third of people with LLA had body image disturbances, which negatively affected sexual functioning, primarily due to body exposure self-consciousness[77]. A recent study of people (n = 19) with LLA was completed at an inpatient rehabilitation facility in London, Canada. This study assessed body image at discharge from inpatient rehabilitation and at four-month follow-up. Scores indicated moderate body image disturbance and scores were not significantly different at the two time points[75]. More research is needed to fully explore the effect of LLA on body image, particularly in the long-term.

1.2.5 Depression in people with Lower Limb Amputation

Depression in people with LLA is sometimes included in assessments of quality of life but has been studied on its own as well. Prevalence of depression in people with LLA is higher than in general populations[78]. A review of levels of depression in people with traumatic amputation of the upper or lower limb found prevalence of 21% to 63% [78]. The authors noted heterogeneity in the populations studied and the tools to measure depression, making comparisons difficult. Evidence from another review of literature indicates that depression amongst people with limb amputation was higher than the general population in the first two years after amputation but subsequently became comparable to the general population[79]. Depressive symptoms are a serious concern. Turner et al. showed that in a sample of people with LLA due to diabetes or vascular disease (n = 239), 16% had suicidal ideations one year after amputation[80]. Suicidal ideations were associated with lower levels of mobility and dependence in activities of daily living. Whether mood disorders impact the success of prosthetic fitting is not known. More longitudinal studies, rather than cross-sectional studies, are required to identify the prevalence of psychosocial outcomes and whether they predict outcomes over time[81].

1.2.6 Mortality related to Lower Limb Amputation

The most serious concern with any medical procedure is potential loss of life. Mortality associated with LLA can be quite high. The 30-day mortality rate has been reported between 9%[82] and 10%[83] in the United States. A study of people with LLA (n = 122) in the United Kingdom reported a 30-day mortality of 15% and even higher at 29% for overall in-hospital mortality[84]. Most in-hospital deaths of patients were due to cardiovascular complications (45%) and pneumonia (18%), with another 29% from unknown causes[84]. The rate of hospital mortality in Canada (9%)[61] was lower than the rate for the United Kingdom and similar to the rates for United States noted above. A study of 5342 people who had a LLA between 2006 and 2009, which was included in the Canadian Institute for Health Information database, found having surgery in the province of Newfoundland and Labrador was associated with higher rates of in-hospital mortality (Odds Ratio 1.7) compared to having surgery in Ontario; the authors were unable to explain this finding based on the available dataset[61]. Further study is needed to uncover the determinants of in-hospital mortality after LLA and develop mitigating strategies.

People who survive a hospital admission for LLA are still at high risk of death in the years to follow. According to Dillingham et al., one-year mortality was higher for people having a transfemoral amputation (50%) than a transtibial amputation (36%)[85], but both mortality rates were quite high. In another study in the United States, one-year mortality was 30% and mortality was higher for people with diabetes[82]. A recent systematic review and meta-analysis of mortality rates for people with LLA due to diabetes and/or peripheral vascular reported rates at 48% for one year, 61% for two years, 71% for three years, and 62% for five years[86]. In this analysis, co-morbid factors associated with a greater than two-fold increase in risk of mortality included coronary artery disease, cerebrovascular disease, renal dysfunction, dementia, and non-ambulatory status[86]. Another study attempted to develop a model for predicting one-year mortality after LLA (includes minor and major amputations). The variables retained in this predictive model were higher level of amputation, older age, African American race, higher body mass index, lower functional status, receiving dialysis, having congestive heart failure, higher blood urea nitrogen level, elevated white blood cell counts, and low platelet counts[87]. It is not known whether prosthetic rehabilitation can affect long-term mortality for people with LLA.

1.2.7 Revisions after amputation surgery

Many people with LLA require more than one surgery, especially those with amputation due to diabetes and/or peripheral arterial disease[13, 85]. The surgical approach to LLA involves preserving as much of the limb as possible. However, amputations often require revisions at the same level or revision to a more proximal level as the underlying disease process progresses. In fact, studies suggest that more proximal amputations (higher on the leg) are less likely to require revision and may be more likely to heal[13]. A study in the United States of 3565 Medicare records for people with LLA showed that 20% of toe amputations progressed to a transtibial amputation or higher within one year[85]. As well, 9% of transtibial amputations progressed to a higher level of amputation[85]. In this sample of people with LLA, 74% had a readmission for amputation related reasons within one year[85]. Aulivola et al. showed that 18% of below-knee amputations had to be revised, 9% to an above-knee amputation[82]. In a United Kingdom sample of people with LLA (n = 122), 9% of LLAs required revision at the same level and 13% progressed to a higher level[84]. In this study, 22% of people having a transtibial amputation eventually underwent a transfemoral amputation[84]. LLA does not only affect a single limb. Dillingham et al. observed that 9% of people having a LLA had an amputation on the contralateral limb within one year[85]. How the condition of the residual limb or the integrity of the other potentially intact limb impacts LLA outcomes and length of stay has not been fully elucidated. The study presented in this thesis examines these important factors.

1.2.8 Financial Burden for people with Lower Limb amputation

The financial burden associated with LLA can be direct or indirect. There are direct medical costs for people with LLA. If the costs associated with their prosthesis or the cost of the procedure itself and associated hospitalization are not fully covered by private or government insurance plans, patients are required to pay out of pocket. Indirect financial costs to people with

LLA may include lost income. As many as 42% of people with a traumatic LLA are still unable to return to work seven years after the initial injury[88]. The high costs of the procedure, hospitalizations and prosthesis, combined with lost income, can prohibit people with LLA from accessing the healthcare they require to avoid the negative sequelae often associated with LLA.

1.2.9 Healthcare costs associated with Lower Limb Amputation

Most studies to date typically focus on the direct medical costs of LLA to the healthcare system. The Amputee Coalition of America now estimates total costs (direct and indirect) associated with LLA in the United States to be more than $10 billion per year[36]. A United States study examined costs associated with veterans with diabetes undergoing LLA and estimated the per person cost at $71,067 in 2012 USD per year; based on inflation rates, this equates to about $93,872 USD in 2020[89]. These costs did not appear to include the cost of a prosthesis. Amongst the US veteran population, the 2005 USD cost of an above-knee prosthesis was estimated to be between $9360 ($12,262 in 2020 USD) for a community ambulator and $25,196 ($33,281 in 2020 USD) for someone engaging in high-impact sports and as high as $45,563 ($60,183 in 2020 USD) for a prosthesis with a microprocessor knee[90]. The same study estimated the five-year, ten-year, 20-year and lifetime prosthetic costs for veterans of Operation Iraqi Freedom/Operation Enduring Freedom with unilateral LLA at $228,665 ($302,042 in 2020 USD), $473,951 ($625,564 in 2020 USD), $855,907 ($1,130,564 in 2020 USD), and $1,463,624 ($1,933,295 in 2020 USD), respectively[90]. These costs are very high and may be a barrier to accessing appropriate prostheses for patients without adequate financial resources or access to third party payers.

There are no studies from Canada that estimate the direct or indirect costs associated with LLA[2]. However, there are published reports on hospital resource utilization for people with LLA in Canada in terms of length of stay, and we know that total inpatient costs and length of stay are highly correlated[91]. A study of acute care length of stay in Canada based on Canadian Institute for Health Information data from 2006 to 2009 (n = 5342) found the median length of stay varied from 16 to 21 days, depending on the type of surgeon (orthopedic, general or vascular) completing the LLA[61]. When they examined variables associated with a prolonged hospital length of stay, having surgery in the province of Newfoundland and Labrador was an independent predictor of a longer length of stay (Odds Ratio 3.5, 95% Confidence Interval 2-6, $p < 0.001$)[61]. A study on rehabilitation trends for people with LLA in Canada found that 36% of people undergoing LLA between 2006 and 2009 were admitted to an inpatient rehabilitation facility and had a median length of stay of 36 days (range 1-560 days)[9]. Imam found the mean acute length of stay for people undergoing major LLA in Canada between 2006 and 2012 (n = 16,114) to be 29 days and the mean inpatient rehabilitation (n = 2902) length of stay to be 37 days[25]. They reported that only 18% of people with major LLA received inpatient rehabilitation[25]. It was interesting to note that the mean rehabilitation length of stay was longest in Newfoundland and Labrador at 65 days[25]. These findings demonstrated the high healthcare costs of rehabilitation associated with people with LLA, particularly in the province of Newfoundland and Labrador.

1.3 Rehabilitation of people with Lower Limb Amputation

1.3.1 Delivery of Rehabilitation Services for people with Lower Limb Amputation

It is clear that LLA, no matter the cause, has profound effects on people. One of the most important elements of care for people with LLA is rehabilitation. A clinical practice guideline for the rehabilitation of people with LLA was developed by the US Departments of Veteran's Affairs and Defense. They identified that the overall goal of rehabilitation was to optimize health status, function, independence, and quality of life[5]. This guideline outlined five stages of rehabilitation for people with LLA, starting with the pre-operative phase and progressing through the immediate post-operative, pre-prosthetic rehabilitation, prosthetic training, and rehabilitation and prosthesis follow-up stages (see Figure 1.2 below).

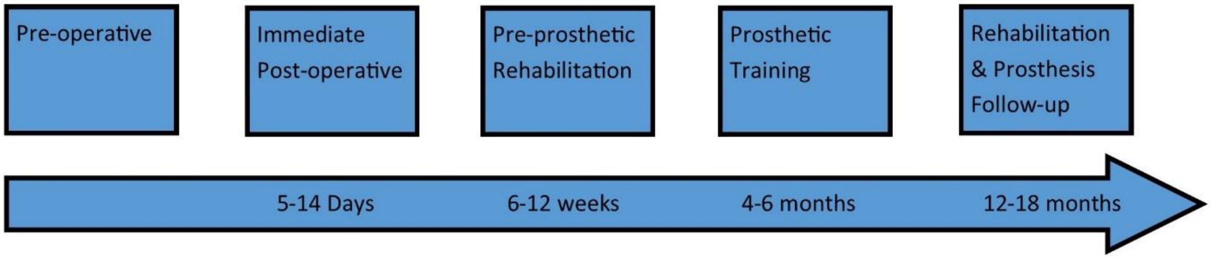

Figure 1. 2 Stages of Rehabilitation

Timeline presented above represents time since surgery. This is an original figure created for this thesis, based on stages of rehabilitation described in the text of the US Department of Veteran's Affairs and Defense clinical practice guideline[5].

Across these five stages (Figure 1.2) there were several core elements of rehabilitation for people with LLA described, including the delivery of service by an interdisciplinary team containing physicians, physical therapists, occupational therapists, prosthetists, social workers, nurses, mental health professionals, nutrition, and recreational therapists[5]. In addition, several rehabilitation interventions were described as important elements of care as people move through the phases. These interventions included pain management, medical co-morbidity management, behavioral health, residual limb management, education, prosthetic fitting, improving joint range of motion, muscle strengthening, cardiovascular exercise, balance training, mobility practice, functional training for activities of daily living and community integration[5]. The British Association of Chartered Physiotherapists in Amputee Rehabilitation also recommends that care be delivered by multidisciplinary teams and emphasizes that interventions for people with LLA should include compression therapy for the residual limb, mobility, early walking aids (devices to simulate prosthetic walking), falls management, wheelchair and seating prescription, prevention/reduction of joint contractures, exercise programs, and management of phantom sensation and pain[92].

While the key elements of rehabilitation for people with LLA are well described, the way in which they are optimally delivered remains less conclusive. In Canada, there are widely varying models for the delivery of rehabilitation to people with LLA[25]. Some provinces provide rehabilitation services for people with LLA on an inpatient basis, delivered by interdisciplinary teams, while others provide services in less structured ways that may include admission to less specialized inpatient programs or services delivered primarily on an outpatient basis[93]. As well, some prosthetic clinicians are employed within publicly funded rehabilitation facilities while others are private providers who provide consultative services. Inpatient rehabilitation is a resource intensive process that requires a commitment from the rehabilitation facility and the person with LLA. Outpatient services are less costly for healthcare systems but may not involve specialized interdisciplinary teams and may not be accessible to all people with LLA. A review of admissions to inpatient rehabilitation facilities in Canada for people with major LLA, showed that the percentages of people admitted were generally low at 18% and varied from province to province[25]. British Columbia reported rates as low as 5%, whereas in Nova Scotia, 29% of patients received inpatient rehabilitation[25]. Kayssi et al. reported that as many as 36% of people with LLA received inpatient rehabilitation; however, this sample only included patients admitted directly from an acute care hospital and had a smaller sample size[9].

A survey of 59 prosthetic rehabilitation facilities across Canada showed that 66.1% provided both inpatient and outpatient prosthetic rehabilitation services; 16.9% provided only inpatient rehabilitation and 17% provided only outpatient prosthetic rehabilitation[94]. Most provided 4-6 weeks of rehabilitation for people with a transtibial amputation, whether the service was delivered on an inpatient or outpatient basis[94]. Facilities reported that 77% of people with LLA receiving inpatient rehabilitation were fit with a prosthesis and 91% of people with LLA receiving outpatient rehabilitation were fit with a prosthesis[94]. These high rates of prosthetic fitting likely reflect screening for prosthetic candidacy, in that the people selected for these services are those deemed to have a reasonable likelihood of success.

Optimal timing of rehabilitation is also a source of debate. Stineman et al. investigated the difference in outcomes for people with major LLA (n = 2763) who were either admitted to inpatient rehabilitation in the United States after their acute post-surgical stay, without going home, or those who did not receive inpatient rehabilitation in the first year post amputation[95]. People who did not receive inpatient rehabilitation were more commonly living in extended care facilities prior to surgery and had more co-morbidities. Adjusting for these potential confounders, the study showed that people with LLA who received early inpatient rehabilitation had significantly greater one-year survival and were significantly more likely to be discharged home[95]. After establishing the benefits of early rehabilitation compared to no rehabilitation, Stineman et al. studied the effects of early (directly from post-surgical hospital) rehabilitation compared to late (after being discharged home from post-surgical hospital) rehabilitation on functional recovery. Comparable gains in FIM® scores were achieved for participants with either early or late initiation of rehabilitation[59]. This challenges previously published work that suggests earlier initiation of inpatient rehabilitation after LLA leads to improved outcomes[40].

In Newfoundland and Labrador, rehabilitation for people with LLA is delivered on an inpatient or outpatient basis depending on geographic factors. If the person resides in close enough proximity to the provincial rehabilitation service at the Dr. L.A. Miller Centre, or can arrange temporary accommodations, they receive rehabilitation on an outpatient basis. If people are unable to commute for rehabilitation, they may be admitted to inpatient rehabilitation services for their initial prosthetic fitting. They may also be admitted for inpatient rehabilitation if the acute care hospital team determines that the patient could benefit from a period of inpatient rehabilitation to improve basic mobility and function prior to discharge to the community.

Once rehabilitation is initiated, fabrication and fitting of the prosthetic limb begins. Fabrication of a prosthetic limb is a labour intensive process. Prosthetic fitting involves taking a plaster cast or 3D scan of the person's residual limb to fabricate a plastic temporary socket. The temporary socket is custom fit to the person's residual leg and modified as necessary to obtain comfort and stability[4]. Prosthetic components, such as the foot, are selected based on the activity level of the person, with consideration of costs as well[4]. If the amputation is above the level of the knee there must be selection of a prosthetic knee. Some of the choices include single-axis hinged, polycentric, pneumatic, hydraulic and microprocessor which increase in technological complexity and cost from the basic mechanical hinged knee to the microprocessor-controlled knee[96]. Selection is again, based on the activity level of the person, with consideration given to cost. All components are attached to the socket and optimally aligned by the Prosthetist. Once the person can begin wearing the prosthesis, they work with the interdisciplinary team to learn how to walk and function with it, progressing from static standing balance to taking steps and advancing to higher level walking and dynamic balance practice[11, 97]. Changes to the temporary socket and alignment may be necessary as the person improves and their residual limb volume (swelling) decreases with use of the prosthesis[4]. Once these changes stabilize, a final laminated socket, that provides greater durability, is fabricated and fit. There may be ongoing maintenance and adjustments made for months after the next fitting, though this decreases in frequency over time. The process from the initial cast to a final functioning prosthetic limb takes four-six weeks[5]. However, the need for periodic adjustments and maintenance remains a life-long commitment.

1.3.2 Predicting prosthetic fitting for people with Lower Limb Amputation

Rehabilitation for people with LLA does not necessarily involve receiving a prosthetic limb. Identifying people who are able to complete rehabilitation and be successfully fit with a prosthesis involves consideration of a multitude of variables. There have been many studies that have assessed either retrospectively or prospectively which variables were associated with successful outcomes in people with LLA being fit with a prosthesis. Two systematic reviews have been performed summarizing the findings of such studies. The first, by Sansam et al.[40] reviewed 57 retrospective and prospective cohort studies that aimed to predict walking ability in people with LLA. Walking ability did not have a consistent definition and included a variety of objective measurements of walking with a prosthesis (measures of distance, speed, activity levels), as well as subjective measures of ambulatory ability and functional outcomes such as the Barthel Index and FIM®[40]. The review included studies in any language that were published up to the year 2007, with 38 of 57 published prior to the year 2000; many of these studies may no longer be relevant in the current healthcare environment. As well, only 19 were of high methodologically quality, with 25 being medium quality and 13 poor quality. Most were retrospective in nature gathering data from health records or patient recall and included people already using a prosthesis[40]. Many only reported simple tests of association rather than multivariate regression analysis. The settings for the included studies were not described. Due to the high degree of variation in populations, design, analysis, and outcomes in these studies a meta-analysis was not possible so only qualitative review was provided. Several variables were identified as having the strongest evidence for predicting walking ability, including older age, requiring a higher level of amputation, and cognitive impairment. Even though older age was identified as an independent predictor of walking ability in several studies, authors cautioned that age should not be considered the only factor in determining suitability for fitting with a prosthesis since people older than 90 have been able to achieve independent ambulation with a prosthesis[40]. Higher level of amputation was consistently associated with less walking ability in terms of distance, speed, and activity level. However, in studies using the FIM® as an outcome, level of amputation was not a significant predictor[40]. Again, this does not necessarily mean that those with a higher level of amputation are unsuitable for prosthetic fitting. Decreased cognitive ability was significantly associated with less walking ability in several studies. Better scores on a memory/learning ability test was the only independent predictor of ability to don (put on the prosthesis), doff (remove the prosthesis), and walk with a prosthesis in one study[40].

Delays in treatment, deconditioning and characteristics of the residual limb problems such as pain, shorter length, contractures, and poor wound healing were associated with less walking ability[40]. Two studies showed that better pre-rehabilitation cardiovascular fitness was significantly associated with greater ability to walk at least 100 metres after rehabilitation[40]. Ability to stand on one leg, independence in activities of daily living, and higher pre-operative mobility levels were associated with better walking ability. However, motor function on admission to an inpatient rehabilitation facility, measured by the FIM® motor subscore or the Rivermead Mobility Index, was not associated with walking ability[40]. A shorter time from surgery to rehabilitation was associated with better walking ability in several studies; however, those with longer intervals between surgery and rehabilitation may have had other variables influencing the outcome such as delayed wound healing or infections[40]. The authors concluded that sex was not likely a significant predictor of walking ability after LLA since most studies found no differences between males and females and those reporting differences had conflicting results.[40]

An updated systematic review was completed by Kahle et al.[10] that followed the original search strategy used by Sansam et al. but included articles published in English from 2007 to 2015, excluding manuscripts from developing nations. This review included an additional 21 articles of medium (six articles) to high (15 articles) methodological quality, which largely confirmed the findings of the previous review[10]. The setting for these studies varied, but most were completed in rehabilitation centres and major medical centres. Based on the strength of the combined reviews, Kahle et al. added vascular etiology and multiple comorbidities as moderate to strong predictors of poor prosthetic walking ability[10]. Additional predictors of poor prosthetic walking ability with more limited evidence included lower levels of motivation, lower levels of social support, smoking, and phantom limb pain[10]. With respect to age, the authors observed that there is disagreement regarding the extent to which age should be considered as a factor in determining successful outcomes. They argued that studies suggesting that older age plays a role in walking ability and functional outcomes should not be used to exclude someone from consideration for prosthetic rehabilitation[10]. Similarly, while higher levels of amputation likely lead to lower levels of walking ability, the evidence did not suggest that people with higher levels of amputation were not reasonable candidates for prosthetic rehabilitation[10].

In a study published since the review by Kahle et al., Davie-Smith et al. assessed the impact of diabetes, level of amputation, and sex on prosthetic fitting rates in a sample of people (n = 1735) with non-traumatic transtibial or transfemoral amputation in Scotland[98]. They retrospectively assessed data on these people from time of surgery to completion of rehabilitation and classified them as either fit with a prosthesis (i.e., discharged from rehabilitation using a prosthetic limb), not fit with a prosthesis (i.e., did not start prosthetic fitting), or abandoned prosthetic fitting (i.e., started prosthetic fitting but did not complete). Overall, only 38% were fit with a prosthesis, with significantly more people with transtibial amputation being fit with a prosthesis compared to people with transfemoral amputation (72% versus 16%)[98]. However, only 3% of people who initiated prosthetic fitting abandoned the process before being successfully fit with a prosthesis; this rate was not significantly different between people with transtibial and transfemoral amputations[98]. In their binary logistic regression analysis of those fit with a prosthesis or not (including those who did not start and those who abandoned), being male, younger and transtibial level of amputation significantly predicted being fit with a prosthesis[98]. Having diabetes was a negative predictor of prosthetic fitting at the transfemoral level but not at the transtibial level[98]. This study reinforces the impact of age on prosthetic fitting and brings into question previous findings that sex does not impact prosthetic fitting success. The authors were unable to explain why females were less likely to be fit with a prosthesis and suggested that this warrants further investigation[98]. Interestingly, while females and people with transfemoral amputation were less likely to be fit with a prosthesis, they were no more likely to abandon prosthetic fitting once given an opportunity to begin the process[98]. There was a distinct difference between who was likely to be considered a suitable prosthetic candidate and who could complete prosthetic fitting rehabilitation once initiated.

With a plethora of frequently conflicting predictors, predictive assessment tools would help guide the interdisciplinary team in deciding whether a person with LLA would be a good prosthetic candidate or not. However, few studies have attempted to develop tools from this body of research. Gailey et al.[99] developed a tool called the Amputee Mobility Predictor. This tool was designed to be able to predict an amputee's ability to walk with a prosthesis. It included 21 tasks that primarily assessed balance, strength, and functional mobility and was designed to be used to assess amputees with or without a prosthesis. The weakness of the Amputee Mobility Predictor was that predictive ability was examined by scoring the patient with and without their prosthesis in a single session. Although the tool was a significant predictor of ability to ambulate with a prosthesis as measured by the six-minute walk test, the prediction was based on the current state rather than predicting future ability to ambulate. This study included a convenience sample of 191 lower limb amputees who were already fit with a prosthesis and only seven were not using their prosthesis at the time [99]. The study findings have limited value in predicting future outcomes in people with LLA yet to be fit with a prosthesis; arguably, the most important utility of a predictive tool. As well, because the tool assessed physical capacity, it would have to be used in combination with other known variables (e.g., co-morbid conditions, cognitive impairment) to provide any level of prediction for prosthetic candidacy.

Condie et al.[100] developed a similar tool , called the Trans-femoral Fitting Predictor. Like the Amputee Mobility Predictor, the Trans-femoral Fitting Predictor only measured balance and mobility. This tool was able to discriminate between people who did and did not eventually receive a prosthesis, but no long-term follow-up was examined. Unfortunately, scores derived from the Trans-femoral Fitting Predictor were not generalizable to people having amputation at the transtibial level, which is the most common level of amputation in Canada[2].

Roffman et al.[101] used a questionnaire to gather potentially predictive variables from people with LLA (n = 135) in Australia. They then retrospectively identified variables associated with prosthetic use at four, eight, and 12 months after completion of rehabilitation to develop a model to predict prosthetic use or non-use at four, eight, and 12 months after rehabilitation. This model was validated using a new prospective sample (n = 66). Validity of the study was limited by recall bias since client questionnaires regarding prosthetic use were completed an average of 1.9 years and 1.3 years after discharge for the retrospective and prospective cohorts, respectively. Furthermore, the client questionnaire had not been validated. While this study did identify variables predictive of prosthetic use (amputation level, mobility aid at discharge, walking ability outdoors, presence of type II diabetes, 19 or more comorbidities), the predictive model was only useful for predicting long-term use of clients already fit with a prosthesis and does not necessarily assist with the initial decision regarding prosthetic candidacy.

Another recent study attempted to develop and validate a model for predicting mobility outcomes in people with LLA living in large urban areas of the United States. This study involved two prospective cohorts (n = 75 and n = 82) to develop and validate a predictive tool, which was assessed at baseline and on 12-month follow-up[102]. The study identified variables associated with achieving a basic (able to independently get up from a chair, walk in the house, walk outside on even ground, go upstairs with a handrail, go downstairs with a handrail, step up a sidewalk curb, step down a sidewalk curb) or advanced (able to pick up an object from the floor when you are standing up with your prosthesis, get up from the floor, walk outside on uneven ground, go down a few steps without a handrail, go up a few steps without a handrail, walk outside in inclement weather, walk while carrying an object) level of mobility based on the Locomotor Capabilities Index[102]. The significant variables were then used to develop a model which would provide a percent probability of achieving a basic or advanced mobility level. The predictors of achieving a basic level of mobility were: (1) amputation level (odds transmetatarsal > below-knee > above-knee); (2) Decreasing age; (3) Body Mass Index (Increasing up to 30 kg/m2, decreasing thereafter); (4) Race (white versus not); (5) Being married or partnered (versus single); (6) High school diploma or greater; (7) Not diabetic; (8) Not currently on dialysis; (9) No presence of Chronic Obstructive Pulmonary Disease; (10) No history of treatment for anxiety or depression; (11) Good to very good self-rated health[102]. Predictors of achieving an advanced level of mobility were: (1) Amputation level (odds transmetatarsal > below-knee > above-knee); (2) Decreasing age; (3) Decreasing Body Mass Index; (4) Race (white versus not); (5) Being married or partnered (versus single); (6) Not currently on dialysis; (7) No history of treatment for anxiety or depression; (8) Good to very good self-rated health[102]. The sample included a large proportion of people with transmetatarsal amputations (27%)[102], reducing its generalizability to samples of people with transtibial and transfemoral amputations. As well, the sample only included amputations due to vascular disease, so the study results would not be generalizable to a broader population of people with LLA.

Bowery et al. developed a tool called the Blatchford Allman Russell tool to predict ability to walk with a prosthesis based on variables available pre-operatively. They suggested that such a tool would be useful to provide a more accurate prognosis regarding ability to use a prosthesis after surgery when surgeons are obtaining informed consent from people preparing to undergo LLA. They proposed that this tool would help avoid unrealistic expectations from patients based on the portrayal of amputee athletes in the media, and ensure that surgeons did not provide overly optimistic prognoses[103]. The study included development of the tool based on a retrospective analysis of 338 records of people undergoing major LLA in the United Kingdom. Univariate and multinomial analyses of potential predictor variables were completed to determine which variables should be included and additional variables (body mass index and pre-amputation mobility) deemed important by the clinical and research team were added. Variables included in the tool were sex, age, body mass index, mobility before amputation, co-morbidities, cause of amputation, level of amputation, and cognitive capacity[103]. Variables were weighted based on the results of univariate and multinomial analyses. The tool was then validated with a sample of 199 people with major LLA and was found to significantly predict functional outcome[103]. Overall success rates were very low in the creation (11% for transfemoral and 41% for transtibial) and validation datasets (36% for transfemoral and 69% for transtibial)[103], possibly because they included patient deaths as unsuccessful functional outcomes. Patients may die for many reasons unrelated to their amputation and determining prosthetic candidacy would likely be most relevant for those patients being actively considered for prosthetic rehabilitation. By basing their prediction only on pre-operative values, the authors acknowledged that they failed to consider important post-operative factors such as residual limb healing, joint contractures, pain, and psychosocial factors that could affect functional outcomes[103]. As well, it may be difficult to use the tool as intended pre-operatively due to the urgent nature of many LLA surgeries[103].

1.3.3 Limitations in the literature regarding Prediction of Prosthetic Candidacy

There are several limitations in the current body of literature regarding predicting which people with LLA should be considered candidates for prosthetic rehabilitation. Firstly, there is not a large body of high quality research available and results cannot be easily combined for analysis due to variation in participant characteristics and outcomes used[10]. As well, very few studies of rehabilitation for people with LLA have been completed in Canada[9].

For the factors that have been identified to predict successful outcomes, most were based on a small number of studies[10, 40]. As well, most studies were retrospective or cross-sectional in nature and subject to issues with variable availability and recall bias[10, 40]. Studies that have attempted to develop prediction tools often developed the tools based on findings at their own facility, rather than considered the entire body of literature, or limited their generalizability to a very specific population. For example, they may limit the tool to a single level of amputation as with the Trans-femoral Fitting Predictor or only select variables available pre-operatively as with the Blatchford Allman Russell tool. Additionally, studies often did not make a distinction between whether they were assessing suitability for prosthetic fitting selection, ability to complete prosthetic fitting or ability to become highly functional long-term prosthetic users.

One of the biggest limitations was the variation in outcomes used and the definition of 'success'. Outcomes often included specific measures of walking ability such as ability to walk 100 metres, the Timed Up and Go test , six-minute walk test, or other measures of walking ability and prosthetic use[10, 40]. By using these measures to define success, we lose the focus on the individual and what the person with LLA considers a successful outcome. Norvell et al. argued for using a dichotomous outcome for mobility success based on whether the person with LLA was able to achieve a level of mobility the same or greater than their pre-morbid level of function[104]. They also assessed mobility success based on patient reports of satisfaction with their level of mobility[104]. The problem with these measures of success was the high chance of failure since people undergoing a major LLA were unlikely to return to a level of mobility the same as prior to the development of their limb issues that lead to LLA. Using return to pre-morbid mobility as the measure, the mobility success rate was only 37% and patient satisfaction with their level of mobility was only 57%[104]. In the inpatient rehabilitation setting, it seems more reasonable to define success based on whether the patient can achieve the goal of the admission; that is, being fit with a prosthesis and being able to use it at discharge. If we wish to measure long-term success, the specific level of mobility and function in terms of walking distance, speed, and gait aid use will vary so it may be more valuable to measure success in terms of patient-reported outcomes such as quality of life.

1.3.4 Predicting inpatient rehabilitation length of stay

All of the tools described above focus on the prediction of prosthetic fitting and functional outcomes, but when inpatient rehabilitation is being contemplated, it is also important to consider how long the length of stay would be for a person with LLA. This is helpful for the healthcare teams to plan admissions, manage patient flow, and assign adequate resources to inpatient services. It is equally important for people with LLA to plan how long they will be in hospital and understand the time commitment required to successfully complete inpatient prosthetic rehabilitation.

Several studies have sought to understand factors associated with longer inpatient rehabilitation lengths of stay. A retrospective study of rehabilitation outcomes in Australia across a 15-year period (n = 531) found that the median length of stay was 39 days. Factors associated with a longer length of stay included older age, having transfemoral amputation, and experiencing complications such as wound breakdown[105]. A prospective cohort study of all people with LLA admitted to an inpatient rehabilitation facility in Israel (n = 117) found that patients deemed suitable for prosthetic fitting had a significantly longer length of stay (96 days vs 58 days) than those who received fitting and training for a wheelchair [58]. A study of United States veterans with a new major LLA admitted to inpatient rehabilitation facilities (n = 1536) identified factors associated with longer lengths of stay in these facilities. The average length of stay was 31 days[91]. Being older, unmarried, and male were demographic factors associated with longer lengths of stay[91]. Medical factors associated with longer length of stay included: having LLA due to sepsis; having previous amputation complications; having comorbidities such as congestive heart failure, arrhythmias, fluid and electrolyte imbalances, weight loss, anemia, and paralysis[91]. People admitted from home rather than from another hospital had 30% shorter length of stay, while those admitted to larger and more specialized rehabilitation facilities had longer length of stay[91]. Another study in the United States analyzing records from 901 inpatient rehabilitation facilities (n = 26,501) also found being older, unmarried, and male as being predictive of longer lengths of stay[106]. In this sample, being a non-white race, having a bilateral amputation, having diabetes, having multiple co-morbidities, and having a lower admission motor FIM® were also predictive of longer rehabilitation length of stay[106]. It is unclear why being male has been associated with longer length of stay in the United States. In the Davie-Smith et al. study from Scotland described above, the length of stay for females being fit with a prosthesis was approximately three weeks longer than the length of stay for males completing prosthetic fitting[98]. There does seem to be a mix of sociodemographic and physical/medical factors at play. As well, it seems that when the goal of rehabilitation involves prosthetic fitting rather that improving function for someone primarily using a wheelchair, the length of stay may be longer.

There is limited published data available describing the length of stay of people with LLA undergoing inpatient rehabilitation in Canada. A study of rehabilitation trends after LLA, evaluating data reported to the Canadian Institute for Health Information's Discharge Abstract Database (n = 5342), identified several predictors of longer rehabilitation length of stay, including older age, history of ischemic heart disease or congestive heart failure, amputation by an orthopedic surgeon (compared to a vascular surgeon), acute hospital stay longer than seven days, and rehabilitation in the province of Manitoba[9]. While having surgery in Newfoundland and Labrador did not reach significance ($p = 0.06$) in the predictive model, it was next highest province to Manitoba in terms of long length of stay. Another study in Manitoba, Canada, determined that end-stage renal disease was associated with prolonged rehabilitation length of stay and decreased functional outcomes in patients with LLA[62]. More studies are needed to identify the reasons for prolonged rehabilitation length of stay in the context of the Canadian healthcare system.

The few available studies of people with LLA using rehabilitation length of stay as an outcome contribute to our understanding of variables that may predict length of stay for people admitted to an inpatient rehabilitation facility. Only one study to date has attempted to develop a tool for predicting length of stay in people being considered for admission to an inpatient rehabilitation facility. The Lower Limb Amputee Measurement Scale (LLAMS) is a tool that was developed to predict rehabilitation length of stay specifically for people with LLA. This tool includes 31 items, framed as yes/no questions (Appendix 3), in six subsections (Medical, Cognitive, Social, Physical, Activities of Daily Living, and Other), that the creators expected, from review of patients admitted to their facility, to be key indicators for increased length of stay[107]. Cheifetz et al. completed a study of 147 people with LLA undergoing rehabilitation at the Chedoke Campus, Hamilton Health Sciences to validate the LLAMS. This study showed a moderately strong positive correlation ($r = 0.465$, $p < 0.01$) between the LLAMS score and actual length of stay[107]. The analysis did not adjust for potential confounders such as age, sex, or level of amputation. As well, the researchers tested the ability of the LLAMS to differentiate between patients requiring a six- or seven-week rehabilitation program; it was not applied in a setting with a more open-ended program. No subanalysis was completed to determine if all 31 items in the LLAMS were essential for its ability to predict length of stay. It is not known whether the LLAMS would be valid when controlling for factors such as age and level of amputation or whether it can predict length of stay in an inpatient rehabilitation program with a more open-ended length of stay.

The ability of the LLAMS to determine successful prosthetic fitting was not assessed, but it was not strongly correlated with the two-minute walk test or gait aid use on discharge[107]. However, the tool does contain several variables such as comorbidities, cognitive status, contracture and residual limb condition, social support, independence in activities of daily living, and motivation which have been shown to have some ability to predict successful prosthetic use[10, 40]. Because of this integration of broad variables, it is possible that the LLAMS could be used as a base on which to develop a tool capable of predicting both inpatient length of stay and successful fitting with a prosthesis after LLA.

1.3.5 Limitations in the literature regarding predicting inpatient rehabilitation length of stay

The body of literature identifying potential predictors of inpatient rehabilitation length of stay for people with LLA is sparse. While studies suggest that variables such as age, sex, level of amputation, social support (marital status), and medical factors play a role, this is based on a small number of primarily retrospective studies. Kayssi et al. point out that there are limited studies on rehabilitation trends after LLA published in Canada[9]. They argue that such studies are integral to gaining a better understanding of the variation in delivery of services and in identifying avenues for improving quality of care for people with LLA[9]. People who undergo LLA in Newfoundland and Labrador have higher initial hospital and rehabilitation length of stays compared to other provinces[9, 25, 61]. As well, Newfoundland and Labrador has the highest rate of LLA in Canada[2]. To be able to make informed decisions regarding how to improve these outcomes it is important to gain an understanding of the variables affecting length of stay in the context of the Canadian healthcare system, specifically in the province of Newfoundland and Labrador.

There remains a need to develop and test a predictive tool that can be quickly and easily administered in a clinical setting. Of all the tools described above, the LLAMS has the most promise as a predictor of length of stay for people with LLA undergoing rehabilitation for prosthetic fitting. The LLAMS has not been validated in a rehabilitation setting without a pre-defined length of stay. As well, it is not known if the LLAMS can predict whether a person will be successfully fit with a prosthesis and the length (31 items) of the LLAMS makes it less practical in a busy clinical environment. Further, there is minimal information regarding the relationship between length of stay and other factors including admission FIM®, level of amputation, and time since amputation, that are not included in the LLAMS.

1.4 Objectives and Hypotheses

1.4.1 Objectives

The objectives of this thesis were to address limitations in the literature by designing a study to determine how well the LLAMS predicted inpatient rehabilitation length of stay for people with LLA admitted for prosthetic fitting and whether the LLAMS could also predict successful prosthetic fitting. This study was designed as a retrospective analysis of data collected by Eastern Health for quality improvement purposes, which included a sample of people with LLA admitted to the Dr. L.A. Miller Centre between 2010 and 2017. Other available variables including admission FIM®, level of amputation, age, sex, and time from amputation to admission were examined to determine their ability to predict length of stay and/or successful prosthetic fitting. A secondary objective was to explore whether the LLAMS could be shortened from its original 31 items.

1.4.2 Research Question

Is the LLAMS a tool that can predict rehabilitation length of stay and/or successful fitting better than other variables such as admission FIM®, level of amputation, age, sex, and time since amputation in adults with LLA undergoing prosthetic fitting in Newfoundland and Labrador?

Table 1. 2 Specific Research Question in Population Intervention Control Outcomes (PICO) Format

Research Question		
Population (P)	Adults with major lower limb amputations admitted for prosthetic fitting at the Dr. L.A. Miller Centre, Eastern Health, St. John’s, Newfoundland and Labrador, Canada.	
	Inclusion Criteria	Exclusion Criteria
	• Age 18 years or older • Major (above the ankle) amputation of lower limb • First unilateral or bilateral amputation	• Previous prosthetic fitting for an amputation on the same limb (i.e., re-fitting or revision to higher level) • Clients discharged from inpatient rehabilitation within two weeks to continue outpatient rehabilitation • Incomplete data
Intervention/Indicator (I)	LLAMS	
Control/Comparison (C)	Other indicators not included in the LLAMS (i.e., admission FIM®, level of amputation, age, sex, and time since amputation)	
Outcomes (O)	LOS and Successful fitting. Successful fitting (yes/no) was determined by the treating physiotherapist based on the patient’s ability to use the prosthesis at discharge.	

1.4.3 Hypotheses:

(i) The LLAMS will be a strong predictor of length of stay and successful prosthetic fitting, with high scores being predictive of a longer length of stay and lower probability of successful prosthetic fitting.

(ii) Admission FIM® will be an independent predictor of length of stay and successful fitting.

(iii) Patients with above knee (transfemoral) amputation will have longer length of stay and less fitting success than those with below knee (transtibial) amputation.

(iv) Longer time since amputation will be associated with longer length of stay and less success in prosthetic fitting.

(v) The LLAMS will be able to be shortened from its original 31 items

1.5 Co-authorship statement

This research was conducted under the supervision of Dr. Michelle Ploughman, Dr. Holly Etchegary, and Dr. Jason McCarthy. I was responsible for the study design, data acquisition, and analysis. I wrote the original drafts of the manuscripts that constitute the chapters of this thesis. The manuscripts were revised based on comments from Dr. Ploughman, Dr. Etchegary, and Dr. McCarthy. Chapter Two contains a manuscript that has been submitted on February 19, 2020 to the peer-reviewed journal, Archives of Physical Medicine and Rehabilitation. The abstract/poster of the same data was presented at the American Congress of Rehabilitation Medicine Annual Conference in Chicago, Illinois on November 5-8, 2019 and received the 1st Place Poster Award.

In order to maintain consistency of formatting, the manuscript in Chapter Two as well as the entire thesis, is structured as required for Archives of Physical Medicine and Rehabilitation.

CHAPTER TWO

2.1 Introduction

Healthcare costs associated with lower limb amputation (LLA) are estimated to be $4 billion/year[85] and the number of people in the United States living with LLA is expected to double over the next 30 years[14]. The primary cause of LLA in most Western Countries is complications arising from Diabetes Mellitus (DM)[2], including peripheral vascular disease. In fact, the risk of LLA is 28.9 times higher for people with DM compared to those without[2]. Compromised circulation in the remaining limb, cognitive impairment, and low cardiorespiratory fitness are just some of the additional challenges faced by amputees with vascular co-morbidities who are candidates for prosthetic fitting[3].

In Canada, about one third of people with LLA require admission to an inpatient rehab facility[9]. Prosthetic rehabilitation is a resource intensive process that does not always lead to successful fitting. With an average length of stay (LOS) of 36 days[9] in Canada, it may not be wise to invest resources into prosthetic rehabilitation if the likelihood of a successful outcome is low. Identifying factors that predict prolonged LOS and/or fitting failure can help avoid unnecessary admissions and streamline processes for people with LLA and healthcare providers.

Consolidated evidence from systematic reviews demonstrates that higher amputation level, advanced age, lower physical fitness, and having multiple comorbidities are the strongest predictors of prosthetic fitting failure[10, 40]. Other potential predictors of poor prosthetic candidacy and/or limited walking ability include cognition/mood disturbances, poor balance, female sex, increased time from surgery to prosthetic rehabilitation, and limited social support[10, 40, 45, 98, 102, 108, 109]. Several groups have attempted to develop prediction tools for prosthetic candidacy, walking potential, or long-term prosthetic use[99-103]. Neither tool was specifically designed to predict outcomes for people with LLA who were being considered for inpatient rehabilitation.

Developed by an inpatient amputee rehabilitation team, the lower limb amputee measurement scale (LLAMS), is the only published tool designed to predict inpatient LOS prior to admission for prosthetic rehabilitation. Based on a review of health records, the authors compiled 31 factors in six subcategories (i.e., medical, cognitive, social, physical, functional, other), which they felt could contribute to prolonged LOS[107]. In a sample of 147 people with LLA, the LLAMS score was moderately correlated with LOS, but did not predict functional outcome (walking and independence)[107]. The analysis did not control for potential confounders such as age and level of amputation. Since some of the items in the LLAMS have been reported as predictors of prosthetic fitting, it is possible that the LLAMS could also predict whether the fitting would be successful.

The main objective of this study was to identify the strongest predictors of LOS and prosthetic fitting for people with LLA undergoing inpatient rehabilitation. The LLAMS was examined as well as other potential predictors such as admission Functional Independence Measure (FIM®), level of amputation, age, sex, and time from amputation to admission. A secondary objective was to explore whether the LLAMS could be shortened from its original 31 items.

2.2 Methods

2.2.1 Study Design and Participants:

This was a retrospective analysis of data collected by an inpatient rehabilitation facility in Canada on 105 consecutive people with LLA admitted for prosthetic fitting between 2010 and

2017. All patients were screened for prosthetic candidacy by either a multidisciplinary amputee clinic team or the facility intake committee. Patients were included in the database if they were (1) 18 years of age or older, (2) underwent major amputation (above the ankle), and (3) admitted for first unilateral or bilateral prosthetic fitting. Patients were excluded if they (1) had a previous prosthetic fitting on the same limb (i.e., re-fitting or revision), (2) were discharged within two weeks to continue fitting as an outpatient, or (3) data was incomplete. The data was anonymized and collected as part of a quality improvement initiative. Permission to access the database was received from the health authority and was approved by the provincial Health Research Ethics Board.

2.2.2 Predictive variables:

Three main subgroups of predictive factors were considered, (1) the 31 items of the LLAMS[107], (2) functional and physical status (admission FIM® score, level of amputation), and (3) demographic (age, sex, time since surgery).

LLAMS score: The LLAMS has 31 questions with binary responses, yes/no (coded as 1/0)[107]. Higher scores are indicative of greater resource needs and poorer health. The LLAMS was completed by the treating physiotherapist on admission and has high inter-rater reliability[107].

Functional/Physical: FIM® scores were completed by rehabilitation team members credentialed in FIM® scoring. Admission FIM® scores have been shown to predict LOS for amputees in several studies[106, 110] but not successful fitting[60]. Level of amputation (including bilateral) was coded as either below-knee (BKA) or above-knee (AKA) based on the level of amputation being fit during the admission. Being a bilateral amputee was one of the items included in the LLAMS.

Demographic: Since older age has been shown to be associated with increased LOS [9, 91, 106] and failure of prosthetic fitting[10], age was included as a potential predictor as well as a potential confounder. Sex was included as a predictor although the evidence regarding its effect on outcomes has been conflicting[40, 45, 98, 103, 111]. Time (days) from surgery to rehabilitation admission was considered in the model since earlier initiation of prosthetic rehabilitation has been associated with better outcomes[45, 111].

2.2.3 Outcome variables:

There were two main outcomes, LOS (days) and whether the prosthetic fitting was considered ‘successful’. Successful fitting was coded at discharge by the treating physiotherapist as yes/no (1/0) depending on whether the patient was able to use the prosthetic limb for transfers or walking.

2.2.4 Data Analysis:

Descriptive statistics were summarized using measures of central tendency for continuous variables and frequencies for categorical variables. In order to examine the strength of individual predictors, multiple linear regression was conducted with total LLAMS score, admission FIM® score, level of amputation (BKA as reference), age, sex (male as reference), and time from surgery to admission as the independent variables and LOS as the outcome. Since prosthetic fitting was a binary outcome, logistic regression was conducted using the same independent variables, with successful fitting as the outcome.

The association between each of 31 indicators in the LLAMS and the dependent variables was assessed by a separate analysis for each item. Rather than univariate analysis, each item was assessed under the control of the admission FIM®, level of amputation, age, sex, and time from surgery to admission. For longer LOS, items with $\beta > 0$, $p < 0.10$ were retained for inclusion in a revised LLAMS, which was tested by substituting it for the full LLAMS in the original linear regression. This process was repeated with unsuccessful prosthetic fitting as the outcome for items with Odds Ratio < 1 and $p < 0.10$. A significance level of 90% was chosen for this subanalysis to not miss potentially important items in the LLAMS.

Based on a significance level of 0.05, a power of 0.8, with a medium effect size ($f^2 = 0.15$), the sample size was adequate for regression analysis with 6 independent variables[112]. All analysis was conducted using IBM SPSS version 25.

2.3 Results

Two statistical outliers for time from surgery to admission were removed from analysis. The sample (n=103) primarily included older individuals (age 65.3 years ± 10.6), 68% being male, and 64% being admitted for BKA with the main etiology due to DM and/or vascular disease (Table 2.1). Of the four bilateral amputees, two were admitted for BKA prosthetic fitting after a previous BKA fitting on the contralateral limb, one for bilateral BKA fitting, and one for bilateral AKA fitting. On discharge, 21.4% of patients had a prosthetic fitting attempt that was deemed unsuccessful; these patients spent a total of 1447 days in inpatient rehabilitation.

In terms of variables that predicted longer LOS, the significant predictors included: higher LLAMS, lower admission FIM®, and having an AKA (Table 2.2). Figure 2.1 shows the relationship between LOS and these three variables. Age, sex, and time from surgery to admission did not significantly predict LOS. In terms of predicting prosthetic fitting, the LLAMS score was the only significant predictor (Table 2.2).

Within the LLAMS, there were five items that were retained as being associated with longer LOS and five items that were retained as being associated with unsuccessful prosthetic fitting (Table 2.3). Since there was no overlap between the items retained for LOS and prosthetic fitting, two separate revised LLAMS tools were created. The revised five-item LLAMS tools improved the predictive ability of the original regression models for LOS (R^2 from 0.36 to 0.51) and prosthetic fitting (R^2 from 0.15 to 0.32; $p = 0.12$ to $p = 0.001$) (Table 2.4).

Table 2. 1 Patient Characteristics (n=103)*

	Mean (Minimum-Maximum)	**SD**	**Frequency**	**Percent (%)**
Age (years)	65.3 (38 - 90)	10.6		
Sex				
Male			70	68.0
Female			33	32.0
Level of Amputation				
BKA			66	64.1
AKA			33	32.0
Bilateral			4	3.9
Amputation Etiology				
DM and/or Vascular			93	90.3
Orthopedic			4	3.9
Cancer			1	1.0
Infection			2	1.9
Other			3	2.9
Time from Surgery to Admission (days)	127.0 (7 – 592)	118.8		
LLAMS	10.5 (2 – 22)	4.6		
Admission FIM®	101.4 (50 – 124)	14.4		
LOS (days)	63.6(8 – 184)	33.3		
Prosthetic Fitting				
Successful			81	78.6
Unsuccessful			22	21.4

*Two outliers were removed from the analysis whose time from surgery to admission was more than three times the Inter Quartile Range above the 75th percentile.

Table 2. 2 Predictors of LOS and successful prosthetic fitting

	Model predicting Length of Stay				**Model predicting Prosthetic Fitting**			
Variable	Beta	95% CI	p-value	R^2	Odds Ratio	95% CI	p-value	Nagelkerke R^2
LLAMS	1.77	0.16, 3.39	0.032		0.85	0.73, 0.99	0.032	
Admission FIM®	-0.85	-1.41, -0.29	0.004		0.99	0.94, 1.04	0.56	
Level of Amputation	21.4	9.35, 33.5	0.001		0.40	0.14, 1.17	0.095	
Age	-0.40	-0.97, 0.17	0.16		1.00	0.96, 1.05	0.89	
Sex	-7.71	-20.0, 4.61	0.22		0.51	0.17, 1.56	0.23	
Time from Surgery to Admission	-0.036	-0.084, 0.011	0.13		1.00	1.00, 1.01	0.67	
Model Summary			< 0.001	0.36			0.12	0.15

Abbreviation: CI, confidence interval.

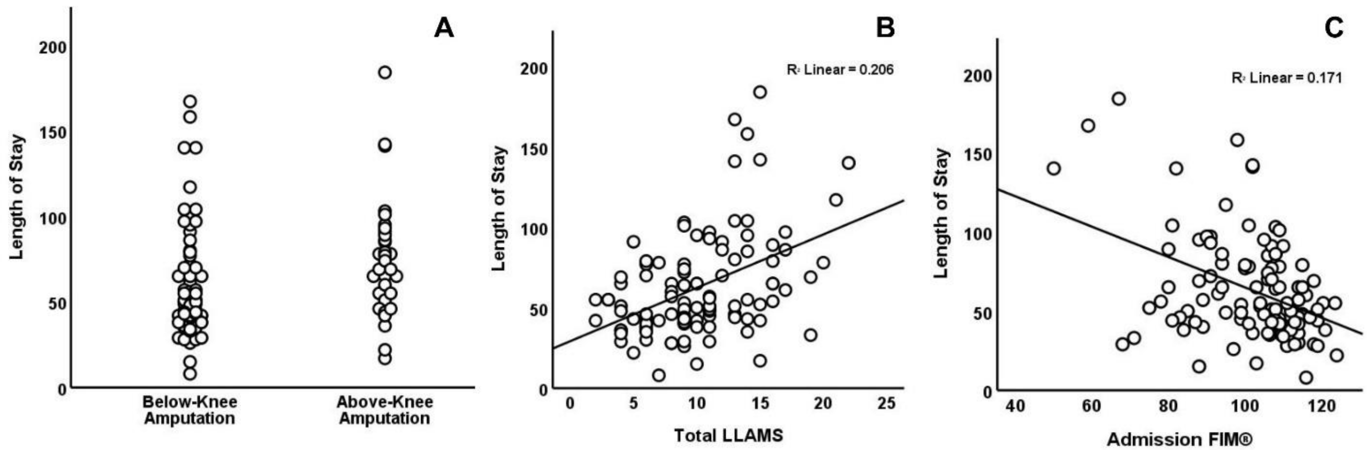

Figure 2. 1 Relationship between LOS (in days) and Level of Amputation (A), LLAMS score (B), and Admission FIM® (C).

Table 2. 3 Individual LLAMS items associated with LOS and prosthetic fitting

Description	**Length of Stay**	
	Beta (95% CI)	**p-value**
History of cognitive impairment/psychiatric illness	26.4 (12.7, 40.2)	< 0.001
Assessor's gut feeling about fitting with a prosthesis (i.e., patient will not benefit from receiving prosthetic leg)	23.4 (7.60, 39.2)	0.004
Lives alone on discharge	17.1 (5.46, 28.8)	0.004
Incontinence of bowel and/or bladder	15.2 (-1.16, 31.5)	0.068
Lives in inaccessible environment	10.9 (-0.77, 22.6)	0.067
	Successful Prosthetic Fitting	
	Odds Ratio (95% CI)	**p-value**
Requires assistance in dressing	0.19 (0.048, 0.78)	0.021
Stump not healed – skin ulcer grade 1-4	0.23 (0.068, 0.78)	0.018
Being a bilateral amputee	0.24 (0.046, 1.28)	0.095
Skin ulceration on the remaining foot/heel	0.25 (0.084, 0.77)	0.015
Inability to complete stump bandaging independently	0.26 (0.082, 0.80)	0.019

Abbreviation: CI, confidence interval.

Table 2. 4 Predictors of LOS and successful prosthetic fitting using revised LLAMS

	Model predicting Length of Stay			Model predicting Prosthetic Fitting		
Variable	Beta (95% CI)	p-value	R^2	Odds Ratio (95% CI)	p-value	Nagelkerke R^2
Revised LLAMS	14.5 (9.69, 19.3)	< 0.001		0.30 (0.16, 0.56)	< 0.001	
Admission FIM®	-0.70 (-1.11, -0.28)	0.001		0.97 (0.93, 1.03)	0.31	
Level of Amputation	18.1 (7.52, 28.7)	0.001		0.34 (0.11, 1.12)	0.075	
Age	-0.016 (-0.53, 0.50)	0.95		1.00 (0.94, 1.06)	0.98	
Sex	-4.51 (-15.3, 6.32)	0.41		0.50 (0.15, 1.73)	0.27	
Time from Surgery to Admission	-0.022 (-0.064, -0.020)	0.30		1.00 (1.00, 1.01)	0.90	
Model summary		< 0.001	0.51		0.001	0.32

Abbreviation: CI, confidence interval.

2.4 Discussion

The objective of this study was to examine predictors of prolonged LOS and unsuccessful prosthetic fitting for people with LLA in an inpatient rehabilitation facility. There were four main findings. First, despite undergoing pre-screening for prosthetic candidacy prior to admission, 21.4% of patients were unable to use the prosthesis on discharge, amounting to 1447 inpatient days that did not lead to successful prosthetic fitting. Secondly, the LLAMS tool was a significant predictor of LOS and prosthetic fitting. Lower admission FIM® and AKA also significantly predicted longer LOS. Thirdly, when deconstructing the LLAMS, items that described cognitive/mental health, clinical judgement, and living situation more strongly predicted LOS, while functional ability and physical impairments predicted prosthetic fitting. Revising the LLAMS improved the predictive power of the models. However, the LLAMS predictors were entirely different between the two models (LOS and prosthetic fitting). Finally, variables that had been previously identified as predictors (i.e., age, sex, and time since surgery), were not significant predictors in this analysis.

The results of this study highlight the need for better management of LOS and improved screening among people with LLA being admitted to an inpatient rehabilitation facility. The mean LOS (63.6 days; Table 2.1) was longer than that of other inpatient rehabilitation centers in Canada (36 days)[9] which may be partially explained by the high proportion of patients with DM and/or peripheral vascular disease in this sample. The failed prosthetic fitting rate was also high compared to previous reports[45, 84] from other countries but similar to the rate (23.3%) reported by other Canadian facilities[94]. Identifying and targeting factors, prior to admission, that impact outcomes could improve prosthetic candidate selection and improve likelihood of success. Data supporting the use of screening for amputees is sparse[113] and further research is required to verify the potential benefits of pre-emptively addressing barriers to successful prosthetic fitting.

A key finding in this study was that LLAMS was strongly predictive in both models (LOS and prosthetic fitting), but when deconstructing the 31 items of LLAMS, the items associated with LOS did not overlap with those associated with unsuccessful prosthetic fitting. When examining the relative predictive strength of the 31 LLAMS items, history of cognitive impairment/psychiatric illness was the strongest predictor of increased LOS, adding an average of 26 days to the LOS. Impaired cognition has been previously associated with poor outcomes[10, 40, 108, 109]. Cognitive capacity and motor learning are inherently required in order to safely walk with a prosthesis[114], therefore patients with cognitive deficits may require longer to gain competence with tasks such as donning/doffing a prosthesis and prosthetic gait. In a recent systematic review[109], 15 different cognitive scales were used in nine studies to predict prosthetic use among older adults with amputation due to vascular etiology. The authors recommended that a comprehensive cognitive assessment tool accounting for various subdomains (e.g., visuospatial ability, memory) should be considered. This would allow researchers to more clearly identify the aspects of impaired cognition that affect rehabilitation of people with LLA.

When the assessors' "gut feeling" about prosthetic fitting was negative, the LOS was approximately 23 days longer. This gut feeling item in the LLAMS may take into account other factors involved in appraising the patient and making a clinical judgement, such as critically evaluating the patient's ability to match the high metabolic costs of walking with a prosthetic limb[41]. Clinical reasoning involves a complex interplay of memory, anecdotal evidence, and results of objective tests[115] and in this case, was a stronger predictor than many other variables. However, it is important to consider that the LLAMS assessors were also sometimes the same clinicians who were providing the interventions such that there was a risk of confirmation bias. Therefore, the assessors could have influenced LOS for patients that they felt would require more rehabilitation effort. Future research should examine the role of clinicians' gut feeling in predicting success in rehabilitation.

This study demonstrated that a person's living situation on discharge can significantly affect prosthetic rehabilitation LOS. Inadequate social support has been previously associated with poor outcomes[10]. Specifically, people who live alone or in an inaccessible environment may require additional supports to be discharged home or be discharged to another institution if they are not able to be accommodated in the community. This underscores the need to identify and plan for resources required for post-discharge living as early as possible to avoid prolonged LOS.

Although one may expect that co-morbidities or cognitive and physical impairments would be major impediments to successful prosthetic fitting, in fact, of all the items included in the LLAMS, functional dependence in dressing was the strongest predictor, reducing the odds ratio for successful fitting to 0.19. Dependence in ADLs has been previously associated with poor outcomes for people with LLA[111]. In this study, overall level of function as measured by the FIM® did not significantly predict prosthetic fitting. Dependence in dressing may represent a specific issue for people with LLA. If a person is unable to manage tasks such as dressing, they are likely to struggle with more complex tasks such as donning/doffing a prosthesis and managing changes in limb volume that affect prosthetic fit. To address important functional deficits, rehabilitation teams should include skilled allied health professionals who are familiar with the specific functional needs of people with LLA undergoing prosthetic fitting[113].

Physical factors in the LLAMS, specifically skin ulceration of the residual limb or the remaining foot, were strong predictors of failed prosthetic fitting, reducing the odds ratio for successful fitting to 0.23 and 0.25, respectively. This is consistent with previous findings[40, 45] and warrants examination in people being considered for prosthetic fitting. Interventions that improve wound healing should be utilized to address these issues prior to initiation of prosthetic fitting.

This study suggests that revising the LLAMS may be of value since a revised five-item LLAMS was a stronger predictor of both LOS and prosthetic fitting than the full 31-item LLAMS. Consideration should be given to separating the LLAMS into two tools since items that predicted LOS were not the same ones that predicted prosthetic fitting. Before recommending changes to the current LLAMS, predictive modelling including all 31 indicators in a single model should be completed. Due to sample size limitations, this was not possible in this study.

The FIM® is widely used in inpatient rehabilitation but its role in predicting outcomes for people with LLA is less clear. As in a previous study involving people with LLA[106], lower admission FIM® significantly predicted longer LOS. Since admission FIM® is typically completed within 72 hours following admission to an inpatient rehabilitation facility it is not useful in predicting the anticipated LOS prior to admission. Admission FIM® score was not predictive of prosthetic fitting. This is consistent with a previous finding by Leung et al.[60], although Erjavec et al.[110] reported that FIM® was a good predictor of prosthetic fitting among transfemoral amputees. FIM® has been shown to predict LOS and functional outcomes in other rehabilitation groups such as stroke[116] but its use for people with LLA requires further evaluation.

Although level of amputation (BKA versus AKA) did not predict prosthetic fitting success in this study, having an AKA predicted longer LOS. On average, patients with an AKA stayed 21 days longer (Table 2.2). Clearly, having an AKA requires greater energy expenditure to walk and there is an added cognitive requirement in order to learn to walk with a prosthetic knee[117]. Previous studies have shown that having an AKA may affect walking ability but not necessarily ability to be fit with a prosthesis[10]. The results presented here suggest the same. Although people with an AKA did require longer to complete inpatient rehabilitation, they were not significantly less likely to be successfully fit with a prosthesis.

Contrary to currently accepted evidence, age, sex, and time from surgery to admission did not significantly predict LOS or prosthetic fitting in this study. Previous research has reported that advanced age[9, 10, 91, 106], and longer time from surgery to rehabilitation[10, 45] negatively affects outcomes, while there have been more equivocal findings regarding sex[10, 98]. Our findings may be reflective of both screening for candidacy prior to admission and the use of short-term outcomes. However, they do suggest that age, sex, and time from surgery to rehabilitation should not be used to anticipate a longer inpatient rehabilitation LOS or exclude patients from consideration for prosthetic fitting.

2.5 Study Limitations

Due to the homogeneity of this sample, findings can only be generalized to populations with major LLA caused by DM and/or peripheral vascular disease completing prosthetic rehabilitation at an inpatient rehabilitation facility. Since the data was collected on admission, the effects of some variables may have been muted by pre-screening for prosthetic candidacy. In this study the definition of successful prosthetic fitting outcome was subjective and short-term, determined by the treating physical therapist at discharge. As a retrospective analysis, variables were limited to those available for analysis and potentially important variables were not able to be considered.

2.6 Conclusions

The LOS in inpatient rehabilitation for people with LLA can be lengthy and does not always lead to a successful prosthetic fitting at discharge. The LLAMS was a useful tool in predicting both LOS and successful fitting. LLAMS score, admission FIM®, and level of amputation can be used to predict LOS. Within the LLAMS, the main predictors of longer LOS were history of cognitive impairment/psychiatric illness, clinical judgement, and living alone. Dependence in dressing, incomplete wound healing on the residual limb, and ulceration of the remaining foot were the strongest predictors of a failed prosthetic fitting. Future studies should further investigate shortening the LLAMS and creating separate tools for the prediction of LOS and prosthetic fitting. This study demonstrated that in a cohort of pre-screened prosthetic candidates, advanced age, sex, and increased time from surgery to rehabilitation did not significantly predict LOS or ability to successfully complete inpatient prosthetic fitting.

CHAPTER THREE

Discussion

3.1 How helpful is length of stay as a health outcome?

The two main outcomes in this study were inpatient rehabilitation length of stay and whether the prosthetic fitting was considered successful. The length of stay was long compared to previous reports of inpatient rehabilitation lengths of stay in Canada[9, 25]. At 64 days, the length of stay in the current study was nearly two to three times longer than data from the United States (13 to 31 days)[91, 106] and Australia (39 days)[105]. It is important to appreciate that length of stay for patients admitted for prosthetic fitting is longer than that for people with LLA receiving inpatient rehabilitation but who are <u>not</u> being fit with a prosthesis[58, 98]. For instance, in the United Kingdom, the duration of rehabilitation was on average more than 100 days longer for people being fit with a prosthesis[98]. Previous data on rehabilitation length of stay for people with LLA in Canada disregards the differences between the two groups (being fit with prosthesis or not). Therefore, it is not known what proportion of these admissions were for prosthetic fitting nor the specific lengths of stay for this subgroup of patients. Our sample included only those people for which prosthetic fitting was prescribed. The differences in how data was reported could account for the seemingly excessive length of stay in our sample. Future studies and administrative data collection methods should consider dividing the data gathered by category of patient with LLA, those being fit and those who are not.

Even though our study presents findings within the context that longer length of stay for prosthetic fitting is an undesirable outcome, long length of stay may, in fact, not be an indicator of a poor outcome. For example, Munin et al. demonstrated that longer inpatient rehabilitation length of stay was a significant predictor of successful prosthetic fitting for a sample (n = 75) of people with LLA admitted with a goal of prosthetic fitting[118]. Additionally, from the patients' points of view, the majority wished they had spent more time in rehabilitation[67]. Perhaps being able to use a prosthesis at discharge is a more valid outcome than length of hospital stay, at least from the patient's perspective.

3.2 How we define 'success' determines the rate of success

The other main outcome considered in this thesis was successful prosthetic fitting. We defined successful prosthetic fitting dichotomously based on whether or not the patient was able to use the prosthesis on discharge from inpatient rehabilitation. What exactly delineates being "able to use the prosthesis" from "not able to use the prosthesis" is perhaps ambiguous. Patients may achieve a range of mobility tasks with their new prosthesis, from being limited to only using the prosthesis for bed-to-chair transfers to being functional community ambulators. Defining success in terms of achieving the patient's goal was meant to reduce issues related to pre-defining a specific mobility level as "successful", given that patients have varying levels of pre-morbid function and individualized goals for the level of mobility they wished to achieve with prosthetic fitting. With goal achievement, as opposed to walking, as our measure of success, 79% of our sample was able to achieve successful prosthetic fitting. If we had used a higher metric of success, such as ability to walk 100 metres without a gait aid, the rate of success in our study would likely have been much lower. Despite setting the success bar rather low, our rate of prosthetic fitting success seems low compared to other reports, especially compared to Davie-Smith et al., who observed a success rate of 97% for people with transtibial or transfemoral amputation who initiated prosthetic fitting[98]. Future research should examine the full range of what success means in terms of prosthetic fitting, keeping in mind that success does not always equate to walking independently.

3.3 LLAMS was the only variable to predict both length of stay and prosthetic fitting

The LLAMS score was able to predict inpatient rehabilitation length of stay in our sample. Higher LLAMS scores were significantly associated with longer length of stay. This was consistent with the previous finding by Cheifetz et al.[107], but our study was the first to demonstrate this relationship in a rehabilitation program with an open-ended length of stay. In the previous study, patients were admitted for a planned duration of either a six- or seven-week length of stay. In the current study, length of stay was not pre-defined and was determined based on the rehabilitation needs of the patients. Some components of the LLAMS such as having diabetes, end-stage renal disease/dialysis dependence, history of congestive heart failure or ischemic heart disease, having bilateral amputation, and poor wound healing have been identified in other studies as being associated with a longer rehabilitation length of stay[9, 62, 91, 105, 106]. Therefore, combining these and additional factors into a single tool, as the LLAMS does, was expected to be predictive of a longer length of stay.

Higher LLAMS scores were also predictive of failing to successfully complete prosthetic fitting. This was a novel finding. Cheifetz et al. did not assess the relationship between LLAMS score and successful prosthetic fitting, but they did report a low correlation with two-minute walk test and gait aid use at discharge[107]. The 31-item LLAMS is a rich tool that includes a combination of medical, cognitive, social, physical, functional, and other factors. Though these items were originally identified as factors that might predict a longer length of stay, it was not surprising that the tool could also predict failed prosthetic fitting. Many of these factors were the same as those identified by previous literature as potential predictors of prosthetic walking ability or prosthetic candidacy[10, 40]. Our study confirms the value of the LLAMS as a tool that can be used to predict prolonged rehabilitation length of stay and was the first to show its value as a tool for predicting failure to complete prosthetic fitting. The LLAMS can be completed prior to admission and as such is of value in determining prosthetic candidacy and planning admission to an inpatient rehabilitation facility.

3.4 Higher functional dependence at admission predicts longer length of stay but not failed prosthetic fitting

Higher levels of dependence in functional activities, as measured by the admission FIM® score, predicted longer of length of stay in our sample. One previous study involving rehabilitation of people with LLA also reported an association between admission FIM® score and length of stay[106]. FIM® has been well-established as a strong predictor of length of stay in other rehabilitation populations such as stroke[116]. Based on the strength of our results, admission FIM® should be considered when determining inpatient rehabilitation length of stay for people with LLA. However, because FIM is completed after admission, its usefulness as a predictor is limited. The Alpha FIM®, because it is completed during acute care hospitalization and is a condensed version of FIM®, holds promise[55]. However, it is important to appreciate that if there is a substantial delay between acute care discharge and rehabilitation admission, the Alpha FIM® score may no longer represent the person's current level of independence.

Lower admission FIM® scores did not predict less success with inpatient prosthetic rehabilitation. Consolidated evidence from two systematic reviews lead Kahle et al. to state that *"the preponderance of evidence suggests that independence in completion of activities of daily living is a factor worth considering when determining prosthetic candidacy"*[10]. The average admission FIM® score in our sample was high at 101, and this may partly explain why it was not able to predict successful prosthetic fitting. Most patients were near independence in activities of daily living prior to admission. As well, we considered the total admission FIM® score rather than focusing on the motor subscore, which other researchers have suggested may be more valuable in predicting outcomes[60]. In predicting successful prosthetic fitting, it is of most value if this assessment is made leading up to an inpatient rehabilitation admission, rather than after admission. Again, the utility of the FIM® is limited by its timing of completion.

3.5 Above-knee amputation predicts longer length of stay but not failed prosthetic fitting

As hypothesized, level of amputation was a significant predictor of inpatient rehabilitation length of stay in our sample. Having an above-knee amputation predicted a longer length of stay compared to having a below-knee amputation. This association was identified in one previous study that found people with transfemoral amputation to have a longer inpatient rehabilitation length of stay compared to people with transtibial amputation[105]. People with an above-knee amputation have the added complication of learning to walk with a prosthetic knee, while having greater loss of lower limb musculature and a greater disruption to their centre of gravity[11]. It seems rational to expect that the higher the level of amputation, the longer the length of stay will be to achieve prosthetic fitting. Having a higher level of amputation could be considered as a more severe disease state. In other rehabilitation populations, such as stroke, disease severity has been associated with a longer rehabilitation length of stay[119]. We should expect that people with higher levels of amputation will require a longer inpatient rehabilitation length of stay.

Higher level of amputation was also hypothesized to predict less success in prosthetic fitting based on the available body of literature. However, level of amputation did not predict successful prosthetic fitting in our sample. While the majority of studies suggest that amputation level affects ability to walk with a prosthesis, several other studies have found similar findings to the results presented here[10]. These differences may be due to the variation in outcomes used as well as the fact that many studies include people with minor amputations, who face far less challenges than people with major amputation. Higher level of amputation may lead to lower levels of function and walking ability[10, 40] but should not be used to preclude people from being considered for prosthetic candidacy.

3.6 Some variables did not predict length of stay or prosthetic fitting

3.6.1 Age

Older age was previously found to be associated with longer length of stay in inpatient rehabilitation for people with LLA[9, 91, 105, 106]. In our study, age did not significantly predict length of stay. The most likely explanation for this is that since candidates were pre-screened for admission, people with the most severe age-related factors, such as co-morbid conditions and limited mobility, may have been excluded. These confounding factors were also controlled for in LLAMS and FIM®, two variables that could interact with age. Considering these factors, age alone did not significantly increase the length of stay required for prosthetic fitting in inpatient rehabilitation

Age was previously identified as a major factor in determining ability to walk with a prosthesis after LLA[3, 10, 40, 98, 102], though in this study it was not a significant predictor of successful prosthetic fitting. The definition of success in our study may have accounted for this discrepancy. While older age may reduce the likelihood of being fit with a prosthesis, our findings support the theory that age alone should not be an absolute contraindication to selection for prosthetic fitting. The average age in our sample was 65, with a range from 38 to 90 years old. The average age for people who were successfully fit or not was the exact same at 65 years old. There were two people in this sample who were 90 years old and successfully fit with a prosthesis. Clearly, age alone was not a barrier to prosthetic fitting.

3.6.2 Sex

Sex was included in our model to control for confounding and to further elucidate its impact on length of stay and prosthetic fitting. Sex did not appear to play an important role in determining inpatient rehabilitation length of stay in our sample. Two previous studies found being male to be associated with longer length of stay[91, 106] and in one study being female was associated with longer duration of rehabilitation[98]. Another study found no difference between males and females with respect to inpatient rehabilitation length of stay[105]. No explanation has been put forth to explain these apparent sex-based differences. The relationship between sex and inpatient rehabilitation length of stay for people with LLA requires further study.

The impact of sex on prosthetic fitting was not clear in the literature. Kahle et al. concluded it was not a factor in predicting walking ability after LLA[10], but others subsequently found sex differences in prosthetic fit rates[98, 103]. In our study, sex was not a significant predictor of prosthetic fitting success. Studies finding differences in outcomes based on sex should attempt to isolate the specific attributes contributing to this difference. Davie-Smith et al. suggested that their observed lower rate of prosthetic fitting amongst females may have been related to higher rates of specific comorbidities such as coronary heart disease and stroke in females[98]. If this is the case, these factors should be controlled for to avoid confounding the results. Researchers should be careful in making conclusions based on sex so that they do not provide room for gender bias in selection of suitable prosthetic candidates. Our findings support that females are no less likely to be successfully fit with a prosthesis when given the opportunity to participate in inpatient rehabilitation.

3.6.3 Time from surgery to admission

There has been some debate with respect to whether early or late rehabilitation is preferable for people with LLA. Proponents of early rehabilitation argue that this approach avoids the risk of developing complications such as altered gait patterns, joint contractures, and deconditioning, while those favouring late rehabilitation would point to the benefits of more time for wound healing as well experiencing life in a non-hospital context to gain perspective and develop rehabilitation goals[59]. The time from surgery to admission to inpatient rehabilitation did not significantly predict length of stay or successful prosthetic fitting in our sample. No previous studies, that we are aware of, have examined the relationship between timing of rehabilitation and length of stay. Niewczyk et al. did observe that people admitted from home rather than directly from an acute care hospital had a 30% shorter rehabilitation length of stay but the authors did not quantify the time since surgery [91]. Most of the participants in our sample would be considered as late rehabilitation, with an average time from surgery to rehabilitation of 127 days; however, there was considerable variability with a standard deviation of 119 days. More studies may be needed to settle this debate, but our study supports the idea that the timing of rehabilitation is not a determining factor for predicting length of stay or successful prosthetic fitting.

3.7 Not all variables potentially affecting outcomes were included in our models

The overall model for prediction of length of stay in our sample of people with major LLA admitted for inpatient prosthetic fitting was strong. The model explained 36% of the variance in length of stay. However, there were several variables unavailable for analysis, which could have improved the model. Of note, acute care length of stay, marital status and total number of comorbidities are variables associated with rehabilitation length of stay[9, 91, 106] that were not available for analysis. As well, length of stay is difficult to predict due to factors other than measurable patient-related variables. Factors such as patient preference and, in some jurisdictions, insurance company restrictions can come into play. Patients may prefer to be discharged earlier than expected due to family situations, dissatisfaction with inpatient rehabilitation, or deciding to abandon prosthetic fitting. Conversely some patients may disagree with the inpatient rehabilitation team’s decision that they are ready for discharge home and may wish to extend their length of stay. Since our study occurred in a public facility, insurance company restrictions were not a factor, however public systems are often operating near full capacity and there is pressure to keep length of stay and short as possible. There may be times when teams feel pressured to discharge patients before they are ready or decide that a patient will not be able to successfully complete prosthetic fitting without giving the decision full consideration. Conversely, insufficient planning for the discharge destination can lead to a prolonged length of stay. Patients may have to stay in hospital longer to await home renovations or wait for the availability of beds in long-term care or personal care homes, if required. In our study, we included the total length of stay and did not account for days waiting for discharge after the completion of rehabilitation. Geographical differences may occur depending on the services available near the person's home. The inpatient rehabilitation facility from which the data was collected is a provincial rehabilitation centre. If there are limited outpatient rehabilitation services available in their home region, a patient may stay longer to maximize their level of independence prior to discharge, whereas a patient with more access to outpatient rehabilitation services may be able to be discharged earlier to continue their rehabilitation from home. To improve predictive models of length of stay, future research should endeavor to measure and include more of these variables.

The overall model for predicting successful prosthetic fitting was not strong, explaining only 15% of the variance in the outcome. Of the six variables in the model, only the LLAMS score was significant in predicting successful prosthetic fitting. Variables not included in this study, which could have potentially affected ability to successfully complete inpatient prosthetic fitting include balance (ability to stand on one leg), etiology of amputation, smoking status, marital status, phantom or residual limb pain, physical fitness, severity of peripheral arterial disease and number of comorbidities[10, 40]. It would be beneficial to include as many of these variables as possible to increase the strength of predictive models for successful prosthetic fitting.

3.8 Shortening the LLAMS is feasible

One of the objectives of this study was to determine whether the LLAMS could be shortened from its original 31 items. Cheifetz et al. developed the LLAMS by identifying key indicators that may affect length of stay in a review of patients admitted to their rehabilitation program[107]. They did not determine these items based on a literature review or statistical analysis of data. At 31 items, the LLAMS is a relatively long tool to administer in the clinical setting. When Cheifetz et al. completed their validation of the LLAMS, they did not include any subanalysis to determine whether all 31 items had value in predicting length of stay. Therefore, it seemed prudent that we undertake this analysis from the perspective of shortening the tool and removing items that were not strong predictors of length of stay and prosthetic fitting.

Only five of the 31 items in the original LLAMS met our criteria as strong predictors of length of stay and five different items met our criteria for the strongest predictors of successful prosthetic fitting. Since the items that predicted length of stay and successful fitting had no overlap, we created two separate five-item revised LLAMS tools. Our revised five-item LLAMS tools improved the predictive ability of our regression models when substituted for the original 31-item LLAMS. However, due to the size of the retrospective sample we could not assess all the 31 items of the original LLAMS in a single regression model or validate the revised LLAMS with a new sample. Overall, it appears that shortening the LLAMS is feasible to make it easier to administer and may also improve its predictive abilities. If the LLAMS is to be used to predict both outcomes, it may be helpful to split it into two separate tools or to include both sets of predictors if they can be pared down do a reasonable number. The exact number of items would require further study.

3.9 Cognitive and social items predicted length of stay but functional and physical items predicted prosthetic fitting

The LLAMS subanalysis identified that items in the LLAMS cognitive and social categories were the strongest contributors to its predictive ability for length of stay in our sample. There were no previous studies identifying that cognitive status or living situation predicted an increased inpatient rehabilitation length of stay for people with LLA. Having cognitive impairment likely extended length of stay due to difficulties in learning the new tasks required to complete prosthetic fitting. Living alone or in an inaccessible environment spoke to the discharge needs of the patient and the support available to provide this care. Similar to living alone, being single was previously shown to extend length of stay[91, 106]. When these issues are identified early and adequate resources are in place, they should not be factors in the required length of stay for prosthetic fitting.

Cognitive issues may have made prosthetic fitting more difficult, thereby extending length of stay, but these issues did not prevent the client from completing prosthetic fitting. The social items related to living situation made discharge more challenging but also did not prevent successful prosthetic fitting. The measurement of cognitive factors lacked a validated tool and other elements of social support such as marital status or access to support systems were not included. Therefore, the fact that cognitive and social items in the LLAMS did not affect prosthetic fitting success may be related to the way these items were measured.

Prosthetic fitting was mostly predicted by items in functional and physical categories. Functional abilities and physical condition were previously identified in the literature as predictors of walking ability[10, 40]. Dependence in activities of daily living in general, has been identified as a predictor of failed prosthetic fitting, but this is the first study to find specifically that requiring assistance in dressing affects prosthetic fitting. Getting dressed is similar to donning and doffing a prosthesis. Therefore, people who struggled with dressing may have failed prosthetic fitting because they were unable to manage how to properly wear the prosthesis. Physical items in the LLAMS such as an open wound on the residual limb or remaining foot and having bilateral amputations were expected to affect prosthetic fitting. An open wound may require that prosthetic fitting be discontinued, to not further delay healing by putting pressure on the wound. Being a bilateral amputee has been previously identified as limiting prosthetic walking potential[10]. The challenge of being fit with two prosthesis at the same time increases the risk of failing to complete prosthetic fitting. Bilateral amputees must expend up to 280% more energy than able bodied controls to ambulate with a prosthesis[120], which may be beyond the capacity of some patients. Functional limitations in dressing and physical condition of the limbs did not predict a prolonged length of stay, likely because these factors may have precipitated discontinuation of prosthetic fitting, thereby ending inpatient rehabilitation prematurely.

3.10 Medical comorbidities did not predict length of stay or prosthetic fitting

Medical comorbidities such as being dialysis dependent (end-stage renal disease) and having a history of congestive heart failure were not significant predictors of an increased length of stay or failed prosthetic fitting in our sample, despite being previously identified in the literature[9, 62, 91, 106]. People in our sample went through some level of screening prior to admission to rehabilitation. If they were otherwise well enough to be considered prosthetic candidates, these medical issues were likely not severe enough to affect length of stay or ability to successfully complete inpatient rehabilitation. Additionally, the way medical comorbidities were measured in the LLAMS could have affected the results. For example, in the LLAMS history of cerebrovascular accident or brain injury did not include any measure of severity; hemiparesis has a negative effect on prosthetic walking ability but those with mild motor deficits have better outcomes[40]. The medical section in the LLAMS was not helpful in predicting length of stay or successful prosthetic fitting in our sample, which may be due to either sample selection or the way these items were measured. The impact of specific comorbidities on outcomes for people with LLA undergoing prosthetic rehabilitation requires further evaluation.

3.11 Significance for clinicians and people with Lower Limb Amputation

This study has several implications for health care providers and people with LLA. Firstly, we can use this information to provide better patient education, and thereby informed consent. As well, it can inform healthcare providers and people with LLA on how best to prepare for prosthetic fitting in the pre-prosthetic phase and what to expect during the prosthetic fitting phase. Additionally, it informs us on how to increase the likelihood of a successful prosthetic fitting. Earlier in this thesis, many of the negative impacts on people with LLA were reviewed.

As well, we saw that prosthetic fitting has some potential risks but also many benefits. The decision to proceed with prosthetic fitting is complicated and people with LLA need to be fully apprised of the potential benefits and risks associated with prosthetic fitting in order to make an informed decision. When inpatient rehabilitation for prosthetic fitting would be required, they also should understand the length of time that they would need to be in hospital and the likelihood of a successful outcome.

In this study, the LLAMS was the only variable that was a significant predictor of successful prosthetic fitting. Higher LLAMS scores were predictive of a lower odds ratio for success (Odds Ratio = 0.85, $p < 0.05$). Within the LLAMS, the strongest predictors were functional and physical factors. Consideration of these factors should be given when selecting suitable prosthetic candidates. This can be used to educate clients regarding why they may not be suitable candidates and to assist clinicians with this difficult decision. In this study, the assessor's "gut feeling" was not able to predict prosthetic fitting success. This finding suggests that clinicians should rely on objective tools, such as the LLAMS, and evidence-based literature to inform their decisions. Clinical practice guidelines do not specify how to decide whether to proceed with prosthetic fitting[121]. Experienced clinicians in the United Kingdom, across four amputee rehabilitation centres, described relying on clinical judgement rather than objective tools and often weighting subjective patient attributes such as motivation, determination and coping ability to decide whether to proceed with a prosthesis[121]. As a result, the authors observed that there was inconsistency in prosthetic provision practices in these centres[121]. Another study attempted to develop expert consensus on the factors that should be used to predict prosthetic prescription. This panel reached consensus on 19 factors (12 physical and nine psychosocial), which did include the LLAMS items related to residual limb healing and condition of the remaining foot but did not include some functional tasks[122]. More work needs to be done to develop well-rounded tools for the prediction of successful prosthetic fitting.

Factors associated with failure of prosthetic fitting or longer length of stay should be viewed as red flags that need attention. Many of these could be modified to increase the likelihood of successful prosthetic fitting or shorten length of stay. If these issues are addressed in the pre-prosthetic phase, outcomes may improve. For example, wound healing is a modifiable factor. A person with a residual limb that is not healed is less likely to be successfully fit with a prosthesis if admitted to inpatient rehabilitation. However, they should not be ruled out from prosthetic fitting on this basis. Sufficient time for wound healing should be allowed before attempting prosthetic fitting and, for those who are slow to heal, interventions to promote wound healing can be utilized. The same could be said for ulceration of the remaining foot, where a period of off-loading may be required to allow the wound to heal before beginning prosthetic fitting. Likewise, a person who struggles with dressing may benefit from assessment and intervention by an Occupational Therapist or may need an adequate amount of social support if they cannot learn to manage these tasks themselves. If these factors are addressed in the pre-prosthetic phase, they should not become barriers to prosthetic fitting.

When a decision is made to proceed with inpatient prosthetic fitting, the LLAMS can assist health professional teams in estimating and informing people with LLA with respect to their length of stay. The average LLAMS score in our sample was 10.5±4.6, which was similar to the previous LLAMS study (10.4±4.1)[107]. Cheifetz et al. suggested that people who scored above the cut-off of 10 would likely require the longer (seven week) program at their facility[107], helping patient and providers plan for their program of care. Additionally, level of amputation should also be used to aid in this estimation. In our sample, people with above-knee amputations had a length of stay that was on average three weeks longer than those with below-knee amputation. Therefore, people with an above-knee amputation should be advised to plan for a longer length of stay, regardless of their LLAMS score. As well, identification of specific factors such as cognitive deficits and living alone indicated that a longer length of stay may be necessary.

Length of stay can be kept to a minimum if impairments likely to extend the persons rehabilitation stay are addressed in the pre-prosthetic phase. People with cognitive deficits or psychiatric illness may benefit from cognitive rehabilitation or intervention by mental health professionals to ensure they are best prepared to begin prosthetic fitting. As well, their living situation should be assessed prior to initiation of prosthetic fitting. A person who lives alone may need to consider having assistance arranged so they have an adequate amount of support when they are discharged from inpatient rehabilitation and they should ensure that their home is ready for them to return to at discharge. For example, clients with stairs to enter their home can have a ramp installed to facilitate accessibility. Clients may require assistance from Occupational Therapists and Social Workers to facilitate access to the appropriate resources. Identification and treatment of these impairments in people with LLA in the pre-prosthetic phase may lead to a smoother transition to the prosthetic fitting phase.

By utilizing the LLAMS prior to admission to rehabilitation, such as on discharge from the acute care hospital or in a follow-up clinic, people with LLA can be optimally managed to improve prosthetic fitting outcomes. The total LLAMS score can be used to predict outcomes and modifiable items identified in the LLAMS can be addressed to minimize their effect on prosthetic fitting success and length of stay.

3.12 Healthcare System changes are needed to improve outcomes for rehabilitation of people with LLA

Hospital staff and administrators attempt to limit the length of stay to the minimum length that is required to achieve the patient's goal. Patients need to move through inpatient rehabilitation as quickly as possible so that patients waiting for admission are not required to wait longer than is necessary. Some outcomes take length of stay into account as a measure of efficiency and the healthcare team's effectiveness in relation to the time required for the patient to achieve their goals. For example, length of stay efficiency in rehabilitation is measured by the change in FIM® scores from admission to discharge divided by the length of stay. Length of stay efficiency is reported by the Canadian Institute for Health Information for comparison of similar rehabilitation facilities nationally. Changes to the way rehabilitation is delivered to people with LLA may be necessary to improve rehabilitation length of stay. It is interesting to note that there was a trend in our data towards a reduced length of stay over the duration of the data collection period (2010-2017; Figure 3.1). Several measures to reduce length of stay were implemented at the facility during this time, such as use of the LLAMS tool and early identification of an estimated date of discharge. Although outside the scope of this thesis, these strategies did seem to have some impact on length of stay. Similar results were observed in Australia where streamlining multidisciplinary services and the introduction of an interim prosthesis program resulted in significant reductions in rehabilitation length of stay and time to walking with a prosthesis[105].

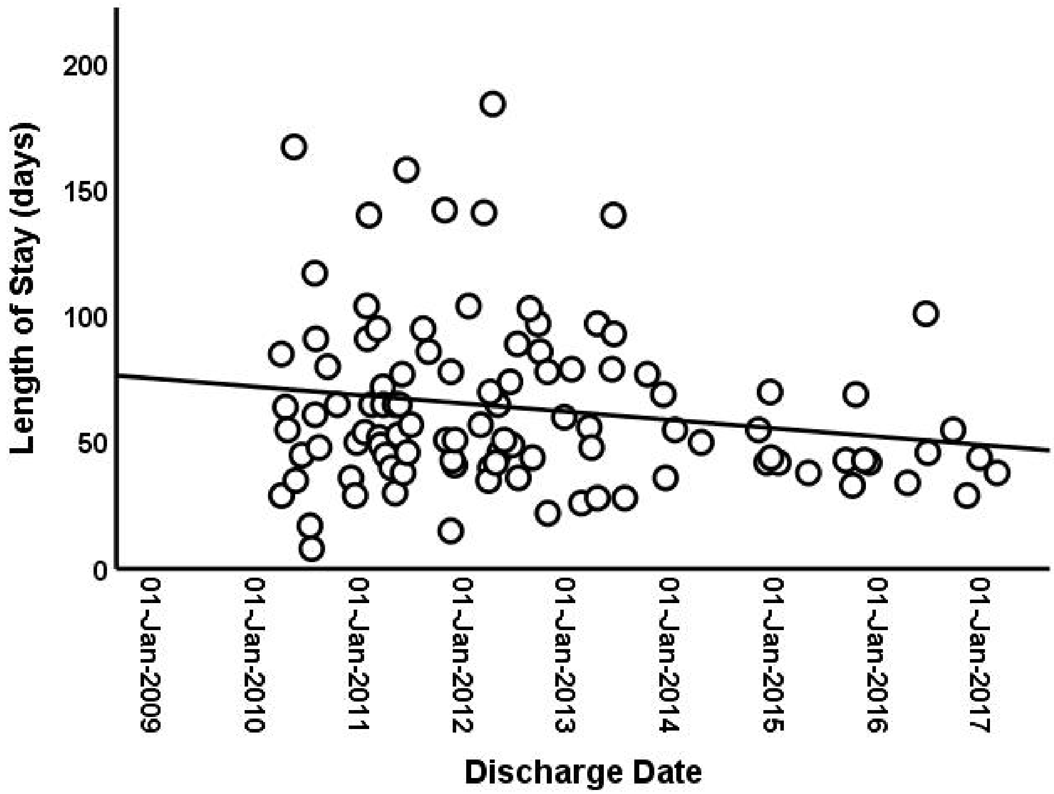

Figure 3. 1 Length of stay across the data collection period

The total inpatient length of stay for the 22 patients in our study who failed prosthetic fitting was 1447 days, which appears to represent a considerable misuse of rehabilitation resources. Each of these patients underwent admission to a rehabilitation facility only to leave without achieving their admission goal. From the perspective of healthcare utilization, substantial resources were invested which did not lead to successful outcomes. While prosthetic fitting was not successful, patients may have still benefitted from rehabilitation in terms of improving function without a prosthesis. Although not analysed in this thesis, our data suggested that there were fewer failures of prosthetic fitting during the last three years (2014-2017) of data collection compared to the first three years (2010-2013). Interestingly, there were no prosthetic failures in the last half of the data collection period (Figure 3.2). Several initiatives were implemented at the facility over this timeframe to improve prosthetic candidate selection, including use of the LLAMS tool and establishing an interdisciplinary amputee clinic. It is likely that these initiatives provided more careful screening of potential admissions, suggesting that the facility is already on its way towards improving the utilization of inpatient rehabilitation resources. As well, this trend towards fewer fitting failures over time coincided with a reduced length of stay.

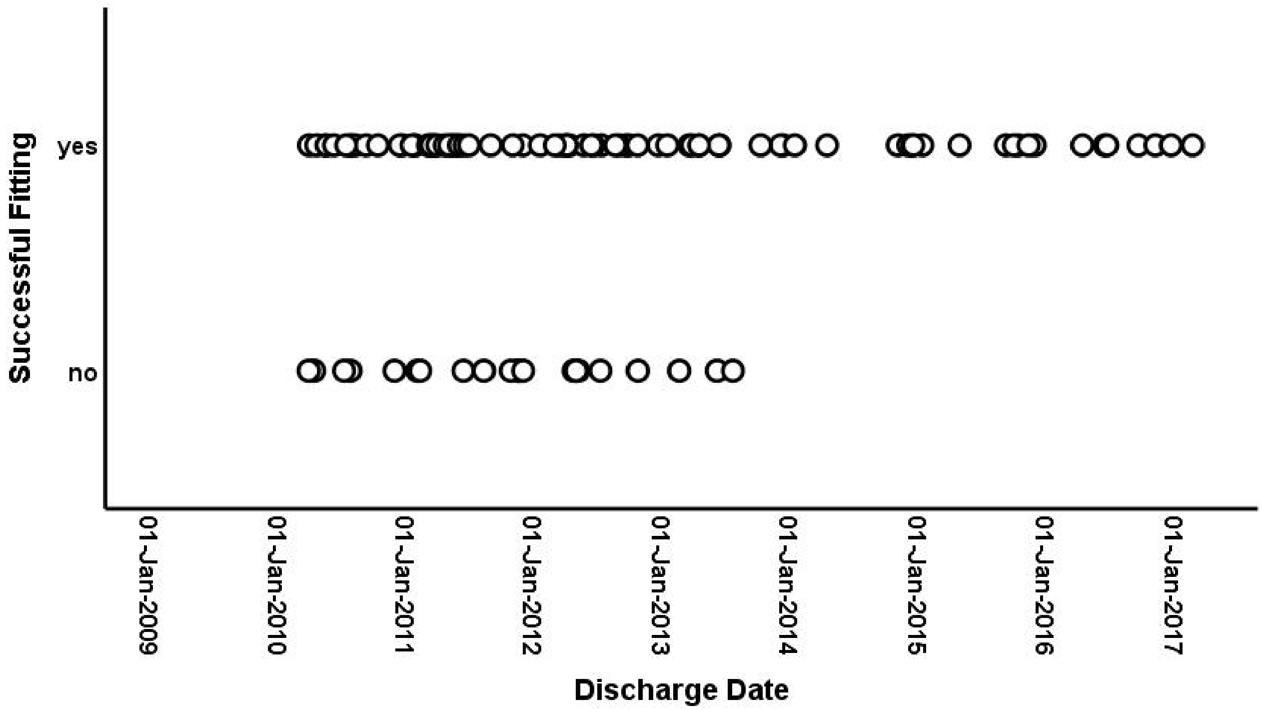

Figure 3. 2 Successful prosthetic fitting across the data collection period

To further improve delivery of rehabilitation to people with LLA, different approaches should be considered. Effective strategies could include addressing major risk factors for LLA, such as diabetes and peripheral arterial disease, as well as improving vascular interventions to prevent the need for LLA. Efforts to reduce traumatic amputations from motor vehicle accidents and workplace injuries should continue. Other strategies could include provincial or national initiatives to standardize the approach to post-amputation care, follow-up, and rehabilitation. Provision of rehabilitation services for people with LLA in Canada is quite varied[94]. Considering the expected increase in prevalence of LLA[14], and the already high incidence in places like Newfoundland and Labrador[2], consistent strategies are necessary to provide high quality rehabilitation services for people with LLA. Imam et al. stated that there is a *"dearth of evidence based data on lower limb prosthetic rehabilitation in Canada"*[94]. Our study provides further evidence to help describe the state of prosthetic rehabilitation in one province in Canada. In this study, we reported data on length of stay and successful prosthetic fitting as well as variables that can be used as predictors of these two outcomes. Our research added to the body of literature in this area and had several novel findings related to the use of the LLAMS to predict prosthetic fitting and the subanalysis of the LLAMS to identify specific predictors of length of stay and prosthetic fitting in this sample. The effects of strategies to improve prosthetic candidate selection and process efficiency requires further study.

3.13 Study Limitations

The patient characteristics in our sample limit the generalizability of the results. The sample was in some ways typical of the population of people with LLA in Canada, in that it had a high proportion of males and below-knee amputations, with an average age around 65[2]. However, there was a very high proportion of patients with a diabetic/vascular etiology in our sample. Therefore, the results can only be generalized to people with LLA due to diabetes and/or vascular disease. As well, there are a mix of inpatient and outpatient rehabilitation programs available in Canada[94], but this sample was from an inpatient rehabilitation facility so should not be generalized to other rehabilitation settings. Since people in this sample had some level of screening prior to admission to inpatient rehabilitation, the results regarding successful prosthetic fitting rates of success were likely higher than if we had taken a sample from all amputees referred to the facility. However, the focus of this study was on inpatient rehabilitation and understanding variables associated with prolonged length of stay and failed prosthetic fitting in this setting. As such, success was defined based on whether the patient was able to use the prosthesis at discharge. Data was not collected on walking ability with the prosthesis or continued use of the prosthesis after discharge, so results should not be interpreted as being directly applicable to these outcomes. The LLAMS was a significant predictor of LOS and successful fitting at the 95% confidence level, however the confidence intervals were wide meaning the actual effect could be small compared to the point estimates. This decreases the overall strength of our findings and is a limitation related to this study's relatively small sample size. As a retrospective study, there were potentially important variables that could not be analyzed because they were not available in the database provided for analysis. The data was originally collected by the inpatient rehabilitation facility for a quality improvement project. If we had designed this as a prospective study, we may have had the opportunity to collect more variables, based on our review of the literature, that could have impacted our key outcomes.

Even with more variables available, we may have been limited by the sample size available to adequately power analysis of additional variables.

3.14 Future Research Directions

There is a need for more research in the area of rehabilitation for people with LLA in Canada[9, 94]. While the study presented here contributes to filling this gap, more research is needed to provide high quality evidence to inform health care decision makers and people with LLA. A recent publication involving a panel of experts in amputation-related research in Canada concluded: *"Compared to other patient population groups, the field of amputation research in Canada lacks cohesion largely due to limited funding sources, lack of connection among research scientists, and loose ties among geographically dispersed healthcare centres, research institutes and advocacy groups. As a result, advances in clinical care are hampered and ultimately negatively influence outcomes of persons living with limb loss."*[123].

The expert panel reached consensus on three research priorities: (1) developing a national database to obtain robust limb loss epidemiological and outcomes data; (2) obtaining health economics data to illustrate the burden of amputation to the healthcare system; and (3) identifying a strategy to improve outcome measurement across various domains[123]. With the highest incidence of LLA[2] and longest length of stay[9, 25, 61] and one of the highest hospital mortality rates[61] in the Canada, it is imperative that Newfoundland and Labrador be included in these research efforts.

Specifically related to the objectives of this thesis, it would be beneficial to prospectively validate the LLAMS as a predictor of length of stay and successful prosthetic fitting in a sample that had not yet been screened for prosthetic candidacy. As well, follow-up after discharge from rehabilitation would help determine whether the LLAMS was able to predict long-term prosthetic use. Similarly, with a follow-up period it would be beneficial to assess other outcomes such as quality of life or healthcare burden data to identify variables that contribute to improvements in these outcomes.

We have demonstrated potential for the LLAMS to be shortened from its original 31 items, however our results had to be viewed with caution since we could not complete a multiple regression model including all 31 items. Other data analysis designs involving stepwise regression could be explored to identify which items should be retained in a revised LLAMS tool and whether there should be one tool for the prediction of length of stay and successful prosthetic fitting or whether the tool should be split into two tools. Again, this would be best completed in an adequately powered prospective cohort of people with LLA who had not yet been screened for prosthetic candidacy so that the results could be more generalizable.

There is still a need for further research to identify all the variables associated with inpatient rehabilitation length of stay and successful prosthetic fitting. Inconsistency in study design and outcomes have hampered the ability to make firm conclusions about even the most well-studied variables. Some variables have only been evaluated in a small number of studies. As well, variables considered important by clinicians such as motivation and determination were not well-studied and even if included as variables, lack a consistent approach to measurement[121].

3.15 Conclusions

Chapter One of this thesis outlined the common causes of LLA, the impact that LLA has on people who undergo this procedure, and the impact on the healthcare system. The usual processes for rehabilitation of people with LLA were outlined. For people with LLA, predictors of successful prosthetic fitting and inpatient rehabilitation length of stay were discussed, as well as the limited tools available to aid clinical decision making. There was a clear gap in the literature without a validated tool to predict successful prosthetic fitting and length of stay in the inpatient rehabilitation setting. The results of this study, described in Chapter Two, demonstrated the need for such tools, since the observed length of stay was long and over one fifth of people admitted for prosthetic fitting were unable to successfully use a prosthesis at discharge. In this sample, the only variable able to predict both prosthetic fitting and length of stay was the LLAMS. Lower admission FIM® score or having an above-knee amputation predicted longer length of stay but not successful prosthetic fitting. Therefore, the LLAMS should be considered as a tool to assist in planning for inpatient rehabilitation of people with LLA.

The subanalysis of the LLAMS revealed that it does have potential to be shortened to make it faster and easier to use in a clinical setting. As well, the strongest predictors of length and stay and successful prosthetic fitting within the LLAMS had no overlap, suggesting that there may be value in splitting it into separate tools for the prediction of these two outcomes. The strongest predictors of length of stay were items related to cognition, clinical reasoning and living situation, whereas the strongest predictors of successful prosthetic fitting were related to functional and physical items.

Chapter Three explored the applicability of the findings in Chapter Two. For instance, age, sex, and time from surgery to admission did not predict length of stay or successful prosthetic fitting in this sample. This may be due to the pre-screening prior to admission or the way success was defined but could also reflect that these variables have less influence on these outcomes in the inpatient rehabilitation setting. Future research is recommended to further elucidate the roles of these and other variables on key outcomes in the inpatient rehabilitation setting.

REFERENCES

1. Jorge, M., *Etiology of Amputation*, in *Orthotics and Prosthetics in Rehabilitation*, K.M. Chui, J; Sheng-Che, Y; Lusardi, MM., Editor. 2020, Elsevier. p. 432-445.
2. Imam, B., W.C. Miller, H.C. Finlayson, J.J. Eng, and T. Jarus, *Incidence of lower limb amputation in Canada.* Can J Public Health, 2017. **108**(4): p. e374-e380.
3. Fleury, A.M., S.A. Salih, and N.M. Peel, *Rehabilitation of the older vascular amputee: a review of the literature.* Geriatr Gerontol Int, 2013. **13**(2): p. 264-73.
4. Kolger, G.B., M; Hilliard, JE; Chui, KK, *Materials and Technology*, in *Orthotics and Prosthetics in Rehabilitation*, K.M. Chui, J; Sheng-Che, Y; Lusardi, MM., Editor. 2020, Elsevier. p. 144-163.
5. Group, T.R.O.L.L.A.W., *VA/DoD CLINICAL PRACTICE GUIDELINE FOR REHABILITATION OF LOWER LIMB AMPUTATION* 2007.
6. Davie-Smith, F., E. Coulter, B. Kennon, S. Wyke, and L. Paul, *Factors influencing quality of life following lower limb amputation for peripheral arterial occlusive disease: A systematic review of the literature.* Prosthet Orthot Int, 2017. **41**(6): p. 537-547.
7. Waters, R.L., J. Perry, D. Antonelli, and H. Hislop, *Energy cost of walking of amputees: the influence of level of amputation.* J Bone Joint Surg Am, 1976. **58**(1): p. 42-6.
8. Chihuri, S. and C.K. Wong, *Factors associated with the likelihood of fall-related injury among people with lower limb loss.* Inj Epidemiol, 2018. **5**(1): p. 42.
9. Kayssi, A., S. Dilkas, D.L. Dance, C. de Mestral, T.L. Forbes, and G. Roche-Nagle, *Rehabilitation Trends After Lower Extremity Amputations in Canada.* Pm r, 2017. **9**(5): p. 494-501.

10. Kahle, J.T., M.J. Highsmith, H. Schaepper, A. Johannesson, M.S. Orendurff, and K. Kaufman, *PREDICTING WALKING ABILITY FOLLOWING LOWER LIMB AMPUTATION: AN UPDATED SYSTEMATIC LITERATURE REVIEW.* Technol Innov, 2016. **18**(2-3): p. 125-137.

11. Ries, J.N., KJ, *Early Rehabilitation in Lower Extremity Dysvascular Amputation*, in *Orthotics and Prosthetics in Rehabilitation*, K.M. Chui, J; Sheng-Che, Y; Lusardi, MM., Editor. 2020, Elsevier. p. 666-703.

12. Grimm, P.P., BK, *Amputation Surgeries for the Lower Limb*, in *Orthotics and Prosthetics in Rehabilitation*, K.M. Chui, J; Sheng-Che, Y; Lusardi, MM., Editor. 2020, Elsevier. p. 471-503.

13. Varma, P., M.G. Stineman, and T.R. Dillingham, *Epidemiology of limb loss.* Phys Med Rehabil Clin N Am, 2014. **25**(1): p. 1-8.

14. Ziegler-Graham, K., E.J. MacKenzie, P.L. Ephraim, T.G. Travison, and R. Brookmeyer, *Estimating the prevalence of limb loss in the United States: 2005 to 2050.* Arch Phys Med Rehabil, 2008. **89**(3): p. 422-9.

15. Moxey, P.W., et al., *Lower extremity amputations--a review of global variability in incidence.* Diabet Med, 2011. **28**(10): p. 1144-53.

16. Canada, P.H.A.o. *Stroke in Canada: HIGHLIGHTS FROM THE CANADIAN CHRONIC DISEASE SURVEILLANCE SYSTEM*. 2017; Available from: https://www.canada.ca/en/public-health/services/publications/diseases-conditions/stroke-canada-fact-sheet.html.

17. Goldberg, J.B., P.P. Goodney, J.L. Cronenwett, and F. Baker, *The effect of risk and race on lower extremity amputations among Medicare diabetic patients.* J Vasc Surg, 2012. **56**(6): p. 1663-8.

18. Shah, B.R., et al., *Peripheral arterial disease in Ontario First Nations people with diabetes: a longitudinal population-based cohort study.* CMAJ Open, 2019. **7**(4): p. E700-e705.

19. McIntyre, I., C. Boughen, E. Trepman, and J.M. Embil, *Foot and ankle problems of Aboriginal and non-Aboriginal diabetic patients with end-stage renal disease.* Foot Ankle Int, 2007. **28**(6): p. 674-86.

20. Pecoraro, R.E., G.E. Reiber, and E.M. Burgess, *Pathways to diabetic limb amputation. Basis for prevention.* Diabetes Care, 1990. **13**(5): p. 513-21.

21. Singh, N., D.G. Armstrong, and B.A. Lipsky, *Preventing foot ulcers in patients with diabetes.* Jama, 2005. **293**(2): p. 217-28.

22. Prompers, L., et al., *Prediction of outcome in individuals with diabetic foot ulcers: focus on the differences between individuals with and without peripheral arterial disease. The EURODIALE Study.* Diabetologia, 2008. **51**(5): p. 747-55.

23. Yang, S.L., L.Y. Zhu, R. Han, L.L. Sun, J.X. Li, and J.T. Dou, *Pathophysiology of peripheral arterial disease in diabetes mellitus.* J Diabetes, 2017. **9**(2): p. 133-140.

24. Althouse, A.D., et al., *Risk factors for incident peripheral arterial disease in type 2 diabetes: results from the Bypass Angioplasty Revascularization Investigation in type 2 Diabetes (BARI 2D) Trial.* Diabetes Care, 2014. **37**(5): p. 1346-52.

25. Imam, B., *Incidence and rehabiliation of lower limb amputation in Canada, and feasibility of a novel training program.*, in *Rehabilitation Sciences*. 2017, University of British Columbia. p. 280.

26. Norgren, L., et al., *Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II).* Eur J Vasc Endovasc Surg, 2007. **33 Suppl 1**: p. S1-75.

27. Swaminathan, A., S. Vemulapalli, M.R. Patel, and W.S. Jones, *Lower extremity amputation in peripheral artery disease: improving patient outcomes.* Vasc Health Risk Manag, 2014. **10**: p. 417-24.

28. Teraa, M., M.S. Conte, F.L. Moll, and M.C. Verhaar, *Critical Limb Ischemia: Current Trends and Future Directions.* J Am Heart Assoc, 2016. **5**(2).

29. Reinecke, H., et al., *Peripheral arterial disease and critical limb ischaemia: still poor outcomes and lack of guideline adherence.* Eur Heart J, 2015. **36**(15): p. 932-8.

30. Bumpus, K. and M.A. Maier, *The ABC's of wound care.* Curr Cardiol Rep, 2013. **15**(4): p. 346.

31. Lindbloom, B.J., E.R. James, and W.C. McGarvey, *Osteomyelitis of the foot and ankle: diagnosis, epidemiology, and treatment.* Foot Ankle Clin, 2014. **19**(3): p. 569-88.

32. Lam, A., et al., *Chronic Osteomyelitis of the tibia and ankle treated with Limb Salvage Reconstruction.* J Bone Jt Infect, 2019. **4**(6): p. 306-313.

33. Ahn, J., et al., *Lower Extremity Necrotizing Fasciitis in Diabetic and Nondiabetic Patients: Mortality and Amputation.* Int J Low Extrem Wounds, 2019. **18**(2): p. 114-121.

34. Leiblein, M., I. Marzi, A.L. Sander, J.H. Barker, F. Ebert, and J. Frank, *Necrotizing fasciitis: treatment concepts and clinical results.* Eur J Trauma Emerg Surg, 2018. **44**(2): p. 279-290.

35. Gotts, J.E. and M.A. Matthay, *Sepsis: pathophysiology and clinical management.* Bmj, 2016. **353**: p. i1585.

36. America, L.L.T.F.A.C.o., *Roadmap for improving patient-centred outcomes research and advocacy.* 2019, Amputee Coalition of America: Knoxville, Tennessee.

37. Loder, R.T., *Demographics of traumatic amputations in children. Implications for prevention strategies.* J Bone Joint Surg Am, 2004. **86**(5): p. 923-8.

38. Ephraim, P.L., T.R. Dillingham, M. Sector, L.E. Pezzin, and E.J. Mackenzie, *Epidemiology of limb loss and congenital limb deficiency: a review of the literature.* Arch Phys Med Rehabil, 2003. **84**(5): p. 747-61.

39. Radhakrishnan, S., et al., *The use of the International Classification of Functioning, Disability and Health to classify the factors influencing mobility reported by persons with an amputation: An international study.* Prosthet Orthot Int, 2017. **41**(4): p. 412-419.

40. Sansam, K., V. Neumann, R. O'Connor, and B. Bhakta, *Predicting walking ability following lower limb amputation: a systematic review of the literature.* J Rehabil Med, 2009. **41**(8): p. 593-603.

41. Czerniecki, J.M. and D.C. Morgenroth, *Metabolic energy expenditure of ambulation in lower extremity amputees: what have we learned and what are the next steps?* Disabil Rehabil, 2017. **39**(2): p. 143-151.

42. van Schaik, L., J.H.B. Geertzen, P.U. Dijkstra, and R. Dekker, *Metabolic costs of activities of daily living in persons with a lower limb amputation: A systematic review and meta-analysis.* PLoS One, 2019. **14**(3): p. e0213256.

43. Halsne, E.G., M.G. Waddingham, and B.J. Hafner, *Long-term activity in and among persons with transfemoral amputation.* J Rehabil Res Dev, 2013. **50**(4): p. 515-30.

44. Czerniecki, J.M., A.P. Turner, R.M. Williams, K.N. Hakimi, and D.C. Norvell, *The effect of rehabilitation in a comprehensive inpatient rehabilitation unit on mobility outcome after dysvascular lower extremity amputation.* Arch Phys Med Rehabil, 2012. **93**(8): p. 1384-91.

45. Fajardo-Martos, I., O. Roda, R. Zambudio-Periago, A. Bueno-Cavanillas, F. Hita-Contreras, and I. Sanchez-Montesinos, *Predicting successful prosthetic rehabilitation in major lower-limb amputation patients: a 15-year retrospective cohort study.* Braz J Phys Ther, 2018. **22**(3): p. 205-214.

46. Fortington, L.V., G.M. Rommers, J.H. Geertzen, K. Postema, and P.U. Dijkstra, *Mobility in elderly people with a lower limb amputation: a systematic review.* J Am Med Dir Assoc, 2012. **13**(4): p. 319-25.

47. Davies, B. and D. Datta, *Mobility outcome following unilateral lower limb amputation.* Prosthet Orthot Int, 2003. **27**(3): p. 186-90.

48. Stepien, J.M., S. Cavenett, L. Taylor, and M. Crotty, *Activity levels among lower-limb amputees: self-report versus step activity monitor.* Arch Phys Med Rehabil, 2007. **88**(7): p. 896-900.

49. Parker, K., R.L. Kirby, J. Adderson, and K. Thompson, *Ambulation of people with lower-limb amputations: relationship between capacity and performance measures.* Arch Phys Med Rehabil, 2010. **91**(4): p. 543-9.

50. Klute, G.K., J.S. Berge, M.S. Orendurff, R.M. Williams, and J.M. Czerniecki, *Prosthetic intervention effects on activity of lower-extremity amputees.* Arch Phys Med Rehabil, 2006. **87**(5): p. 717-22.

51. Miller, M.J., P.F. Cook, P.W. Kline, C.B. Anderson, J.E. Stevens-Lapsley, and C.L. Christiansen, *Physical Function and Pre-Amputation Characteristics Explain Daily Step Count after Dysvascular Amputation.* Pm r, 2019.

52. Zidarov, D., B. Swaine, and C. Gauthier-Gagnon, *Quality of life of persons with lower-limb amputation during rehabilitation and at 3-month follow-up.* Arch Phys Med Rehabil, 2009. **90**(4): p. 634-45.

53. Madsen, U.R., C. Baath, C.B. Berthelsen, and A. Hommel, *A prospective study of short-term functional outcome after dysvascular major lower limb amputation.* Int J Orthop Trauma Nurs, 2018. **28**: p. 22-29.

54. Traballesi, M., S. Brunelli, L. Pratesi, M. Pulcini, C. Angioni, and S. Paolucci, *Prognostic factors in rehabilitation of above knee amputees for vascular diseases.* Disabil Rehabil, 1998. **20**(10): p. 380-4.

55. Rehabilitation, U.D.S.M. *The FIM instrument: Its Background, Structure, and Usefulness.* 2012; Available from: https://www.udsmr.org/Documents/The_FIM_Instrument_Background_Structure_and_Usefulness.pdf.

56. Panesar, B.S., P. Morrison, and J. Hunter, *A comparison of three measures of progress in early lower limb amputee rehabilitation.* Clin Rehabil, 2001. **15**(2): p. 157-71.

57. Stineman, M.G., et al., *The Functional Independence Measure: tests of scaling assumptions, structure, and reliability across 20 diverse impairment categories.* Arch Phys Med Rehabil, 1996. **77**(11): p. 1101-8.

58. Hershkovitz, A., I. Dudkiewicz, and S. Brill, *Rehabilitation outcome of post-acute lower limb geriatric amputees.* Disabil Rehabil, 2013. **35**(3): p. 221-7.

59. Stineman, M.G., et al., *Prognostic differences for functional recovery after major lower limb amputation: effects of the timing and type of inpatient rehabilitation services in the Veterans Health Administration.* Pm r, 2010. **2**(4): p. 232-43.

60. Leung, E.C., P.J. Rush, and M. Devlin, *Predicting prosthetic rehabilitation outcome in lower limb amputee patients with the functional independence measure.* Arch Phys Med Rehabil, 1996. **77**(6): p. 605-8.

61. Kayssi, A., C. de Mestral, T.L. Forbes, and G. Roche-Nagle, *A Canadian population-based description of the indications for lower-extremity amputations and outcomes.* Can J Surg, 2016. **59**(2): p. 99-106.

62. Arneja, A.S., J. Tamiji, B.M. Hiebert, P.S. Tappia, and L. Galimova, *Functional outcomes of patients with amputation receiving chronic dialysis for end-stage renal disease.* Am J Phys Med Rehabil, 2015. **94**(4): p. 257-68.

63. Organization, W.H. *Health statistics and information systems*. [cited 2020; Available from: https://www.who.int/healthinfo/survey/whoqol-qualityoflife/en/.

64. Xu, J., F. Kohler, and H. Dickson, *Systematic review of concepts measured in individuals with lower limb amputation using the International Classification of Functioning, Disability and Health as a reference.* Prosthet Orthot Int, 2011. **35**(3): p. 262-8.

65. Legro, M.W., G.D. Reiber, D.G. Smith, M. del Aguila, J. Larsen, and D. Boone, *Prosthesis evaluation questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life.* Arch Phys Med Rehabil, 1998. **79**(8): p. 931-8.

66. Gallagher, P. and M. MacLachlan, *Development and psychometric evaluation of the Trinity Amputation and Prosthesis Experience Scales (TAPES).* Rehabilitation Psychology, 2000. **45**(2): p. 130-154.

67. Suckow, B.D., et al., *Domains that Determine Quality of Life in Vascular Amputees.* Ann Vasc Surg, 2015. **29**(4): p. 722-30.

68. Fortington, L.V., P.U. Dijkstra, J.C. Bosmans, W.J. Post, and J.H. Geertzen, *Change in health-related quality of life in the first 18 months after lower limb amputation: a prospective, longitudinal study.* J Rehabil Med, 2013. **45**(6): p. 587-94.

69. Sinha, R. and W.J. Van Den Heuvel, *A systematic literature review of quality of life in lower limb amputees.* Disabil Rehabil, 2011. **33**(11): p. 883-99.

70. Davis, R.W., *Phantom sensation, phantom pain, and stump pain.* Arch Phys Med Rehabil, 1993. **74**(1): p. 79-91.

71. Gallagher, P., D. Allen, and M. Maclachlan, *Phantom limb pain and residual limb pain following lower limb amputation: a descriptive analysis.* Disabil Rehabil, 2001. **23**(12): p. 522-30.

72. Ehde, D.M., et al., *Chronic phantom sensations, phantom pain, residual limb pain, and other regional pain after lower limb amputation.* Arch Phys Med Rehabil, 2000. **81**(8): p. 1039-44.

73. Smith, E., C. Comiskey, and N. Ryall, *Prevalence and patterns of back pain and residual limb pain in lower limb amputees at the National Rehabilitation Hospital.* Ir J Med Sci, 2008. **177**(1): p. 53-7.

74. Uustal, H. and R.H. Meier, 3rd, *Pain issues and treatment of the person with an amputation.* Phys Med Rehabil Clin N Am, 2014. **25**(1): p. 45-52.

75. Desrochers, J., C. Frengopoulos, M.W.C. Payne, R. Viana, and S.W. Hunter, *Relationship between body image and physical functioning following rehabilitation for lower-limb amputation.* Int J Rehabil Res, 2019. **42**(1): p. 85-88.

76. Holzer, L.A., F. Sevelda, G. Fraberger, O. Bluder, W. Kickinger, and G. Holzer, *Body image and self-esteem in lower-limb amputees.* PLoS One, 2014. **9**(3): p. e92943.

77. Woods, L., D. Hevey, N. Ryall, and F. O'Keeffe, *Sex after amputation: the relationships between sexual functioning, body image, mood and anxiety in persons with a lower limb amputation.* Disabil Rehabil, 2018. **40**(14): p. 1663-1670.

78. McKechnie, P.S. and A. John, *Anxiety and depression following traumatic limb amputation: a systematic review.* Injury, 2014. **45**(12): p. 1859-66.

79. Horgan, O. and M. MacLachlan, *Psychosocial adjustment to lower-limb amputation: a review.* Disabil Rehabil, 2004. **26**(14-15): p. 837-50.

80. Turner, A.P., et al., *Suicidal ideation among individuals with dysvascular lower extremity amputation.* Arch Phys Med Rehabil, 2015. **96**(8): p. 1404-10.

81. Luza, L.P. and E.G. Ferreira, *Psychosocial and physical adjustments and prosthesis satisfaction in amputees: a systematic review of observational studies.* 2019: p. 1-8.

82. Aulivola, B., et al., *Major lower extremity amputation: outcome of a modern series.* Arch Surg, 2004. **139**(4): p. 395-9; discussion 399.

83. Nehler, M.R., et al., *Functional outcome in a contemporary series of major lower extremity amputations.* J Vasc Surg, 2003. **38**(1): p. 7-14.

84. Jordan, R.W., A. Marks, and D. Higman, *The cost of major lower limb amputation: a 12-year experience.* Prosthet Orthot Int, 2012. **36**(4): p. 430-4.

85. Dillingham, T.R., L.E. Pezzin, and A.D. Shore, *Reamputation, mortality, and health care costs among persons with dysvascular lower-limb amputations.* Arch Phys Med Rehabil, 2005. **86**(3): p. 480-6.

86. Stern, J.R., et al., *A Meta-analysis of Long-term Mortality and Associated Risk Factors following Lower Extremity Amputation.* Ann Vasc Surg, 2017. **42**: p. 322-327.

87. Norvell, D.C., et al., *Mortality prediction following non-traumatic amputation of the lower extremity.* Br J Surg, 2019. **106**(7): p. 879-888.

88. MacKenzie, E.J., et al., *Early predictors of long-term work disability after major limb trauma.* J Trauma, 2006. **61**(3): p. 688-94.

89. Franklin, H., M. Rajan, C.L. Tseng, L. Pogach, A. Sinha, and M. Mph, *Cost of lower-limb amputation in U.S. veterans with diabetes using health services data in fiscal years 2004 and 2010.* J Rehabil Res Dev, 2014. **51**(8): p. 1325-30.

90. Blough, D.K., S. Hubbard, L.V. McFarland, D.G. Smith, J.M. Gambel, and G.E. Reiber, *Prosthetic cost projections for servicemembers with major limb loss from Vietnam and OIF/OEF.* J Rehabil Res Dev, 2010. **47**(4): p. 387-402.

91. Niewczyk, P., et al., *Factors associated with total inpatient costs and length of stay during surgical hospitalization among veterans who underwent lower extremity amputation.* Rehabil Res Pract, 2013. **92**(3): p. 203-14.

92. Smith S, P.H., Jones A, Baker H, Springate G, Randell T, Moloney C, Hancock A, Newcombe L, Shaw C, Rose A, Slack H, Norman C. . *Clinical guidelines for the pre and post-operative physiotherapy management of adults with lower limb amputations*. 2016; 2nd:[Available from: http://bacpar.csp.org.uk/.

93. Deathe, B., W.C. Miller, and M. Speechley, *The status of outcome measurement in amputee rehabilitation in Canada.* Arch Phys Med Rehabil, 2002. **83**(7): p. 912-8.

94. Imam, B., W.C. Miller, H.C. Finlayson, J.J. Eng, and T. Jarus, *Lower Limb Prosthetic Rehabilitation in Canada: A Survey Study.* Physiother Can, 2019. **71**(1): p. 11-21.

95. Stineman, M.G., et al., *The effectiveness of inpatient rehabilitation in the acute postoperative phase of care after transtibial or transfemoral amputation: study of an integrated health care delivery system.* Arch Phys Med Rehabil, 2008. **89**(10): p. 1863-72.

96. Michael, J., *Prosthetic Suspensions and Components*, in *Atlas of Amputations and Limb Deficiencies: Surgical, Prosthetic, and Rehabilitation Principles*, M.J. Smith DG, Bowker JH, Editor. 2004, American Academy of Orthopedic Surgeons: Rosemont, IL. p. 409-427.

97. Gailey, R.C., CR, *Physical Therapy*, in *Atlas of Amputations and Deficiencies: Surgical, Prosthetic, and Rehabilitation Principles*, M.J. Smith DG, Bowker JH, Editor. 2004, American Academy of Orthopaedic Surgeons. p. 589-619.

98. Davie-Smith, F., L. Paul, N. Nicholls, W.P. Stuart, and B. Kennon, *The impact of gender, level of amputation and diabetes on prosthetic fit rates following major lower extremity amputation.* Prosthet Orthot Int, 2017. **41**(1): p. 19-25.

99. Gailey, R.S., et al., *The amputee mobility predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate.* Arch Phys Med Rehabil, 2002. **83**(5): p. 613-27.

100. Condie, M.E., A.K. McFadyen, S. Treweek, and L. Whitehead, *The trans-femoral fitting predictor: a functional measure to predict prosthetic fitting in transfemoral amputees--validity and reliability.* Arch Phys Med Rehabil, 2011. **92**(8): p. 1293-7.

101. Roffman, C.E., J. Buchanan, and G.T. Allison, *Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules.* J Physiother, 2014. **60**(4): p. 224-31.

102. Czerniecki, J.M., et al., *The development and validation of the AMPREDICT model for predicting mobility outcome after dysvascular lower extremity amputation.* J Vasc Surg, 2017. **65**(1): p. 162-171.e3.

103. Bowrey, S., H. Naylor, P. Russell, and J. Thompson, *Development of a scoring tool (BLARt score) to predict functional outcome in lower limb amputees.* Disabil Rehabil, 2019. **41**(19): p. 2324-2332.

104. Norvell, D.C., A.P. Turner, R.M. Williams, K.N. Hakimi, and J.M. Czerniecki, *Defining successful mobility after lower extremity amputation for complications of peripheral vascular disease and diabetes.* J Vasc Surg, 2011. **54**(2): p. 412-9.

105. Hordacre, B., V. Birks, S. Quinn, C. Barr, B.L. Patritti, and M. Crotty, *Physiotherapy rehabilitation for individuals with lower limb amputation: a 15-year clinical series.* Physiother Res Int, 2013. **18**(2): p. 70-80.

106. Karmarkar, A.M., J.E. Graham, T.A. Reistetter, A. Kumar, and J.M. Mix, *Association between Functional Severity and Amputation Type with Rehabilitation Outcomes in Patients with Lower Limb Amputation.* 2014. **2014**: p. 961798.

107. Cheifetz, O., M. Bayley, S. Grad, D. Lambert, C. Watson, and K. Minor, *The Lower Limb Amputee Measurement Scale: reliability and predictive validity.* Prosthet Orthot Int, 2007. **31**(3): p. 300-12.

108. Frengopoulos, C., J. Burley, R. Viana, M.W. Payne, and S.W. Hunter, *Association Between Montreal Cognitive Assessment Scores and Measures of Functional Mobility in Lower Extremity Amputees After Inpatient Rehabilitation.* Arch Phys Med Rehabil, 2017. **98**(3): p. 450-455.

109. Lee, D.J. and M.C. Costello, *The effect of cognitive impairment on prosthesis use in older adults who underwent amputation due to vascular-related etiology: A systematic review of the literature.* Prosthet Orthot Int, 2018. **42**(2): p. 144-152.

110. Erjavec, T., M. Presern-Strukelj, and H. Burger, *The diagnostic importance of exercise testing in developing appropriate rehabilitation programmes for patients following transfemoral amputation.* Eur J Phys Rehabil Med, 2008. **44**(2): p. 133-9.

111. Highsmith, M.J., et al., *Prosthetic interventions for people with transtibial amputation: Systematic review and meta-analysis of high-quality prospective literature and systematic reviews.* J Rehabil Res Dev, 2016. **53**(2): p. 157-84.

112. Soper, D.; Available from: www.danielsoper.com/statcalc.

113. Uustal, H., *Prosthetic rehabilitation issues in the diabetic and dysvascular amputee.* Phys Med Rehabil Clin N Am, 2009. **20**(4): p. 689-703.

114. Sawers, A., M.E. Hahn, V.E. Kelly, J.M. Czerniecki, and D. Kartin, *Beyond componentry: How principles of motor learning can enhance locomotor rehabilitation of individuals with lower limb loss--a review.* J Rehabil Res Dev, 2012. **49**(10): p. 1431-42.

115. Langridge, N., L. Roberts, and C. Pope, *The role of clinician emotion in clinical reasoning: Balancing the analytical process.* Man Ther, 2016. **21**: p. 277-81.

116. Brown, A.W., T.M. Therneau, B.A. Schultz, P.M. Niewczyk, and C.V. Granger, *Measure of functional independence dominates discharge outcome prediction after inpatient rehabilitation for stroke.* Stroke, 2015. **46**(4): p. 1038-44.

117. Moller, S., D. Rusaw, K. Hagberg, and N. Ramstrand, *Reduced cortical brain activity with the use of microprocessor-controlled prosthetic knees during walking.* Prosthet Orthot Int, 2019. **43**(3): p. 257-265.

118. Munin, M.C., M.C. Espejo-De Guzman, M.L. Boninger, S.G. Fitzgerald, L.E. Penrod, and J. Singh, *Predictive factors for successful early prosthetic ambulation among lower-limb amputees.* J Rehabil Res Dev, 2001. **38**(4): p. 379-84.

119. Meyer, M.J., et al., *A systematic review of studies reporting multivariable models to predict functional outcomes after post-stroke inpatient rehabilitation.* Disabil Rehabil, 2015. **37**(15): p. 1316-23.

120. Huang, C.T., et al., *Amputation: energy cost of ambulation.* Arch Phys Med Rehabil, 1979. **60**(1): p. 18-24.

121. Sansam, K., R.J. O'Connor, V. Neumann, and B. Bhakta, *Clinicians' perspectives on decision making in lower limb amputee rehabilitation.* J Rehabil Med, 2014. **46**(5): p. 447-53.

122. Schaffalitzky, E., P. Gallagher, M. Maclachlan, and S.T. Wegener, *Developing consensus on important factors associated with lower limb prosthetic prescription and use.* Disabil Rehabil, 2012. **34**(24): p. 2085-94.

123. Hitzig, S.L. and A.L. Mayo, *Identifying priorities and developing strategies for building capacity in amputation research in Canada.* 2020: p. 1-11.

APPENDIX 1 – Health Research Ethics Board Approval Letter

NEWFOUNDLAND AND LABRADOR
HREB
HEALTH RESEARCH ETHICS BOARD

Ethics Office
Suite 200, Eastern Trust Building
95 Bonaventure Avenue
St. John's, NL
A1B 2X5

July 11, 2018

Faculty of Medicine
Discipline of Medicine

Dear Dr. Chislett:

Researcher Portal File # 20190122
Reference # 2018.077

RE: "Determining Predictors of Rehabilitation Length of Stay in Adult Lower Limb Amputees Admitted for Prosthetic Fitting "

This will acknowledge receipt of your correspondence dated June 26, 2018.

Your application was reviewed by a sub-committee of the Health Research Ethics Board (HREB) via a delegated review process. Your revised application has been reviewed by the *Co-Chair under the direction of the HREB*.

Ethics approval of this research study is granted for one year effective July 10, 2018. This ethics approval will be reported to the HREB at the next scheduled meeting.

This is your ethics approval only. Organizational approval may also be required. It is your responsibility to seek the necessary organizational approval from the Regional Health Authority (RHA) or other organization as appropriate. You can refer to the HREA website for further guidance on organizational approvals.

This is to confirm that the HREB reviewed and approved or acknowledged the following documents (as indicated):

- Application, approved
- Research proposal, approved
- Letter of request, approved
- Budget, approved

MARK THE DATE

This ethics approval will lapse on July 10, 2019. It is your responsibility to ensure that the Ethics Renewal form is submitted prior to the renewal date; you may not receive a reminder. The Ethics Renewal form can be found on the Researcher Portal as an Event Form.

If you do not submit the completed Ethics Renewal form prior to date of renewal:

- **You will no longer have ethics approval**
- You will be required to stop research activity immediately
- You may not be permitted to restart the study until you reapply for and receive approval to undertake the study again
- Lapse in ethics approval **may result in interruption or termination of funding**.

You are solely responsible for providing a copy of this letter, along with your approved HREB application form; to **Research Grant and Contract Services** should your research depend on funding administered through that office.

Modifications of the protocol/consent are not permitted without prior approval from the HREB. **Implementing changes in the protocol/consent without HREB approval may result in your ethics approval being revoked, meaning your research must stop.** Request for modification to the protocol/consent must be outlined on an amendment form available on the Researcher Portal website as an Event Form and submitted to the HREB for review. Please refer to the attached guidance document regarding on-going reporting requirements to the HREB.

The HREB operates according to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), the Health Research Ethics Authority Act (HREA Act) and applicable laws and regulations.

You are responsible for the ethical conduct of this research, notwithstanding the approval of the HREB.

We wish you every success with your study.

Sincerely,

Elizabeth Dicks

Dr. Elizabeth Dicks (Co-Chair, Non-Clinical Trials Health Research Ethics Board Delegated Reviews)

CC: Dr. Michelle Ploughman

APPENDIX 2 – Research Proposals Approval Committee Approval Letter

Eastern Health

Department of Research
5th Floor Janeway Hostel
Health Sciences Centre
300 Prince Philip Drive
St. John's, NL A1B 3V6
Tel: (709) 752-4636
Fax: (709) 752-3591

August 15, 2018

Mr. Michael Chislett
100 Forest Road
St. John's, NL
A1A 1E5

Dear Mr. Chislett,

Your research proposal *HREB Reference #: 2018.077 "Determining Predictors of Rehabilitation Length of Stay in Adult Lower Limb Amputees Admitted for Prosthetic Fitting"* was reviewed by the Research Proposals Approval Committee (RPAC) of Eastern Health at a meeting dated August 14, 2018 and we are pleased to inform you that the proposal has been granted full approval.

The approval of this project is subject to the following conditions:

- The project is conducted as outlined in the HREB approved protocol;
- Adequate funding is secured to support the project;
- In the case of Health Records, efforts will be made to accommodate requests based upon available resources. If you require access to records that cannot be accommodated, then additional fees may be levied to cover the cost;
- A progress report being provided upon request.

If you have any questions or comments, please contact Krista Rideout, Manager of the Patient Research Centre at 777-7283 or by email at krista.rideout@easternhealth.ca.

Sincerely,

Farah McCrate

Farah McCrate
Regional Director, Research and Innovation
Co-Chair, RPAC

FM/rg

APPENDIX 3 – LLAMS

Lower Limb Amputee Measurement Scale (LLAMS)

Medical
1. Does the patient have Diabetes? Score 1 if answer is yes.
2. Is the patient Dialysis Dependent? Score 1 if answer is yes.
3. Does the patient have Chronic Obstructive Pulmonary Disease? Score 1 if answer is yes.
4. Does patient have history of Cerebrovascular Accident or Acquired Brain Injury? Score 1 if answer is yes.
5. Does patient have history of Myocardial Infarction or Congestive Heart Failure? Is the patient on diuretic or antihypertensive medication? Is there a history of Angina? Score 1 if answer is yes.
6. Does the patient have bilateral amputations? Score 1 if answer is yes.
Cognitive
7. Is the patient oriented to person (ask full name), place (ask for current location of the patient), and time (ask for full date, dd/mm/yyyy)? Score 1 if patient is wrong in any of the above. Patient can be wrong on the day by +/- 2, CANNOT be wrong on month or year.
8. Ask patient for the history of the current amputation. Score 1 if patient is vague and not sure of what caused the amputation and when. Do NOT score 1 if the difficulty is due to language only.
9. Does the patient have a history of cognitive impairments or psychiatric illness? Score 1 if answer is yes.
10. Ask patient to remember 4 items (tulip, baseball, telephone, orange). Patient is asked to repeat the items now and in 5 minutes. Score 1 if patient does NOT remember ALL items.
11. Is the patient able to wrap the stump? Score 1 if no.
12. Ask patient to name his/her medications and purpose. Score 1 if patient can NOT complete both tasks. Patient HAS to know ALL medications and their purpose to score a 0.
13. Ask the patient who organizes their medications. Score 1 if medications are NOT organized by patient, or if patient is in hospital.
Social
14. Will the patient live alone on discharge? Score 1 if yes.
15. Does patient live in a nursing home? Was the patient transferred from hospital (i.e. was the patient in hospital since amputation until they were transferred to Rehab)? Does the patient receive Home Care assistance? Score 1 if yes for any of the above. Circle which one.

16. Does the patient live in an inaccessible environment? Score 1 if yes or if patient has more than 2 stairs that are required to do (to enter or in the living environment). If patient is temporarily living on same level, score 1.
Physical
17. Does the patient have Neuropathy severe enough to impair proprioception in knee or other foot and ankle? Score 1 if yes.
18. Perform Thomas Test – Does patient have hip flexion contracture > 15 degrees; for B/K, does patient have knee flexion contracture > 15 degrees? Score 1 if yes for hip or knee of either side.
19. Does patient have muscle strength less than grade 4 for hip abductor, flexors, extensors, knee extensors or flexors of either side? Score 1 if strength in ANY of these muscles in less than 4/5.
20. Assess residual limb healing. Score 1 if there is a skin ulcer of grade 1-4.
21. Assess residual limb for swelling or poor shape (e.g. bulbous shape). Score 1 if edematous or poorly shaped residual limb.
22. Assess for skin ulceration on remaining foot or heel. Score 1 if ulceration is present.
23. Assess remaining leg for problems with pain, vascular system, joints or muscles. Score 1 if any problems exist.
24. Ask patient to do a standing pivot transfer. Score 1 if patient is NOT independent (i.e. requires assistance, supervision, or is unable).
Activities of Daily Living
25. Does the patient require assistance in dressing? Does the patient require assistance to put on their own shoes? Score 1 if yes to either of these.
26. Does the patient require assistance or supervision in transfers (not including tub)? Score 1 if yes.
27. Does the patient require assistance or supervision in bathing (including transfer to tub)? Score 1 if yes.
28. Does the patient have incontinence of Bowel or Bladder? Does the patient require medications to control Bowel and Bladder (this includes dribbling)? Stress incontinence should NOT be scored as a 1. Score 1 if yes to any of above.
Other
29. What is the Assessor's gut feeling about fitting with a prosthesis? Score 1 if bad (i.e. the patient will not benefit from a prosthetic leg).
30. Does the patient understand English? Score 1 if the patient does NOT understand English.
31. Does the patient appear motivated to get prosthesis and work in the program? Does the patient have realistic goals? Score 1 if NO.