School of Physiotherapy and Exercise Science

Optimising Outcomes in Rehabilitation of Lower Limb Amputation

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Doctor of Philosophy
of
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Declaration

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made.

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

Signature: …….

Date: ……...

Abstract

Background

There is limited research on outcomes following lower limb amputation to assist health professionals with clinical decision making. Comorbidities contribute to high mortality and potentially impact on functional outcome in people with atraumatic causes of amputation however there is no gold standard for measuring burden of disease. Amputee rehabilitation models of care have been based predominantly on low quality studies and expert opinion. In Western Australia, long term rehabilitation outcomes were unknown. No clinical prediction rules (CPRs) have been developed or validated to identify people with lower limb amputation at risk of becoming prosthetic non-users after discharge from rehabilitation. During prosthetic gait retraining, locomotor tests including the 10 metre walk test (10MWT), timed up and go test (TUGT), 6 minute walk test (6MWT) and four square step test (FSST) may be used by health professionals to measure locomotor performance and gauge progress with rehabilitation but data to assist with interpretation of locomotor test performance for people with lower limb amputation is scarce. It was unknown whether performance on a single locomotor test can be used during rehabilitation to identify future prosthetic non-use in people with lower limb amputation.

Objectives

The studies in this thesis were developed to address the knowledge gaps associated with predicting and measuring outcomes following lower limb amputation. The global objectives were:

1. To develop Clinical Prediction Rules (CPRs) for prosthetic non-use at 4, 6, 8 and 12 months after discharge from rehabilitation in people with lower limb amputation.
2. To validate CPRs for prosthetic non-use at 4, 6, 8 and 12 months after discharge from rehabilitation in people with lower limb amputation.

3. To develop performance thresholds for locomotor tests during rehabilitation that identify risk of prosthetic non-use in people with lower limb amputation within 12 months of rehabilitation discharge.
4. To describe long term rehabilitation outcomes such as locomotor function, return to driving and work in people with lower limb amputation using the Locomotor Capabilities Index 5 (LCI5) and a previously piloted survey.
5. To map comorbidities (including musculoskeletal and mental health issues) present at rehabilitation admission in a cohort with lower limb amputation.

Methods

CPR development

A retrospective cohort study of 135 consecutive participants from Royal Perth Hospital (RPH), the state rehabilitation centre, was performed to develop CPRs. Potential predictor variables were abstracted from the medical records blinded to the participant interviews. The participants were interviewed to determine if they were prosthetic non-users and the time after physiotherapy discharge that they stopped using their prosthetic limb. Chi squared tests were used to determine if the potential predictor variables had a significant univariate association ($p < .1$) with prosthetic non-use. The significant variables were further reduced to a subset of predictor variables or flags ($p < .05$) using backwards stepwise logistic regression. CPRs were generated for 4, 6, 8 and 12 months for prosthetic non-use. Chi squared analysis was used to determine the positive and negative likelihood ratio of prosthetic non-use for having 1 or more variables for prosthetic non-use ($p < .05$).

CPR validation

A prospective cohort study of 66 consecutive participants from RPH was performed to validate the CPRs generated from the retrospective study. CPR and descriptive variables were abstracted from the medical records. Participants were interviewed to determine if they had become prosthetic non-users and the time they stopped using their prosthetic limb after physiotherapy discharge. Chi squared analysis was used to determine the

positive and negative likelihood of prosthetic non-use if 1 or more variables were present for the timeframes ($p < .05$).

Locomotor tests

A retrospective cohort study of 201 consecutive participants from RPH was performed to determine if locomotor tests during rehabilitation could identify people at risk of prosthetic non-use at 12 months after discharge. Locomotor tests performed during rehabilitation and descriptive variables were abstracted from the medical records. Participants were interviewed to determine if they were prosthetic users or non-users at 12 months after physiotherapy discharge. Receiver operating characteristic curves were used to determine performance thresholds for people who were prosthetic non-users at 12 months after rehabilitation discharge. Chi squared analysis was performed to determine the relative risk (RR) of prosthetic non-use if the threshold was present.

Long term rehabilitation outcomes

A survey study of 201 consecutive participants from RPH was performed to determine long term, self reported rehabilitation outcomes including wheelchair use, locomotor function, return to driving and work. The Locomotor Capabilities Index 5 (LCI5) was used to measure locomotor function in people who continued to use their prosthesis after rehabilitation discharge. Descriptive statistics were generated for the survey items.

Comorbidities

Comorbidities (including musculoskeletal pathology and mental illness) were abstracted from the medical records for 201 consecutive participants from RPH. Comorbidities present at hospital admission were analysed. Number of comorbidities, Charlson Comorbidity Index (CCI), Combined Age - Charlson Comorbidity Index (CA-CCI) and Functional Comorbidity Index (FCI) scores were generated for each participant and analysed for the cohort.

Results

CPR development

At 4 (& 6), 8 and 12 months after discharge prosthetic non-use was 11% (15), 15% (20) and 19% (25). CPRs were identified for 3 timeframes as results were identical for 4 and 6 months after discharge. Likelihood Ratios of non-use were retrospectively 32.0 (4 & 6 months), LR+ = 3.5 (8 months) and LR+ = 26.4 (12 months).

CPR validation

The developed CPRs were prospectively validated for 4 (& 6), 8 and 12 months. There was a high level of concordance for continued prosthetic use between the CPR development and validation cohorts. Likelihood Ratios of non-use were prospectively 43.9 (4 & 6 months), LR+ = 33.9 (8 months) and LR+ = 2.8 (12 months).

Locomotor Tests

At 12 months post-discharge 18% (36) of participants were prosthetic non-users. Performance measure thresholds and RR of prosthetic non-use (95% CI) were:

10MWT: If speed was $\leq$ 0.44 ms^{-1} (Area Under the Curve (AUC) = 0.743), RR of non-use = 2.76 (CI, 1.83 to 3.79, $p < .0001$).

6MWT: If distance was $\leq$ 191 m (AUC = 0.788), RR of non-use = 2.84 (CI, 2.05 to 3.48, $p < .0001$).

TUGT: If time was $\geq$ 21.4s (AUC = 0.796), RR of non-use = 3.17 (CI, 2.17 to 4.14, $p < .0001$).

FSST: If time was $\geq$ 36.6s (AUC = 0.762), RR of non-use = 2.76 (CI, 1.99 to 3.39, $p < .0001$).

Long term rehabilitation outcomes

At median, 1.5 (IQR, 1.2 to 2.2) years after discharge, 74% (n = 149) of participants reported that they were prosthetic users. LCI5 scores were significantly different ($z \geq 2.10$, $p \leq .036$) for all known groups at high risk of prosthetic non-use except the Aboriginal and above transtibial amputation level ($z \leq 1.56$, $p \leq .12$) groups. Ceiling

effect for Total LCI5 score was observed in 25% of the cohort. Return to driving and work were 91% (n = 111) and 62% (n = 56) respectively in sub-groups who were drivers and workers prior to amputation.

Comorbidities

Comorbidities that impact on mortality and function were high in the cohort with lower limb amputation. For the total cohort, the number of comorbidities were median = 10 (Interquartile range (IQR) = 5 to 15), FCI median = 3 (IQR = 1 to 5), CCI median = 2 (IQR = 1 to 4) and CA-CCI median = 4 (IQR = 1 to 6).

Discussion and conclusion

Very few Clinical Prediction Rules are established in rehabilitation and rarely prospectively validated. This thesis generates and validates a set of prediction rules to assist clinicians in testing modified models of care to optimise outcomes for individuals at higher risk. These validated CPRs for prosthetic non-use in people with lower limb amputation contribute to evidence based health reform of the amputee rehabilitation model of care and assist health professionals to develop targeted models of care for people at high risk of prosthetic non-use. The locomotor performance thresholds will help health professionals to identify people with lower limb amputation at higher risk of prosthetic non-use. The 10MWT and 6MWT had the greatest utility however further validation is required. The long term, self reported rehabilitation outcomes will assist with future resource allocation however high ceiling effect was observed for the LCI5 scale so further research to develop a measure of self reported locomotor function is warranted. Comorbidity indices defined mortality risk and the impact that disease has on function. The CCI would be useful in future studies of people with amputation to enable standardised comparison of case mix between institutions.

Statement of Originality

This thesis is presented for the degree of Doctor of Philosophy at Curtin University. The research was undertaken between 2009 and 2014 at Royal Perth Hospital.

I declare that all material presented in this thesis is original, all efforts have been made to report the original source of all content not originally generated within the program of research.

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Publications, presentations and awards arising from this thesis

Attributions

All outputs derived from this thesis have been attributed according to the peer review referencing. The candidate is the primary and lead author on all outputs. In every case, the co-authors have contributed not only as thesis supervisors but also in accordance to the minimal requirements of authorship as defined by the International Committee of Medical Journal Editors. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals.* Updated May 2000. Available at: http://www.icmje.org.

Publications

Roffman, Caroline E., Buchanan, John, & Allison, Garry T. (2014). Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules. *Journal of Physiotherapy, 60*(4), 224-231. doi: 10.1016/j.jphys.2014.09.003

Roffman, Caroline E., Buchanan, John, & Allison, Garry T. (2016). Charlson Comorbidities Index. *Journal of Physiotherapy, 62*(3), 171. doi: 10.1016/j.jphys.2016.05.008

Roffman, Caroline E., Buchanan, John, & Allison, Garry T. (2016). Locomotor Performance During Rehabilitation of People With Lower Limb Amputation and Prosthetic Nonuse 12 Months After Discharge. *Physical Therapy, 96*(7), 985-994. doi: 10.2522/ptj.20140164

Conference Presentations

14th International Society for Prosthetics and Orthotics (ISPO) World Congress 2013, Hyderabad, India

Predictors of prosthetic use in individuals with lower limb amputation at 6 and 12 months after discharge from rehabilitation.

Caroline E Roffman, John Buchanan and Garry T Allison

In *14th World Congress of the International Society for Prosthetics and Orthotics (ISPO)*, 4th to 7th February 2013, Hyderabad, India.

15th ISPO World Congress 2015, Lyon, France

Locomotor performance characteristics following lower limb amputation.

Caroline E Roffman, John Buchanan, Garry T Allison

Long term locomotor function in individuals with lower limb amputation following discharge from rehabilitation.

Caroline E Roffman, John Buchanan, Garry T Allison

In *15th World Congress of the International Society for Prosthetics and Orthotics (ISPO)*, 22nd to 25th June 2015, Lyon, France.

16th ISPO World Congress 2017, Cape Town, South Africa

Self reported activity and participation following rehabilitation in people with lower limb amputation

Caroline E Roffman, John Buchanan, Garry T Allison

In *16th World Congress of the International Society for Prosthetics and Orthotics (ISPO)*, 8th to 11th May 2017, Cape Town, South Africa.

Australian New Zealand Society for Vascular Surgery (ANZSVS), 13th to 16th October 2017, Perth, Western Australia

Measuring locomotor performance in people with lower limb amputation.

Caroline E Roffman, John Buchanan, Garry T Allison

Momentum 2017 Physiotherapy Conference, Australian Physiotherapy Association, 19th to 21st October 2017, Sydney, Australia

Prosthetic outcome in people with lower limb amputation following rehabilitation discharge: Development and validation of clinical prediction rules.
Caroline E Roffman, John Buchanan, Garry T Allison

Do locomotor tests used during rehabilitation identify increased risk of prosthetic non-use in people with lower limb amputation?
Caroline E Roffman, John Buchanan, Garry T Allison

Awards

$10 000 ISPO Australia Research Grant awarded in 2009

Elsevier Book Prize, School of Physiotherapy and Exercise Science, Curtin University, for best publication in 2014

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Abbreviations

10MWT – 10 Metre Walk Test

6MWT – 6 Minute Walk Test

ABI – Ankle Brachial Index

ABS – Australia Bureau of Statistics

AMP – Amputee Mobility Predictor

AMPNoPro - Amputee Mobility Predictor No Prosthesis

AMPPro - Amputee Mobility Predictor Prosthesis

AOPA – Australia Orthotic and Prosthetic Association

ARDS – Acute Respiratory Distress Syndrome

ARIA – Accessibility Remoteness Index of Australia

ASCO – Australian Standard Classification of Occupations

AUC – Area Under the Curve

AUD – Australian Dollars

CA-CCI – Combined Age Charlson Comorbidity Index

CCI – Charlson Comorbidity Index

CI – Confidence Interval

Clinical Prediction Rule – CPR

COPD – Chronic Obstructive Pulmonary Disease

CVA – Cerebrovascular Accident

FCI – Functional Comorbidity Index

FIM – Functional Independence Measure

FSST – Four Square Step test

GBP – Great British Pounds

HbA1c – Glycated Haemoglobin

ICF – International Classification of Functioning, Disability and Health

ICRC – International Committee of the Red Cross

IEDs – Improvised Explosive Devices

IQR – Interquartile Range (25^{th} to 75^{th} percentile)

ISPO – International Society for Prosthetics and Orthotics

LCI – Locomotor Capabilities Index

LCI5 – Locomotor Capabilities Index 5

LR- – Negative Likelihood Ratio

LR+ – Positive Likelihood Ratio

MFCL – Medicare Functional Classification Level, K-level 0 to 4

MWUT – Mann Whitney U Test

n – Number

NSW – New South Wales

p – Significance level

PTB – Patella Tendon Bearing Prosthesis

PTS – Supracondylar Suspended Patella Tendon Bearing prosthesis

ROC – Receiver Operating Characteristic

RPH – Royal Perth Hospital

RR – Relative Risk

SAT-PRO – Satisfaction with Prosthesis Questionnaire

SD – Standard Deviation

TENS – Transcutaneous Electrical Nerve Stimulation

TIA – Transient Ischaemic Attack

TSB – Total Surface Bearing Prosthesis

TUGT – Timed Up and Go Test

UK – United Kingdom

USA – United States of America

USD – United States Dollars

VA DoD – Veteran Affairs, Department of Defence

VO_{2rel} – Relative Aerobic Load

WA – Western Australia

WALSA – Western Australian Limb Service for Amputees

WHO – World Health Organisation

Glossary

Term	Definition
Aboriginal	Aboriginal and Torres Strait Islander people are the first inhabitants of Australia. An Aboriginal person is of Aboriginal descent, identifies as Aboriginal and is accepted as an Aboriginal person by their community. The research in this thesis was conducted in Western Australia (WA) and only people who identified as Aboriginal participated. People of the Torres Strait are of Melanesian origin from the Torres Strait Islands and east coast of Australia.
Above transtibial amputation level	Amputation at knee disarticulation level and above.
Activities of daily living	Functional tasks that a person performs every day (e.g. showering, dressing, eating, sit to stand).
Admission date	The date that the intervention or service commenced.
Ambulation	Movement also referred to as walking.
Amputation	The surgical removal of part or all of an upper limb or lower limb.
Amputee	A person with limb loss or deficiency
Amputee rehabilitation	The process that aims to restore function, vocation, recreation and socially reintegrate a person who has undergone amputation.
Ankle disarticulation	Amputation through the ankle removing the foot.
Atraumatic amputation	Amputation that results from circulatory, infective or cancer causes.
Bilateral amputation	Amputation of limbs on both sides (i.e. both upper limbs or both lower limbs amputated).

Clinical Prediction Rule	Clinical prediction rules are statistically derived tools that assist health professionals with clinical decision making based on a parsimonious subset of predictor variables.
Clinical utility	The usefulness of a test at determining a diagnosis or outcome for an intervention and how effectively the test can be implemented into clinical practice.
Comorbidity	Any disease or procedure a patient has in addition to their primary disorder (e.g. a person with diabetes and peripheral neuropathy). The operational definition of comorbidity in this thesis was any condition that was documented in the medical record including musculoskeletal pathology and mental illness.
Componentry	Parts of the prosthesis (e.g. socket, knee, foot, pylon, liner, suspension system).
Congenital limb deficiency	Absence of a limb or part of a limb that is present from birth
Contracture	Tightening of a muscle resulting in reduced joint range of movement (e.g. hip and knee flexion contractures).
Contralateral limb	The limb on the opposite side.

Definitive prosthesis	The prosthesis which is prescribed approximately 6 months after commencing prosthetic gait retraining once the residual limb volume has stabilised and the person with lower limb amputation has learned to walk. In WA the new prosthetic components are funded based by Western Australian Limb Service for Amputees (WALSA) on the patient's Medicare Functional Classification Level (MFCL) K-level (mobility level), clinical assessment and approved by the Therapeutic Goods Act (TGA). This prosthesis is replaced approximately every 3 years in WA. The definitive prosthesis meets standardised criteria for comfort, fit, alignment, function, appearance and durability.
Disarticulation	Amputation through a joint (e.g. wrist, knee, ankle).
Discharge date	The endpoint of an intervention or service (e.g. physiotherapy discharge).
Doffing	Taking the prosthesis off.
Domiciliary	Rehabilitation that takes place in a patient's home.
Donning	Putting on the prosthesis.
Dysvascular amputation	An amputation that is caused by circulatory issues associated with peripheral arterial disease and diabetes.
Early walking aids	An inflatable device (e.g. Pneumatic Post Amputation Mobility Aid (PPAM Aid)) that is used by physiotherapists in some rehabilitation services (e.g. United Kingdom) to enable patients to mobilise prior to commencing prosthetic gait retraining. Early walking aids are not used in the RPH model of care in WA.
Fall	An unexpected event where a person comes to rest on the ground, floor or lower level.

Full-time prosthetic user	A person who functionally uses their prosthesis 7 days per week.
Gait	Walking
Gait speed	How fast a person is walking.
Inpatient	A patient residing in the hospital to receive treatment or rehabilitation.
Interim prosthesis	The first prosthesis that is fitted after amputation surgery (approximately 3 weeks and onwards) so that prosthetic gait retraining can commence. The prosthetic components used in manufacturing the prosthesis are approved by the TGA. This prosthesis is generally used for the first 6 months of walking while the residual limb maturates and oedema stabilises. The fit is managed using stump socks, packing of the prosthetic liner and socket. If the socket becomes too large a new socket is cast, manufactured and fitted by the prosthetist. A cosmetic cover is generally not fitted to this prosthesis because it is adjusted frequently. This prosthesis is also referred to as the temporary prosthesis in some countries. In WA this prosthesis has basic prosthetic components (e.g. SACH foot, total elastic suspension belt and mechanical knees) unless clinically indicated (e.g. residual limb with split skin graft requiring a silicone liner, pin lock total surface bearing prosthesis).
Intermittent pneumatic compression pump therapy	A pump machine that is used to manage oedema and shape the residual limb in people with amputation.
Knee disarticulation	Amputation through the knee joint.

Locomotor tests	Tests administered by physiotherapists and health professionals to assess gait speed, endurance and balance (e.g. 10MWT, TUGT, 6MWT, FSST).
Major lower limb amputation	Amputation from transtibial level and above.
Managing prosthetic fit	Adding or removing stump socks to accommodate changes in the volume of the residual limb.
Mechanical knee	A prosthetic knee component that enables a stance and swing phase of gait in people with knee disarticulation, transfemoral and higher levels of lower limb amputation. Mechanical knees may be single axis, polycentric, hydraulic, pneumatic, have weight activated stance control or manual locking. The amount of stability during the stance phase of gait and responsiveness during swing phase to changes in gait speed depend on the mechanical set up of the knee component.
Medical record	The written and electronic data that a hospital maintains on an individual patient receiving assessment and treatment.
Medicare functional classification level (MFCL) K-level	A 5 point scale is used by amputee rehabilitation services to subjectively classify patients with lower limb amputation and allocate prosthetic components. Patients are rated from K0 (i.e. non-prosthetic) to K4 (i.e. high functioning active adult, child or athlete).
Mental illness	A health problem that affects how a person feels, thinks, behaves or interacts with other people that is diagnosed based on a set of criteria (e.g. depression, anxiety, personality disorder, schizophrenia).
Microprocessor knee	A knee that has a computer processor (sensor) that enables stance control and modifies the swing phase of gait as walking speed changes (e.g. C leg and Rheo knee). In WA microprocessor knees are only available to compensable patients and are not funded by the WALSA.

Minor lower limb amputation	Amputation at ankle disarticulation level and below including partial foot and toe amputations.
Mobility aid	A device used to reduce weight bearing or improve balance when walking (e.g. walking stick, elbow crutches, walking frame).
Model of care	The way health services are delivered for a person, sub-group or clinical cohort. In a model of care evidence based practice is implemented to match patients to interventions.
Monitoring skin on residual limb (stump)	Checking the skin on the residual limb for signs of pressure, blisters or wounds when using a prosthetic limb.
Multidisciplinary team	Team of health professionals providing specialised amputee rehabilitation to patients including: rehabilitation medicine physician, physiotherapist, prosthetist, nurse, occupational therapist, podiatrist, clinical psychologist, social worker, dietitian, orthotist and other health professionals or specialties as required by individual patients with amputation.
Musculoskeletal pathology	Any injury to the muscle, joint, bones, ligaments or tendons in a person.
Oedema	Swelling of the tissues (e.g. residual limb).
Osseointegration	A surgical procedure that involves the insertion of an implant to the residual skeleton so an artificial limb can be suspended without a prosthetic socket.
Outcome measures	An objective test that can be used to assess a patient before and after an intervention has been performed. In cohorts with amputation outcome measures may encompass physical and psychosocial domains of function (e.g. Locomotor Capabilities Index 5, Amputee Mobility Predictor, Trinity Amputation and Prosthesis Experiences Scale (TAPES)).

Outpatient	A person receiving medical treatment or rehabilitation who is residing in their own accommodation.
Outreach	A service that travels to and provides rehabilitation to patients that live in country regions and are not residing close to metropolitan healthcare facilities.
Partial foot amputation	Amputation through the bones of the foot.
Part-time prosthetic user	A person who functionally uses their prosthesis less than 7 days per week.
Phantom pain	Pain that extends beyond the end of the residual limb in the limb that has been amputated.
Phantom sensation	The feeling that the limb which has been amputated is still present without pain.
Physiotherapist	A health professional that provides exercise, mobility and prosthetic gait retraining, oedema management, pain management and other interventions to patients with amputation.
Prosthesis	The artificial limb.
Prosthetic adjustment	Modifying the prosthesis to improve comfort, fit and function (e.g. packing the liner, changing alignment, modifying the socket).
Prosthetic alignment	The position of the prosthetic socket in relation to the knee and foot components including bench, static and dynamic alignment of prosthesis.
Prosthetic casting	Plaster of Paris model of the residual limb taken by the Prosthetist to manufacture the prosthesis.
Prosthetic fitting	Application of the customised artificial limb to the person with amputation after it has been manufactured by the prosthetist.

Prosthetic foot	Artificial foot that can be non-articulated (e.g. SACH foot), articulated (e.g. single or multiaxial), dynamic response (store and return energy, e.g. Vari-Flex), range of motion (height adjustable foot), hydraulic or microprocessor (e.g. Ossur proprio foot).
Prosthetic gait retraining	The process of learning to walk, do functional, vocational and recreational activities using a prosthetic limb.
Prosthetic knee	Artificial knee joint component that may be mechanical (e.g. single axis, polycentric, weight activated stance control, manual locking, hydraulic, pneumatic) or microprocessor (e.g. C-leg, Rheo knee).
Prosthetic liner	Soft material that is used between the residual limb and prosthetic socket to protect the residual limb, improve the socket comfort and in some cases provide suspension.
Prosthetic non-user	A person who does not use their prosthesis on any days of the week for functional activities or has a prosthesis for cosmesis only. Also referred to as abandonment of prosthetic use.
Prosthetic running	A method of locomotion that involves moving fast with a flight phase where both the prosthetic and remaining feet (in people with unilateral amputation) are off the ground.
Prosthetic suspension	System that is used to attach the prosthesis to the person with amputation (e.g. Total elastic suspension (TES) belt, supracondylar suspension, silicone liner with pin lock, vacuum suspension).
Prosthetic user	A person who functionally uses their prosthetic limb for locomotor activities on all or some days of the week.

Prosthetist	A health professional who designs, fabricates and fits prostheses.
Pylon	A rigid tube between the socket or knee component and foot component to enable weight bearing.
Rehabilitation Medicine Physician	Doctor with specialist training in rehabilitation.
Remaining limb	The upper and lower limbs that have not been amputated.
Residual limb (stump)	The part of the limb that remains after amputation surgery, also referred to as a stump.
Rigid Removable Dressing	Dressing applied in the early post-operative stage to patients with transtibial amputation to protect the residual limb from trauma and manage residual limb oedema in preparation for an interim prosthesis.
Senior Physiotherapist Amputee Rehabilitation	Physiotherapist with specialised training in amputee rehabilitation who manages the physiotherapy team.
Silicone liner	A roll on liner used to minimise the shear forces on the residual limb and suspend the prosthesis.
Silicone sock	A sock made out of silicone material to minimise the shear forces on the residual limb.
Socket	Part of the prosthesis where the residual limb is enclosed.
Solid Ankle Cushion Heel (SACH) foot	Non-articulated prosthetic foot that simulates normal gait through compression of a heel cushion and flexibility of the toe. This type of foot is used for interim prosthesis in WA.
Stump bandaging	The use of a compression bandaging to manage oedema and shape the residual limb for a prosthesis.
Stump pain	Pain occurring from structures within the residual limb (e.g. neuroma, wound pain)

Stump shrinker	Compression garment (e.g. Juzo) that is used to manage oedema and shape a residual limb for a prosthesis.
Stump sock	Cotton or woollen sock that is used to manage the fit of a prosthesis.
Telemedicine	The use of encrypted videoconferencing to provide healthcare for patients that reside in country regions (e.g. Telehealth videoconferencing is used by RPH amputee multidisciplinary rehabilitation team for assessment and treatment of patients who live in regional and remote WA).
Transfemoral amputation	Amputation above the knee joint, through the femur bone.
Transtibial amputation	Amputation below the knee joint, through the tibia and fibula bones.
Traumatic amputation	An amputation that is caused by injuries sustained in an event or accident (e.g. motor bike accident, shark attack, bomb blast).
Unilateral amputation	Amputation of one upper or lower limb on the body.

Chapter 1 Introduction

1. Introduction

People with lower limb amputations can be classified into two population profiles: traumatic and atraumatic (Meier & Melton, 2014; Schoppen et al., 2003). The person with traumatic amputation is characterised by younger age, less comorbidities and the potential to rehabilitate to a high level of functional ability. The person with atraumatic amputation is generally older, with multiple comorbidities and circulatory or infective impairments that ultimately led to the amputation (Meier & Melton, 2014; Schoppen et al., 2003). Chronic systemic diseases including diabetes, peripheral arterial disease, cardiac disease and renal failure combined with risk factors such as smoking, physical inactivity and obesity are common in this sub-group (Fortington et al., 2013; Jones et al., 2013; Schoppen et al., 2003; World Health Organisation, 2016). These comorbidities may influence the ability to participate in prosthetic rehabilitation successfully and increase the risk of mortality (Fortington et al., 2013; Jones et al., 2013; Schoppen et al., 2003). In atraumatic cases, the remaining lower limb is often in a 'pre-amputation' state with up to one third of patients having their contralateral lower limb amputated within 3 years of the primary amputation (Lim et al., 2006).

Multidisciplinary rehabilitation plays an important role in restoring function of people with lower limb amputation for activities of daily living, work and recreation (Broomhead et al., 2012; Czerniecki, Turner, Williams, Hakimi, & Norvell, 2012a; Meier & Melton, 2014; US Department of Veterans Affairs, 2008). However, limited research exists regarding long term functional outcomes of people with lower limb amputation who have been discharged from rehabilitation services (Department of Health, 2008; Jones, Hall, & Schuld, 1993; Lim et al., 2006; Meier Iii & Heckman, 2014; Schoppen et al., 2003). In Western Australia, it was identified that rehabilitation outcomes of people with lower limb amputation including prosthetic use were unknown (Department of Health, 2008).

Diabetes is the leading cause of lower limb amputation in developed countries (Moxey et al., 2011; World Health Organisation, 2016). The World Health Organisation (WHO) identified that lower limb amputation is 10 to 20 times greater in people with diabetes (World Health Organisation, 2016). Aboriginal people (the first inhabitants of Australia) have high rates of diabetes related lower limb amputation and often reside in locations that are geographically isolated from health services however their rehabilitation outcomes have not been reported (Norman, Schoen, Gurr, & Kolybaba, 2010).

The costs associated with rehabilitation following lower limb amputation represent high and long term expenditure to healthcare services (Blough et al., 2010; Ma, Chan, & Carruthers, 2014; Schaffalitzky, Gallagher, MacLachlan, & Wegener, 2012). However, studies have reported rates as great as 51% for abandonment of prosthetic use at 1 year after amputation and 5 year mortality up to 77% in people with atraumatic causes of lower limb amputation (Davies & Datta, 2003; Fortington et al., 2013; Jones et al., 2013; Nehler et al., 2003; Schaffalitzky et al., 2012). Therefore, functional outcome of people with lower limb amputation warrants further investigation due to the potential for high levels of disability, healthcare costs and resource utilisation.

1.1. Predictors of locomotor outcome following lower limb amputation

Locomotor outcome of people with lower limb amputation has been associated with several variables including comorbidities, age, condition of the remaining limb, mobility status prior to amputation, skin integrity, ethnicity, socioeconomic status, cognition, social support, level and number of limbs amputated, quality of residual limb, contractures, wound healing, post-operative complications, residual limb oedema, pain, energy cost of prosthetic gait, falls and rehabilitation models of care (Adams, 2005; Bhangu, Devlin, & Pauley, 2009; Czerniecki et al., 2012a; Meier Iii & Heckman, 2014; Nehler et al., 2003; Sansam, Neumann, O'Connor, & Bhakta, 2009; Schoppen et al., 2003; Taylor et al., 2005; Waters, Perry, Antonelli, & Hislop, 1976). Not fitting a prosthetic limb and prosthetic non-use after discharge from rehabilitation have been associated with different comorbidities (Resnik & Borgia,

2015; Sansam et al., 2009; Schoppen et al., 2003). However, since there is no standardisation for measurement of comorbidity in people with lower limb amputation (Fletcher et al., 2001; Gailey, Allen, Castles, Kucharik, & Roeder, 2008; Gailey et al., 2002; Resnik & Borgia, 2015; Schoppen et al., 2003; Taylor et al., 2005), the ability to determine the impact of multiple comorbidities (the usual presentation) on outcomes is yet to be investigated.

From a clinical perspective, single limb balance, muscle strength and endurance in the remaining limb are important pre-prosthetic measures of impairment that determine walking ability, however these assessments have rarely been included in lower limb amputation cohort studies (Gailey et al., 2002; Raya, Gailey, Fiebert, & Roach, 2010; Schoppen et al., 2003).

To date studies have focused on surgical outcomes, people with limited rehabilitation potential (e.g. house or bed bound prior to amputation), variables associated with not fitting a prosthesis rather than abandonment of prosthetic use or sub-groups (e.g. geriatric, unilateral, vascular amputation) limiting the generalisability of results (Lim et al., 2006; Resnik & Borgia, 2015; Sansam et al., 2009; Schoppen et al., 2003; Taylor et al., 2005).

The literature has demonstrated univariate association of many variables with prosthetic non-use following lower limb amputation but few studies have employed multivariate regression or prospectively validated findings derived from retrospective cohort analysis (Sansam et al., 2009; Schoppen et al., 2003; Taylor et al., 2005). Therefore the combination of variables which are most significant for predicting prosthetic non-use following amputation are poorly understood (Sansam et al., 2009).

1.2. Clinical Prediction Rules (CPRs)

Clinical Prediction Rules (CPRs) are tools that assist health professionals to make evidence based decisions and assign patients to interventions using a subset of predictor variables (Beneciuk, Bishop, & George, 2009; Cleland, Childs, Fritz, Whitman, & Eberhart, 2007; Laupacis, Sekar, & Stiell, 1997). CPRs have been developed and validated for patients with neck pain, lower back pain and ankle

fractures (Beneciuk et al., 2009; Cleland et al., 2007; Laupacis et al., 1997). If CPRs were developed and validated to identify accurately people with lower limb amputation who were at risk of prosthetic non-use, health professionals could use this evidence to improve clinical decision making and stratify patients into targeted models of care (Childs & Cleland, 2006; Laupacis et al., 1997). CPRs have the potential to improve efficiency of health services and lead to cost savings (Childs & Cleland, 2006). Accurately matching patients to rehabilitation interventions is important due to resource limitations (Childs & Cleland, 2006; Sansam, O'Connor, Neumann, & Bhakta, 2014). For example, the health policy of Slovenia allows people with lower limb amputation to be issued with a either prosthesis or wheelchair, but not both of these mobility devices (Erjavec, Vidmar, & Burger, 2014).

1.3. Locomotor outcome measures following lower limb amputation

Evaluation of locomotor outcome following rehabilitation for lower limb amputation is important for determining if rehabilitation interventions and models of care have been effective (Heinemann, Connelly, Ehrlich-Jones, & Fatone, 2014; Meier Iii & Heckman, 2014). However, studies (Borrenpohl, Kaluf, & Major, 2016; Gaunaurd et al., 2015; Heinemann, Ehrlich-Jones, Connelly, Semik, & Fatone, 2016) have demonstrated that the use of outcome measures to assess locomotor function in people with lower limb amputation by health professionals was inconsistent. Gaunaurd et al. (2015) and Jette, Halbert, Iverson, Miceli, and Shah (2009) reported that more than 48% of health professionals surveyed did not routinely use outcome measures with patients. Health professionals have identified cost, equipment, time, training, staffing levels, difficulty with interpretation and relevance of the test as some of the barriers to using outcome measures in clinical practice (Gaunaurd et al., 2015; Heinemann et al., 2014; Heinemann et al., 2016; Jette et al., 2009; Smart, 2006).

The Functional Independence Measure (FIM) and the Medicare Functional Classification Level (MFCL) are two commonly used outcome measures during amputee rehabilitation (Borrenpohl et al., 2016; Condie, Scott, & Treweek, 2006;

Gaunaurd et al., 2015). The FIM has issues with observed ceiling effect and responsiveness in amputation cohorts (Condie et al., 2006). The MFCL is used to subjectively classify potential or actual locomotor function of a person with lower limb amputation from non-prosthetic (K-level 0) to high functioning (K-level 4) (Borrenpohl et al., 2016; Gaunaurd et al., 2015). Studies have called for the MFCL to be supplemented with objective outcome measures (Borrenpohl et al., 2016; Gaunaurd et al., 2015).

The 10 metre walk test (10MWT), timed up and go test (TUGT), 6 minute walk test (6MWT) and four square step test (FSST) are examples of objective outcome measures that health professionals may use during prosthetic rehabilitation to assess locomotor function (Dite, Connor, & Curtis, 2007; Heinemann et al., 2014; Resnik & Borgia, 2011; Stevens, 2010). Reduced walking distance, low walking speed and increased time taken on balance tasks following lower limb amputation have been associated with impaired locomotor function and increased risk of falling (Dite et al., 2007; Heinemann et al., 2014; Resnik & Borgia, 2011; Stevens, 2010). It is unclear whether performance on locomotor tests during rehabilitation can be used to identify people with lower limb amputation at future risk of abandoning prosthetic use.

The Locomotor Capabilities Index 5 (LCI5) is an amputee specific outcome measure that has been used to assess locomotor function with a prosthesis for a series of basic and advanced locomotor tasks (Franchignoni et al., 2007; Franchignoni, Orlandini, Ferriero, & Moscato, 2004). The questionnaire format of the LCI5 makes it a useful tool for long term follow-up of people with lower limb amputation. In a longitudinal study of a cohort with lower limb amputation from vascular causes, it was demonstrated that LCI5 scores at 12 months after amputation had not returned to pre-operative levels (Czerniecki et al., 2012a).

There are no gold standards for measuring locomotor function in people with lower limb amputation and few health professionals use objective outcome measures with their clients (Gaunaurd et al., 2015; Heinemann et al., 2014; Heinemann et al., 2016; Resnik & Borgia, 2011). Further research is required to determine the utility of locomotor tests during rehabilitation and whether a single locomotor test can be used across functional domains to identify risk of future prosthetic non-use.

1.4. Statement of the problem

Lower limb amputation is a public health issue of global significance due to the potential for high disability, costs and utilisation of health resources (Blough et al., 2010; Moxey et al., 2011). People with atraumatic causes of amputation have increased risk of mortality at 1 and 5 years after surgery due to high burden of disease but there is no consensus on the most effective method for measuring comorbidity (Fortington et al., 2013; Jones et al., 2013). Prosthetic gait retraining is an intensive intervention that occurs over a protracted timeframe following lower limb amputation with the aim of restoring quality of life (Reiber et al., 2010; Schaffalitzky et al., 2012). However, a high proportion of people with lower limb amputation who participate in this expensive multidisciplinary rehabilitation intervention abandon prosthetic use after discharge (Blough et al., 2010; Reiber et al., 2010; Schaffalitzky et al., 2012). Prosthetic gait retraining is not without health risk due to potential complications such as falls, fractures and myocardial infarction (Bailey & MacWhannell, 1997; Broomhead et al., 2012; Broomhead et al., 2006; Sansam et al., 2014).

There is limited research on rehabilitation outcomes following lower limb amputation to guide clinical practice and develop amputee rehabilitation models of care (Department of Health, 2008; Sansam et al., 2009). In Western Australia, long term rehabilitation outcomes such as rates of prosthetic and wheelchair use, return to driving and work were unknown (Department of Health, 2008). Locomotor function has been associated with several variables in univariate studies however clinical prediction rules have not been developed to identify people at risk of prosthetic non-use following discharge from rehabilitation (Sansam et al., 2009). Furthermore, clinical prediction rules have been developed for many medical conditions but validation studies are rare (Childs & Cleland, 2006; Laupacis et al., 1997). The use of outcome measures during rehabilitation is low so there is a paucity of performance data on locomotor tests for lower limb amputation cohorts (Gailey et al., 2002; Gaunaurd et al., 2015; Heinemann et al., 2014; Resnik & Borgia, 2011). Therefore, further studies are warranted to improve prediction of prosthetic non-use, measure comorbidity, assist with interpretation of locomotor tests and evaluate rehabilitation interventions in cohorts with lower limb amputation (Heinemann et al., 2014; Sansam et al., 2009).

1.5. Significance of this research

Research in this thesis will make the following original and significant contributions to evidence based practice for people with lower limb amputation:

- The first study to develop CPRs for prosthetic non-use following discharge from rehabilitation.
- The first study to validate CPRs for prosthetic non-use following discharge from rehabilitation.
- The first study to generate performance thresholds for locomotor tests that identify increased risk of prosthetic non-use at 12 months following discharge from rehabilitation.
- The first study to determine rehabilitation outcomes for Australian Aboriginal people with lower limb amputation.
- Determine the clinical utility of comorbidity indices and locomotor tests in people with lower limb amputation.
- Improve knowledge of long term rehabilitation outcomes and sociodemographics of people with lower limb amputation in Australia.

This research will contribute to evidence based health reform of the Amputee Rehabilitation Model of Care in Western Australia (Department of Health, 2008) and lead to potential cost savings through development of targeted models of care. Accurate prediction of prognosis following lower limb amputation facilitates more effective patient counselling regarding expected outcome (Sansam et al., 2014; Schaffalitzky et al., 2012) and potentially drives technical innovations to restore locomotor function in sub-groups at high risk of prosthetic non-use. The findings of this thesis may be potentially transferable or translated to other healthcare settings across the world.

1.6. Study objectives

The aims of this research were:

1. To develop a set of Clinical Prediction Rules (CPRs) for people with lower limb amputation that identify which factors in combination are predictive of prosthetic non-use at 4, 6, 8 and 12 months after discharge from rehabilitation.
2. To validate the CPRs that identify prosthetic non-use at 4, 6, 8 and 12 months after discharge from rehabilitation in a prospective cohort of people with lower limb amputation.
3. To determine whether different tests of locomotor performance during rehabilitation were associated with significantly greater risk of prosthetic non-use at 12 months post-discharge from rehabilitation.
4. To gain knowledge on the balance and locomotor skills of known groups at high risk of discontinuing prosthetic use and test the construct validity of the 10MWT, TUGT, 6MWT and FSST in these groups.
5. To describe long term self reported outcomes of people with lower limb amputation after rehabilitation discharge including sociodemographic characteristics, complications of amputation, prosthetic locomotor function using the locomotor capabilities index 5 (LCI5), mobility without a prosthesis, use of wheelchair and assistive devices, return to driving and work.
6. To investigate rehabilitation outcomes in Aboriginal people with lower limb amputation.
7. To map comorbidities (including musculoskeletal pathology and mental illness) that are present at hospital admission in a cohort with lower limb amputation and evaluate construct validity of using comorbidity indices in people with lower limb amputation.

1.7. Thesis Outline

This research addresses the limited literature on rehabilitation outcomes following lower limb amputation. The Royal Perth Hospital (RPH) amputee rehabilitation model of care, physiotherapy intervention, outcome studies and measurement of locomotor function have been explored in the literature review (Chapter 2). How to read the thesis and common methods have been outlined in Chapter 3.

Chapters 4 and 5 detail the development and validation of clinical prediction rules for prosthetic non-use. The relationship between locomotor test performance during rehabilitation and prosthetic non-use at 12 months after discharge from rehabilitation is reported in Chapter 6. The construct validity of locomotor tests in known groups at high and lower risk of prosthetic non-use is examined in Chapter 7, Part A. To improve knowledge on long term activity and participation limitations following amputation, self reported locomotor function, return to driving and work have been analysed in Chapter 7, Part B. This chapter includes a known groups analysis using the LCI5.

Comorbidities have been mapped and the utility of comorbidity indices to measure burden of disease have been explored in Chapter 8. The contribution of this research to the evidence base, limitations of the research and future research directions have been discussed in the final thesis chapter.

Chapter 2 Literature Review

2. Introduction

Lower limb amputation is a life changing event that impacts on functional, work, social and recreational activities. In this thesis chapter key principles of amputee rehabilitation including: levels of lower limb amputation, aetiology, incidence, comorbidities, the amputee rehabilitation model of care, selection criteria for prosthetic rehabilitation, rehabilitation interventions, prosthetic use and prosthetic non-use have been defined. Significant literature on functional outcomes following lower limb amputation and common outcome measures have been explored to identify knowledge gaps in the evidence base and support the research directions of this thesis. This literature review has also incorporated grey literature such as clinical practice guidelines and health policy documents where published research was not available.

2.1. Definition of Lower Limb Amputation

Lower limb amputation is the acquired surgical removal of the leg, foot or toes from the body (Lusardi & Pepe, 2013). Congenital limb deficiency is the partial or complete absence of a limb that is present at birth, which may or may not result in a future lower limb amputation to enable fitting of a prosthetic limb (Lusardi & Pepe, 2013; Nielsen & Jorge, 2013). The focus of this thesis is on outcomes following lower limb amputation. Common levels of lower limb amputation have been summarised in Table 2.1 (Lusardi & Pepe, 2013; Murphy, 2013). The residual limb or stump is the part of the lower limb that remains after amputation surgery. In this thesis, major lower limb amputation has been defined as amputation from transtibial level and above. Minor lower limb has been defined as ankle disarticulation and below, including partial foot and toe amputations.

Table 2.1: Common levels of amputation defined.

Major Lower Limb Amputation Levels	Definition
Hemipelvectomy	Amputation through the sacroiliac joint or ala of the ilium.
Hip disarticulation	Amputation removing the whole lower limb at the hip joint.
Transfemoral amputation	Amputation through the femur.
Knee disarticulation	Amputation removing the tibia and fibula at the knee joint.
Transtibial amputation	Amputation through the tibia and fibula.
Minor Lower Limb Amputation Levels	**Definition**
Ankle Disarticulation (Syme)	Amputation through the talocrural joint.
Partial foot amputations Boyd Pirrogoff Chopart Lisfranc Transmetatarsal Metatarsal ray resection	 Fusion of the calcaneus and tibia with removal of distal structures. Wedging transection of the calcaneus, with fusion of the calcaneus and tibia and removal of all distal structures. Amputation through the midtarsal joints. Amputation through the tarsometatarsal joint. Removal of all 5 metatarsals proximal to their metatarsal heads. Amputation removing a whole metatarsal bone.
Toe amputation Phalangeal amputation	 Digit amputation at the distal, middle or proximal interphalangeal joints.

(Lusardi & Pepe, 2013; Murphy, 2013).

For the studies in this thesis amputation level has been classified as transtibial and above transtibial level of amputation (i.e. knee disarticulation amputation level and above). Major bilateral lower limb amputation has been defined as transtibial amputation level or higher of both lower limbs.

Osseointegration involves the surgical insertion of an implant to the residual skeleton so an artificial limb can be suspended without a prosthetic socket (Brånemark et al., 2014; Haggstrom, Hansson, & Hagberg, 2013). This procedure represents a potential treatment option for people with transfemoral amputation who have had difficulties with conventional prosthetic socket fit, skin breakdown and fluctuations in residual limb volume due to oedema (Brånemark et al., 2014; Haggstrom et al., 2013). The studies in this thesis do not include participants who have undergone osseointegration surgery as in Western Australia (WA) at the time this research was conducted osseointegration was not a routine surgical procedure for people with lower limb amputation.

2.2. Aetiology of Amputation

The main causes of amputation include circulatory issues, infection, trauma and cancer (Nielsen & Jorge, 2013). Peripheral arterial disease is a common cause of circulatory amputations (Nielsen & Jorge, 2013). Infected diabetic foot ulcers, osteomyelitis and meningococcal septicaemia are examples of infective causes of amputation (Nielsen & Jorge, 2013). Lower limb injury sustained in motor bike accidents, work place accidents, burns, shark attack, warfare, civil unrest and terrorism are some mechanisms of traumatic amputation (Nielsen & Jorge, 2013). Osteosarcoma and skin cancer are forms of cancer that may result in amputation (Nielsen & Jorge, 2013). In this thesis the cause of amputation has been dichotomised for analyses into traumatic and atraumatic amputation. The participants with circulatory, infective and cancer causes of amputation were classified as having an atraumatic amputation.

2.3. Incidence and prevalence of amputation

There is wide global variation in lower limb amputation as the incidence ranges from 5.8 to 31 per 100 000 total population (Moxey et al., 2011). The incidence is higher in people with diabetes, ranging from 46.1 to 9600 per 100 000 population (Moxey et al., 2011). Ziegler-Graham, MacKenzie, Ephraim, Travison, and Brookmeyer (2008) estimated that 1.6 million people from the United States of America (USA) had an amputation in 2005 and projected that this figure would rise to 3.6 million by 2050. The aetiology of amputation included atraumatic (peripheral arterial disease and diabetes related amputation) in 54% (n = 846 000), trauma in 45% (n = 704 000) and cancer in 1% (n = 18 000) of cases (Ziegler-Graham et al., 2008).

In contrast to the public health context of developed nations, higher prevalence of traumatic amputation has been documented in developing nations, warzones and areas of civil unrest (Department of Health, 2008; ICRC, 2015; Pasquina, 2010; Van Brakel, Poetsma, Tam, & Verhoeff, 2010; Wallace, 2012; Ziegler-Graham et al., 2008). For example, Van Brakel et al. (2010) reported traumatic causes of amputation for 91.2% (n = 746) of people from Vietnam with 48.4% (n = 396) of amputations due to injury from land mines. In 2014, the International Committee of the Red Cross (ICRC) provided physical rehabilitation services to over 318 000 people with a disability and fitted 20 101 prostheses to people with amputation of developing nations (ICRC, 2015).

In the Iraq and Afghanistan conflicts improvised explosive devices (IEDs) were the main weapon that caused traumatic amputation and complex limb injuries in soldiers (Clasper & Ramasamy, 2013; Pasquina, 2010; Wallace, 2012). Wallace (2012) reports that until September 2010, the number of major and minor limb amputations in soldiers from the USA were 1158 in Iraq, 249 in Afghanistan, 214 in unaffiliated conflicts and 34 in Yemen, Pakistan and Uzbekistan. High rates of traumatic amputation have also been reported in soldiers from the United Kingdom (UK) (Wallace, 2012). Three Australian soldiers sustained traumatic amputations from 2002 to 2012 during the Afghanistan conflict (Wallace, 2012).

In Australia the literature has focused on the incidence of lower limb amputation caused by diabetes and peripheral arterial disease with limited published data on

other causes of lower limb amputation (Baba, Davis, Norman, & Davis, 2015; Davis, Norman, Bruce, & Davis, 2006; Dillon, Kohler, & Peeva, 2014; Dillon, Fortington, Akram, Erbas, & Kohler, 2017b; Kurowski et al., 2015). The age standardised incidence of major lower limb amputation was stable at 37.41 ± 1.01 procedures per 100 000 population per annum in Australia between 2000 and 2010 but there has been a significant rise in minor lower limb amputations (Dillon et al., 2014). Dillon et al. (2017b) reported that of the 3409 amputation procedures performed in WA between 2007 and 2012 a total of 10.7% (n = 366) were transfemoral and 15.2% (n = 519) were transtibial levels of amputation. The WA rates of major and minor lower limb amputation levels were consistent with the other Australian states and territories in this study (Dillon et al., 2017b).

The geographic variation for incidence rate of lower limb amputation in Australia between 2007 and 2012 was described by Dillon et al. (2017b). The crude national incidence rate of lower limb amputation (all causes) was 44.0 per 100 000 person-years for males and 20.9 per 100 000 person-years for females in this study (Dillon et al., 2017b). In Western Australia, the crude incidence rate of lower limb amputation was 40.6 per 100 000 person-years for males and 20.2 per 100 000 person-years for females (Dillon et al., 2017b). The majority of states and territories had similar crude and age adjusted incidence rates of lower limb amputation for males and females to the national incidence rate (Dillon et al., 2017b). Higher relative risk of lower limb amputation was associated with older age, male gender and type 2 diabetes for the majority of states and territories (Dillon et al., 2017b). However, in the Northern Territory both the crude and age standardised incidence rates of lower limb amputation were higher than the national rate and amputation occurred at a younger age (Dillon et al., 2017b). Reduced relative risk of lower limb amputation was associated with male gender and type 2 diabetes in the Northern Territory with younger age at amputation being identified as a confounding factor related to these findings (Dillon et al., 2017b). Dillon et al. (2017b) identified that the effect of indigenous status on the incidence rate of lower limb amputation was an area for future research.

It has been estimated that a lower limb amputation is performed due to diabetes related complications every 3 hours in Australia and reported that Aboriginal people

aged 25 to 49 years from WA, were 38 times more likely to have a lower limb amputation from diabetic causes (AIHW, 2008; Bergin et al., 2012; Department of Health, 2010; Norman et al., 2010). However, amputation has been the primary endpoint of epidemiological research in Australia and rehabilitation outcomes of Aboriginal people have not been investigated (Bergin et al., 2012; Department of Health, 2010; Norman et al., 2010; Schoen & Norman, 2014; Vos, Barker, Begg, Stanley, & Lopez, 2009). Rehabilitation outcomes for Aboriginal people with amputation may potentially be affected by higher disease burden and rates of diabetes, geographical isolation from health services and cultural factors which influence health behaviours (Schoen, Balchin, & Thompson, 2010; Vos et al., 2009).

A total of 2095 major lower limb amputations were performed in WA from 2000 to 2010 (Kurowski et al., 2015). Kurowski et al. (2015) reported that the average annual rate of total amputations were 724 per 100 000 population per annum in people with type1 diabetes, 564 per 100 000 population per annum in people with type 2 diabetes and 66 per 100 000 population per annum in people with cardiovascular disease without diabetes. Baba et al. (2015) investigated the temporal changes of prevalence and associated variables in people with lower limb amputation and type 2 diabetes for phases 1 (1993 to 1996) and 2 (2008 to 2011) of the Fremantle Diabetes Study in WA. There were 15 lower limb amputations at baseline for both phases 1 and 2 (Baba et al., 2015). After adjustment for diabetes and important between group differences, it was demonstrated that the risk of amputation had declined by 72% over the 15 year duration of study (Baba et al., 2015). The variables independently associated with lower limb amputation during phase 2 were: history of lower limb bypass surgery or revascularisation, past or current hospitalisation for foot ulcer and fasting glucose serum (Baba et al., 2015). The decline in lower limb amputations were attributed to health systems change with the introduction of government funded primary podiatry services and multidisciplinary high risk foot clinics in tertiary hospitals (Baba et al., 2015).

The Department of Health in WA reported that 2553 amputations were performed in public and private hospitals from 2000 to 2007 (Department of Health, 2008). Of these 68.3% (n = 1743) were from atraumatic causes including atherosclerosis, diabetes and osteomyelitis (Department of Health, 2008). The remaining 31.7% (n =

810) were from other causes of amputation including trauma, cancer and acquired deformities of the toes (Department of Health, 2008). Amputation was higher in the elderly, as individuals aged 65 years and older accounted for 59% of the cases (Department of Health, 2008). A further 30% of lower limb amputations included individuals aged 45 to 64 years (Department of Health, 2008). Major lower limb amputations represented 38.1% (n = 973) and minor lower limb amputations represented 61.9% (n = 1580) of all amputations (Department of Health, 2008). A diagnosis of diabetes was present in 46.2% (n = 1179) of all cases of lower limb amputation (Department of Health, 2008).

2.4. Comorbidities

Diabetes, peripheral arterial disease, cardiovascular disease, renal failure, chronic obstructive pulmonary disease and dementia are common comorbidities that may be present in people with atraumatic causes of lower limb amputation (Fortington et al., 2013; Jones et al., 2013). These chronic diseases contribute to high mortality rates up to 48.3% at 1 year and 77% at 5 years post-surgery in people with atraumatic amputation (Fortington et al., 2013; Jones et al., 2013). Comorbidities are an important consideration for health professionals when stratifying patients for rehabilitation interventions and predicting outcomes however there is no consensus on the most appropriate method of measuring comorbidity in lower limb amputation cohorts (Roffman, Buchanan, & Allison, 2016a).

Musculoskeletal pathology (e.g. back and shoulder pain, knee and hip osteoarthritis) and mental health issues (e.g. depression, anxiety) impact on functional outcome following lower limb amputation however little is known about the type or prevalence of these comorbidities at rehabilitation admission because research has focused on these conditions as long term sequelae of amputation (Gailey et al., 2008; Gallagher & Maclachlan, 2004; Singh et al., 2009; Struyf, van Heugten, Hitters, & Smeets, 2009). Furthermore it was highlighted in a literature review by Mueller (2016), that physiotherapists were not recognising the musculoskeletal pathology associated with patients having a comorbid diagnosis of diabetes. The prevalence of musculoskeletal pathology such as tendinopathy, neck, shoulder and low back pain is higher in people with diabetes (Mueller, 2016). Structural changes to bones and soft

tissues (i.e. skin, nerve, tendon, ligament and muscle) may occur due to the metabolic complications of diabetes (Mueller, 2016). Mueller (2016) reported that these structural changes increase the potential for injury with lower force and impair locomotor function. This has implications for exercise prescription and rehabilitation outcomes following lower limb amputation. The research in this thesis will contribute to the evidence base for clinical practice by examining musculoskeletal pathology in known high risk groups including people with diabetes and amputation.

Comorbidity indices including the Charlson Comorbidity Index (CCI) and Functional Comorbidity Index (FCI) have been developed for predicting mortality, function and measuring burden of disease in other clinical populations (Charlson, Pompei, Ales, & MacKenzie, 1987; Groll, To, Bombardier, & Wright, 2005; Roffman et al., 2016a). There have been limited studies using comorbidity indices in people with lower limb amputation (Davie-Smith, Paul, Nicholls, Stuart, & Kennon, 2016; de Laat, Dijkstra, Rommers, Geertzen, & Roorda, 2014; Fortington et al., 2013; Gailey et al., 2002; van Eijk et al., 2012; Webster et al., 2012). Comparison of these studies is difficult due to variation in study methodologies with some researchers excluding diagnoses such as diabetes or peripheral arterial disease, others reporting scores or using the comorbidity indices to generate a standardised list of conditions (Davie-Smith et al., 2016; de Laat et al., 2014; Fortington et al., 2013; Gailey et al., 2002; van Eijk et al., 2012; Webster et al., 2012). Further research in heterogeneous amputation cohorts is indicated to map comorbidities (including musculoskeletal pathologies and mental health issues) and to establish clinical utility of comorbidity indices in the WA public health context.

2.5. Amputee Rehabilitation Models of Care

The Department of Veterans Affairs (2008) in the USA recommend a 5 stage rehabilitation model of care for people with amputation. The 5 stages of rehabilitation documented in the literature (Department of Health, 2008; Knapp, 2013; Lusardi, 2013; Nielsen & Jorge, 2013; Roffman, Buchanan, & Allison, 2016b; US Department of Veterans Affairs, 2008) include: pre-operative, post-operative, pre-prosthetic, prosthetic and long term follow-up (see figure 2.1 for the Royal Perth Hospital (RPH) multidisciplinary model of care for amputation rehabilitation).

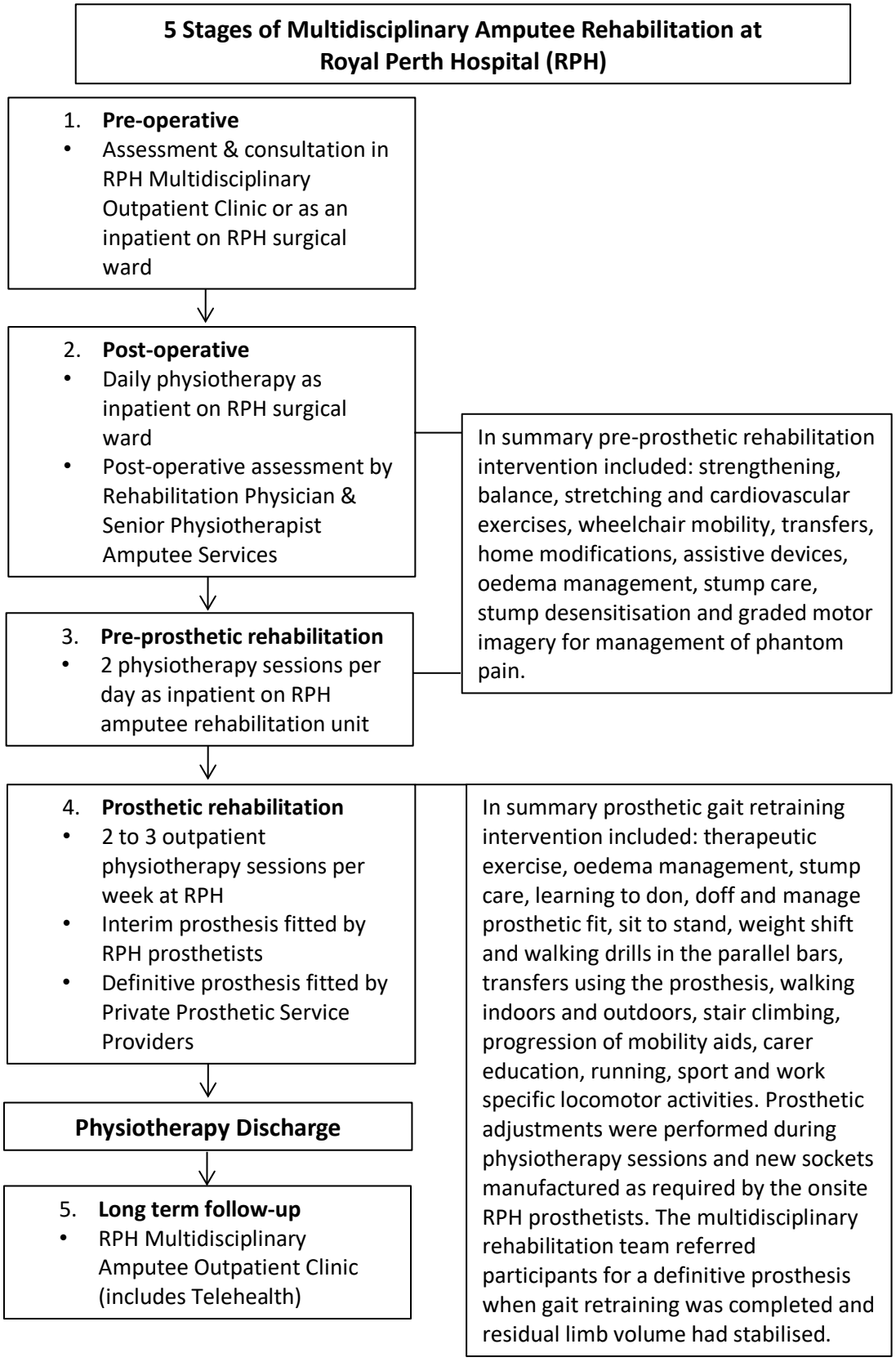

Figure 2.1: The 5 stages of Multidisciplinary Amputee Rehabilitation model of care at Royal Perth Hospital (RPH)

(Roffman et al., 2016b; US Department of Veterans Affairs, 2008).

Although amputee models of care vary between inpatient, outpatient, domiciliary, outreach and telemedicine settings, the consensus of contemporary literature (Broomhead et al., 2012; Czerniecki et al., 2012a; Department of Health, 2008; Geertzen et al., 2015a; Geertzen et al., 2015b; ICRC, 2015; Kurichi et al., 2009; Meier Iii & Heckman, 2014; Pasquina, 2010; Sansam et al., 2014; Stineman et al., 2010; US Department of Veterans Affairs, 2008; Wong et al., 2016a) has been that healthcare from a comprehensive multidisciplinary team specialised in amputee rehabilitation optimises outcomes for people with lower limb amputation. The multidisciplinary team includes: rehabilitation medicine physician, physiotherapist, prosthetist, nurse, occupational therapist, podiatrist, clinical psychologist, social worker, dietitian, orthotist and other health professionals or specialities as required by individual patients (Broomhead et al., 2012; Department of Health, 2008; Meier Iii & Heckman, 2014; Nielsen & Jorge, 2013; Pasquina, 2010; Sansam et al., 2014; US Department of Veterans Affairs, 2008).

Meier Iii and Heckman (2014) emphasised the importance of inpatient, outpatient and long term follow-up stages in their review of contemporary amputee rehabilitation principles but identified that there has been a shift away from inpatient rehabilitation in many USA healthcare facilities. Meier and Melton (2014) report that an interim prosthesis can be cast and fitted, once the residual limb wound has healed and the oedema has been managed. An interim prosthesis is the first prosthesis fitted (approximately 3 weeks and onwards) after amputation surgery so that prosthetic gait retraining can commence. The interim prosthesis is generally used by the patient for the first 6 months of walking while the residual limb maturates and oedema stabilises (Meier & Melton, 2014). Oedema management following amputation surgery minimises healthcare costs by reducing the number of prosthetic sockets required during the interim prosthetic stage (Meier & Melton, 2014). A definitive prosthesis is usually prescribed at approximately 6 to 8 months once residual limb oedema has stabilised and the patient has learned to walk with a prosthesis (Meier & Melton, 2014). Meier Iii and Heckman (2014) also called for health professionals to evaluate the rehabilitation outcomes of people with lower limb amputation. In the UK model of care, Sansam et al. (2014) reported that prosthetic gait retraining was performed as an outpatient service with patients trialling an early walking aid (i.e. an inflatable

device such as the Pneumatic Post Amputation Mobility Aid (PPAM Aid)) during physiotherapy sessions until a definitive prosthesis was prescribed.

Improved locomotor and mortality outcomes in people with lower limb amputation have been associated with amputee models of care that include an inpatient admission to a specialised multidisciplinary rehabilitation unit (Czerniecki et al., 2012a; Stineman et al., 2008). In a prospective cohort study by Czerniecki et al. (2012a) of 199 participants with dysvascular lower limb amputation (due to diabetes or peripheral arterial disease), successful mobility at 12 months was 17% more likely in participants who underwent rehabilitation as inpatients in a comprehensive multidisciplinary rehabilitation unit. Successful mobility was defined as the same or improved locomotor capabilities index 5 (LCI5) score for participants in this study (Czerniecki et al., 2012a). Stineman et al. (2008) reported improved rates of 1 year survival and discharge home in people with amputation who underwent rehabilitation during the acute post-operative stage in a comprehensive multidisciplinary inpatient rehabilitation unit.

In developing nations people with amputation may travel from remote regions to receive prosthetic rehabilitation at healthcare facilities (ICRC, 2015; Rau, Bonvin, & de Bie, 2007). In contrast to developed nations, prosthetic gait retraining is performed over short time frames of 3 to 7 days in developing nations such as Myanmar to address social needs of the patients (Rau et al., 2007). A polypropylene prosthesis has been designed to ensure prostheses are useable in the environmental conditions of developing nations and cost effective (ICRC, 2015). In parallel to their physical rehabilitation program, the ICRC have implemented a social inclusion and participation program to facilitate social and economic reintegration of people with disabilities into their community (ICRC, 2015).

In the Western Australian public health context at Royal Perth Hospital (RPH), the state amputee rehabilitation centre, patients received specialised amputee rehabilitation from a comprehensive multidisciplinary team during both the inpatient and outpatient stages of their rehabilitation (see figure 2.1) (Department of Health, 2008; Roffman et al., 2016b). In WA amputee services have been centralised in the capital city of Perth (Department of Health, 2008; WALSA, 2016).

In the patient centric amputee rehabilitation model of care at RPH, amputation surgery was day 0 and physiotherapy commenced day 1 in the post-operative stage. During the inpatient admission (pre-prosthetic stage of rehabilitation) patients achieved independent mobility without a prosthesis and participated in twice daily physiotherapy sessions (Department of Health, 2008; Roffman et al., 2016b). There were no breaks in physiotherapy intervention between the pre-prosthetic and prosthetic rehabilitation stages (i.e. after inpatient discharge, patients received outpatient physiotherapy for exercise training and oedema management 2 to 3 times per week while waiting for their residual limb wound to heal). This was to ensure that patients did not decondition while waiting to commence prosthetic rehabilitation.

In the RPH model of care, 3 weeks after amputation surgery and 6 months after commencing prosthetic gait retraining were the earliest timeframes for prescription of interim and definitive prostheses respectively. These timeframes for interim and definitive prostheses were similar to those described by Meier and Melton (2014). In WA all prosthetic components used to manufacture prostheses were approved by the Therapeutic Goods Administration (TGA) (WALSA, 2016). Interim prostheses were manufactured using lower cost, basic prosthetic components except for complex cases where non-standard prosthetic components were clinically indicated (WALSA, 2016). The interim and definitive prostheses provided to RPH patients in this thesis have been outlined below.

Prosthetic feet can be non-articulated (e.g. solid ankle cushion heel (SACH) foot), articulated (e.g. single or multiaxial), dynamic response (store and return energy, e.g. Vari-Flex), range of motion (height adjustable foot), hydraulic or microprocessor (e.g. Ossur proprio foot) (Carroll, Rheinstein, & Pollard, 2013). All interim prostheses at RPH had WillowWood Ohio SACH feet with titanium pyramids. The SACH foot is the most basic type of prosthetic foot that simulates normal gait through compression of a heel cushion and flexibility of the toe (Carroll et al., 2013).

For patients with transtibial amputation, a supracondylar suspended patella tendon bearing prosthesis (PTS) with a pelite liner was the most common interim prosthetic suspension system, socket and liner manufactured at RPH. For patients with transfemoral amputation, quadrilateral and ischial containment sockets were

manufactured depending on the individual's clinical needs. A total elastic suspension (TES) belt was the main type of suspension used for people with transfemoral amputation. For complex transtibial and transfemoral amputation cases (e.g. split skin graft, short residual limb or invaginated scar tissue) total surface bearing prostheses with pin lock silicone liners were used for sockets and suspension. These prosthetic socket, liner and suspension systems have been well documented for clinical management of patients with lower limb amputation in the literature (Knapp, 2013; Psonak, 2013).

Prosthetic knee components may be mechanical (e.g. single axis, polycentric, weight activated stance control, manual locking, hydraulic, pneumatic) or microprocessor (e.g. C-leg, Rheo knee) with a computer processor (sensor) that enables stance control and modifies the swing phase of gait as walking speed changes (Psonak, 2013). Mechanical knee components were used in interim knee disarticulation and transfemoral prostheses at RPH. Polycentric knee components with 4 bar linkage systems were the main type of mechanical knees used in the manufacture of interim prostheses. Polycentric knee components have been reported in the literature as having increased stability during the stance phase of gait which is helpful in patients with short residual limbs and hip extensor muscle weakness (Psonak, 2013). Due to the linkage system of 4 bars (or more) the design of the polycentric knee is closer to the anatomical knee than single axis prosthetic knee components (Psonak, 2013). The following mechanical knee brands and product codes were used for the manufacture of interim prostheses at RPH:

- Regal, 2-01-4S3S 4 bar mechanical knee joint (AK)
- Regal, 2-01-S700 polycentric K2 knee joint with stance flexion (AK/KD)
- Regal, 2-01-S500 polycentric 4 bar knee joint (AK/KD)
- Regal, 2-01-S400 polycentric 4 bar knee joint (AK/KD) for patients with higher body weight and knee disarticulation
- Regal, 2-01-A41 polycentric 4 bar linkage knee joint (AK)
- Ottobock, 3R60 hydraulic controlled polycentric knee joint
- Ottobock, 3R80 modular knee joint with rotatory hydraulic
- ST&G, 1321 polycentric 4 bar
- ST&G, 1322 polycentric pneumatic 4 bar knee.

Similar to the literature (Knapp, 2013; Psonak, 2013; Ries & Vaughan, 2013), prosthetic fit was managed using stump socks, packing of the prosthetic liner and socket modification at RPH. Law Comfort Stump Socks were used for managing prosthetic fit in patients with transtibial amputation. The cotton stump sock product codes of the most frequently used Law Comfort stump socks include:

- 28M16
- 26M16
- 27M16.

Nylon stocking was used for the pull through stockings in the PTS transtibial prostheses. Tubifast stockinette (yellow line) and Heller woollen stump socks were used for patients with tranfemoral amputation. Dermaseal silicone socks and Iceross silicone liners were used with patients that had fragile skin and split skin grafts. Silicone socks and liners protect bony prominences and reduce shear forces on the residual limb to minimise skin breakdown (Knapp, 2013). If the socket became too large a new socket was cast, manufactured and fitted by the RPH prosthetist. A cosmetic cover was generally not fitted to the interim prosthesis because it was frequently adjusted by the RPH prosthetists during physiotherapy sessions for prosthetic gait retraining.

Prosthetic gait retraining was performed as an outpatient rehabilitation service 2 to 3 times per week for approximately 6 to 12 months and patients were discharged when their rehabilitation goals had been achieved (Department of Health, 2008; Roffman et al., 2016b). Telehealth videoconference (Department of Health, 2008; Roffman et al., 2016b) was used for follow-up of patients that lived in rural and remote locations of WA. The principles of this WA amputee rehabilitation model of care with the use of telemedicine[1] were similar to those described in the literature (Broomhead et al., 2012; Geertzen et al., 2015a; Geertzen et al., 2015b; Meier Iii & Heckman, 2014; Meier & Melton, 2014; Sansam et al., 2014; US Department of Veterans Affairs, 2008). However, the WA model of care differed from other Australian states where prosthetic gait retraining was performed as an inpatient rehabilitation service (Batten,

[1] This was the endorsed WA amputee rehabilitation model of care during the period research this thesis was conducted and prior to implementation of activity based funding in 2014.

Kuys, McPhail, Varghese, & Nitz, 2015; Hordacre et al., 2013a; Hordacre, Stevermuer, Simmonds, Crotty, & Eagar, 2013b; Wu, Chan, & Bowring, 2010).

In WA, the definitive prosthesis was prescribed by the rehabilitation medicine physician once the patient's residual limb volume had stabilised and the person with lower limb amputation could walk. In the definitive prosthesis stage, patients were funded for prosthetic sockets, suspension systems, knee and foot components with more advanced technology (e.g. vacuum suction or pin lock suspension, multi axial or dynamic response feet, pneumatic or hydraulic knees) and greater cost. The patient selected a private prosthetic service provider from Fremantle Orthotic Services (FOS), The Limb Clinic (TLC), South West Orthotic and Prosthetic Services (SWOPS) and Orthotic and Prosthetic Solutions (OPS) (private prosthetic companies in WA during this research) to manufacture their definitive prosthesis once it was prescribed (WALSA, 2016).

The new definitive prosthetic components funded by WALSA (2016) were based on clinical assessment of the patient's Medicare Functional Classification Level (MFCL) K-level (mobility level). Levels of funding by WALSA (2016) for prosthetic components (per foot and knee unit) in the definitive stage were as follows:

- K1 (mobility level 1) – home walker, funded for a standard SACH foot, standard knee or safety knee
- K2 (mobility level 2) – restricted outdoors walker, funded for a prosthetic foot up to a maximum of $850 (AUD) and a standard knee
- K3 (mobility level 3) – unrestricted outdoors walker, funded for a prosthetic foot up to a maximum of $850 (AUD) and a prosthetic knee up to a maximum of $2900 (AUD)
- K4 (mobility level 4) – unrestricted outdoors walker with very high demands, funded for a prosthetic foot up to a maximum of $1300 (AUD) and a prosthetic knee up to a maximum of $3200 (AUD).

WALSA (2016) did not fund microprocessor knees, recreational or waterproof prostheses (e.g. swimming or shower prostheses). These prostheses or components were accessible in the definitive phase by patients who were compensable or self

funding. Patients were able to self fund the gap between their maximum level of WALSA funding and a higher rated prosthetic component (WALSA, 2016). In WA, the definitive prosthesis was replaced approximately every 3 years (WALSA, 2016). The WALSA funding model described was stable during the research in this thesis.

In the literature, clinical research has examined the impact of the prosthetic components and design on functional outcome and quality of life (Ali et al., 2014; Esquenazi, 2004; Fatone & Caldwell, 2017; Gailey et al., 2010; Laferrier & Gailey, 2010; Samuelsson, Toytari, Salminen, & Brandt, 2012). In people with transfemoral amputation the use microprocessor knees have been associated with improved function, reduced falls and healthcare costs (Hafner & Smith, 2009; Mundell, Maradit Kremers, Visscher, Hoppe, & Kaufman, 2017). However, abandonment of prosthetic technology such as microprocessor knees for wheelchairs as a primary mobility device has also been identified (Karmarkar et al., 2009; Schaffalitzky et al., 2012). The reality of working in the public health context is that budgets are limited and resources need to be allocated to optimise the prosthetic outcome for the case mix efficiently. Cost effectiveness is therefore a major consideration for the use of prosthetic technologies in amputee rehabilitation models of care.

The literature has demonstrated that amputee rehabilitation models of care vary widely throughout the world and have largely evolved through the political, funding and sociodemographic contexts of the countries where they were implemented as well as the patient's own rehabilitation goals and expectations (Broomhead et al., 2012; Department of Health, 2008; Department of Veterans Affairs, 2008; Hordacre et al., 2013b; ICRC, 2015; Rau et al., 2007). Although locomotor outcomes and survival rates for subgroups with lower limb amputation have been associated with specialised amputee rehabilitation from comprehensive multidisciplinary teams and inpatient settings (Czerniecki et al., 2012a; Stineman et al., 2008) there are no clear guidelines on the most effective method of service delivery (e.g. inpatient, outpatient, domiciliary, outreach) or the intervention intensity and duration required to achieve successful outcomes. A proposed advantage of the long term follow-up phase in the RPH 5 stage amputee rehabilitation model of care (see figure 2.1) is, if a patient develops any issues related to their amputation there is linkage with the specialist amputee rehabilitation multidisciplinary team so the issues that may lead to

prosthetic non-use could be addressed. However, there is limited literature on the impact of amputee rehabilitation models of care on locomotor outcomes and cost effectiveness. Yamato et al. (2016) identified that inadequate reporting of interventions in clinical research were a major challenge to using the research for clinical decision making or replicating studies. This statement holds true for the reporting of amputee models of care with the majority being grey literature developed by expert multidisciplinary rehabilitation teams. By reporting the RPH amputee model of care and rehabilitation interventions (see section 2.8 and appendix 2.1), this thesis contributes to the evidence base for future clinical research and model of care development at other healthcare facilities around the world.

2.6. Costs associated with amputation

In a systematic review Highsmith et al. (2016a) demonstrated that there has been limited literature on the economic impact of major lower limb amputation and the cost effectiveness of prosthetic interventions. Blough et al. (2010) estimated that the projected lifetime prosthetic costs for a veteran with unilateral lower limb amputation potentially range from $466 227 to $1 841 585 (USD). In this study, the costs of prostheses were lower for the veterans from Vietnam in contrast to those from Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) due to the use of technologically less advanced prosthetic limbs and higher rates of prosthetic abandonment (Blough et al., 2010). Similar to the USA, the estimated 40 year costs were high for the 265 UK Afghanistan war veterans who sustained 461 amputations from 2003 to 2014 at £288 million GBP ($444 million USD) (Edwards, Phillip, Bosanquet, Bull, & Clasper, 2015). Dillingham, Pezzin, and Shore (2005) reported that in 1996, the 1 year acute and post-acute healthcare costs of people with atraumatic amputation exceeded $4.3 billion (USD). In 2009 the cumulative national hospital costs related to amputation were greater than $8.3 billion (USD) and $655 million (USD) were reimbursed for lower limb prosthetic services by Medicare in the USA (Highsmith et al., 2016a; Ma et al., 2014).

Highsmith et al. (2016a) performed a systematic review of the literature evaluating the cost of interventions for people with transtibial amputation. From the 6 articles analysed, the 3 topics related to rehabilitation of people with transtibial amputation

identified were: models of care, prosthetic treatment and prosthetic sockets (Highsmith et al., 2016a). Five empirical evidence statements were generated from the articles analysed by the reviewers (Highsmith et al., 2016a). The evidence statement reported with moderate confidence was that patella tendon bearing and total surface bearing sockets were functionally and economically equivalent in the short term, however longer term outcomes had not been investigated (Highsmith et al., 2016a). Highsmith et al. (2016a) concluded that further research and economic analyses on interventions for people with transtibial amputation were required.

Microprocessor knees have been reported as improving the safety and efficiency of prosthetic gait compared to conventional prosthetic knee components in people with transfemoral amputation (Highsmith et al., 2016b). Highsmith et al. (2016b) performed a randomised AB crossover study of 20 people with transfemoral amputation using the C-leg and Genium microprocessor knees to determine functional and economic benefits. The Genium was demonstrated to have significantly reduced ($p < .05$) four square step test (FSST) time, increased functional level (as measure by the Amputee Mobility Predictor (AMP)) and step activity compared to the C-leg (Highsmith et al., 2016b). The Genium knee was reported by participants as their preferred microprocessor knee during the study (Highsmith et al., 2016b). Highsmith et al. (2016b) concluded that due to improved function with activities of daily living the Genium knee component may be worth funding despite costing more at the time of purchase (approximately $30 000 to $55 000 USD) than the C-leg. However, a microprocessor knee component does not ensure long term functional use of a prosthesis in people with high levels of amputation. Karmarkar et al. (2009) investigated prosthesis and wheelchair use in 42 war veterans and demonstrated that a non-significant ($p = .65$) but higher number of participants who had a prosthesis with a microprocessor knee used a wheelchair as their primary mobility aid.

There is the potential for cost savings if a person with transfemoral amputation has osseointegration as the prosthetic sockets required in conventional prostheses that are manufactured approximately every 3 years no longer having to be produced (Haggstrom et al., 2013). Haggstrom et al. (2013) compared the costs of conventional and osseointegrated transfemoral prostheses over a 10 year time frame

for 50 participants in a retrospective single centre study. The total costs of osseointegration and conventional prostheses were not significantly different in terms of new prostheses, services, repairs and adjustments however the people with osseointegrated prostheses had significantly fewer visits to the prosthetics workshop per year (Haggstrom et al., 2013). Haggstrom et al. (2013) concluded that the cost outcomes were most likely due to technologically more advanced prosthetic components being used with people who had osseointegration.

The defence service budgets for USA and UK war veterans do not represent the budgets of public health services rehabilitating civilians with lower limb amputation in Australia or aide organisations working in developing nations (Department of Health, 2008; ICRC, 2015; Sansam et al., 2014; WALSA, 2016). In WA microprocessor knees are not publicly funded by WALSA and only available to compensable or self funding patients with transfemoral amputation (WALSA, 2016). In the majority of countries resource limitations exist so optimising the allocation of healthcare resources (e.g. prosthetic components) to patients is an important issue (Erjavec et al., 2014; Sansam et al., 2014; Schaffalitzky et al., 2012).

There is a paucity of literature on the economic costs of amputee rehabilitation in Australia (Davis et al., 2006; Gordon, Magee, Frazer, Evans, & McCosker, 2010). Gordon et al. (2010) compared the labour costs, functional outcomes and satisfaction of patients with unilateral transtibial amputation who underwent rehabilitation in the public (n = 34) and private (n = 26) model of care in New South Wales (NSW). Gordon et al. (2010) concluded that the public model of care was more cost effective with labour costs per patient being 29% lower at $1391.11 (AUD) than the private model at $1917.19 (AUD). The methodology used by Gordon et al. (2010) for calculating labour costs was challenged as underestimating the costs for the publicly funded prosthetist by Kohler (2010), Dillon (2010) and North (2010) on behalf of the Australian Orthotists and Prosthetists Association (AOPA). Functional and satisfaction outcomes were similar for both models of care (Gordon et al., 2010) as Dillon (2010) identified an error in the published SAT-PRO calculation.

Davis et al. (2006) reported that the costs for the acute inpatient surgical admission of people who underwent major and minor lower limb amputation during the

Fremantle Diabetes Study in WA were median, $12 485 AUD (interquartile range (IQR), $6037 to $24 415 AUD) from 1993 to 2000 using a case mix approach. The length of stay was median, 24 (IQR, 10 to 14) days and a total of 44 patients without lower limb amputation at recruitment had their first ever diabetes related lower limb amputation during the period of study (Davis et al., 2006). Foot ulceration, ankle brachial index (ABI) of $\leq$ 0.90, glycated haemoglobin (HbA1c) increase > 1%) and neuropathy were demonstrated by Davis et al. (2006) as being independent predictors of lower limb amputation. Davis et al. (2006) did not report on rehabilitation outcomes or costs.

The Western Australian Limb Service for Amputees (WALSA) reported that the total number of interim prosthetic limbs provided was 153 in 2005 to 2006 and 125 in 2006 to 2007 (Department of Health, 2008). RPH provided 69 interim prostheses in 2005 to 2006 and 55 in 2006 to 2007 (Department of Health, 2008). G. Caldwell (personal communication, November 23, 2016) estimates that the approximate cost of interim prostheses manufactured by the RPH onsite prosthetists were as follows:

1. Transtibial prostheses with a supracondylar suspended patella tendon bearing socket (PTS) start at $2500 (AUD) for a homopolymer socket to $3400 (AUD) with a laminated socket and heavy duty componentry. Total surface bearing prostheses (TSB) with a silicone liner and pin lock cost $4300.
2. Transfemoral prostheses start at $4500 and increase to $6000 for a silicone liner with a pin lock and a custom silicone insert.

WALSA pay $138.80 per hour for manufacture of prostheses by the private prosthetic service providers with the hours of manufacture paid for outlined in the WALSA manual (G. Caldwell, personal communication, November 23, 2016; WALSA, 2016). The hours that are reimbursed for labour are determined by the level of amputation and complexity of the prosthesis being manufactured (WALSA, 2016). The cost of definitive prostheses manufactured by private prosthetic service providers is higher than interim prostheses due to the use of more expensive componentry determined by the person with amputation's K-level classification (mobility class) and for billing per occasion of service (WALSA, 2016). The maximum funding from WALSA for a K-level 4 person with lower limb amputation is up $1300 (AUD) for a prosthetic foot and up to $3200 (AUD) a prosthetic knee

(WALSA, 2016). Costs may vary in both the interim and definitive phases of prosthetic manufacture depending on the level of amputation and complexity of the patient (G. Caldwell, personal communication, November 23, 2016; WALSA, 2016).

2.7. Prosthetic prescription

In a multicentre observational study of 151 people with major lower limb amputation, Van der Linde, Geertzen, Hofstad, Van Limbeek, and Postema (2003) identified that clinical expertise was the main factor used for prosthetic prescription in the Netherlands. It was concluded that clinical practice guidelines for prosthetic prescription were needed in the Netherlands as there was no statistical consensus at study centres between prosthetic component prescription criteria and factors that may affect outcome such as activity level, amputation level, age or time since amputation (Van der Linde et al., 2003).

Sansam et al. (2014) identified the following 4 key themes of clinical decision making for prosthetic prescription through interviewing 23 health professionals from the UK experienced in amputee rehabilitation: estimating outcome, difficulties predicting outcome, patient choice and barriers to prescribing. Only 1 of the 4 rehabilitation centres involved in this study used formal prosthetic prescription guidelines. Similar to Van der Linde et al. (2003), a need for national prescription guidelines was identified by Sansam et al. (2014) to improve prescription consistency and equity of access to healthcare resources.

The literature (Broomhead et al., 2012; Geertzen et al., 2015a; Kahle et al., 2016a; Meier & Melton, 2014; Sansam et al., 2014) recommends assessment by a multidisciplinary team to determine if the patient is a prosthetic candidate. Several factors have been associated with exclusion of patients from prosthetic prescription in the literature (Geertzen et al., 2015a; Geertzen et al., 2015b; Kahle et al., 2016a; Kurichi et al., 2007; Meier & Melton, 2014; Mundell, Kremers, Visscher, Hoppe, & Kaufman, 2016; Resnik & Borgia, 2015; Sansam et al., 2014; Schaffalitzky et al., 2012; Van Velzen et al., 2006): comorbidities (e.g. congestive heart failure, renal failure, cerebrovascular accident), medications (e.g. warfarinisation), cognitive impairment, older age, high-level amputation, multiple limb amputation, remaining

limb pathology, increased body weight, mental health issues, poor motivation, lack of social support, poor premorbid mobility, history of falls, presence of residual limb contractures, impaired muscle strength, poor balance and inadequate cardiovascular fitness. In the Dutch evidence based guidelines for rehabilitation and prosthetics of people with lower limb amputation,Geertzen et al. (2015a) reported that adequate wound healing and management of residual limb oedema were important factors prior to prosthetic fitting. Mundell et al. (2016) demonstrated in a retrospective cohort study of 93 patients with transfemoral amputation that those who walked independently prior to amputation were 30 times more likely to be prescribed a prosthesis.

Kahle et al. (2016a) noted that while several factors contribute to the clinical decision of prosthetic candidacy the guidelines reported in the literature remain unclear. This may potentially lead to a mismatch of patient to intervention and increase healthcare costs. Kahle et al. (2016a) advised that a full patient history and physical examination by the multidisciplinary team were warranted to determine prosthetic candidacy. Furthermore, it was recommended that the factors predictive of prosthetic candidacy including aetiology, physical fitness, living status prior to amputation, amputation level, age, comorbidities, cognition and mood disturbance should be documented in the patient's medical record (Kahle et al., 2016a). The research in this thesis moves onto the next step: assessing the outcomes of people with lower limb amputation who were selected for prosthetic rehabilitation by the RPH multidisciplinary team based on factors associated with prosthetic outcome in the literature.

2.8. Physiotherapy intervention

The physiotherapy intervention following lower limb amputation that has been documented in the literature (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Geertzen et al., 2015a; Geertzen et al., 2015b; Lusardi, 2013; Meier & Melton, 2014; Rau et al., 2007; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008; Yamato et al., 2016) is intensive, multimodal and individualised based on patient assessment findings and goals. Physiotherapy interventions contribute to the complexity of predicting rehabilitation outcomes following lower limb amputation (Meier & Melton, 2014; Wong et al., 2016a; Yamato et al., 2016). However, the majority of published evidence on physiotherapy inventions for people with lower limb amputation is based on expert opinion or low quality studies and clinical practice varies between rehabilitation centres (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Geertzen et al., 2015a; Geertzen et al., 2015b; Lusardi, 2013; Meier & Melton, 2014; Rau et al., 2007; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008; Wong et al., 2016a). The physiotherapy assessments and interventions were performed and progressed by a physiotherapist trained in amputee rehabilitation for studies in this thesis as advised in the literature (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013). The core components of physiotherapy intervention after amputation surgery include: mobility retraining without a prosthesis, oedema management, desensitisation of the residual limb, therapeutic exercise, pain management, scar tissue and wound management, prosthetic gait retraining, prescription of mobility aids or assistive devices and education (Butler & Moseley, 2013; Deutsch, English, Vermeer, Murray, & Condous, 2005; Gailey, 2004; Gailey, Gailey, & Angulo, 1989, 1994a, 1994b; Gailey, Gailey, Sendelbach, & Angulo, 1995; Geertzen et al., 2015a; Geertzen et al., 2015b; Lusardi, 2013; MacLachlan, McDonald, & Waloch, 2004; Meier & Melton, 2014; Moseley, 2012; Mulvey et al., 2013; Rau et al., 2007; Ries & Vaughan, 2013; Stokes et al., 2008; Stokes et al., 2009; US Department of Veterans Affairs, 2008). These physiotherapy interventions and some important interventions by other multidisciplinary team members have been summarised in appendix 2.1.

2.9. Outcome Studies and predictors of locomotor function following lower limb amputation

Amputee rehabilitation is an intensive, protracted and costly process however long term functional outcomes are poorly understood and quantified by health services (Department of Health, 2008; Meier Iii & Heckman, 2014). It was identified by the working party for the Western Australian Amputee Rehabilitation Model of Care in 2008, that rehabilitation outcomes and the rate of functional prosthetic use were unknown (Department of Health, 2008). In this thesis a successful prosthetic user was defined as a person who functionally uses their prosthetic limb for locomotor activities on all or some days of the week. A full-time prosthetic user was a person who uses their prosthesis on all 7 week days. A part-time prosthetic user was a person who uses their prosthesis on less than 7 week days. A prosthetic non-user was a person who did not functionally use their prosthesis for locomotor activities on any week days. People who reported wearing their prosthesis for cosmesis only were classified as prosthetic non-users.

It has been identified that pre-operative factors such as comorbidities, age, condition of remaining limb, mobility status prior to amputation, skin integrity, ethnicity, socioeconomic status, cognition and social support influence ability to walk using a prosthesis (Meier & Melton, 2014; Sansam et al., 2009; Taylor et al., 2005). Post-operative factors such as level and number of limbs amputated, quality of residual limb, contractures, wound healing, post-operative complications, residual limb oedema, pain, energy cost and falls have been associated with walking ability using a prosthetic limb (Adams, 2005; Bhangu et al., 2009; Lim et al., 2006; Meier & Melton, 2014; Nehler et al., 2003; Sansam et al., 2009; Schoppen et al., 2003; Waters et al., 1976; Wezenberg, van der Woude, Faber, de Haan, & Houdijk, 2013). Improved functional outcome and reduced mortality have also been reported for high intensity, comprehensive multidisciplinary rehabilitation in specialised amputee units (Czerniecki et al., 2012a; Kurichi et al., 2009; Stineman et al., 2010).

The majority of studies in lower limb amputation cohorts have demonstrated univariate association with limited high quality multivariate regression studies to guide clinical decision making (Sansam et al., 2009). Studies have reported on sub-groups with poor rehabilitation capacity (e.g. bed bound prior to amputation),

focused on surgical outcome or factors associated with *not fitting or prescribing* a prosthetic limb as opposed to abandonment of prosthetic use after participating in rehabilitation (Fletcher et al., 2001; Fletcher et al., 2002; Resnik & Borgia, 2015). In the USA not fitting a prosthesis was associated with high amputation level, advanced age, cognitive impairment, comorbidities (e.g. renal failure, cardiovascular, cerebrovascular and neurological diseases) and geographical location (Fletcher et al., 2001; Fletcher et al., 2002; Resnik & Borgia, 2015). Other studies have been limited to specific sub-groups (e.g. atraumatic amputation cause, unilateral transfemoral amputation) or recruited samples of convenience so the results were not generalisable to heterogeneous lower limb amputation cohorts managed by amputee rehabilitation services (Raya et al., 2010; Schoppen et al., 2003). Studies have reported high variation in functional prosthetic use following rehabilitation with rates ranging from 36% to 95% (Fletcher et al., 2001; Jones et al., 1993; Lim et al., 2006; Pohjolainen & Alaranta, 1998; Schaffalitzky et al., 2012; Wu et al., 2010).

A systematic review by Sansam et al. (2009) of 57 studies revealed that successful locomotor outcome after lower limb amputation was associated with factors including cognition, fitness, unilateral and distal levels of amputation, younger age, independence with single limb stance, activities of daily living and walking pre-operatively. Poor outcome was associated with delay to rehabilitation and complications with the residual limb (Sansam et al., 2009). Comparison of studies was difficult due to the different methodologies, definitions for successful locomotor function and outcome measures used by researchers (Sansam et al., 2009). Sansam et al. (2009) called for further research to better define predictors of locomotor outcome following lower limb amputation.

Cochrane reviews of prosthetic rehabilitation in older people (aged $\geq$ 60 years) with atraumatic causes of unilateral transfemoral amputation demonstrated that there was limited quality evidence to guide clinical decision making in this sub-group (Cumming, Barr, & Howe, 2006; Cumming, Barr, & Howe, 2015). Cumming et al. (2006) and Cumming et al. (2015) included one short term randomised cross over clinical trial that tested the preference of different transfemoral prosthesis weights on 10 participants when walking in their 2006 and 2015 Cochrane reviews. Both reviews concluded there was an urgent need for research on outcomes of older

people following atraumatic amputation (Cumming et al., 2006; Cumming et al., 2015).

In a consecutive audit of 553 subjects with lower limb amputation the factors identified as predictive of not wearing a prosthesis were: being non-ambulant or a home bound ambulator before amputation surgery, transfemoral level of amputation, age of 60 years or greater, having dementia, end stage renal failure and coronary artery disease (Taylor et al., 2005). These predictor variables were similar to factors reported for not fitting a prosthesis (Fletcher et al., 2001; Fletcher et al., 2002; Resnik & Borgia, 2015). However, the focus of the study by Taylor et al. (2005) was to improve surgical decision making through comparison of outcomes for limb revascularisation and amputation surgery therefore limited rehabilitation variables and participants with poor rehabilitation potential were included (Taylor et al., 2005).

Schoppen et al. (2003) reported that at 2 weeks after amputation single limb balance of less than 10 seconds in combination with age, cognitive impairment and severe comorbidity were predictive of not using a prosthesis in a prospective cohort of 46 subjects with unilateral lower limb amputation. In the 37 geriatric participants who were followed up at 12 months, only 49% (n = 18) had achieved functional prosthetic use as measured by an 8 point classification scale which ranged from non-ambulatory requiring a wheelchair through to independent without mobility aids (Schoppen et al., 2003). This study highlighted that condition of the remaining lower limb was important for achieving functional mobility using a prosthesis following amputation (Schoppen et al., 2003).

Australian studies of lower amputation cohorts have been descriptive with small numbers of participants, reported on institution specific variables (e.g. length of stay), and focused on sub-groups or surgical outcomes (Jones et al., 1993; Lim et al., 2006; Wu et al., 2010). In a consecutive cohort of 65 people with lower limb amputation from the Royal South Sydney Hospital in 1988 to 1989, 82% (n = 52) had survived at 1 year after discharge (Jones et al., 1993). From the interview it was determined that a total of 93% of participants were community dwelling, 94% were successful prosthetic users and 25% had returned to driving (Jones et al., 1993). Only 6 participants from the working age group had returned to work (Jones et al., 1993).

Wu et al. (2010) et al reported on a retrospective cohort of 208 people with lower limb amputation from 1994 to 2006 who underwent rehabilitation at the Prince of Wales Hospital. During this time frame only 135 (71%) of patients were assessed by the Rehabilitation Medicine Physician as suitable to participate in rehabilitation (Wu et al., 2010). In this study 24% of people used a wheelchair only for mobility and 76% used a prosthesis for locomotor activities (Wu et al., 2010). Of the people who used a prosthesis, 44% were community ambulators, 20% used their prosthesis for household ambulation and 12% for transfers or exercise only (Wu et al., 2010).

Lim et al. (2006) performed a retrospective audit of 87 people with lower limb amputation from 2000 to 2002 at Royal Perth Hospital to describe factors affecting contemporary surgical outcomes. High numbers of participants had atraumatic amputation with 75.9% of people having an amputation due to critical ischaemia and 17.2% from diabetic foot infection (Lim et al., 2006). A total of 47 patients underwent rehabilitation and 39 of these people participated in prosthetic gait retraining (Lim et al., 2006). The short term outcome within 3 months of discharge was that 79.5% of people used a prosthesis for locomotor activities (Lim et al., 2006).

2.10. Clinical prediction rules (CPRs)

Clinical prediction rules (CPRs) are statistically derived tools that assist health professionals with clinical decision making (Childs & Cleland, 2006; Cleland et al., 2007; Laupacis et al., 1997). CPR research methodology involves a 3 stage process of: derivation, validation and after a period of CPR implementation, impact analysis is performed (Childs & Cleland, 2006; Cleland et al., 2007; Laupacis et al., 1997). CPRs provide levels of evidence that enable health professionals to directly modify a model of care, improve patient outcomes or stratify patients to interventions based on a parsimonious set of predictor variables (Childs & Cleland, 2006; Cleland et al., 2007; Laupacis et al., 1997). The most effective CPRs have been developed for heterogeneous conditions, with multiple treatment options and complex decision making (Fritz, 2009). The 4 levels of evidence for CPRs identified by Childs and Cleland (2006) and how they can be translated into clinical practice by health professionals have been described in figure 2.2.

Review of the literature demonstrated there were no clinical prediction rules to identify patients at increased risk of abandoning prosthetic use after discharge from rehabilitation however there were many potential predictor variables that influenced functional outcome of people with lower limb amputation that made selection of patients for prosthetic gait retraining challenging (Gailey et al., 2002; Schoppen et al., 2003; Taylor et al., 2005). The rehabilitation model of care for amputation is varied and incorporates a lot in differential long term investments in time and personnel. Therefore, if developed and validated CPRs could be used to assist in optimising the investment by the health system as well as the informed decision making in a patient centric model of rehabilitation (given the high mortality rate).

The first CPRs developed and validated for prosthetic non-use after rehabilitation discharge were published by Roffman, Buchanan, and Allison (2014). A second CPR was later developed by Wong, Young, Ow-Wing, and Karimi (2016b) to assist with determining ability of people with lower limb amputation to ambulate in the community.

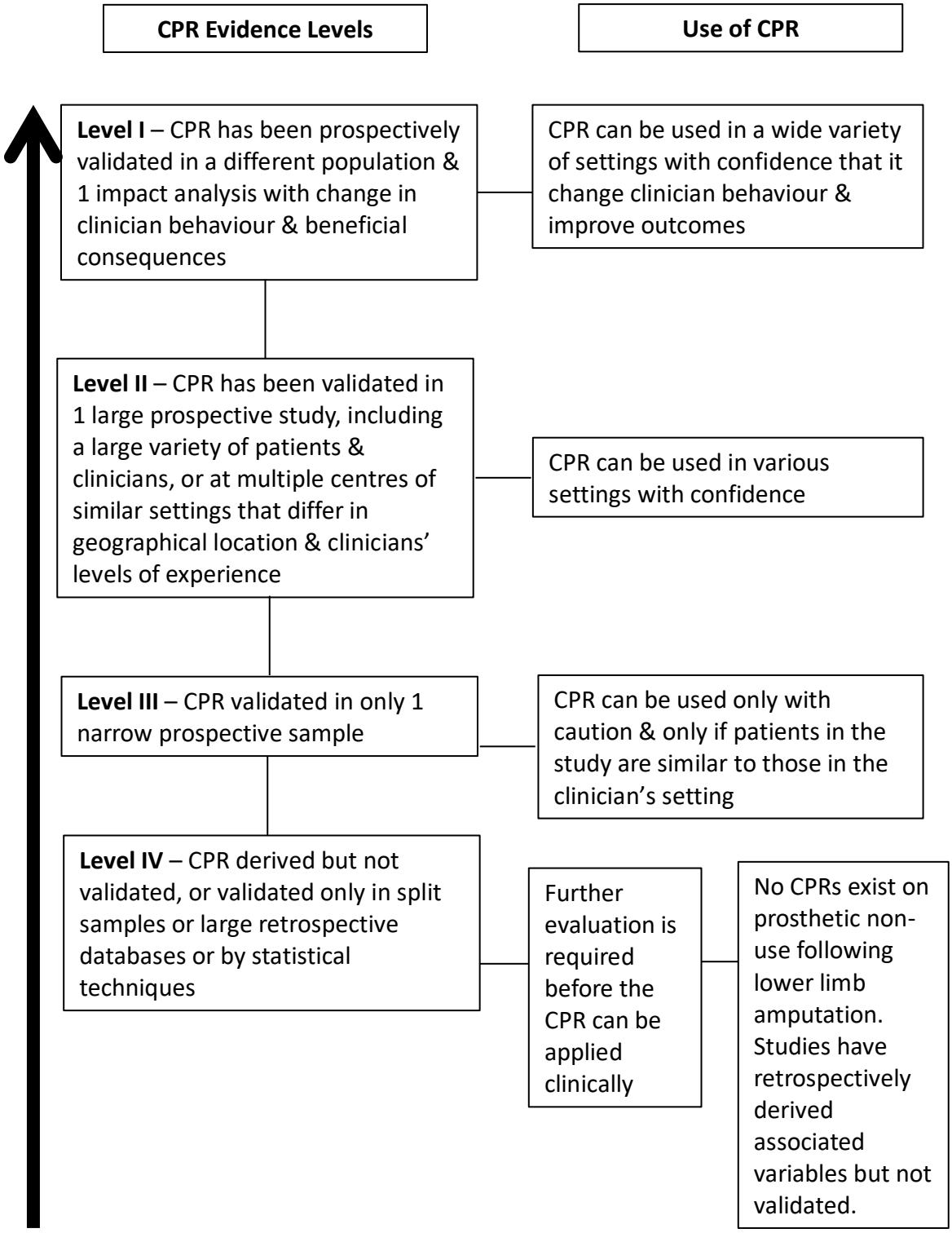

Figure 2.2: Levels of evidence for clinical prediction rules (CPR).

Adapted from Childs and Cleland (2006).

2.11. Measurement of locomotor function following lower limb amputation

Measurement of outcome following lower amputation is complex as recovery encompasses physical and psychosocial domains. The international classification of functioning, disability and health (ICF) provides a framework and common language to allow comparison of outcomes for health conditions such as lower limb amputation (Gaunaurd, 2012; Sansam et al., 2009; World Health Organization, 2001). The ICF model involves the interaction of 5 domains which include: body structure and function, activity, participation, personal and environmental factors (see Figure 2.3) (Gaunaurd, 2012; Sansam et al., 2009; World Health Organization, 2001).

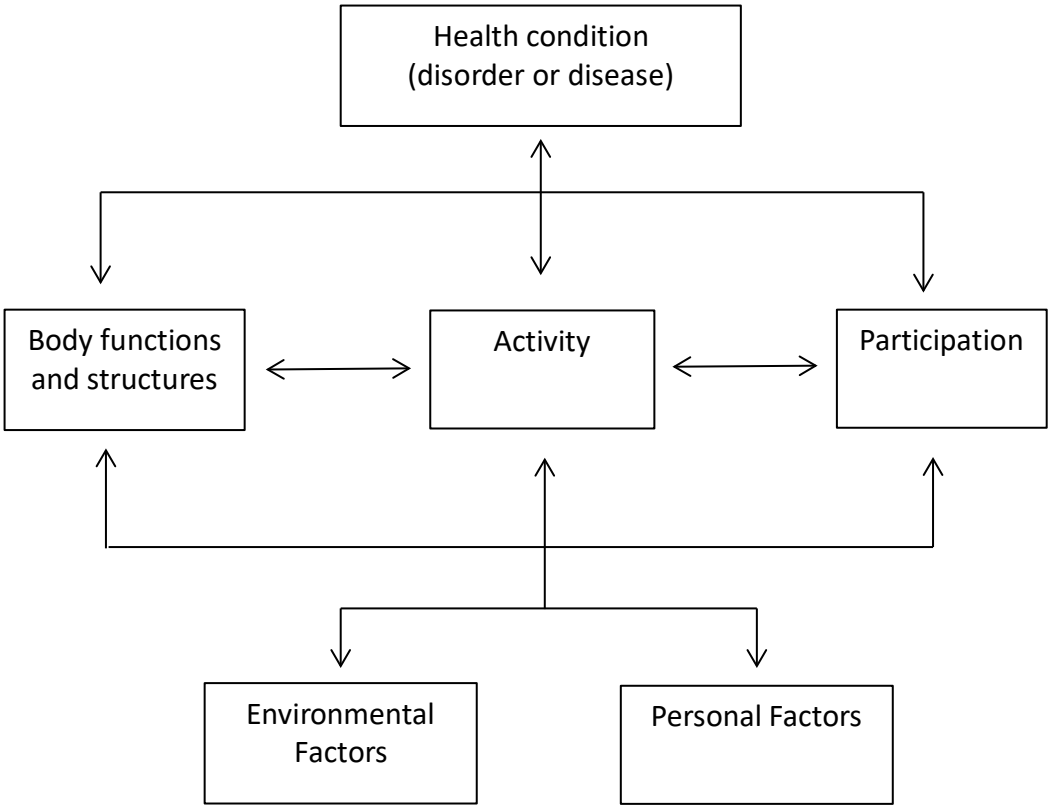

Figure 2.3: Interactions of International classification of functioning, disability and health (ICF) categories.

Figure from the World Health Organization (2001).

Amputation level and physical fitness are examples of body structure and function (Gaunaurd, 2012; Sansam et al., 2009; World Health Organization, 2001). Impairments of body structure and function may include reduced muscle strength or poor aerobic capacity (Gaunaurd, 2012; Sansam et al., 2009; World Health Organization, 2001). The ability to perform a specific task is an activity (e.g. donning or walking with a prosthesis) (Gaunaurd, 2012; Sansam et al., 2009; World Health Organization, 2001). Participation is involvement of the person in life situations such as work, sport or social gatherings (Gaunaurd, 2012; Sansam et al., 2009; World Health Organization, 2001). Examples of personal and environmental factors that may affect outcome include age, comorbidities, resource limitations in developing countries and social stigma surrounding the health condition (Gaunaurd, 2012; Sansam et al., 2009; World Health Organization, 2001).

If CPRs for prosthetic non-use were developed and validated they would represent the multidimensional relationship of the 5 ICF domains in the social and political context of the country they were developed. The Medicare functional classification level (MFCL), Amputee Mobility Predictor (AMP), Functional Independence Measure (FIM), Locomotor Capabilities Index 5 (LCI5), 10 metre walk test (10MWT), timed up and go test (TUGT), 6 minute walk test (6MWT) and four square step test (FSST) are some examples of outcome measures that may be used by health professionals to identify activity and participation limitations in people with lower limb amputation during the 5 phases of amputee rehabilitation (Condie et al., 2006; Dite et al., 2007; Franchignoni et al., 2004; Gailey et al., 2002; Heinemann et al., 2014; Schoppen et al., 2003; Stevens, 2010). The relationship of these outcome measures to locomotor function in lower limb amputation cohorts is now discussed.

2.11.1. Medicare functional classification level (MFCL)

The Medicare functional classification level (MFCL) K-level system is used by amputee rehabilitation services to subjectively classify patients and allocate prosthetic components based on their potential or actual level of locomotor function (Borrenpohl et al., 2016; Gailey et al., 2002; Knapp, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Patients are

classified on a 5 point scale from K0 to K4 (see Table 2.2 for full definitions) (Borrenpohl et al., 2016; Gailey et al., 2002; Meier & Melton, 2014; US Department of Veterans Affairs, 2008). People with K0 classification are not prosthetic candidates and those with K4 classification are eligible for prosthetic components that enable high level function depending on the budget of the funding organisation or health service (Borrenpohl et al., 2016; Gailey et al., 2002; Meier & Melton, 2014; US Department of Veterans Affairs, 2008). Due to the subjectivity of the MFCL, health professionals and researchers have called for the use of objective outcome measures to supplement K-level classification in patients (Borrenpohl et al., 2016; Gaunaurd et al., 2015; Heinemann et al., 2016). However, clinicians have been slow to use objective outcome measures for people with lower limb amputation (Borrenpohl et al., 2016; Gaunaurd et al., 2015; Heinemann et al., 2016).

Table 2.2: Medicare Functional Classification Level (MFCL) K-level system defined for prosthetic potential in people with lower limb amputation (Borrenpohl et al., 2016; Gailey et al., 2002; Knapp, 2013; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008).

MFCL K-level	Definition
K0	The patient does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility.
K1	The patient has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulatory.
K2	The patient has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of a limited community ambulator.
K3	The patient has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
K4	The patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

2.11.2. Amputee Mobility Predictor (AMP)

Gailey et al. (2002) developed the Amputee Mobility Predictor (AMP) in a convenience sample of 191 people with lower limb amputation to provide an objective measure of walking potential. The AMP can be performed without a prosthesis (AMPnoPro) and with a prosthesis (AMPPro). The AMP consists of activities including sitting balance, sit to stand, standing balance and locomotor activities using a prosthesis. The AMP has been demonstrated as a valid outcome measure with high inter-rater and intra-rater reliability with and without prosthesis for people with lower limb amputation (Gailey et al., 2002). The AMP was able to discriminate between 4 K-levels of the MFCL (as K-level 0 and 1 were combined into a single group) and was highly correlated with 6 minute walk test (6MWT) performance (Gailey et al., 2002).

2.11.3. Functional Independence Measure (FIM)

The Functional Independence Measure (FIM) was developed for neurological populations and is the most common outcome measure performed by rehabilitation services following lower limb amputation (Condie et al., 2006; Hordacre et al., 2013b). The FIM is assessed on admission and discharge from inpatient rehabilitation and scored using a 7 point ordinal scale that ranges from total dependence to complete independence (Condie et al., 2006; Hordacre et al., 2013b). The FIM consists of 18 items on motor and cognition subscales (Condie et al., 2006; Hordacre et al., 2013b). The 13 items in the motor subscale include: eating; grooming; bathing; dressing the upper body; dressing the lower body; toileting; bladder management; bowel management; transfers to the bed, chair and wheelchair; transfers to the toilet; bath and shower transfers; walking and wheelchair use; and stairs (Condie et al., 2006; Hordacre et al., 2013b). The 5 items in the cognition subscale include: comprehension; expression; social interaction; problem solving; and memory (Condie et al., 2006; Hordacre et al., 2013b).

Condie et al. (2006) reported that the FIM was problematic as an outcome measure for people with lower limb amputation due to observed ceiling effect and lack of responsiveness. People with lower limb amputation can never score full points on the FIM for locomotion as the prosthesis is classified as an assistive device. Leung,

Rush, and Devlin (1996) have shown in 41 people with lower limb amputation that FIM score at admission was not predictive of future prosthetic use however the motor sub-scale score at discharge was predictive of prosthetic use. These issues with the FIM highlight the need for development and validation of clinical prediction rules that identify people at risk of future prosthetic non-use.

In many countries funding of amputee rehabilitation services is based on change in FIM scores (Hordacre et al., 2013b). Hordacre et al. (2013b) reported change in FIM scores after inpatient rehabilitation in Australia between 2004 to 2010 of people with unilateral or bilateral major lower limb amputations. This study only reported separately on rehabilitation outcomes of New South Wales, Victoria, Queensland and South Australia (Hordacre et al., 2013b). The FIM scores of other Australian states and territories including WA were combined which assumes uniformity in the amputee rehabilitation models of care for these locations (Hordacre et al., 2013b). However in WA prosthetic gait retraining was performed as an outpatient service so the FIM scores submitted were for pre-prosthetic rehabilitation and do not reflect locomotor outcomes of people who underwent prosthetic rehabilitation. The study by Hordacre et al. (2013b) lacks validity as the FIM was measuring and comparing different phases of amputee rehabilitation between Australian rehabilitation facilities. This study highlights the importance of further research into locomotor outcomes of people with lower limb amputation after discharge from outpatient rehabilitation.

2.11.4. Locomotor Capabilities Index 5 (LCI5)

The Locomotor Capabilities Index (LCI) and the Locomotor Capabilities Index 5 (LCI5) are validated amputee specific questionnaires, that assess basic (e.g. walk indoors) and advanced (e.g. walking while carrying an object) locomotor activities using a prosthesis and have been translated into many languages (Franchignoni et al., 2007; Franchignoni et al., 2004; Salavati et al., 2011). Appendix 7.1B details the full LCI5 questionnaire (Franchignoni et al., 2007; Franchignoni et al., 2004). The 4 point ordinal scale of the LCI was revised to a 5 point ordinal scale of the LCI5 to address the ceiling effect observed in younger people with traumatic causes of amputation (Franchignoni et al., 2007; Franchignoni et al., 2004). The basic, advanced and total test scores of the LCI5 provide clinicians with self reported

ability to perform locomotor activities and ambulate in the community using a prosthetic limb (Condie et al., 2006; Franchignoni et al., 2007; Franchignoni et al., 2004). The LCI5 has been used to measure locomotor function across the amputee rehabilitation continuum (i.e. pre-operative to the long term follow-up phase) (Czerniecki, Turner, Williams, Hakimi, & Norvell, 2012b). The LCI5 may have utility as an outcome measure in the long term follow-up phase of amputee rehabilitation as its questionnaire format enables health professionals to efficiently assess if locomotor function has been sustained after rehabilitation discharge. Therefore, further investigation of the LCI5 is warranted.

2.12. Energy cost and walking ability with a prosthesis

Laboratory studies of people with lower limb amputation treadmill walking have demonstrated that the energy cost of walking with a prosthesis is greater than walking in able bodied controls (Waters et al., 1976; Wezenberg et al., 2013). Waters et al. (1976) demonstrated that the energy cost of prosthetic gait increases as amputation level becomes higher. Wezenberg et al. (2013) investigated the relative aerobic load (VO_{2rel}), walking speed and economy of people with vascular amputation (n = 10), traumatic amputation (n = 26) and able bodied controls (n = 21). People with vascular and traumatic amputation walked at a slower preferred walking speed, had a higher VO_{2rel} and had lower walking economy than able bodied people (Wezenberg et al., 2013). People with vascular amputation walked with a VO_{2rel} that was 45.2% higher (p = .001) than those with traumatic amputation (Wezenberg et al., 2013). Wezenberg et al. (2013) estimated that a 10% increase in peak aerobic capacity of people with lower limb amputation, could reduce VO_{2rel} and improve walking ability in terms of speed and economy. This study confirms the importance of pre-prosthetic rehabilitation of appropriate intensity. However, treadmill walking was identified as a study limitation because it was less efficient than walking overground (Wezenberg et al., 2013). It also did not consider the potential role that balance impairment may have played in the preferred walking speed of people with lower limb amputation. This study (Wezenberg et al., 2013) highlights the need for further research into field based locomotor tests (e.g. 10MWT, TUGT, 6MWT and FSST) to improve understanding of the functional

domains of walking speed, distance and balance that contribute to walking ability in people with lower limb amputation.

2.13. Locomotor tests

Locomotor tests including the 10 metre walk test (10MWT), timed up and go test (TUGT), 6 minute walk test (6MWT) and four square step test (FSST) have been used by clinicians to goal set and monitor a person's progress with prosthetic gait retraining (Dite et al., 2007; Franchignoni et al., 2004; Gailey et al., 2002; Heinemann et al., 2014; Meier & Melton, 2014; Raya et al., 2010; Resnik & Borgia, 2011; Schoppen et al., 2003; Stevens, 2010). Increased time to complete balance tasks, reduced walking speed and distance on locomotor tests following lower limb amputation have been associated increased risk of recurrent falls and poorer performance on outcome measures such as the LCI5 and AMP (Dite et al., 2007; Franchignoni et al., 2004; Gailey et al., 2002; Heinemann et al., 2014; Raya et al., 2010; Resnik & Borgia, 2011; Schoppen et al., 2003; Stevens, 2010). There is limited locomotor performance data for lower limb amputation cohorts, studies have been on samples of convenience or sub-groups (e.g. military service personnel, unilateral transtibial amputation) and it remains unclear if performance on locomotor tests during rehabilitation can be used to identify people at future risk of abandoning prosthetic use (Dite et al., 2007; Gailey et al., 2002; Heinemann et al., 2014; Linberg et al., 2013; Resnik & Borgia, 2011; Stevens, 2010). The 10MWT, TUGT, 6MWT and FSST have been summarised below (Chapter 6 eAppendix details the procedures and psychometric properties of these locomotor tests in lower limb amputation cohorts).

2.13.1. 10 metre walk test (10MWT)

The 10MWT is a timed walking test and walking speed can be derived from this test (Condie et al., 2006). Ability to walk the distance of 10 metres has been reported as the definition of successful prosthetic gait retraining by some rehabilitation services (Hordacre et al., 2013a). The 10MWT can be performed early in rehabilitation of people with lower limb amputation when the patient first starts to walk outside the parallel bars. The ability to modulate walking speed has been associated with balance

and the energy cost of walking with a prosthesis (Gailey et al., 2002; Wezenberg et al., 2013). The validity of 10MWT has been established in lower limb amputation cohorts however reliability has not been reported (Franchignoni et al., 2004).

2.13.2. Timed up and go test (TUGT)

The TUGT is a measure of dynamic balance and functional ability as the person being assessed needs to perform the locomotor tasks of sit to stand, walking and turning around (Condie et al., 2006; Dite et al., 2007; Resnik & Borgia, 2011; Schoppen et al., 2003). The TUGT can be performed early in rehabilitation of people with lower limb amputation and reflects locomotor tasks that are performed by indoors ambulators (Condie et al., 2006; Dite et al., 2007; Resnik & Borgia, 2011; Schoppen et al., 2003). Increased risk of multiple falls has been reported in people with unilateral transtibial amputation who have TUGT of $\geq$19s (Dite et al., 2007). The TUGT has been demonstrated as reliable and valid for geriatric cohorts with lower limb amputation however ceiling effect has been demonstrated in the locomotor performance of people with lower limb amputation who were younger and fitter (Deathe & Miller, 2005; Resnik & Borgia, 2011; Schoppen et al., 2003).

2.13.3. 6 minute walk test (6MWT)

The 6MWT in people with lower limb amputation reflects capacity to ambulate in the community (Gailey et al., 2002). The 6MWT is performed later in rehabilitation once a patient develops cardiovascular endurance (Brooks, Parsons, Hunter, Devlin, & Walker, 2001; Gailey et al., 2002). Some health professionals advocate use of the 2 minute walk test (2MWT) as the shorter time frame allows people with atraumatic amputation to complete the test earlier in rehabilitation (Brooks et al., 2001). The use of a rectangular walking track is recommended for cohorts with lower limb amputation to optimise walking distance by minimising the impact of pivot turning (that is performed in the corridor 6MWT) on balance and cadence (Linberg et al., 2013). Reliability and validity of the 6MWT has been established in cohorts with lower limb amputation (Gailey et al., 2002).

2.13.4. Four square step test (FSST)

The FSST involves dynamic balance, the ability to negotiate obstacles and change directions (Dite et al., 2007). It uses dual tasking and represents high level balance skills for people with lower limb amputation (Dite et al., 2007). A FSST performance of ≥24s identified people with unilateral transtibial amputation who became multiple fallers (Dite et al., 2007). The relationship of FSST performance and future walking ability using a prosthesis has not been investigated for people with higher or multiple levels of lower limb amputation.

2.14. Conclusion

This review of the literature has demonstrated that functional outcome following lower limb amputation is multifactorial and complex but there has been limited research on outcomes (Sansam et al., 2009). There have been no clinical prediction rule studies to determine the most important variables for discontinuing prosthetic use after rehabilitation discharge in people with lower limb amputation (Sansam et al., 2009). Amputee rehabilitation models of care and intervention guidelines are based mainly on low quality studies and expert opinion (Broomhead et al., 2012; Department of Health, 2008; Geertzen et al., 2015a; Geertzen et al., 2015b; Meier & Melton, 2014). Comorbidities influence mortality and functional outcomes following lower limb amputation however there is no consensus on how to measure burden of disease (Fortington et al., 2013). In WA, long term rehabilitation outcomes after lower limb amputation for prosthetic use, return to driving and work were unknown (Department of Health, 2008). Aboriginal people have high rates of amputation however their rehabilitation outcomes have not been reported (Department of Health, 2010; Department of Health, 2008). There are few studies to assist with interpretation of locomotor tests (e.g. 10MWT, TUGT, 6MWT and FSST) for lower limb amputation cohorts during rehabilitation (Heinemann et al., 2014; Resnik & Borgia, 2011; Stevens, 2010). These issues make it difficult to determine the effectiveness of the intensive, multimodal physiotherapy intervention and other rehabilitation interventions (Gailey, 2004; Lusardi, 2013; Ries & Vaughan, 2013). This thesis will focus on the development and validation of CPRs for prosthetic non-use following discharge from rehabilitation, mapping and measurement of comorbidities (including musculoskeletal pathology and mental health issues),

establishing utility of locomotor tests for identifying people at risk of future prosthetic non-use, and measurement of long term self reported outcomes in people with lower limb amputation. Lower limb amputation results in high global costs to health care systems and reduction in quality of life therefore further research is warranted to determine rehabilitation outcomes following amputation and develop targeted models of care.

Chapter 3

3. Common methods and how to read this thesis

This thesis started in the rehabilitation gym where almost all people who have a lower limb amputation spend time. Similar to any public health system the optimal service should be one that is patient centric and have clinical utility. Although many studies had examined optimal care pathways to improve prosthetic technology or the rehabilitation strategy to optimise outcome – after speaking to clients it was apparent that many abandoned using their prosthesis and yet the rehabilitation goal was to ensure that they used the prosthesis. Therefore, the decision was to study questions that were clinically focused about the use of prostheses and outcomes for clients. In this sense it was to make a significant and original contribution to the knowledge in the area of amputee rehabilitation from a clinical perspective.

From review of the literature it was determined that there was limited research on outcomes following lower limb amputation therefore a series of translational research projects were developed for this thesis to contribute to the knowledge base for models of care and clinical practice. The projects examine measurement of functional outcome from pre-operative through to the long term follow-up phase of amputee rehabilitation.

Ethics approval was obtained from Royal Perth Hospital (RPH) and Curtin University Ethics committees. The Ethics approval numbers were EC 2009 / 090 for RPH and HR138/2009 for Curtin University. Full details in Appendix 3.1.

The sample size estimates for the studies in this thesis were based on an understanding of the availability of data and the number of potential patients that could be recruited from the RPH Amputee Rehabilitation Service during the 3 years preceding commencement of this research in 2009. The sample size of 200 in the retrospective cohort reflects approximately 2 years of data. It was twice as large as the next published prognostic paper in this area (Schoppen et al., 2003). However, this was not over sampling since this number was appropriate for the number of potential factors that were independently associated with poor outcomes (Childs &

Cleland, 2006; Cohen, 1992). Furthermore, if we extended the data to a larger number of participants a greater proportion of patients would have died and therefore the data for the primary outcome of prosthetic non-use would be missing. The date of death for deceased participants was examined and deceased sub-group sensitivity analyses were performed for the clinical prediction rule development and validation studies. In a regression model with power at 80% and the assumption that the regressors were moderately related then a sample size of 100 (50% missing data) is able to detect a very weak association Rho (R^2 in the regression model) less than 0.3 (Cohen, 1992). With 40 participants in stage 2 (clinical prediction rule validation) and power at 80% we were 95% confident of detecting a rho of 0.45 (Cohen, 1992). A predictive model of less than 45% explained variance was unlikely to be of clinical value.

The following figures (Figures 3.1 to 3.4) are provided to assist the readers with the flow of data and specific derived variables from different cohort studies that in some cases resulted in specific publications.

Chapters 4 and 5 report on the development and validation of clinical prediction rules for prosthetic non-use. This research was published in the Journal of Physiotherapy and the manuscript is presented in Appendix 4.1. These were the first clinical prediction rule development and validation studies to be published for prosthetic non-use (Roffman et al., 2014).

Chapter 6 is a manuscript that was published in Physical Therapy Journal on locomotor performance and prosthetic non-use following lower limb amputation (Roffman et al., 2016b). This is the first study to generate performance thresholds using receiver operator characteristic curves for common locomotor tests (i.e. 10 metre walk test, timed up and go test, 6 minute walk test, four square step test) that health professionals may use during rehabilitation of people with lower limb amputation. Relative risk of prosthetic non-use at 12 months after discharge from rehabilitation was determined so that health professionals may use locomotor performance during rehabilitation to modify their intervention or allocation of resources based on presence of the performance threshold.

Chapter 7, Part A examines the construct validity of locomotor tests in a cohort with lower limb amputation. This study was developed due to the lack of performance data for locomotor tests in cohorts with lower limb amputation. Chapter 7, Part B examines long term self reported function following lower limb amputation. This research investigates the construct validity of the Locomotor Capabilities Index 5 (LCI5) (Franchignoni et al., 2004) as a measure for the long term follow-up phase in the amputee rehabilitation model of care.

Chapter 8 investigates comorbidity in a cohort with lower limb amputation at hospital admission. There is no gold standard for measuring comorbidity in cohorts with lower limb amputation. Therefore this study investigates common methods of measuring comorbidity. A manuscript that was published in Journal of Physiotherapy on the psychometric properties of the Charlson Comorbidity Index (Roffman et al., 2016a) is presented in Appendix 8.1.

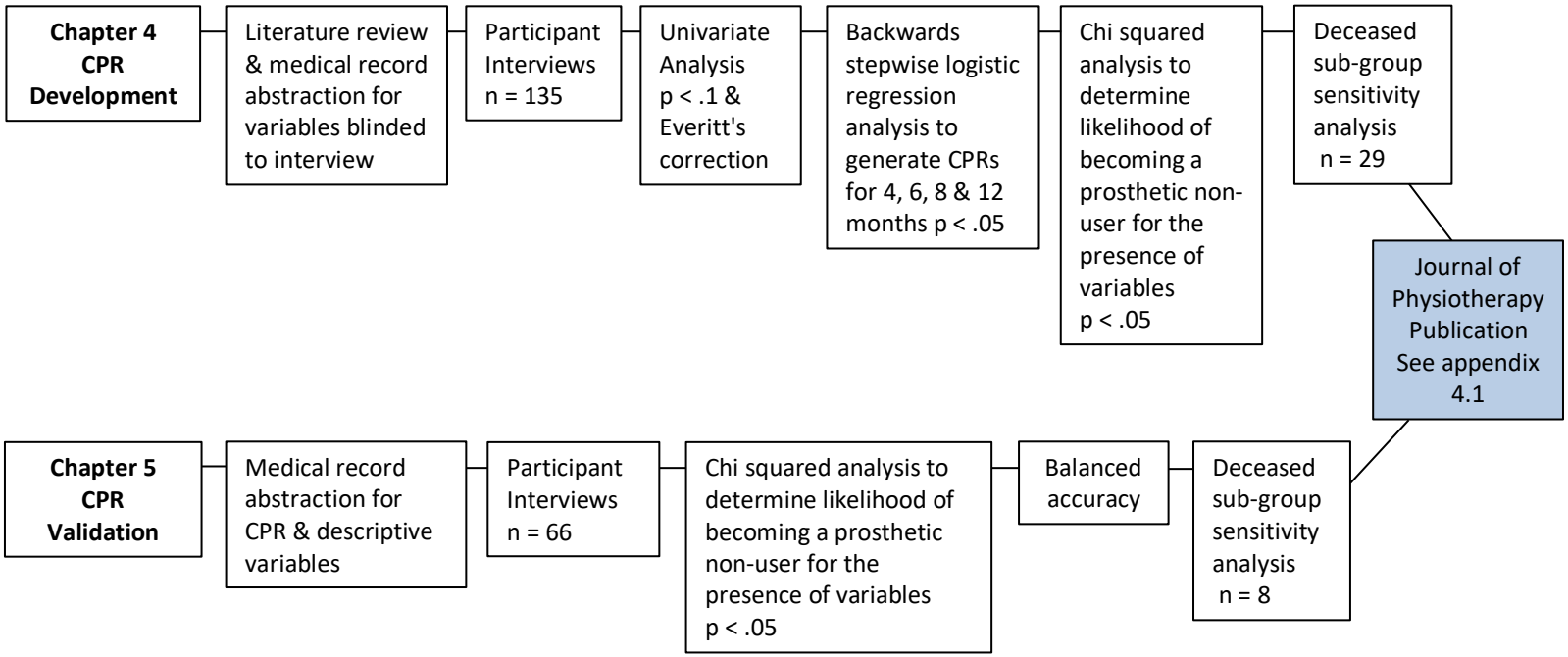

Figure 3.1: Methods and how to read Chapters 4 and 5 have been summarised in this figure.

The development and validation of clinical prediction rules for prosthetic non-use was published in Journal of Physiotherapy (see appendix 4.1).

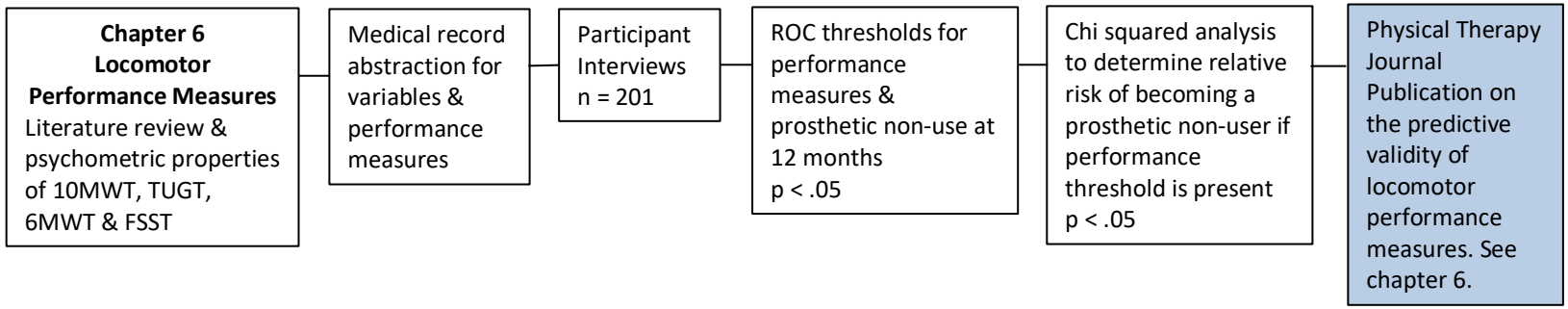

Figure 3.2: Methods and how to read Chapter 6.

The Locomotor Tests manuscript was published in Physical Therapy (see Chapter 6).

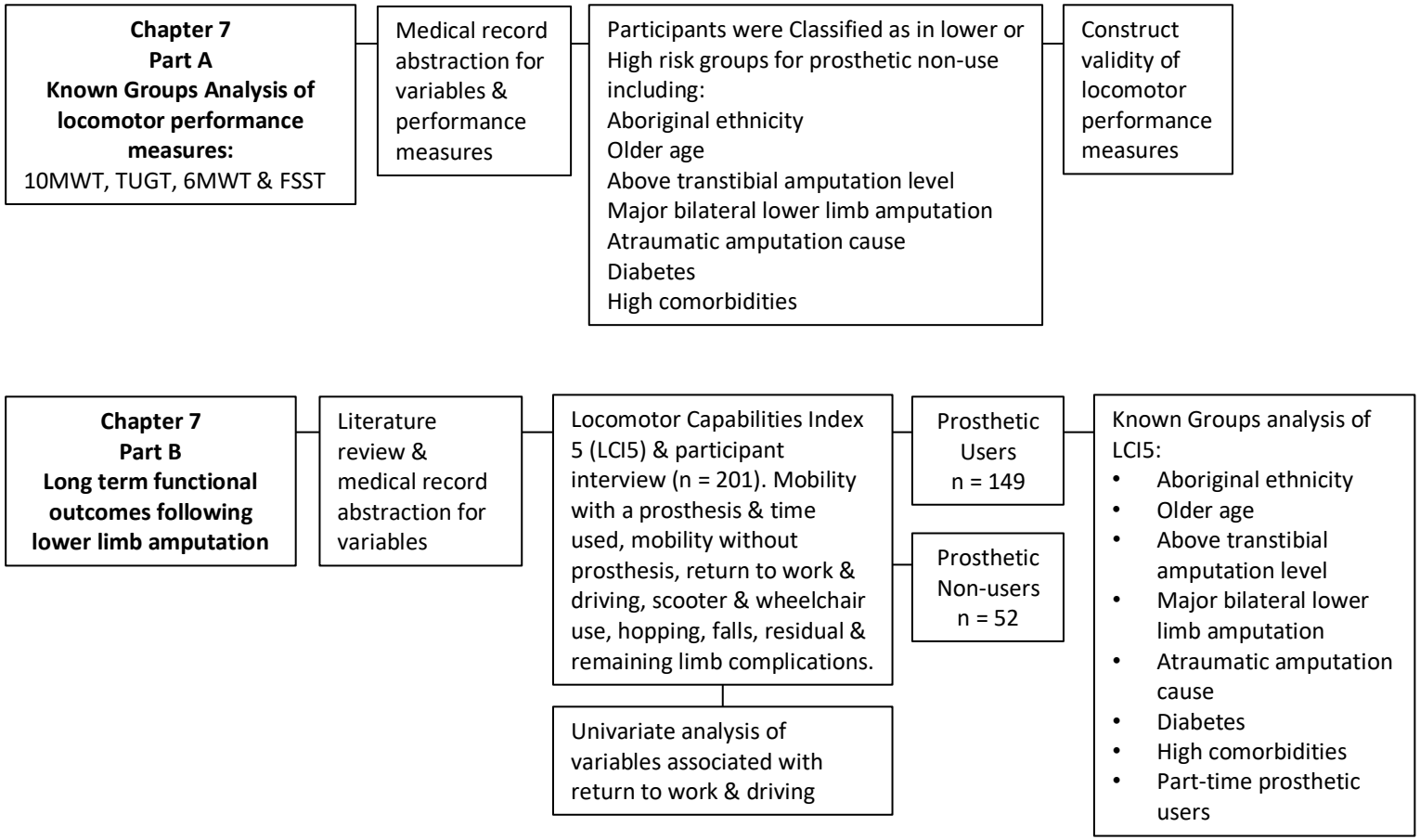

Figure 3.3: Methods and how to read the Chapters 7A and 7B of this thesis.

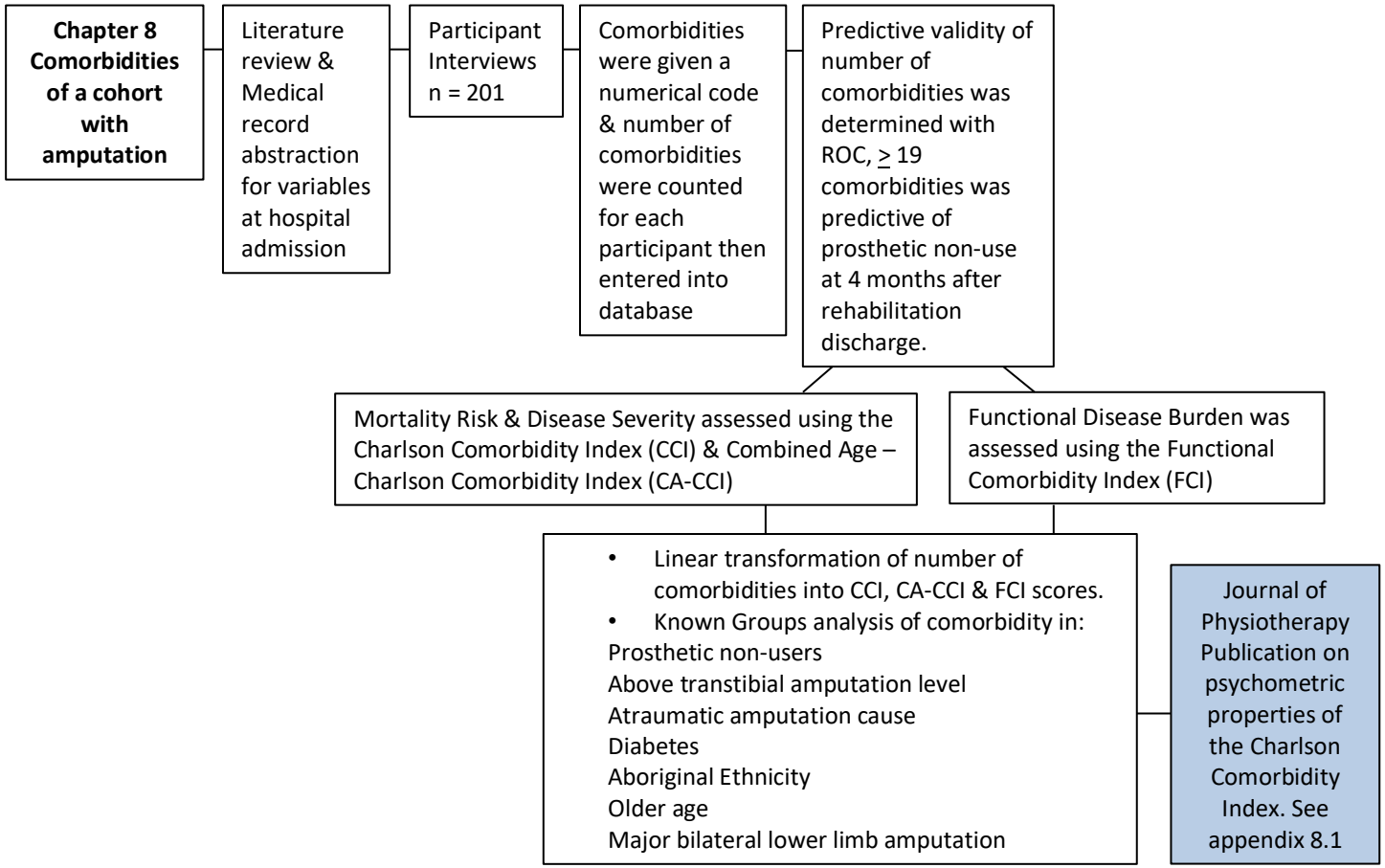

Figure 3.4: Methods and how to read Chapter 8.

The Charlson Comorbidity Index manuscript was published in the Journal of Physiotherapy (see appendix 8.1).

Chapter 4

4. Predictors of prosthetic non-use in individuals with lower limb amputation after discharge from rehabilitation– the development of clinical prediction rules.

Synopsis

This thesis chapter details development of clinical prediction rules for prosthetic non-use. It forms 1 part of the manuscript in appendix 4.1 that was published in the Journal of physiotherapy:

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Momentum 2017 Physiotherapy Conference, Australian Physiotherapy Association, 19th to 21st October 2017, Sydney, Australia.

Predictors of prosthetic non-use in individuals with lower limb amputation after discharge from rehabilitation– the development of clinical prediction rules.

Abstract

Research Question: Can clinical prediction rules (CPRs) be developed to identify increased risk of prosthetic non-use in individuals with lower limb amputation at 4, 6, 8 and 12 months after discharge from rehabilitation?

Design: Retrospective cohort study

Participants: 135 consecutive tertiary rehabilitation patients (n = 103 males, age mean = 56.1 (SD = 15.1) years).

Methods: Medical records were audited for potential predictor variables and participants interviewed at median = 1.9 (IQR = 1.4 to 2.5) years after discharge.

Results: At 4, 8 and 12 months after discharge prosthetic non-use was 11% (15), 15% (20) and 19% (25) and CPRs were identified. The significant predictors and associated accuracy statistics (95% CI) for having a combination of predictor variables were:

4 months: Amputation level above transibial, very high number of comorbidities, not having type 2 diabetes, using a mobility aid and dependence walking outdoors on concrete. If 4 out of 5 predictor variables were present, (LR+ = 32.0, CI = 3.61 to 748) probability of non-use increased to 80% ($p < .0001$).

8 months: Amputation level above transibial, using a mobility aid and dependence walking outdoors on concrete. If 2 out of 3 variables were present, (LR+ = 3.5, CI = 2.31 to 3.98) probability of non-use increased to 38% ($p < .0001$).

12 months: Amputation level above transibial, using a mobility aid and delay to prosthesis. If all 3 predictor variables were present (LR+ = 26.4, CI = 3.4 to 580) probability of non-use increased to 86% ($p < .0001$).

Conclusions: These CPRs have implications for rehabilitation and service model development. Validation is warranted.

Key words: *Clinical prediction rule, lower extremity, amputation, leg prosthesis, rehabilitation outcome*

4.1. Introduction

Multidisciplinary rehabilitation following lower limb amputation plays an important role in restoring function for activities of daily living, work and recreation (Roffman et al., 2014). Amputee rehabilitation service models and clinical practice guidelines for prosthetic prescription vary widely throughout the world and have been developed largely from expert consensus (Broomhead et al., 2003; Roffman et al., 2014; van der Linde, Hofstad, Van Limbeek, Postema, & Geertzen, 2005). In Western Australia, patients achieve independent transfers and wheelchair mobility during inpatient rehabilitation while prosthetic gait retraining is performed as an outpatient service (Department of Health, 2008; Roffman et al., 2014).

Limited research exists on long term prosthetic outcomes following discharge from rehabilitation. In particular, there is a lack of quality evidence to inform clinical decisions that may impact on the continued use of prostheses following lower limb amputation (Adams, 2005; Campbell & Ridler, 1996; Cumming et al., 2006; Jones et al., 1993; Lim et al., 2006; Sansam et al., 2009). In a review of the contemporary literature, Sansam et al. (2009) called for further investigation of predictive factors to more accurately estimate walking potential as the studies they reviewed reported different predictors due to heterogeneous methodology, outcome measures and definitions of prosthetic rehabilitation success.

Some studies have quantified prosthetic rehabilitation success relative to success of the surgical outcome, reported on cohorts with limited rehabilitation potential or duration the prosthesis worn as opposed functional use (Basu, Fassiadis, & McIrvine, 2008; Jones et al., 1993; Lim et al., 2006; Taylor et al., 2005). Taylor et al. (2005) reported that from 553 consecutive vascular surgery patients with major lower limb amputation the factors related to not wearing a prosthesis included: being pre-morbidly non-ambulant or a homebound walker, aged $\geq$60 years, having a transfemoral amputation, dementia, renal failure and heart disease. Lim et al. (2006) focused on surgical outcomes and short term prosthetic use for 39 patients at 3 months after discharge following major lower limb amputation in Western Australia.

Long term functional prosthetic use following discharge from rehabilitation is important in understanding the quality of life of people with lower limb amputation but is poorly defined in the literature. People with atraumatic amputation experience a decline in health status and high 5 year mortality, up to 77% after discharge (Davies & Datta, 2003; Fortington et al., 2013; Jones et al., 2013; Lim et al., 2006). However, while the physical activity associated with prosthetic gait may assist with management of risk factors for chronic disease, as many as 51% of people stop using their prosthesis within 12 months of discharge (Davies & Datta, 2003; Pohjolainen, Alaranta, & Kärkäinen, 1990; Schaffalitzky et al., 2012). In order to optimise the utilisation of healthcare resources a method to accurately identify people at high risk of prosthetic non-use is required so that patients can be stratified to targeted models of care.

In individuals with limited rehabilitation capacity due to severe comorbidities, high level or multiple limb amputations, frailty and advanced age fulfilling goals of prosthetic gait retraining is not without risk of adverse health complications such as residual limb (stump) wounds, falls, fractures and myocardial infarction which may require hospitalisation, impair quality of life and mood. When considered in the context of increased morbidity and mortality, this patient journey to prosthetic non-use is extremely costly to the individual as well as the health care system.

Univariate analyses have considered single factors associated with prosthetic non-use however the relationship between the multiple factors associated with prosthetic non-use in the literature has not been determined. Pre-operative factors such as comorbidities, age, pre-morbid mobility, medications, skin integrity, ethnicity, socioeconomic status, cognition and social support have been reported as influencing prosthetic outcome (Adams, 2005; Kulkarni, Pande, & Morris, 2006; O'Neill & Evans, 2009; Pohjolainen et al., 1990; Sansam et al., 2009; Schoppen et al., 2003; Taylor et al., 2005). The association between prosthetic walking ability and psychological factors, self efficacy and motivation is supported by weak evidence (Sansam et al., 2009). Post-operative factors such as level and number of limbs amputated, post-operative complications, wound healing, oedema, contractures, pain, delay to prosthesis, falls, energy cost of gait

and rehabilitation model of care have been shown to affect outcome (Adams, 2005; Bhangu et al., 2009; Czerniecki et al., 2012a; Dillingham, Pezzin, MacKenzie, & Burgess, 2001; Goktepe, Cakir, Yilmaz, & Yazicioglu, 2010; Lim et al., 2006; Penn-Barwell, 2011; Sansam et al., 2009; Schoppen et al., 2003; Waters et al., 1976). Functional factors have also been identified as predictive of walking potential (Condie, McFadyen, Treweek, & Whitehead, 2011; Gailey et al., 2002; Raya et al., 2010; Schoppen et al., 2003).

Prosthetic outcome is therefore multifactorial and complex. To date, no studies have examined the factors that in combination are able to identify individuals at risk of non-use following discharge from rehabilitation. A methodological approach of developing Clinical Prediction Rules (CPRs) has been used in similar prognostic studies (e.g. ankle fractures, neck pain) (Childs & Cleland, 2006; Cleland et al., 2007) and is yet to be established in the area of lower limb amputation.

CPRs are tools that assist health professionals to make evidence based decisions and assign patients to interventions using a parsimonious subset of predictor variables (Childs & Cleland, 2006; Cleland et al., 2007; Cleland et al., 2010; Laupacis et al., 1997). If CPRs could be generated to accurately identify individuals at risk of early prosthetic non-use then rehabilitation teams could intervene with targeted models of care and prosthetic innovations to optimise functional outcome. Therefore the research question for this study was: Can clinical prediction rules (CPRs) be developed to identify increased risk of prosthetic non-use in individuals with lower limb amputation at 4, 6, 8 and 12 months after discharge from rehabilitation?

4.2. Methods

Participants

This study was approved by the Royal Perth Hospital (RPH) and Curtin University Ethics Committees (see Appendix 3.1). Inclusion criteria were as follows: participants had at least one recent major lower limb amputation (i.e. transtibial level or above), were

community dwelling and ambulant prior to amputation, were Medicare Functional Classification Level K-level 1 to 4 (from Gailey et al. (2002)), had participated in and been discharged from prosthetic rehabilitation at RPH, the state centre for amputee rehabilitation. Individuals with multiple limb amputation were included as this was important for CPR validity.

Participants were excluded if they were not prosthetic candidates (K-level 0), unable to communicate or did not consent. K-level 0 participants were assessed by the Rehabilitation Medicine Physician and Senior Physiotherapist. Participants were K-level 0 due to comorbidities, high or multiple limb amputation, poor premorbid mobility and falls history. These participants were followed up through multidisciplinary amputee outpatient clinic and remained K-level 0.

K-level 0 to 4 participants underwent inpatient rehabilitation to achieve independent transfers, wheelchair mobility and discharge home. Appendix 4.2 defines the standardised outpatient prosthetic rehabilitation service received by K-level 1 to 4 participants (full intervention details in Appendix 2.1).

From the Amputee Physiotherapy Service database 208 consecutive patients with lower limb amputation were identified between June 2006 and June 2009. Audit showed: 176 (85%) were prosthetic users (K-level 1 to 4) at discharge from outpatient physiotherapy and 32 (15%) participants were K-level 0 (non-prosthetic rehabilitation). On review of audit data during the study period, 15 (47%) K-level 0 participants were deceased. Of the 176 (85%) who received full prosthetic targeted rehabilitation (K-level 1 to 4), 29 (16%) were deceased.

Of the remaining 147 patients, 4 participants were excluded as 1 did not have a major lower limb amputation and 3 participants were still receiving rehabilitation. A total of 143 patients were eligible for the study and 138 (98%) were contacted. Five participants were unable to be contacted as they had moved interstate or overseas and 3 participants

did not consent to be interviewed. The final response rate was 94% (n = 135) with participants interviewed at median = 1.9 years (IQR = 1.4 to 2.5) post-discharge.

The interview process involved coordinating telephone interviews with Country Physiotherapists, Aboriginal Health Workers, Nurses and the use of Telehealth. Table 4.1 outlines the geographical distribution of participants as measured by Accessibility Remoteness Index of Australia (ARIA) (Trewin, 2005).

Procedure

A retrospective cohort study design was used. Medical records were audited for potential predictor variables and this was undertaken blind to the telephone interviews. Figure 4.1 outlines the predictor variable domains investigated. Charlson Comorbidity Index (CCI) and Combined Age CCI (CA-CCI) scores were calculated from participant medical comorbidities data (Charlson et al., 1987; Hall, Ramachandran, Narayan, Jani, & Vijayakumar, 2004; Roffman et al., 2014).

Interviews were conducted using a survey previously developed and piloted by the Senior Physiotherapist Amputee Rehabilitation. The interviews were performed by: telephone (n = 123), Telehealth videoconference (n = 2) and in person (n = 10). Twelve interviews were performed with carer assistance due to language interpretation, hearing or intellectual impairment.

The operational definition of a successful prosthetic user was use of the prosthesis for locomotor activities (e.g. transfers, standing, walking) on one or more week days. Prosthetic non-users did not functionally use their prosthesis on any week days or wore it for cosmesis only. Non-users were asked the reasons they stopped using their prosthesis and to recall how many months after physiotherapy discharge they stopped using their prosthesis. Important calendar events (e.g. last amputee outpatient clinic, birthday, Christmas) were used as verbal prompts to assist with recall accuracy. Participants were interviewed on their prosthetic use from 4 months onwards after

discharge and were re-interviewed at 2 monthly intervals until data were collected for 12 months.

Statistical Analyses

The primary outcome variable for prediction was the dichotomous variable of being prosthetic users or non-users at 4, 6, 8 and 12 months after discharge. Descriptive statistics were generated for all variables in each cohort.

The univariate relationship between categorical variables and prosthetic users and non-users were analysed using the chi-square test. For each of the continuous variables, Receiver Operator Characteristic curves were used to determine the threshold at which specificity and sensitivity were equal to generate dichotomous classification for the univariate analyses. Univariate contingency tables were used to identify a smaller subset of variables related to prosthetic non-use that had a significance level of 10% (Chi squared $p < .1$). This conservative significance level was selected to avoid missing critical predictor variables. Sensitivity, specificity, positive and negative likelihood ratios were calculated for the predictor variables.

A backwards stepwise logistic regression model was used to reduce these predictor variables to a set of flags or key variables that contributed to predicting prosthetic non-use. To generate CPRs for the time frames, the set of variables from the regression was used to establish cumulative numbers of items present for any one individual at discharge. A list of Likelihood Ratios (negative and positive, 95% CI) were calculated to determine the cumulative effect of having a number of these predictor variables (1, 2, 3 etc.) on prosthetic non-use.

For the univariate and CPR analyses, in circumstances where zero values were present in the frequency cells of the 2x2 contingency tables, a small positive constant of 0.5 was added to the zero cell values to enable calculation of the likelihood ratios and confidence intervals (Everitt, 1992). Extreme likelihood ratio upper confidence limits were truncated at 999.

Table 4.1: Demographic and amputation details of retrospective cohort.

Demographic and Amputation Details	Prosthetic Users (n = 94)	Prosthetic Non-users (n = 41)	Total (n = 135)
Gender, Male, n (%)	74 (79)	29 (71)	103 (76)
Age at amputation, mean (SD)	55.1 (15.8)	58.3 (13.3)	56.1 (15.1)
Indigenous status, Aboriginal, n (%)	12 (13)	9 (22)	21 (16)
Accommodation after discharge from inpatient rehab'n, n (%)			
Home	91 (97)	37 (90)	128 (95)
Residential Care (Hostel or Nursing Home)	3 (3)	4 (10)	7 (5)
Metropolitan	56 (60)	28 (68)	84 (62)
Country	38 (40)	13 (32)	51 (38)
Accessibility Remoteness Index of Australia (ARIA)*			
Major Cities of Australia (0 to 1.84)	66 (71)	34 (83)	100 (75)
Inner Regional Australia (>1.84 to 3.51)	8 (9)	0 (0)	8 (6)
Outer Regional Australia (>3.51 to 5.80)	5 (5)	2 (5)	7 (5)
Remote Australia (> 5.80 to 9.08)	0 (0)	2 (5)	2 (1)
Very Remote Australia (> 9.08 to 12)	14 (15)	3 (7)	17 (13)
Social Support, lives with others, n (%)	77 (82)	31 (76)	108 (80)
Charlson Comorbidity Index Score, median (IQR)	2 (1 to 4)	5 (2 to 5)	2 (1 to 4)
Combined Age Charlson Comorbiditiy Index Score, median (IQR)	4 (1 to 5)	7 (3 to 7)	4 (1.5 to 6)
Comorbidities, n (%)			
Diabetes	42 (45)	22 (54)	64 (47)
Type 1	7 (8)	3 (7)	10 (7)
Type 2	35 (37)	19 (46)	54 (40)
Peripheral Arterial Disease	44 (47)	25 (61)	69 (51)
Cardiac Condition	33 (35)	26 (63)	59 (44)
Renal Failure	13 (14)	10 (24)	23 (17)
Cerebrovascular accident / Transient Ischemic Attack	8 (9)	5 (12)	13 (10)
Arthritis	36 (38)	16 (39)	52 (39)
Remaining Lower Limb Pathology	78 (83)	36 (88)	114 (84)
Mental health issues, n (%)	24 (26)	8 (20)	32 (24)
Substance abuse, n (%)			
Drugs	7 (8)	4 (10)	11 (8)
Alcohol	10 (11)	5 (12)	15 (11)
Amputation Cause, n (%)			
Circulatory	18 (19)	15 (37)	33 (24)
Infection	42 (45)	17 (41)	59 (44)
Trauma	29 (31)	9 (22)	38 (28)
Cancer	5 (5)	0 (0)	5 (4)
Amputation Level, n (%)			
Transtibial	78 (83)	25 (61)	103 (76)
Knee disarticulation	4 (4)	2 (5)	6 (4)
Transfemoral	20 (21)	28 (68)	48 (36)
Major Bilateral Lower Limb Amputation	8 (9)	14 (34)	22 (16)
Minor Amputation of Remaining Limb	15 (16)	3 (7)	18 (13)
Upper Limb Amputation/s	8 (9)	0 (0)	8 (6)

** n = 134, one user excluded as from overseas*

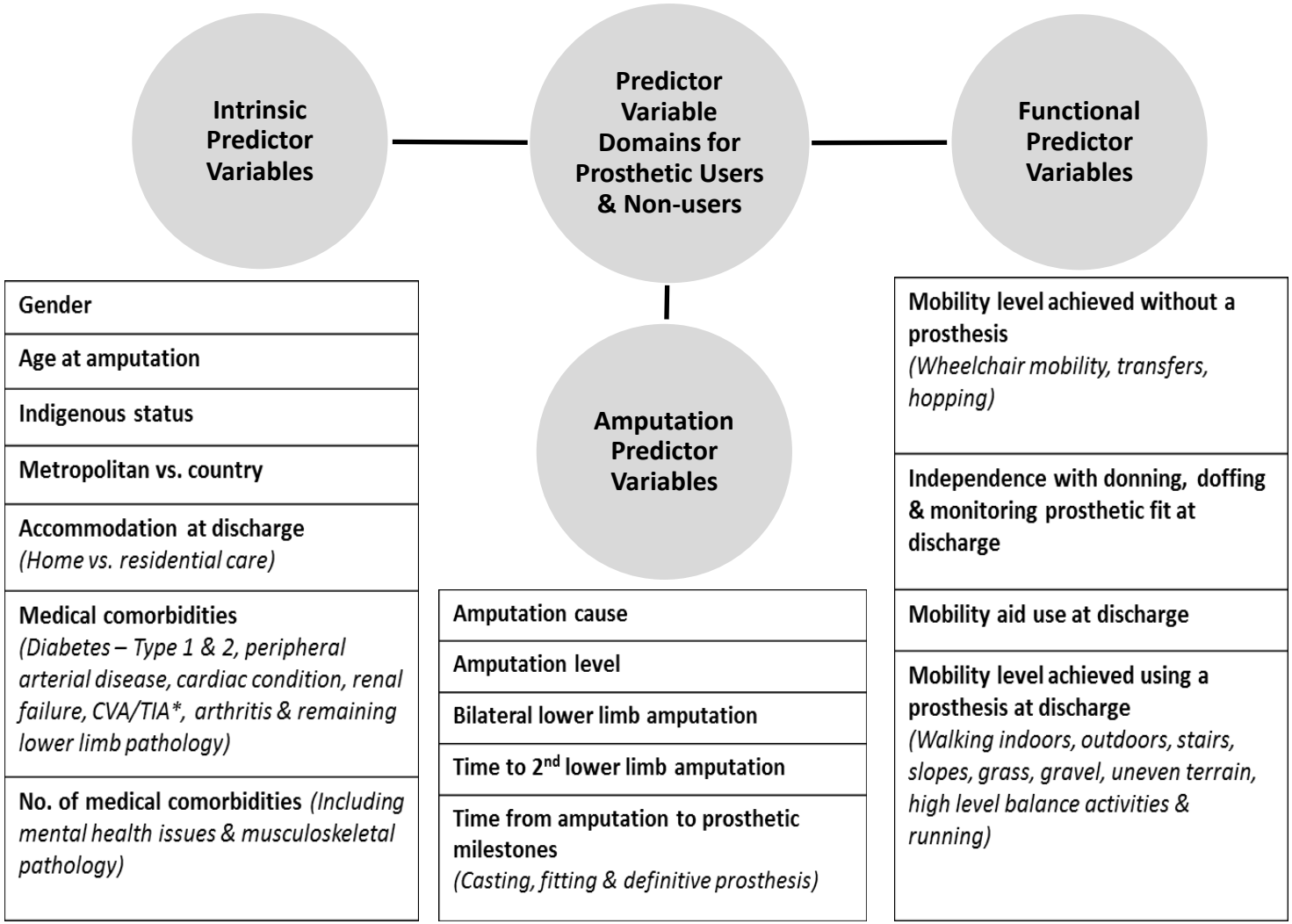

Figure 4.1: Predictor variable domains for prosthetic users and non-users investigated by this study.

*CVA/TIA – Cerbrovascular Accident / Transient Ischaemic Attack

A sensitivity analysis of 29 (16%) deceased prosthetic rehabilitation patients who could not be interviewed was performed for 4, 6, 8 and 12 months after discharge from rehabilitation to identify the presence or absence of CPR variables. Date of death was used as the termination date for prosthetic use.

4.3. Results

Participants were interviewed to determine prosthetic outcome from November 2009 until August 2011. Figure 4.2 reports the timeframes from the post-operative stage of rehabilitation to interview including length of stay and time from initial amputation surgery until rehabilitation milestones (e.g. prosthetic casting, fitting and gait retraining) were achieved by the total cohort (n = 135). Of the 135 participants interviewed a total of 70% (94) were classified as successful prosthetic users and 30% (41) non-users. The multifactorial reasons for non-use reported by the 41 prosthetic non-users have been detailed in Table 4.2. At 4 (& 6), 8 and 12 months after discharge from rehabilitation 11% (15), 15% (20) and 19% (25) of participants respectively were prosthetic non-users. Table 4.1 shows the cohort characteristics. CCI score was higher in non-users median = 5 (IQR = 2 to 5) than users median = 2 (IQR = 1 to 4).

Of the 40 variables investigated for the univariate analysis (Figure 4.1), 16 were significant ($p < .1$) for non-use at 4, 6 and 8 months and 15 were significant at 12 months after discharge. The predictor variables were identical for 4 and 6 months. Table 4.3 shows the significant univariate predictor variables for the time frames.

The univariate predictor variables significant for prosthetic non-use that were common to all time frames included: amputation level above transtibial, mobility aid use, delay to prosthesis, inability to perform high level balance activities, dependence at discharge with locomotor activities, donning, doffing and monitoring prosthetic fit. Age $\geq$58 years, having a very high number of comorbidities (including mental health issues and musculoskeletal pathology) and not having diabetes were predictors of non-use at 4 (& 6) months. Having a cardiac condition, inability to hop or run were predictors of non-use at 8 and 12 months.

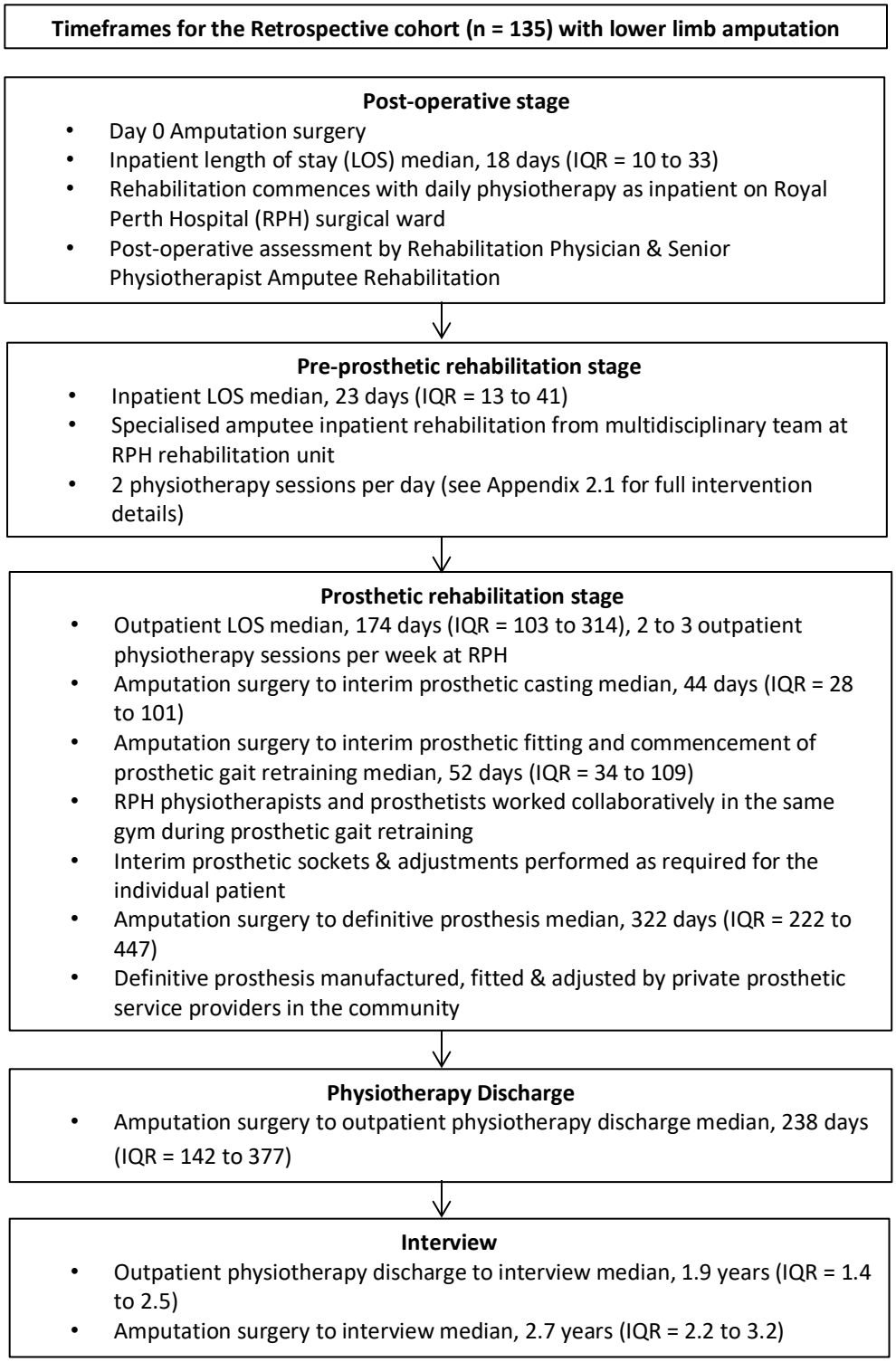

Figure 4.2: Timeframes for the retrospective cohort (n =135) from the post-operative stage of rehabilitation to interview.

Table 4.2: Multifactorial reasons for prosthetic non-use reported by participants classified as prosthetic non-users (n = 41).

Multifactorial reasons for prosthetic non-use reported by prosthetic non-users (n = 41)	% (n)*
Issue with residual limb (stump)	37 (15)
Prosthetic issue	27 (11)
Issue with remaining Limb	24 (10)
Pain	22 (9)
Medical comorbidities	20 (8)
Balance issues	12 (5)
Fear of falling	7 (3)
Energy cost or efficiency	7 (3)
Amputation of remaining limb	7 (3)
Body Weight fluctuations	5 (2)
Unmotivated	5 (2)
Unable to don independently	5 (2)
Falls	2 (1)

*Participants were able to report more than one reason for not using their prosthesis so the cumulative percentage exceeds 100.

Table 4.3: Significant univariate predictor variables (p < .1) for prosthetic non-use for 4 (& 6), 8 and 12 months.

Variable	Sensitivity	Specificity	LR+	LR-	p value
4 (& 6) months					
Age ≥ 58	0.67	0.60	1.67	0.56	.049
Amputation level above transtibial	0.67	0.66	1.95	0.51	.014
Delay to prosthesis†	0.33	0.90	3.30	0.74	.011
Mobility aid use at discharge	0.97	0.53	2.07	0.06	< .0001*
Dependent at discharge with:					
Donning, doffing & monitoring	0.27	0.91	2.91	0.81	.042
Prosthetic gait	0.20	0.94	3.43	0.85	.048
Walking indoors	0.20	0.94	3.43	0.85	.048
Walking outdoors on concrete	0.33	0.89	3.08	0.75	.016
Walking up and down stairs	0.47	0.84	2.95	0.63	.004
Walking up and down slopes	0.40	0.83	2.40	0.72	.031
Walking on grass	0.40	0.84	2.53	0.71	.023
Walking on gravel & uneven terrain	0.47	0.82	2.55	0.65	.012
Inability to perform high level balance activities at discharge	0.97	0.18	1.18	0.18	.133*
High number of co-morbidities ≥19	0.27	0.91	2.91	0.81	.042
Not having diabetes	0.73	0.50	1.47	0.53	.088
Not having type 2 diabetes	0.80	0.43	1.39	0.47	.094
8 months					
Amputation level above transtibial	0.70	0.68	2.18	0.44	.001
Delay to prosthesis†	0.33	0.92	4.19	0.72	.001
Inability to hop	0.50	0.70	1.64	0.72	.087
Mobility aid use at discharge	0.98	0.56	2.20	0.04	< .0001*
Dependent at discharge with:					
Donning, doffing & monitoring	0.30	0.92	3.83	0.76	.004
Prosthetic gait	0.20	0.95	3.83	0.84	.020
Walking indoors	0.20	0.95	3.83	0.84	.020
Walking outdoors on concrete	0.35	0.90	3.66	0.72	.002
Walking up and down stairs	0.50	0.86	3.59	0.58	.0002
Walking up and down slopes	0.45	0.85	3.04	0.65	.002
Walking on grass	0.45	0.86	3.23	0.64	.001
Walking on gravel & uneven terrain	0.55	0.84	3.51	0.53	< .0001
Inability to perform high level balance activities at discharge	0.98	0.19	1.21	0.13	.061*
Inability to run at discharge	0.98	0.15	1.14	0.16	.125*
Having a cardiac condition/s	0.65	0.60	1.63	0.58	.037
Not having arthritis	0.80	0.42	1.37	0.48	.065
12 months					
Amputation level above transtibial	0.64	0.68	2.01	0.53	.003
Delay to prosthesis†	0.32	0.92	3.88	0.74	.001
Inability to hop	0.48	0.70	1.60	0.74	.085
Mobility aid use at discharge	0.96	0.57	2.25	0.07	< .0001
Dependent at discharge with:					
Donning, doffing & monitoring	0.24	0.92	2.93	0.83	.023
Prosthetic gait	0.16	0.95	2.93	0.89	.069
Walking indoors	0.16	0.95	2.93	0.89	.069
Walking outdoors on concrete	0.36	0.92	4.40	0.70	.0002
Walking up and down stairs	0.48	0.87	3.77	0.60	< .0001
Walking up and down slopes	0.44	0.86	3.23	0.65	.001
Walking on grass	0.44	0.87	3.46	0.64	.0003
Walking on gravel & uneven terrain	0.52	0.85	3.58	0.56	< .0001
Inability to perform high level balance activities at discharge	0.98	0.20	1.22	0.09	.027*
Inability to run at discharge	0.98	0.16	1.16	0.13	.067*
Having a cardiac condition/s	0.68	0.62	1.78	0.52	.007

*0.5 was added to 0 cell in 2 x 2 contingency table so a positive likelihood ratio could be reported.
† n = 134, missing data for 1 subject.

Table 4.7: Significant predictor variables for prosthetic non-use and associated accuracy statistics with 95% confidence intervals for having a combination of predictor variables.

Significant predictor variables for the time frames from backwards stepwise logistic regression analysis	Associated accuracy statistics for having a combination of variables (e.g. 1, 2, 3… variables) at each of the time frames						
	Number of Predictor variables Present	Sensitivity	Specificity	Positive Likelihood Ratio	Negative Likelihood Ratio	Probability of prosthetic non-use (%)	p value
4 (& 6) months: • Amputation level above transtibial • Mobility aid use at discharge • Dependence walking outdoors on concrete at discharge • Very high number of comorbidities • Not having a diagnosis of type 2 diabetes	1	0.97 (0.74 to 1.00)	0.16 (0.13 to 0.16)	1.2 (0.85 to 1.19)	0.20 (0.0 to 2.04)	13	.183
	2	0.97 (0.72 to 1.00)	0.52 (0.48 to 0.52)	2.0 (1.40 to 2.09)	0.06 (0.0 to 0.57)	21	< .0001*
	3	0.80 (0.53 to 0.95)	0.75 (0.72 to 0.77)	3.2 (1.87 to 4.08)	0.27 (0.07 to 0.65)	29	< .0001*
	4	0.27 (0.10 to 0.33)	0.99 (0.97 to 1.00)	32.0 (3.61 to 748)	0.74 (0.67 to 0.92)	80	< .0001*
	5	0.032 (0.0 to 0.06)	0.99 (0.99 to 1.00)	7.8 (0.00 to 999+)	0.97 (0.94 to 1.01)	0	.223
8 months: • Amputation level above transtibial • Mobility aid use at discharge • Dependence walking outdoors on concrete at discharge	1	0.98 (0.78 to 1.00)	0.43 (0.39 to 0.43)	1.7 (1.29 to 1.76)	0.06 (0.0 to 0.55)	23	.001*
	2	0.90 (0.69 to 0.98)	0.74 (0.70 to 0.75)	3.5 (2.31 to 3.98)	0.14 (0.02 to 0.44)	38	< .0001*
	3	0.15 (0.04 to 0.26)	0.97 (0.96 to 0.99)	5.8 (0.96 to 34.3)	0.87 (0.75 to 1.00)	50	.013*
12 months: • Amputation level above transtibial • Delay to prosthesis • Mobility aid use at discharge	1	0.96 (0.79 to 0.99)	0.42 (0.38 to 0.43)	1.7 (1.28 to 1.74)	0.096 (0.005 to 0.55)	27	< .0001*
	2	0.72 (0.53 to 0.86)	0.76 (0.72 to 0.8)	3.05 (1.88 to 4.25)	0.37 (0.17 to 0.66)	41	< .0001*
	3	0.24 (0.12 to 0.28)	0.99 (0.96 to 1.00)	26.4(3.4 to 580)	0.77 (0.72 to 0.91)	86	< .0001*

*p < .05 is significant

Appendix 4.3 Tables 4.4 to 4.6 summarise the backwards stepwise logistic regression data. The predictor variables significant (95% CI) for prosthetic non-use after being entered into the backwards stepwise logistic regression model for 4 (& 6), 8 and 12 months were as follows (full details in Table 4.7):

CPR 4 months

At 4 (& 6) months the 5 variables predictive of prosthetic non-use included: amputation level above transtibial, using a mobility aid, dependence walking outdoors on concrete, very high number of comorbidities and not having a diagnosis of type 2 diabetes. If subjects had 4 out of 5 variables, LR+ = 32.0 (CI = 3.6 to 748) the probability of non-use increased from 11% to 80% ($p < .0001$).

CPR 8 months

At 8 months the 3 variables predictive of prosthetic non-use included: amputation level above transtibial, using a mobility aid and dependence walking outdoors on concrete. If 2 out of 3 variables were present, LR+ = 3.5 (CI = 2.31 to 3.98) the probability of non-use increased from 15% to 38% ($p < .0001$).

CPR 12 months

At 12 months the 3 variables predictive of prosthetic non-use included: amputation level above transtibial, using a mobility aid and delay to prosthesis. For prosthetic non-users cause of delay was multifactorial and included: wound complications (89%, n=8), medical comorbidities (33%, n=3), orthopaedic injuries (22%, n=2) and physical deconditioning (11%, n = 1). If all 3 variables were present, LR+ = 26.4 (CI = 3.4 to 580) the probability of non-use increased from 19% to 86% ($p < .0001$).

Table 4.8: Significant predictor variables for prosthetic non-use and associated accuracy statistics with 95% confidence intervals for having a combination of predictor variables in the deceased sub-group (16% (n=29)).

Associated accuracy statistics for having a combination of variables (e.g. 1, 2, 3… variables) at each of the time frames						
Number of Predictor variables present	**Sensitivity**	**Specificity**	**Positive Likelihood Ratio**	**Negative Likelihood Ratio**	**Probability of prosthetic non-use (%)**	**p value**
1	0.889 (0.833 to 0.994)	0.024 (0 to 0.071)	0.911 (0.833 to 1.07)	4.56 (0.085 to 999+)	29	.324
2	0.889 (0.629 to 0.994)	0.200 (0.083 to 0.247)	1.11 (0.686 to 1.32)	0.556 (0.024 to 4.48)	33	.558
3	0.444 (0.170 to 0.739)	0.600 (0.476 to 0.732)	1.11 (0.324 to 2.76)	0.926 (0.356 to 1.74)	33	.822
4	0.111 (0.006 to 0.371)	0.800 (0.753 to 0.917)	0.556 (0.024 to 4.48)	1.11 (0.686 to 1.32)	20	.558
5	0.053 (0 to 0.105)	0.976 (0.951 to 1.00)	2.16 (0 to 999+)	0.971 (0.895 to 1.05)	50	.689
1	0.929 (0.893 to 0.996)	0.032 (0 to 0.093)	0.960 (0.893 to 1.10)	2.21 (0.04 to 999+)	46	.629
2	0.857 (0.708 to 0.973)	0.200 (0.061 to 0.308)	1.07 (0.753 to 1.41)	0.714 (0.087 to 4.82)	50	.684
3	0.357 (0.166 to 0.569)	0.533 (0.355 to 0.731)	0.765 (0.257 to 2.12)	1.20 (0.589 to 2.35)	42	.550
4	0.071 (0.004 to 0.242)	0.733 (0.670 to 0.892)	0.286 (0.011 to 2.24)	1.27 (0.850 to 1.49)	20	.164
5	0.034 (0 to 0.069)	0.968 (0.935 to 1.00)	1.07 (0 to 999+)	0.998 (0.931 to 1.07)	50	.973
1	0.941 (0.912 to 0.997)	0.04 (0 to 0.116)	0.980 (0.912 to 1.13)	1.47 (0.028 to 999+)	57	.818
2	0.647 (0.487 to 0.810)	0.417 (0.190 to 0.647)	1.11 (0.601 to 2.30)	0.847 (0.294 to 2.70)	61	.728
3	0.294 (0.138 to 0.419)	0.750 (0.529 to 0.927)	1.18 (0.293 to 5.70)	0.941 (0.627 to 1.63)	62	.793
1	0.947 (0.921 to 0.997)	0.048 (0 to 0.138)	0.995 (0.921 to 1.16)	1.10 (0.021 to 999+)	64	.953
2	0.421 (0.270 to 0.533)	0.700 (0.412 to 0.912)	1.404 (0.459 to 6.07)	0.827 (0.512 to 1.77)	73	.523
3	0.026 (0 to 0.051)	0.952 (0.905 to 1.00)	0.538 (0 to 999+)	1.02 (0.949 to 1.10)	50	.749

*$p < .05$ is significant

Of the 16% (29) participants who participated in prosthetic rehabilitation but were deceased and could not be interviewed: 29% (9) were deceased and non-users at 4 months, 45% (14) at 6 months, 55% (17) at 8 months and 61% (19) at 12 months after discharge. There were no significant associations ($p \geq .164$) between having a number of CPR variables at these time frames and cessation of prosthetic use due to death (see Table 4.8 for full details).

4.4. Discussion

Few studies have examined factors at the time of discharge to determine future prosthetic use. This study is the first to propose CPRs for timelines of 4, 8 and 12 months post-discharge which use statistical optimisation modelling to select a parsimonious set of variables that predict increased likelihood of prosthetic non-use. Previous research has examined univariate associations with poor functional outcomes. This current study examined a much wider range of peri-operative and demographic factors and confirmed that a large number of factors are significantly related to prosthetic non-use. We have grouped these into intrinsic, amputation and functional domains.

This study found that having a very high number of medical comorbidities (including mental health issues and musculoskeletal pathology) was significantly predictive of prosthetic non-use at 4 months but not at later time periods. This was an interesting finding as depending on how comorbidities are managed they may become worse with age (Charlson et al., 1987); however this finding may suggest that if prosthetic use can be sustained for the first 4 months after discharge in the presence of these comorbidities then such systemic conditions may not be most highly related to non-use at a later time. CCI and CA-CCI scores suggest that prosthetic non-users were at greater risk of mortality from comorbid disease than users (Charlson et al., 1987; Roffman et al., 2016a).

Poor pre-amputation mobility, cardiac disease, renal failure, severe comorbidities, cognitive impairment and advanced age have been shown to affect prosthetic outcome

(Bhangu et al., 2009; O'Neill & Evans, 2009; Sansam et al., 2009; Schoppen et al., 2003; Taylor et al., 2005). This current study's univariate analysis found that having a cardiac condition was predictive of non-use at 8 and 12 months after discharge. Similar to findings within the literature (Schoppen et al., 2003; Taylor et al., 2005) individuals older than 58 years at the time of amputation were more likely to be non-users at 4 months.

The univariate results for this study were consistent with the literature on the importance of optimising a patient's locomotor function prior to discharge (Gauthier-Gagnon, Grisé, & Potvin, 1999). Inability to walk on different surfaces (e.g. grass, gravel, slopes) and levels of prosthetic mobility attained were all predictors of non-use. Inability to don, doff and monitor prosthetic fit was a univariate predictor of non-use for all time frames. Inability to run was a predictor of non-use at 8 and 12 months.

Mobility level achieved without a prosthesis including wheelchair mobility, transfers and hopping were analysed as some rehabilitation services (Department of Health, 2008) use these milestones as criteria for prosthetic prescription. Inability to hop was a significant univariate predictor of prosthetic non-use at 8 and 12 months. Inability to hop may be a marker of frailty, comorbidities, strength, balance, fitness and cognitive impairments that have been associated with poor prosthetic outcome in past studies (Raya et al., 2010; Schoppen et al., 2003).

The key point of this study however, was the fact that multivariate predictive models were used with all the variables to determine a predictive model of outcome at three time points. Three CPRs were generated since the results for the 4 and 6 months outcomes were identic. This suggests that individuals who reported non-use at 6 months had not been using the prosthesis for at least 2 months prior to this date. From this, it would seem that there is a subgroup that ceases using the prosthesis almost immediately after discharge. Having a combination of amputation level above transtibial, very high number of comorbidities, inability to walk outdoors on concrete, using a mobility aid and not having a diagnosis of diabetes were prognostic markers prosthetic non-use 4

months post-discharge. The critical feature here is that these findings call for a validation of this rule to then develop a model of care that optimises outcome for these individuals. Rehabilitation may focus on optimising transfers, wheelchair mobility, physical fitness and mental wellbeing rather than prosthetic gait.

The predictor variables for prosthetic non-use that all CPRs had in common were amputation level above transtibial and mobility aid use. High level or multiple limb amputation have been associated with poor prosthetic outcome due to the increased energy and skill level required for walking (Bhangu et al., 2009; Davies & Datta, 2003; Gauthier-Gagnon et al., 1999; Waters et al., 1976). From a functional perspective, a transtibial prosthesis assists an individual during transfers while a transfemoral prosthesis is only of assistance once standing or walking. This may result in some functional activities being performed with greater efficiency from a wheelchair (e.g. individuals with transfemoral amputation may use a commode for showering as it is more efficient than donning their prosthesis and walking).

In this study mobility aid use at discharge was a strong predictor ($p < .0001$) of prosthetic non-use at all time periods. Mobility aid use at discharge is more common in individuals who premorbidly used a mobility aid, are frail or deconditioned, have remaining limb pathology (e.g. claudication, osteoarthritis), high or multiple limb amputation (Franchignoni et al., 2004; Gauthier-Gagnon et al., 1999). Mobility aids reduce the functionality of gait by limiting capacity to carry objects however, use may be necessary to prevent falls (Franchignoni et al., 2004; Gauthier-Gagnon et al., 1999). As mobility aid use at discharge is associated with prosthetic non-use clinicians may consider using intervention strategies (e.g. mobility aid type, back pack use) that potentially improve functionality of gait.

At 4 and 8 months after discharge dependence walking outdoors on concrete was a significant predictor of prosthetic non-use. Association of this predictor with early prosthetic non-use following discharge is important as many locomotor activities require

the ability to walk outdoors on concrete (e.g. shopping). Poor prosthetic outcome has been associated with indoors only ambulation (Gailey et al., 2002; Taylor et al., 2005).

Similar to the literature (Sansam et al., 2009), this study demonstrated a critical time frame in which gait retraining needs to occur as a delay to gait retraining was a predictor of non-use at 12 months. Delay to the gait retraining was also a univariate predictor for all the time frames. Wound complications (89%, n=8) were the commonest cause of delay. Delay to walking generally results in reduced physical activity and prolonged wheelchair sitting by individuals. Rehabilitation programs may not provide the exercise intensity to overcome deconditioning or prevent complications (e.g. joint contracture, muscle weakness) that limit walking capacity. Furthermore, individuals with severe comorbidities and frailty may adversely or not respond to the exercise intervention.

Lower limb amputation rate has been reported as 38 times greater in Aboriginals[2] who have diabetes (Department of Health, 2010; Norman et al., 2010). In this study indigenous status, geographical isolation from health services and having diabetes were not predictive of prosthetic non-use. Environmental conditions in Aboriginal communities where the terrain is rough, sociocultural factors and service model strategies such as Telehealth may have contributed to sustained prosthetic use.

Similar to surgical outcome studies (Nehler et al., 2003; Taylor et al., 2005), this study highlights the importance of surgeons performing a transtibial (as opposed to transfemoral) amputation where feasible. However, the major point of difference from other studies (Davies & Datta, 2003; Dillingham et al., 2005; Dillingham et al., 2001) was that causative factors for amputation were not associated with non-use.

These CPRs have the potential to assist with evidenced based health reform, improve quality of life and lead to cost savings within rehabilitation services by improving

[2] Aboriginal and Torres Strait Islander people are the first inhabitants of Australia. An Aboriginal person is of Aboriginal descent, identifies as Aboriginal and is accepted as an Aboriginal person by their community. This study was conducted in Western Australia and only people who identified as Aboriginal participated. People of the Torres Strait are of Melanesian origin from the Torres Strait Islands and east coast of Australia.

patient selection for prosthetic rehabilitation and driving cost effective prosthetic innovation. The social, economic and ethical implications of CPRs for prosthetic non-use may vary between developed and developing nations and different models of care. Future validation of these CPRs at other centres is therefore warranted.

War veterans with lower limb amputation have reported that short residual limb (stump) length, prosthetic device being too heavy, cumulative trauma disorder of remaining lower limb, combat injuries, pain, paralysis and too much fuss were the main reasons they abandoned prosthetic use (Gailey et al., 2010; Laferrier, McFarland, Boninger, Cooper, & Reiber, 2010). Significantly higher rates of prosthetic abandonment were demonstrated in veterans with transfemoral amputation (or higher) and bilateral lower limb amputations (Gailey et al., 2010; Laferrier et al., 2010). Multifactorial reasons for abandoning prosthetic use reported by participants from our study were: issue with the residual limb, issue with the remaining limb, prosthetic issue, pain, medical comorbidities and balance issues.

This retrospective study had some potential limitations. Retrospective studies may have missing data however a strength of this study is that it had minimal missing data. The prosthetic use interview relied on participant recall which is a potential source of error. Mortality rate within the review period was high for this cohort (n = 29 (16%)), however our sensitivity analysis demonstrated that the deceased sub-group did not bias development of the CPRs. The major limitation of the retrospective model of CPR development is the need to prospectively validate the developed CPR in a new cohort (Cleland et al., 2010), this is an area of future investigation.

In conclusion, this study confirmed that many variables can be considered to have univariate associations with prosthetic non-use after discharge. This is consistent with the various reports in the literature. However, this retrospective study is the first to integrate these into a parsimonious set of predictor variables significant for prosthetic non-use in individuals with lower limb amputation at 4, 8 and 12 months after discharge from rehabilitation. This study highlights a need to separate causative factors for amputation that impact on surgical outcome, from those related to prosthetic non-use. These CPRs may assist health professionals with clinical reasoning and rehabilitation service development, however the results should be interpreted with caution as the study requires validation.

Chapter 5

5. Validation of clinical prediction rules for prosthetic non-use in individuals with lower limb amputation at 4, 8 and 12 months after discharge from rehabilitation.

Synopsis

This chapter details validation of clinical prediction rule for prosthetic non-use and forms part of the manuscript published in the Journal of Physiotherapy, please see appendix 4.1:

Roffman, Caroline E., Buchanan, John, & Allison, Garry T. (2014). Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules. *Journal of Physiotherapy, 60*(4), 224-231. doi: 10.1016/j.jphys.2014.09.003

This chapter was presented at the following conferences:
14th World Congress of the International Society for Prosthetics and Orthotics (ISPO), 4th to 7th February 2013, Hyderabad, India.

Momentum 2017 Physiotherapy Conference, Australian Physiotherapy Association, 19th to 21st October 2017, Sydney, Australia.

Abstract

Research Question: Are clinical prediction rules (CPRs) that identify prosthetic non-use in people with lower limb amputation at 4, 6, 8 and 12 months after discharge from rehabilitation valid?

Design: Prospective cohort study

Participants: 66 consecutive tertiary rehabilitation patients (58 males, age mean (SD) 54.4 (16.4) years).

Methods: Medical record and CPR data were collected during rehabilitation. Participants were interviewed at median 1.3 (IQR, 1.1 to 1.4) years after discharge.

Results: CPRs were validated for 4, 8 and 12 months. Amputation level above transtibial and mobility aid use were common predictors for all 3 time frames. The associated accuracy statistics (95% CI) for having a combination of predictor variables were:

4 months: If 4 out of 5 predictor variables were present (LR+ = 43.9, CI = 2.73 to 999+) the probability of non-use increased from 12% to 86% ($p < .0001$).

8 months: If all 3 predictor variables were present **(**LR+ = 33.9, CI = 2.1 to 999+) the probability of non-use increased from 15% to 86% ($p < .0001$).

12 months: If 2 out of 3 predictor variables were present (LR+ = 2.8, CI = 0.9 to 6.6) the probability of non-use increased from 17% to 36% ($p < .031$).

Conclusions: These validated CPRs have implications for changing patient rehabilitation services and clinical decision making.

Key words: *Clinical prediction rule, lower extremity, amputation, leg prosthesis, rehabilitation outcome*

5.1. Introduction

Prosthetic rehabilitation aims to restore locomotor function in individuals with lower limb amputation however, limited research exists on the sustained use of prostheses following discharge from rehabilitation (Adams, 2005; Campbell & Ridler, 1996; Cumming et al., 2006; Jones et al., 1993; Lim et al., 2006; Sansam et al., 2009). While prosthetic gait retraining which involves a combination of exercise, balance and functional locomotor activities in a range of contextual environments is considered standard clinical practice (Broomhead et al., 2003), the effectiveness of this intervention is unknown in Western Australia (WA) or poorly measured by many Australian amputee rehabilitation services (Department of Health, 2008; Hordacre et al., 2013b). Patient selection for prosthetic gait retraining varies between rehabilitation services and clinical practice guidelines have been developed largely through expert consensus (Broomhead et al., 2003; van der Linde et al., 2005).

Clinical Prediction Rules (CPRs) are tools that assist health professionals to make evidence based decisions and assign patients to interventions using a subset parsimonious of predictor variables (Beneciuk et al., 2009; Childs & Cleland, 2006; Cleland et al., 2007; Cleland et al., 2009; Cleland et al., 2010; Fritz, 2009; Laupacis et al., 1997). Fritz (2009) reports that CPRs which have had the greatest impact on health care are those developed for heterogenous conditions, with multiple treatment options and complex decision making. CPRs have been derived for a wide range of medical conditions, some examples include: prediction of ankle and knee fractures and response to treatment for neck and low back pain (Bachmann, Kolb, Koller, Steurer, & Riet, 2003; Cleland et al., 2007; Cleland et al., 2009; Cleland et al., 2010; Stiell et al., 1996).

Prosthetic non-use in individuals with lower limb amputation following discharge from rehabilitation is complex with many pre-operative and post-operative factors identified as having significant univariate associations (Adams, 2005; Bhangu et al., 2009; Dillingham et al., 2001; Gailey et al., 2002; Goktepe et al., 2010; Kulkarni et al., 2006; Lim et al., 2006; Nehler et al., 2003; O'Neill & Evans, 2009; Penn-Barwell, 2011; Pohjolainen et al., 1990; Raya et al., 2010; Sansam et al., 2009; Schoppen et al., 2003; Taylor et al., 2005; Waters et al., 1976). An understanding of the factors

which in combination are predictive of prosthetic non-use could assist multidisciplinary rehabilitation teams to develop targeted models of care and drive prosthetic innovation to improve functional outcome in those at risk of prosthetic non-use.

Roffman et al. (2014) (see chapter 4 and appendix 4.1) derived a set of CPRs for prosthetic non-use at 4, 8 and 12 months after discharge in a retrospective cohort study of 135 consecutive patients with lower limb amputation (Figure 5.1). This CPR development study represented stage 1 in CPR research methodology (Roffman et al., 2014). From a broad range of intrinsic, amputation and functional variables it was determined that amputation level above transtibial and mobility aid use were significant predictors of prosthetic non-use that were common to all CPR time frames (Roffman et al., 2014). Identical predictor variables were derived at 4 and 6 months after discharge suggesting there was a sub-group of patients who were likely to become early prosthetic non-users (Roffman et al., 2014).

The second phase of CPR research methodology is validation of the derived CPRs in a prospective cohort of patients (Childs & Cleland, 2006; Roffman et al., 2014). The research question for this study was: Are clinical prediction rules (CPRs) that identify prosthetic non-use in people with lower limb amputation at 4, 6, 8 and 12 months after discharge from rehabilitation valid?

5.2. Methods

Participants

This study was approved by the Royal Perth Hospital (RPH) and Curtin University Human Research Ethics Committees (see Appendix 3.1). Inclusion criteria were as follows: participants had at least one recent major lower limb amputation (i.e. transtibial level or above), were community dwelling and ambulant pre-amputation, were Medicare Functional Classification Level K-level 1 to 4 (from Gailey et al. (2002)), participated in and had been discharged from prosthetic rehabilitation at the state centre for amputee rehabilitation RPH. Individuals with multiple limb amputation were included for CPR validity.

Participants were excluded from the CPR validation if they were not prosthetic candidates (K-level 0, as assessed by the Rehabilitation Medicine Physician and Senior Physiotherapist Amputee Rehabilitation), unable to communicate or did not consent. K-level 0 individuals participated in inpatient rehabilitation to achieve independent transfers, wheelchair mobility and discharge home. As a strategy to improve external validity of the CPRs these excluded participants were monitored through amputee outpatient clinics to ensure that they were not misclassified. All remained K-level 0 and therefore did not contribute to a selection bias through the exclusion criteria.

All individuals with a K-Level 1 to 4 participated in prosthetic rehabilitation as an outpatient service at RPH, the dedicated state amputee rehabilitation service. Participants progressed through a standardised gait retraining program which included: strengthening, balance, stretching and cardiovascular exercises, learning to don, doff and monitor prosthetic fit, weight shift and walking drills in the parallel bars, walking indoors and outdoors on a range of terrains and environmental conditions, stair climbing and progression of mobility aids. If required, the types of mobility aids issued at discharge to patients for prosthetic gait included: single point walking sticks, elbow crutches, wheeled or non-wheeled Zimmer® frames and 4 wheeled walking frames. If a participant was unable to don their prosthesis or achieve locomotor milestones their carer was taught how to assist. Running, sports and work specific locomotor skills were taught to those patients who identified these as goals. Participants were discharged from physiotherapy when they achieved their individualised rehabilitation goals.

Participants received standardised prosthetic management from the onsite RPH prosthetists during their gait retraining sessions at the physiotherapy gym. This included prosthetic adjustment and new sockets as required. When a participant's gait retraining was completed and their residual limb volume had stabilised they were referred by the multidisciplinary team for a definitive prosthesis.

From the Amputee Physiotherapy Service database 99 consecutive patients with lower limb amputation were identified between July 2009 and July 2011. Eighty seven met the inclusion criteria however 10 were still participating in outpatient

rehabilitation during the study period. Two had minor lower limb amputation. Eleven were excluded as they were K-level 0 (non-prosthetic rehabilitation). The remaining 76 were prosthetic users (K-level 1 to 4) at discharge from outpatient physiotherapy. An independent research assistant attempted to contact these individuals to obtain informed verbal consent. During this process 8 (10%) were deceased. Four (36%) of the non-prosthetic rehabilitation (K-level 0) were deceased.

Of the 68 patients who were eligible to participate in the study, 2 participants were unable to be contacted as they had moved. The final response rate was 97% (n = 66) with participants interviewed at median 1.3 (IQR, 1.1 to 1.4) years post-discharge.

The interview process involved coordinating telephone interviews with Country Physiotherapists during remote community visits, Aboriginal Health Workers, and Nurses. Table 5.1 outlines the geographical distribution and isolation from health and other services for participants using the Accessibility Remoteness Index of Australia (ARIA) (Trewin, 2005).

Procedure

A prospective cohort study design was used. Data were prospectively collected during the participants' rehabilitation using a physiotherapy assessment form developed and implemented by the Senior Physiotherapist during the retrospective study (see Appendix 8.2) (Roffman et al., 2014). Charlson Comorbidity Index (CCI) and combined Age CCI (CA-CCI) scores were calculated from participant medical comorbidities data (Charlson et al., 1987; Hall et al., 2004; Roffman et al., 2014). Figure 5.1 shows the significant predictor variables for prosthetic non-use that were derived in the retrospective study by Roffman et al. (2014). Instructions on how to use the CPRs in figure 5.1 are outlined in Appendix 5.1.

Interviews were performed using a previously piloted survey by telephone (n = 47) and in person (n = 19). Carers assisted with 2 interviews where patients had a hearing or intellectual impairment.

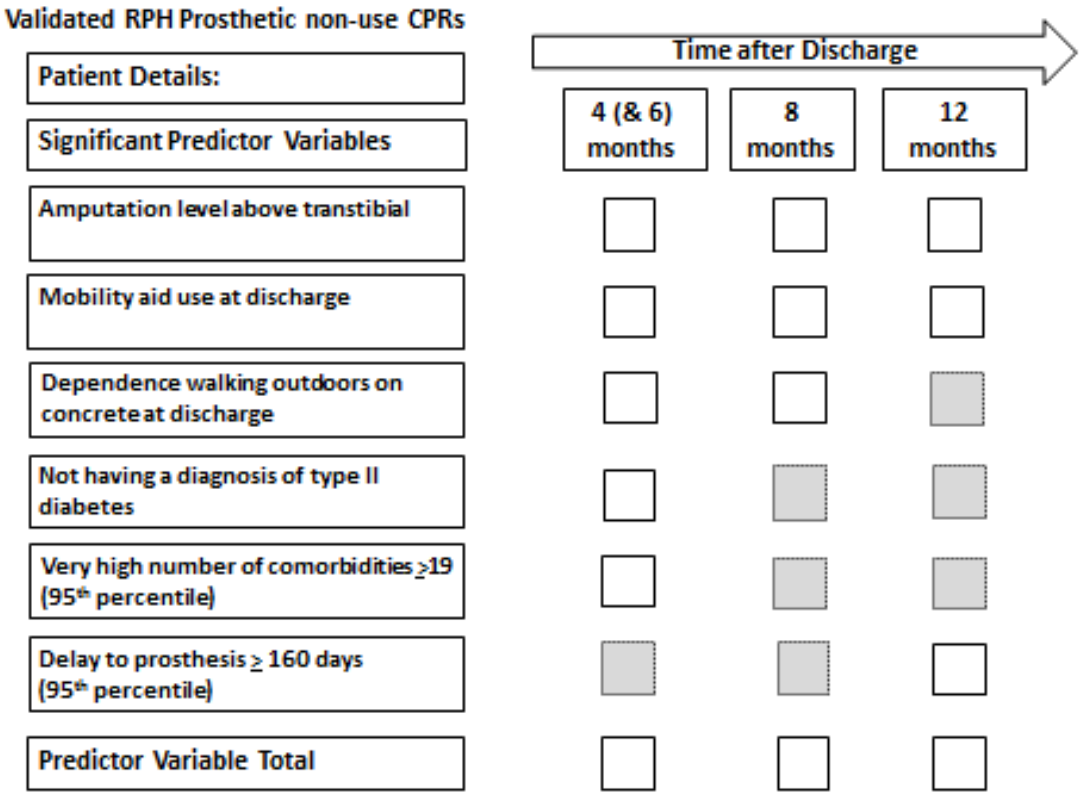

Figure 5.1: Validated CPRs for prosthetic non-use in individuals with lower limb amputation at 4, 8 and 12 months after discharge from rehabilitation

(Roffman et al., 2014).

Table 5.1: Demographic and amputation details of prospective cohort.

Demographic Details of Prospective Cohort	Prosthetic Users (n = 55)	Prosthetic Non-users (n =11)	Total (n = 66)
Gender, Male, n (%)	50 (91)	8 (73)	58 (88)
Age at amputation, mean (SD)	55.3 (15.7)	49.5 (19.9)	54.4 (16.4)
Indigenous status, Aboriginal, n (%)	6 (11)	2 (18)	8 (12)
Accommodation, n (%)			
Home	55 (100)	11 (100)	66 (100)
Residential Care (Hostel & Nursing Home)	0 (0)	0 (0)	0 (0)
Metropolitan	34 (62)	9 (82)	43 (65)
Country	21 (38)	2 (18)	23 (35)
Accessibility Remoteness Index of Australia (ARIA)			
Major Cities of Australia (0 to 1.84)	40 (73)	9 (82)	49 (74)
Inner Regional Australia (>1.84 to 3.51)	7 (13)	0 (0)	7 (11)
Outer Regional Australia (>3.51 to 5.80)	5 (9)	1 (9)	6 (9)
Remote Australia (> 5.80 to 9.08)	2 (4)	0 (0)	2 (3)
Very Remote Australia (> 9.08 to 12)	1 (2)	1 (9)	2 (3)
Social Support, Lives with others, n (%)	42 (76)	10 (91)	52 (79)
Charlson Comorbidity Index Score, median (IQR)	2 (0 to 4)	3 (0.5 to 5)	2 (0 to 4)
Combined Age Charlson Comorbidity Index Score, median (IQR)	4 (1 to 6)	6 (1 to 7)	4 (1 to 7)
Comorbidities, n (%)			
Diabetes	22 (40)	7 (64)	29 (44)
Type I	1 (2)	1 (9)	2 (3)
Type II	21 (38)	6 (55)	27 (41)
Peripheral Arterial Disease	30 (55)	7 (64)	37 (56)
Cardiac Condition	12 (22)	4 (36)	16 (24)
Renal Failure	5 (9)	4 (36)	9 (14)
Cerebrovascular accident / Transient Ischemic Attack	4 (7)	0 (0)	4 (6)
Arthritis	12 (22)	5 (45)	17 (26)
Remaining Lower Limb Pathology	36 (65)	11 (100)	47 (71)
Mental health issues, n (%)	8 (15)	5 (45)	13 (20)
Substance abuse, n (%)			
Drugs	2 (4)	3 (27)	5 (8)
Alcohol	7 (13)	2 (18)	9 (14)
Amputation Details			
Amputation Cause, n (%)			
Circulatory	16 (29)	3 (27)	19 (29)
Infection	22 (40)	6 (55)	28 (42)
Trauma	14 (25)	2 (18)	16 (24)
Cancer	3 (5)	0 (0)	3 (5)
Amputation Level, n (%)			
Transtibial	50 (91)	10 (91)	60 (91)
Knee disarticulation	1 (2)	0 (0)	1 (2)
Transfemoral	9 (16)	5 (45)	14 (21)
Major Bilateral Lower Limb Amputation	5 (9)	4 (36)	9 (14)
Minor amputation of remaining limb	2 (4)	1 (9)	3 (5)
Upper Limb Amputation/s	9 (16)	3 (27)	12 (18)

The same operational definitions for prosthetic users, prosthetic non-users and methodology that were used in the retrospective CPR development study, were used in this CPR validation study (full definitions and methodology are reported in Roffman et al. (2014)). Participants were interviewed on their prosthetic use from 4 months onwards after discharge and were re-interviewed at 2 monthly intervals until data were collected for 12 months after discharge.

Statistical Analyses

Participants were classified as being prosthetic users or non-users at 4 specific time points (4, 6, 8 and 12 months) after discharge. Descriptive statistics were generated. The prospective cohort were analysed for the absence (score = 0) or presence (score = 1) of the significant predictor variables outlined in Figure 5.1 at 4, 6, 8 and 12 months after discharge. Please refer to Appendix 5.1 for full instructions on using the CPRs. The validity of the cohort behaviours of prosthesis use were compared by plotting the pattern of prosthetic non-use over time for the retrospective (n = 135) (Roffman et al., 2014) and prospective (n = 66) cohorts investigated by these CPR studies (see figure 5.2). To enable comparison between research and healthcare facilities survival of prosthetic use from initial amputation surgery were also plotted for the retrospective and prospective cohorts (see figure 5.3).

The thresholds for the continuous variables by Roffman et al. (2014) were used to generate dichotomous classification of these continuous variables in this prospective validation study. To validate the CPRs for each of the time frames, chi-square tests were calculated to generate a progressive list of Likelihood Ratios (negative and positive, 95% CI) to determine the cumulative effect of having a number (i.e. 1, 2, 3 or more) of these predictor variables for prosthetic non-use. Sensitivity, specificity, positive prediction value (PPV), accuracy and balanced accuracy were calculated to define the accuracy and precision of CPRs in the prospective validation cohort (Brodersen, Ong, Stephan, & Buhmann, 2010). Balanced accuracy was calculated from the mean of the sum of the sensitivity and specificity (Brodersen et al., 2010).

In circumstances where zero cases were present in frequency cells of the 2 x 2 contingency tables, 0.5 was added to the cell values to enable calculation of the likelihood ratios for the variables (Everitt, 1992). Extreme likelihood ratio upper confidence limits were truncated at 999.

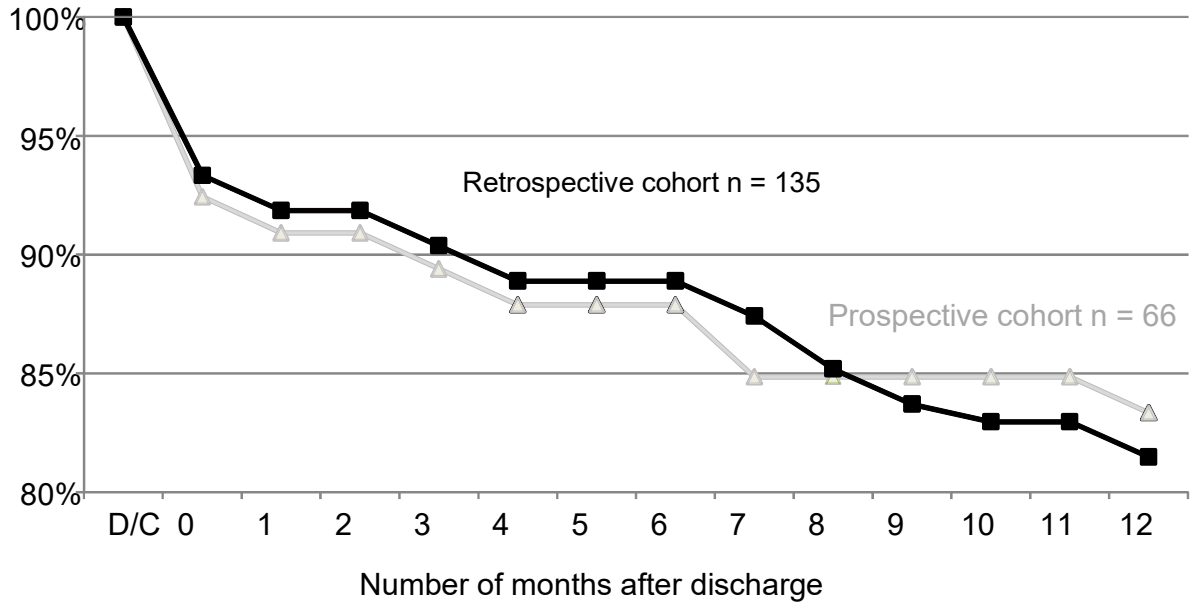

Figure 5.2: A survival curve for the proportion of individuals using the prosthesis for every month in the year following hospital discharge.

Note: The retrospective and prospective cohorts show similar patterns of prosthetic non-use with a similar rate of non-use. Time of initial amputation surgery to outpatient physiotherapy discharge were median 238 days (IQR = 142 to 377) for the retrospective cohort and median, 196 days (IQR = 126 to 260) for the prospective cohort.

(Roffman et al., 2014).

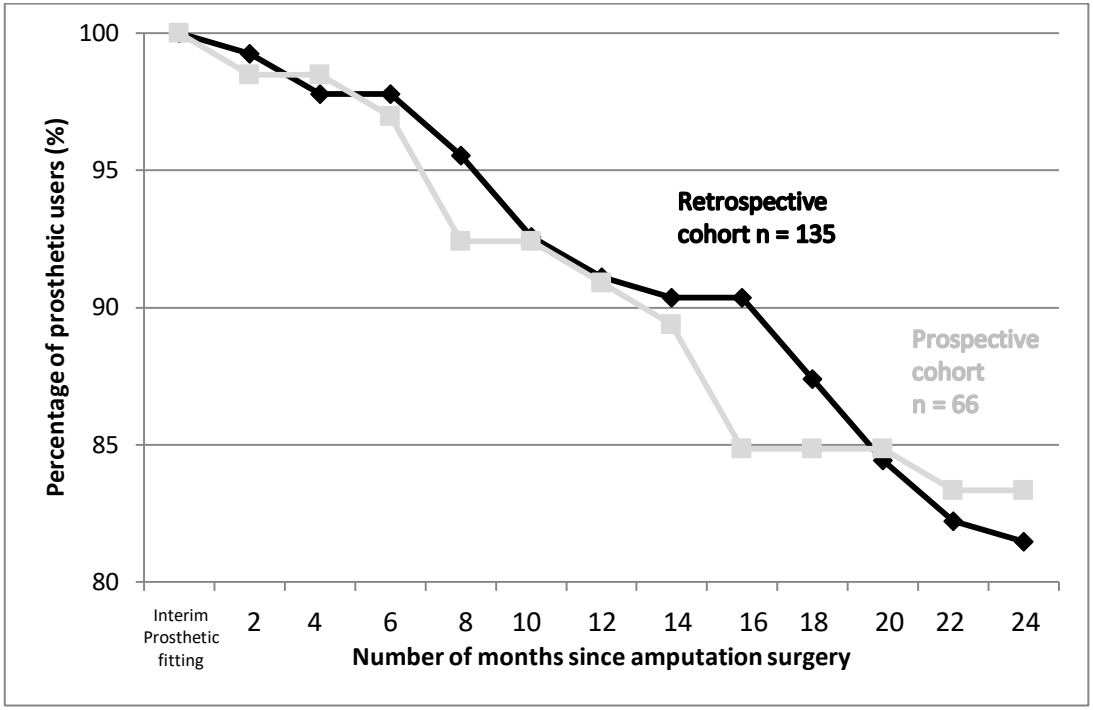

Figure 5.3: Survival of prosthetic use from amputation surgery for the retrospective and prospective cohorts.

Interim prosthetic fitting was median, 52 days (IQR = 34 to 109) for the retrospective cohort and median, 49 days (IQR = 34 to 77) for the prospective cohort from initial amputation surgery. Discharge from physiotherapy was median, 238 days (IQR = 142 to 377) for the retrospective cohort and median, 196 days (IQR = 126 to 260) for the prospective cohort from initial amputation surgery.

A sensitivity analysis of the 8 (10%) deceased prosthetic rehabilitation patients who could not be interviewed was performed for 4, 6, 8 and 12 months after discharge from rehabilitation to identify the presence or absence of CPR variables. Date of death was used as the termination date for prosthetic use.

5.3. Results

Subjects were interviewed to determine prosthetic outcome from March 2011 until December 2012. Figure 5.4 reports the timeframes from the post-operative stage of rehabilitation to interview including length of stay and time from initial amputation surgery until rehabilitation milestones (e.g. prosthetic casting, fitting and gait retraining) were achieved by the total cohort (n = 66). Table 5.1 shows the prospective cohort characteristics. Comorbidities (CCI score) were more frequent in non-users median = 3 (IQR = 0.5 to 5) than users median = 2 (IQR = 0 to 4).

Of 66 participants interviewed, a total of 83% (55) were prosthetic users and 17% (11) were non-users. The multi-factorial, self reported reasons for prosthetic non-use in the 11 participants classified as prosthetic non-users have been detailed in table 5.2. Prosthetic non-use was identical for 4 and 6 month time frames after discharge from rehabilitation at 12% (8). This was the same pattern observed in the retrospective cohort. At the 8 and 12 month timeframes, 15% (10) and 17% (11) of participants respectively were prosthetic non-users.

The survival curves (Figure 5.2) demonstrated a high level of concordance between the retrospective and prospective cohorts. Initially there was a rapid progression to prosthetic non-use which then became linear after approximately 6 months. Time of initial amputation surgery to outpatient physiotherapy discharge were median 238 days (IQR = 142 to 377) for the retrospective cohort and median, 196 days (IQR = 126 to 260) for the prospective cohort. Survival of prosthetic use from initial amputation surgery for the retrospective and prospective cohorts is shown in Figure 5.3.

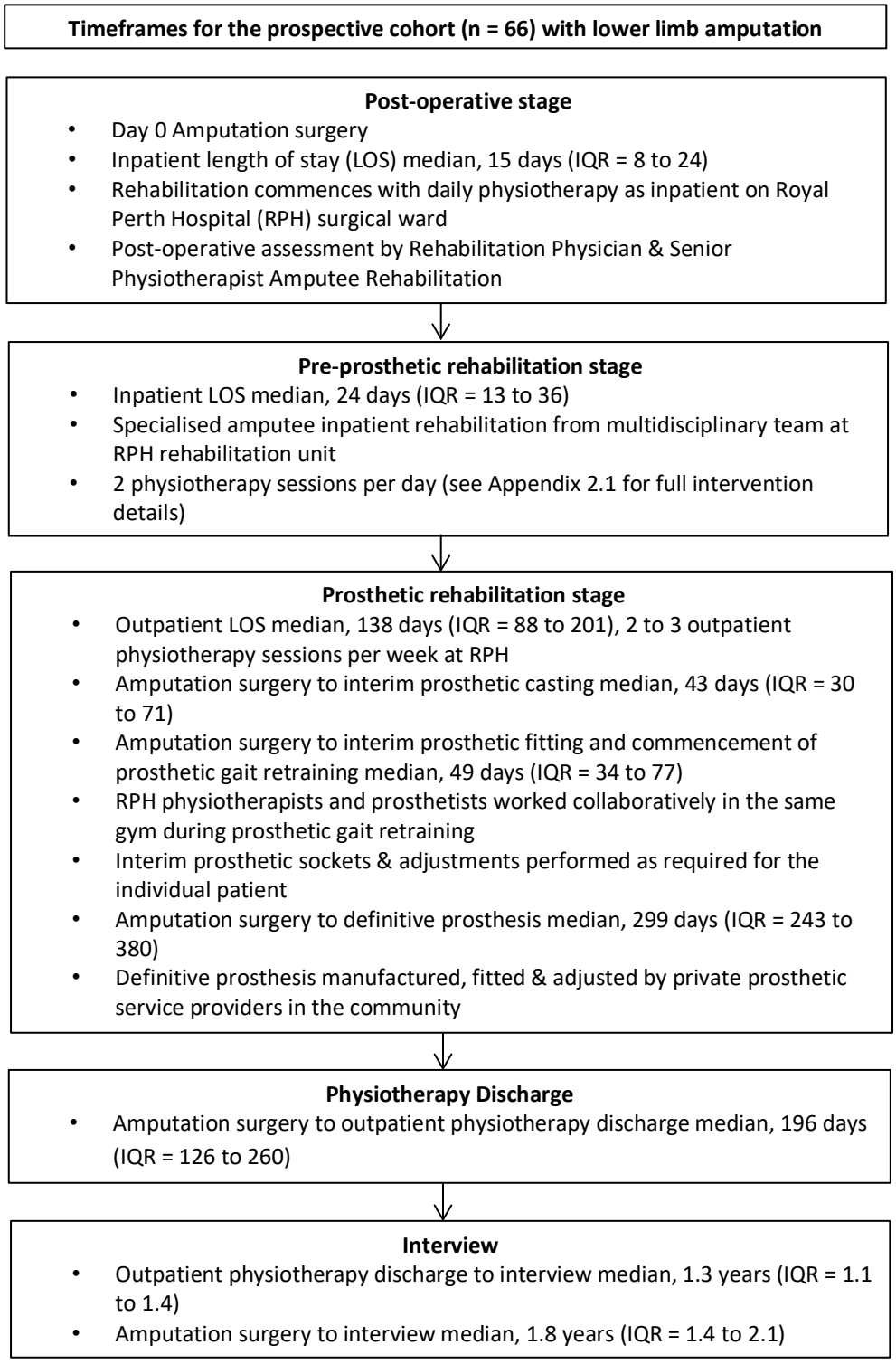

Figure 5.4 Timeframes for the prospective cohort (n = 66) from the post-operative stage of rehabilitation to interview.

Table 5.2: Multifactorial reasons for prosthetic non-use reported by participants classified as prosthetic non-users (n = 11).

Multifactorial reasons for prosthetic non-use reported by prosthetic non-users (n = 11)	% (n)*
Issue with residual limb (stump)	55 (6)
Issue with remaining Limb	46 (5)
Pain	36 (4)
Medical comorbidities	27 (3)
Prosthetic issue	18 (2)
Balance issues	9 (1)
Fear of falling	9 (1)
Unmotivated	9 (1)
Unable to don independently	9 (1)
Falls	0 (0)
Body Weight fluctuations	0 (0)
Energy Cost or efficiency	0 (0)
Amputation of remaining limb	0 (0)

*Participants were able to report more than one reason for not using their prosthesis so the cumulative percentage exceeds 100.

In the prospective cohort, the associated accuracy statistics for having a combination of predictor variables (95% CI) for 4 (& 6), 8 and 12 months were as follows with full details reported in Table 5.3:

CPR 4 months

At 4 (& 6) months the 5 variables predictive of prosthetic non-use that were validated in the prospective cohort included: amputation level above transtibial, using a mobility aid, dependence walking outdoors on concrete, very high number of comorbidities (≥ 19) and a diagnosis of Type 2 diabetes. Very high comorbidities (≥ 19) represented the 95th percentile of this cohort. The cohort probability of non-use was 12%, however in the presence of 4 out of 5 variables in the CPR the probability increased to 86% ($p < .0001$). This represents a LR+ of 43.9 (CI = 2.73 to 999+), sensitivity of 0.38 (CI = 0.12 to 0.44), specificity of 0.99 (CI = 0.96 to 1.0) accuracy of 92% and balanced accuracy of 68%.

CPR 8 months

At 8 months the 3 variables predictive of prosthetic non-use that were validated in the prospective cohort included: amputation level above transtibial, using a mobility aid and dependence walking outdoors on concrete. The cohort probability of non-use was 15%. If all 3 predictor variables in the CPR were present, the probability increased to 86% ($p < .0001$), and the LR+ of 33.9 (CI = 2.1 to 999+), sensitivity of 0.3 (CI = 0.09 to 0.35), specificity of 0.99 (CI = 0.96 to 1.0), accuracy of 89% and balanced accuracy of 65%.

CPR 12 months

At 12 months the 3 variables predictive of prosthetic non-use included: amputation level above transtibial, delay to prosthesis (≥ 160 days) and using a mobility aid. Delay to prosthesis (≥ 160 days) represented the 95th percentile of this cohort. The causes of delay to prosthetic gait retraining in non-users were: wound complications 67% (2) and orthopaedic complications 33% (1). The cohort probability of non-use was 17% and if 2 out of 3 predictor variables in the 12 month CPR were present then the probability rose to 36% ($p = .031$). This represented a LR+ of 2.8 (CI = 0.9

Table 5.3: Associated accuracy statistics with 95% confidence intervals for having at combination of predictor variables at 4 (& 6), 8 and 12 months.

Number of Predictors present for time frame	Sensitivity	Specificity	Positive Likelihood Ratio	Negative Likelihood Ratio	Probability of prosthetic non-use (%)	p value
4 (& 6) months:						
1	0.94 (0.61 to 1.0)	0.14 (0.09 to 0.15)	1.09 (0.67 to 1.17)	0.43 (04.40)	14	.519
2	0.93 (0.53 to 1.0)	0.66 (0.61 to 0.67)	2.8 (1.36 to 3.03)	0.10 (0 to 0.77)	26	.002*
3	0.5 (0.19 to 0.81)	0.86 (0.82 to 0.90)	3.6 (1.02 to 8.5)	0.58 (0.21 to 0.99)	33	.013*
4	0.38 (0.12 to 0.44)	0.99 (0.96 to 1.0)	43.9 (2.73 to 999+)	0.63 (0.56 to 0.92)	86	< .0001*
5	0.06 (0 to 0.12)	0.99 (0.98 to 1.0)	6.9 (0 to 999+)	0.95 (0.88 to 1.0)	50	.259
8 months:						
1	0.90 (0.57 to 0.99)	0.50 (0.44 to 0.52)	1.8 (1.0 to 2.06)	0.20 (0.01 to 0.98)	24	.019*
2	0.70 (0.38 to 0.91)	0.82 (0.76 to 0.86)	3.9 (1.6 to 6.5)	0.37 (0.10 to 0.81)	41	.001*
3	0.30 (0.09 to 0.35)	0.99 (0.96 to 1.0)	33.9 (2.1 to 999+)	0.71 (0.65 to 0.95)	86	< .0001*
12 months:						
1	0.91 (0.60 to 0.99)	0.51 (0.45 to 0.53)	1.85 (1.08 to 2.1)	0.18 (0.009 to 0.9)	27	.011*
2	0.46 (0.19 to 0.72)	0.84 (0.78 to 0.89)	2.8 (0.9 to 6.6)	0.65 (0.31 to 1.03)	36	.031*
3	0.09 (0.005 to 0.14)	0.99 (0.97 to 1.0)	10.1 (0.19 to 999+)	0.92 (0.86 to 1.02)	67	.095

* $p < .05$ is significant

to 6.6), sensitivity of 0.46 (CI = 0.19 to 0.72), specificity of 0.84 (CI = 0.78 to 0.89), accuracy of 77% and balanced accuracy of 65%.

Figures 5.5, 5.6 and 5.7 demonstrate the balanced accuracy for having a combination of predictor variables from the CPRs for each of the timeframes.

Of the 10% (8) patients who participated in prosthetic rehabilitation but were deceased and could not be interviewed: 38% (3) were deceased and non-users at 4 months, 62% (5) at 6 months, 62% (5) at 8 months and 88% (7) at 12 months after discharge from rehabilitation. There were no significant associations ($p \geq .170$) between having a number of CPR variables at these time frames after discharge and cessation of prosthetic use due to death (see Table 5.4 for full details).

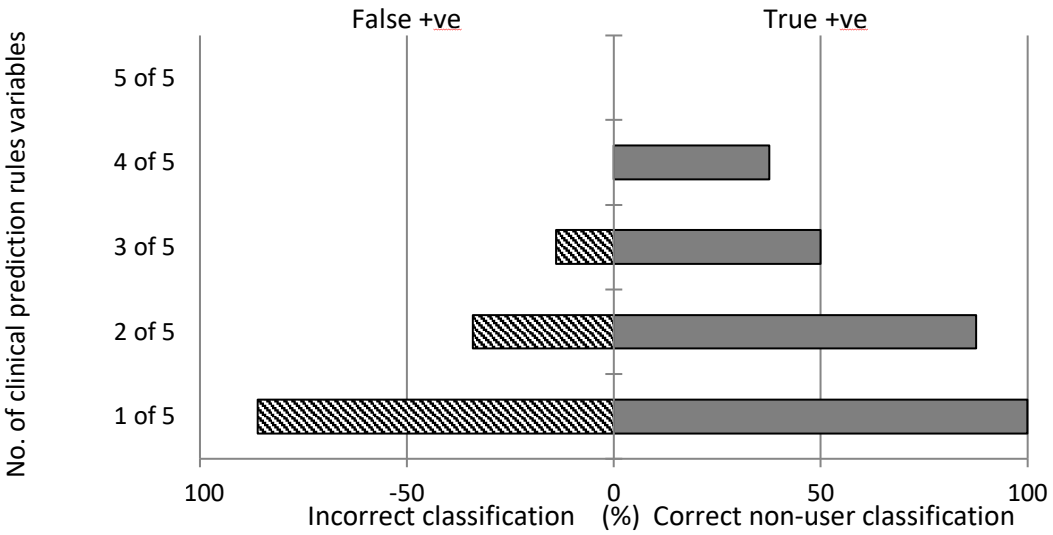

Figure 5.5: Prospective clinical utility figure showing the percentage of users classified as non-users (False +ve) and non-users correctly identified (True +ve) for each risk variable identified for the 4 and 6 months clinical prediction rules.
Note: three of five variables present identified 50% of non-users with a false prediction of 14%. Four of five variables detected 38% of all non-users.

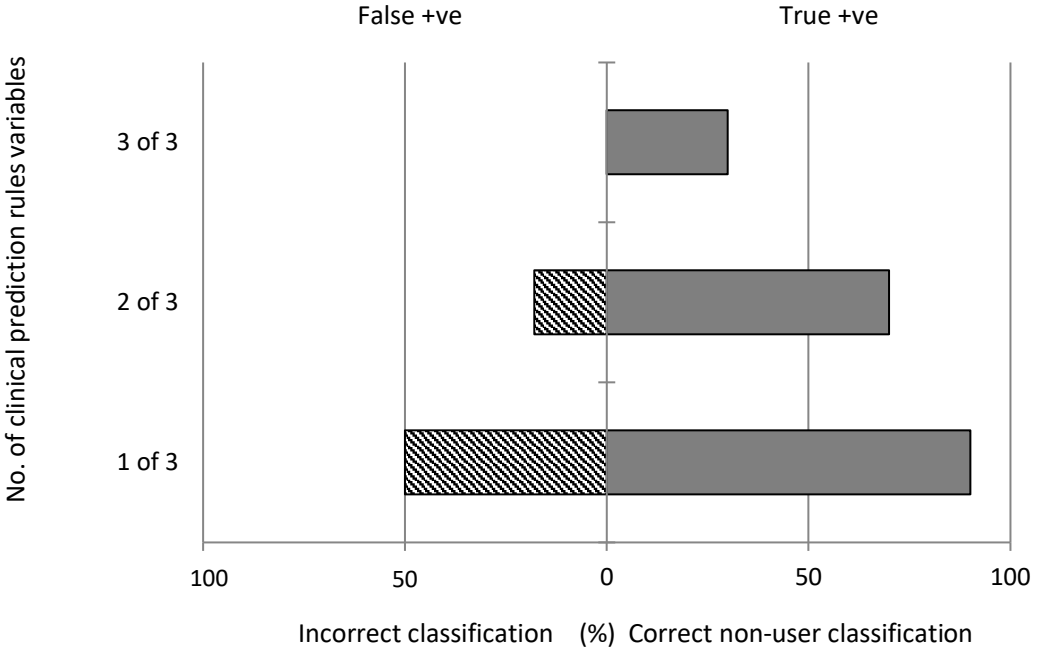

Figure 5.6: Prospective clinical utility figure showing the percentage of users classified as non-users (False +ve) and non-users correctly identified (True +ve) for each risk variable identified for the 8 months clinical prediction rules.
Note: two of three variables present identified 70% of non-users with a false prediction of 18%. Three of three variables detected 30% of all non-users.

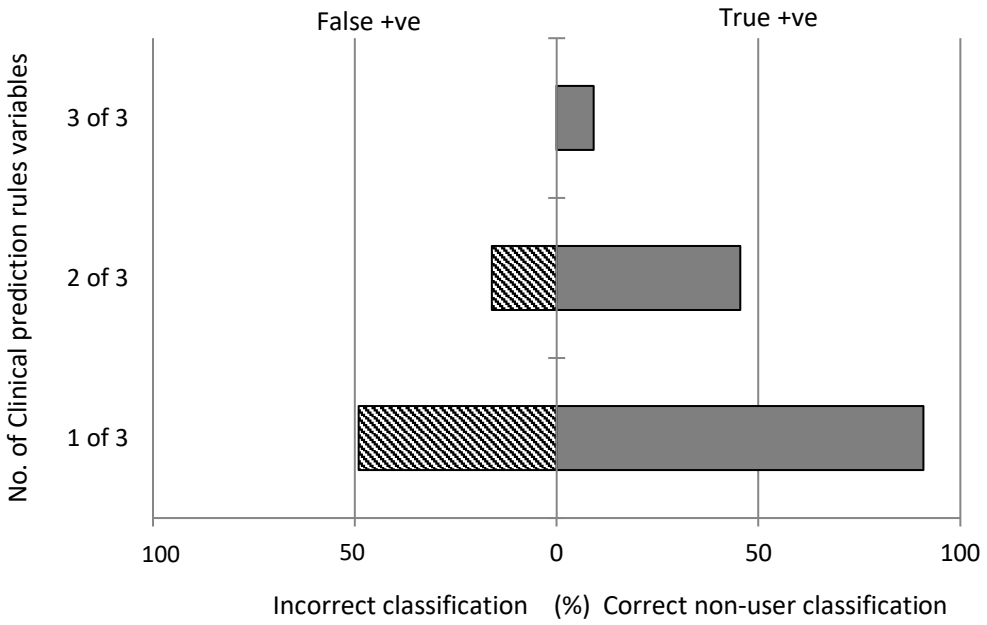

Figure 5.7: Prospective clinical utility figure showing the percentage of users classified as non-users (False +ve) and non-users correctly identified (True +ve) for each risk variable identified for the 12 months clinical prediction rules.
Note: one of three variables present identified 91% of non-users with a false prediction of 49%. Two of three variables detected 45% of all non-users and falsely identified 16% of users.

Table 5.4: Significant predictor variables for prosthetic non-use and associated accuracy statistics with 95% confidence intervals for having a combination of predictor variables in the deceased sub-group (10% (n=8)).

Associated accuracy statistics for having a combination of variables (e.g. 1, 2, 3… variables) at each of the time frames						
Number of Predictor variables present	**Sensitivity**	**Specificity**	**Positive Likelihood Ratio**	**Negative Likelihood Ratio**	**Probability of prosthetic non-use (%)**	**p value**
1	0.857 (0.587 to 1.00)	0.200 (0.011 to 0.300)	1.07 (0.594 to 1.43)	0.714 (0 to 37.2)	43	.830
2	0.667 (0.148 to 0.97)	0.800 (0.489 to 0.982)	3.33 (0.289 to 54.0)	0.417 (0.03 to 1.74)	67	.187
3	0.143 (0 to 0.413)	0.800 (0.700 to 0.989)	0.714 (0 to 37.2)	1.07 (0.594 to 1.43)	33	.830
4	0.143 (0 to 0.286)	0.909 (0.818 to 1.00)	1.57 (0 to 999+)	0.943 (0.714 to 1.22)	50	.809
5	0.143 (0 to 0.286)	0.909 (0.818 to 1.00)	1.57 (0 to 999+)	0.943 (0.714 to 1.22)	50	.809
1	0.909 (0.737 to 1.00)	0.333 (0.018 to 0.500)	1.36 (0.75 to 2.00)	0.273 (0 to 14.3)	71	.376
2	0.400 (0.110 to 0.589)	0.667 (0.184 to 0.982)	1.20 (0.135 to 32.2)	0.900 (0.419 to 4.85)	67	.850
3	0.091 (0 to 0.263)	0.667 (0.500 to 0.982)	0.273 (0 to 14.3)	1.36 (0.751 to 2.00)	33	.376
4	0.143 (0 to 0.286)	0.909 (0.818 to 1.00)	1.57 (0 to 999+)	0.943 (0.714 to 1.22)	50	.809
5	0.091 (0 to 0.182)	0.857 (0.714 to 1.00)	0.636 (0 to 999+)	1.06 (0.818 to 1.40)	50	.809
1	0.909 (0.737 to 1.00)	0.333 (0.018 to 0.500)	1.36 (0.751 to 2.00)	0.273 (0 to 14.3)	71	.376
2	0.091 (0 to 0.263)	0.667 (0.500 to 0.982)	0.273 (0 to 14.3)	1.36 (0.751 to 2.00)	33	.376
3	0.091 (0 to 0.182)	0.857 (0.714 to 1.00)	0.636 (0 to 999+)	1.06 (0.818 to 1.40)	50	.809
1	0.857 (0.722 to 0.929)	0.667 (0.037 to 1.00)	2.57 (0.750 to 999+)	0.214 (0.071 to 7.51)	92	.170
2	0.286 (0.151 to 0.357)	0.667 (0.038 to 1.00)	0.857 (0.157 to 999+)	1.07 (0.643 to 22.6)	80	.908
3	0.067 (0 to 0.133)	0.667 (0.333 to 1.00)	0.200 (0 to 999+)	1.40 (0.867 to 3.00)	50	.343

*$p < .05$ is significant.

5.4. Discussion

CPRs have been developed for a range of medical conditions however, very few have been validated which represents the second stage of CPR research methodology (Beneciuk et al., 2009; Stiell et al., 1993; Stiell et al., 1996). The CPRs for prosthetic non-use in people with lower limb amputation at time frames of 4 (& 6), 8 and 12 months after discharge from rehabilitation that were derived in the retrospective cohort study by Roffman et al. (2014) were statistically validated in this prospective study. Three time points for prosthetic non-use were statistically validated with people who reported prosthetic non-use at 4 months being identical to those prosthetic non-users at 6 months. The number of variables (i.e. 4 out of 5, 3 out 3 and 2 out of 3) associated with the greatest risk of prosthetic non-use were selected for each of the CPR timeframes (as demonstrated in figures 5.5, 5.6 and 5.7).

The CPRs at 4 and 8 months after discharge had positive likelihood ratios of 43.9 and 33.9 improving prediction accuracy of prosthetic non-use from 12% to 86% and 15% to 86% respectively. These values statistically represent large shifts in pre-test to post-test probability and are consistent with the interpretation that a positive likelihood ratio of 5 or greater (Lesher et al., 2006) or greater than 10 (Childs & Cleland, 2006; Jaeschke, Guyatt, & Sackett, 1994) is clinically significant. Similar to the retrospective study there were sub-groups of prosthetic non-users at 4 and 8 months after discharge who in addition to having an amputation level above transtibial were dependent walking outdoors on concrete and used mobility aids at discharge. These validated CPRs at 4 and 8 months have clinical implications for patient selection, interventions and targeted models of care. The findings highlight that ability to sustain prosthetic gait after discharge from rehabilitation should be an early assessment consideration by multidisciplinary teams.

The CPR for 12 months was significantly predictive of prosthetic non-use ($p = .031$). However, the positive likelihood ratio was 2.8 with a small shift in pre-test to post-test probability from 17% to 36%. This suggests that the CPR for 12 months did not have the predictive magnitude or clinical significance of the CPRs for 4 and 8 months. Amputation level above transtibial, using a mobility aid and delay to prosthetic gait retraining were long term predictors of non-use at 12 months after

discharge. Similar to other studies (Sansam et al., 2009) the CPR for 12 months after discharge highlights the importance of optimising wound and fracture healing and commencing prosthetic gait retraining as soon as possible. To improve the clinical utility of the CPR for 12 months future research may incorporate a follow-up assessment at 6 months after discharge to identify predictors which impact on sustained prosthetic use in this sub-group for the subsequent 6 months.

Similar to the retrospective study (Roffman et al., 2014), this prospective study demonstrated there was a sub-group of early prosthetic non-users. Individuals at risk of early prosthetic non-use are likely to have a combination of the following predictor variables: amputation level above transtibial, very high number of comorbidities, not have a diagnosis of Type 2 diabetes, use a mobility aid and dependence walking outdoors on concrete at discharge. CCI and CA-CCI scores suggest that prosthetic non-users were at greater risk of mortality from comorbid disease than users (Charlson et al., 1987; Roffman et al., 2014). Amputation level, number of comorbidities and the absence of Type 2 diabetes are known predictors before patient selection for prosthetic rehabilitation. While absence of Type 2 diabetes cannot be considered in isolation as it is part of a parsimonious set of variables further research is required to determine the interaction of systemic comorbidities such as diabetes with other factors which may impact on the early prosthetic non-use. Subjective history on ambulatory function prior to amputation surgery to identify mobility aid use and ability to walk outdoors on concrete provides an early indication of potential to achieve these 2 predictor variables during rehabilitation. Past studies (Czerniecki et al., 2012b; Taylor et al., 2005) have demonstrated that poor mobility status prior to amputation was a prognostic indictor for poor prosthetic outcome.

The survival curves for prosthetic non-use (figure 5.2) demonstrated a high level of concordance between the retrospective (Roffman et al., 2014) and prospective cohorts suggesting that there was no substantial change in clinical practice during the validation study. In both cohorts, initially, there was rapid progression to prosthetic non-use followed by a more linear decline to non-use after 6 months. A large proportion of the early non-users in both the prospective (63%) and retrospective (53%) cohorts ceased prosthetic use immediately after discharge. Large variation has

been reported in the literature for abandonment of prosthetic use (range 4% to 53%) and the time frame from amputation surgery to prosthetic non-use (range 6 months to 36 years) (Chamlian, 2014; Gailey et al., 2010; Gauthier-Gagnon et al., 1999; Laferrier et al., 2010; McWhinnie, Gordon, Collin, Gray, & Morrison, 1994; Schaffalitzky et al., 2012). McWhinnie et al. (1994) reported that in people with peripheral arterial disease, prosthetic use was 85% (46) at 1 year after amputation surgery but at 5 years had decreased to 31% (17). In our study, prosthetic use at 24 months after amputation surgery was 81% for the retrospective and 83% for the prospective cohorts respectively (figure 5.3). In the USA, the time frame to prosthetic abandonment was significantly shorter in war veterans from Operation Iraqi Freedom (OIF) / Operation Enduring Freedom (OEF) who had used a range of prosthetic technologies than veterans from the Vietnam war who abandoned mainly mechanical devices (Gailey et al., 2010; Laferrier et al., 2010). The main, multifactorial reasons for prosthetic non-use reported by the retrospective and prospective cohorts from our study were: issue with the residual limb (stump), issue with the remaining limb, prosthetic issue, pain, medical comorbidities and balance issues. Similar reasons for prosthetic non-use have been reported in the literature with cumulative trauma to the remaining lower limb from prosthetic gait being a major reason for war veterans ceasing prosthetic use and using a wheelchair as their primary mobility device (Chamlian, 2014; Gailey et al., 2010; Karmarkar et al., 2009; Laferrier et al., 2010).

Prosthetic components and innovations that may potentially assist those at risk of early prosthetic non-use with achieving functional locomotion are often not accessible due to cost and the fact that there is no guarantee that a more expensive prosthesis will sustain prosthetic use in this sub-group. Therefore, rehabilitation of those at risk of early prosthetic non-use may be best focused on transfers, wheelchair mobility, physical fitness, community access and mental wellbeing rather than prosthetic gait retraining. If an individual at risk of early prosthetic non-use has a trial of prosthetic gait retraining then clear time frames should be set for achievement of the locomotor goals. Functional assessment criteria should exist in the amputee model of care for progression from an interim to a definitive prosthesis in this early non-user sub-group as identification of these patients has potential cost savings for

rehabilitation services by minimising the provision of definitive prostheses to non-users.

The validated predictor variables for prosthetic non-use common to all 3 CPRs were amputation level above transtibial and mobility aid use at discharge. Mobility aids reduce the functionality of gait by limiting an individual's ability to carry objects while walking but may be necessary to prevent falls (Gauthier-Gagnon et al., 1999). Mobility aids ranged from single point sticks to walking frames and were not weighted for their associated level of dependence in the statistical analysis. To minimise barriers to locomotor activities, health professionals may teach patients to walk without aids. In cases where it is not safe for an individual to walk unaided, health professionals may provide mobility aids or teach strategies that allow individuals to walk and carry objects. Future research into the efficacy of such strategies is warranted.

Amputation level above transtibial has been associated in the literature (Nehler et al., 2003; Taylor et al., 2005) with poor prosthetic outcome therefore surgeons aim to preserve the residual limb length to optimise locomotor function. Osseointegration is a surgical technique that may potentially improve locomotor outcome for some sub-groups with transfemoral amputation (Guirao et al., 2016; Hagberg, Hansson, & Brånemark, 2014). Our prospective study highlights that health professionals need to ensure patients with high levels of amputation are selected appropriately for prosthetic gait retraining. Raya et al. (2010) demonstrated that strength of the hip extensor muscles and balance were significant predictors of 6 minute walk test distance in people with lower limb amputation. This study (Raya et al., 2010) provides support for optimising modifiable variables such as muscle strength, balance, joint range of movement and cardiovascular fitness so patients can manage the energy requirements and skill of prosthetic gait with a higher level of amputation.

This prospective study had some potential limitations and factors that impact on generalisation in other healthcare settings. The prosthetic use interview relied on participant recall which is a potential source of error. Mortality rate within the review period was high for this cohort (n = 8 (10%)) however our sensitivity analysis demonstrated that the deceased sub-group did not bias validation of the CPRs. For

generalisation into other health care systems it was noted that the number of comorbidities and length of delay for the prosthesis may be population or institutional sensitive. Therefore other institutes may wish to identify comorbidities and delay in prosthetic gait retraining by taking the hospital context and flagging individuals who fall in the top 5 to 10 percentiles for each of these categories.

In conclusion, these CPRs for prosthetic non-use at 4, 8 and 12 months after discharge have been prospectively validated. The CPRs for prosthetic non-use may be used by health professionals to guide their clinical reasoning however it should be noted that the CPRs for 4 and 8 months were statistically and clinically more significant than the CPR for 12 months after discharge. The study has also validated that a sub-group of early prosthetic non-users exist. Individuals with an amputation level above transtibial, who use a mobility aid and were unable to walk independently outdoors on concrete at discharge were more likely to become prosthetic non-users within 8 months of discharge. The evidence from this validation study needs to be implemented into the Western Australian amputee rehabilitation model of care where the current policy is to trial prosthetic gait retraining in people at risk of prosthetic non-use rather than targeting resources into improving quality of life, mobility support systems, home and community access. Translational research is required to determine if the health systems change of modifying clinical pathways for people at risk of prosthetic non-use improves clinical and cost outcomes in Western Australia. This study represents level III evidence in CPR research methodology. Future multicentre validation of these CPRs is warranted to generate the level II evidence for this CPR.

Chapter 6

6. Locomotor Performance During Rehabilitation of People With Lower Limb Amputation and Prosthetic Nonuse 12 Months After Discharge

Synopsis

This chapter is a manuscript published in Physical Therapy Journal:

Roffman, Caroline E., Buchanan, John, & Allison, Garry T. (2016). Locomotor Performance During Rehabilitation of People With Lower Limb Amputation and Prosthetic Nonuse 12 Months After Discharge. *Physical Therapy, 96*(7), 985-994. doi: 10.2522/ptj.20140164

This chapter was presented at the following conferences:
15th World Congress of the International Society for Prosthetics and Orthotics (ISPO), 22nd to 25th June 2015, Lyon, France.

Australian New Zealand Society for Vascular Surgery (ANZSVS), 13th to 16th October 2017, Perth, Western Australia

Momentum 2017 Physiotherapy Conference, Australian Physiotherapy Association, 19th to 21st October 2017, Sydney, Australia.

Research Report

Locomotor Performance During Rehabilitation of People With Lower Limb Amputation and Prosthetic Nonuse 12 Months After Discharge

Caroline E. Roffman, John Buchanan, Garry T. Allison

Background. It is recognized that multifactorial assessments are needed to evaluate balance and locomotor function in people with lower limb amputation. There is no consensus on whether a single screening tool could be used to identify future issues with locomotion or prosthetic use.

Objective. The purpose of this study was to determine whether different tests of locomotor performance during rehabilitation were associated with significantly greater risk of prosthetic abandonment at 12 months postdischarge.

Design. This was a retrospective cohort study.

Method. Data for descriptive variables and locomotor tests (ie, 10-Meter Walk Test [10MWT], Timed "Up & Go" Test [TUGT], Six-Minute Walk Test [6MWT], and Four Square Step Test [FSST]) were abstracted from the medical records of 201 consecutive participants with lower limb amputation. Participants were interviewed and classified as prosthetic users or nonusers at 12 months postdischarge. The Mann-Whitney *U* test was used to analyze whether there were differences in locomotor performance. Receiver operating characteristic curves were generated to determine performance thresholds, and relative risk (RR) was calculated for nonuse.

Results. At 12 months postdischarge, 18% (n=36) of the participants had become prosthetic nonusers. Performance thresholds, area under the curve (AUC), and RR of nonuse (95% confidence intervals [CI]) were: for the 10MWT, if walking speed was ≤0.44 ms^{-1} (AUC=0.743), RR of nonuse=2.76 (95% CI=1.83, 3.79; $P<.0001$); for the TUGT, if time was ≥21.4 seconds (AUC=0.796), RR of nonuse=3.17 (95% CI=2.17, 4.14; $P<.0001$); for the 6MWT, if distance was ≤191 m (AUC=0.788), RR of nonuse=2.84, (95% CI=2.05, 3.48; $P<.0001$); and for the FSST, if time was ≥36.6 seconds (AUC=0.762), RR of nonuse=2.76 (95% CI=1.99, 3.39; $P<.0001$).

Limitations. Missing data, potential recall bias, and assessment times that varied were limitations of the study.

Conclusions. Locomotor performance during rehabilitation may predict future risk of prosthetic nonuse. It may be implied that the 10MWT has the greatest clinical utility as a single screening tool for prosthetic nonuse, given the highest proportion of participants were able to perform this test early in rehabilitation. However, as locomotor skills improve, other tests (in particular, the 6MWT) have specific clinical utility. To fully enable implementation of these locomotor criteria for prosthetic nonuse into clinical practice, validation is warranted.

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Prosthetic nonuse, or abandonment of prosthetic use, after discharge from rehabilitation has been associated with several factors, including higher amputation level, multiple-limb amputation, older age, energy cost, atraumatic amputation cause, multiple comorbidities, poor premorbid mobility, impaired single-limb balance, delay to prosthetic gait retraining, locomotor skills at discharge, mobility aid use, cognition, pain, and psychosocial factors.[1–6] At 12 months, many individuals with lower limb amputation have discontinued using their prosthesis for locomotor activities,[1,7,8] and mortality rates up to 48% for individuals with atraumatic amputation[9,10] have been reported. In contrast to young or elderly able-bodied people,[11–14] those with lower limb amputation may have impaired speed, distance, and balance when walking.[15–19] However, there is limited knowledge[3,6,16,19,20] on how performance in these functional domains during rehabilitation relates to their future ability to perform daily living, work, or recreational activities using a prosthesis.

Clinical utility is the usefulness of a test at determining a diagnosis or outcome for an intervention and how effectively it can be implemented into clinical practice.[21] Some important elements of clinical utility include cost, equipment, training, time, safety, interpretation, and relevance of the test.[21] Although it is recognized that multifactorial assessments are needed to evaluate balance and locomotor function in people with lower limb amputation, there is no consensus on whether a single screening tool could be used to identify future issues with locomotion or prosthetic use.[22,23] The 10-Meter Walk Test (10MWT), Timed "Up & Go" Test (TUGT), Six-Minute Walk Test (6MWT), and Four Square Step Test (FSST) are examples of locomotor tests that may be used during rehabilitation after lower limb amputation.[16–20,22,24–27] Knowledge of walking speed, distance, and balance gained from these tests may inform health professionals about impairments that are potentially modifiable with physical therapy and prosthetic intervention. Normative population data and the implications of respiratory, cardiovascular, aging, and neurological disorders are established for the 10MWT, TUGT, 6MWT, and FSST.[12,14,28–33] However, there are limited studies that assist with interpretation of variation in locomotor performance of amputation cohorts or that identify people who are more likely to abandon prosthetic use within 12 months of discharge.[16,25]

In contemporary rehabilitation models of care for people with amputation, Medicare Functional Classification Level (MFCL) K-levels are the main criteria used to subjectively allocate prosthetic components.[16,34] Health professionals have been slow to adopt performance-based evidence into clinical practice.[16,34–36] Construct validity has been demonstrated through known group differences for MFCL K-levels and 6MWT distance[16] and for multiple faller classification in people with transtibial amputation and FSST time.[17] In cohorts with lower limb amputation, reliability has been reported for the 6MWT[25,37,38] and TUGT[18,25]; however, reliability has not been determined for the 10MWT[19,27,39,40] and FSST.[17] Concurrent validity has been demonstrated for the 10MWT,[19,27] 6MWT,[16] and TUGT[18] with other amputation outcome measures.

The majority of lower limb amputation cohort studies have used samples of convenience whose rehabilitation was completed many years prior to study recruitment[16,20,25,41] or controlled for characteristics such as amputation level.[17,37,38] Analysis of stable prosthetic user subgroups has minimized confounding factors that potentially affect locomotor performance in people with recent amputations (eg, stump and medical complications). However, these results cannot be readily generalized to early, heterogeneous cohorts undergoing rehabilitation after amputation. As prosthetic rehabilitation represents a potential lifelong cost to health care services, early detection of individuals at high risk of prosthetic nonuse by using performance criteria during rehabilitation may inform clinical decision making, lead to prosthetic innovations, and facilitate implementation of targeted models of care.[1]

The hypothesis generated for this study was: People who discontinue prosthetic use at 12 months postdischarge will have poorer performance results on locomotor tests during rehabilitation than those who sustain prosthetic use. Therefore, the study objective was to determine whether different tests of locomotor performance during rehabilitation were associated with significantly greater risk of prosthetic abandonment at 12 months postdischarge.

Method

Participants

A research assistant who was unknown to potential participants recruited and obtained informed verbal consent from participants.

Participants were included if they had at least one recent major lower limb amputation (ie, transtibial level or above) as their primary admission diagnosis; had multiple limb amputation; lived in the community; were ambulant before amputation surgery; were classified at MFCL K-levels 1 to 4; and had received prosthetic rehabilitation and been discharged from Royal Perth Hospital (RPH), the state center for rehabilitation after amputation. Recent major lower limb amputation was defined as surgery in the weeks or months preceding rehabilitation admission. This classification enabled identification of new cases of people undergoing rehabilitation for amputation from multidiagnostic cases with a past medical history of amputation (eg, fractured neck of femur, past amputation).

K-levels were assigned collaboratively in the postoperative period by the rehabilitation physician and senior physical therapist as part of the RPH assessment procedure for rehabilitation admission based on criteria outlined in the study by Roffman et al.[1] Abbreviated MFCL K-level definitions for this study were: K-level 0—nonambulatory; K-level 1—prosthesis used for transfers, limited or unlimited household ambulation; K-level 2—limited community ambulation; K-level 3—community ambulation; and K-level 4—high-level prosthetic use typical of a child, active adult, or athlete.[16]

Exclusion criteria for this study were: K-level 0 classification, unable to communicate, and did not consent to participate. K-level 0 participants were monitored through the multidisciplinary outpatient clinic for amputation rehabilitation for the duration of the study and remained at K-level 0.

Figure 1 details participant eligibility and recruitment into the study. A total of 307 consecutive potential participants were identified from the Amputee Physiotherapy Service database from June 2006 to July 2011, and 264 of these participants were classified at K-levels 1 to 4; however, 37 participants had died. Of the 211 eligible participants, a total of 201 were interviewed, and the final response rate was 95%. No interviewed participants died during the 12-month follow-up period.

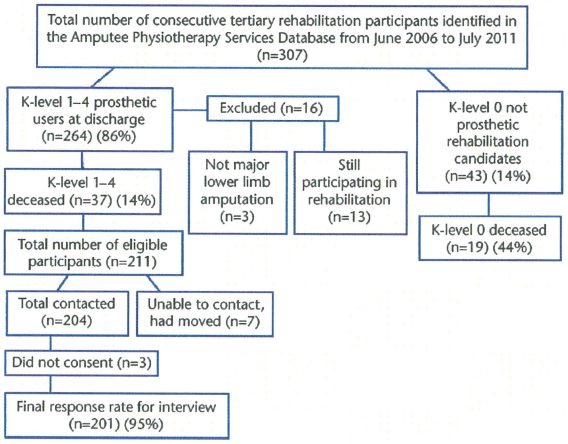

Figure 1.
Flowchart showing participant recruitment and eligibility for the study.

Rehabilitation Intervention

Royal Perth Hospital provides comprehensive multidisciplinary rehabilitation for approximately 85% of all individuals with lower limb amputation in Western Australia.[1,34] The 5 stages of rehabilitation for amputation,[42] service demographics, and rehabilitation interventions are shown in eFigure 1 (available at ptjournal.apta.org) (see Roffman et al[1] for full intervention details). Physical therapy commenced in the postoperative stage once participants were medically stable. K-level 0 to 4 participants received multidisciplinary inpatient rehabilitation. K-level 1 to 4 participants also attended 2 or 3 outpatient physical therapy sessions per week and were discharged when individualized rehabilitation goals were achieved.

Data Collection During Rehabilitation

The RPH senior physical therapist routinely assessed locomotor milestones to monitor rehabilitation progress and to facilitate client goal setting. Once participants were able to walk outside the parallel bars, they were assessed using the 10MWT, TUGT, 6MWT, and FSST. Procedures, scoring, and psychometric properties for these locomotor tests are reported in the eAppendix (available at ptjournal.apta.org). The senior physical therapist provided standardized training for all physical therapy staff in the center in performing the 10MWT, TUGT, 6MWT, and FSST, using standardized equipment. Physical therapy records were kept for participants who were unable to attempt, independently perform, or complete any of the locomotor tests, and for types of mobility aids if used. Locomotor tests were repeated as participants progressed from using mobility aids (eg, walking frames, elbow crutches and sticks) to walking without aids.

Procedure

Locomotor test data (ie, date, results, mobility aid use) and cohort descriptive variables were retrospectively abstracted from the medical records by the senior physical therapist, who was blinded to the participant interviews. Figure 2 details the abstracted descriptive variables, locomotor test data, and assessment time frames relative to physical therapy discharge.

In this study, above transtibial amputation level was defined as knee disarticulation level or above.[1] Major bilateral lower limb amputation was defined as transtibial amputation level or above of both lower limbs.[1] The type and number of medical comorbidities (including musculoskeletal pathology and mental health issues) were counted and recorded for each participant.[1] Charlson Comorbidity Index (CCI) and age-adjusted CCI were calculated[43–45] for each participant. The last participant assessment results obtained prior to discharge for 10MWT, 6MWT, TUGT, and FSST performance were analyzed in this study.

Participants were interviewed by the senior physical therapist regarding their prosthetic use, amputation, social, accommodation, demographic, and general health details from 4 months onward after discharge from physical therapy. To improve recall accuracy, participants were interviewed at approximately 2-month intervals after discharge from physical therapy and verbally prompted using important calendar events (eg, birthday, Christmas) on their prosthetic use over 12 months.[1] If participants were prosthetic nonusers, their reasons for nonuse and time at which they ceased prosthetic use after discharge from physical therapy were recorded.

The operational definition of prosthetic nonuse was permanent abandonment of prosthetic use for locomotor activities on any weekdays, or wearing a prosthesis only for cosmesis.[1] Participants who used their prosthesis for locomotor activities on one or more weekdays were clas-

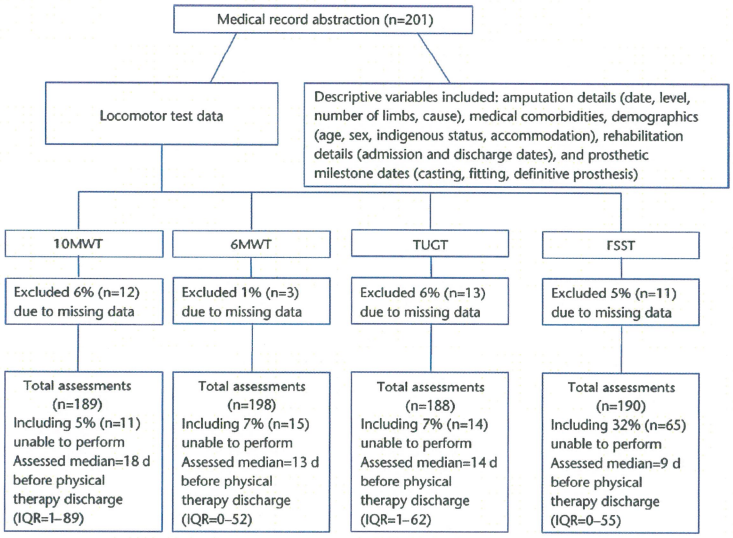

Figure 2.
Descriptive variables, available locomotor test data assessed during rehabilitation, and time frames relative to physical therapy discharge abstracted from the medical records. IQR=interquartile range, 10MWT=10-Meter Walk Test, 6MWT=Six-Minute Walk Test, TUGT=Timed "Up & Go" Test, FSST=Four Square Step Test.

sified as users.[1] Interview data on time elapsed from physical therapy discharge until prosthetic nonuse enabled classifying participants as users or nonusers at 12 months after discharge. Participants were monitored at the multidisciplinary outpatient clinic for amputation rehabilitation to ensure that those who became prosthetic nonusers had remained prosthetic nonusers.

Data Analysis

Walking speed (ms^{-1}), distance (meters), and time (seconds) were derived from the 10MWT, 6MWT, TUGT, and FSST data.

Shapiro-Wilk tests demonstrated that the locomotor test data were not normally distributed ($P<.01$). Nonparametric analyses using the Mann-Whitney U test (95% confidence intervals [95% CI]) were performed to determine whether differences were significant between rankings of locomotor test results for prosthetic users and nonusers.

The descriptive amputation, demographic, and comorbidity variables abstracted from the medical record were analyzed for prosthetic users and nonusers at 12 months postdischarge. Depending on data distribution, 2 population proportion z tests (95% CI) were used to determine whether there were any differences in descriptive variables for prosthetic users and nonusers.

Receiver operating characteristic (ROC) curves were used to generate the performance criteria that balanced sensitivity and specificity,[46,47] predicting prosthetic nonusers for the continuous variables of walking speed, distance, and time derived from the 10MWT, 6MWT, TUGT, and FSST. The nonparametric method of DeLong et al[46] was used to calculate ROC, performance thresholds, area under the curve (AUC), Youden index J, specificity, and sensitivity (95% CI). Optimal performance thresholds (criteria) for prosthetic nonuse were calculated for an equal balance of sensitivity and specificity at the maximum correct classification.[47] The Youden index J was the farthest vertical point on the ROC curve from the diagonal line of chance.[47] Area under the curve was calculated using the trapezoidal method.[46,47]

The risk stratification literature reports that when there is no difference between distributions of 2 groups for the investigated variable, AUC equals 0.5 and is not predictive; however, if there is perfect separation of these distributions, AUC equals 1, and the variable is highly predictive.[47–49] Threshold criteria were derived from 10MWT, 6MWT, TUGT, and FSST performance for prosthetic users and nonusers at 12 months postdischarge, using 2 × 2 contingency tables (95% CI). Relative risk (RR) was calculated as part of the chi-square analyses to determine the ratio of probability for the outcome of prosthetic nonuse.

Data Scoring and Reduction

Figure 2 details the percentage of participants with missing locomotor test data who were excluded from the statistical analyses. Participants with missing data did not systematically differ from the tested cohort in terms of demographic, comorbidity, or amputation details. The main reasons that locomotor test data

were missing included participants being medically unfit to attempt the test (eg, stump wound), declining to perform the test, or not attending their outpatient appointment.

Participants who were unable to complete or perform the assessment during rehabilitation were included in the statistical analyses (Fig. 2). These participants could not independently perform or attempt the locomotor tests (ie, required physical assistance from another person or used their prosthesis for transfers only). To enable statistical analyses, these participants were scored as 0 for the 10MWT and 6MWT (tests where low scores reflect poor performance)[32,33,50] and 999 for the TUGT and FSST (tests where high scores reflect poor performance). As nonparametric (distribution-free) statistics were used in this study, assigning the lowest score (0) and highest score (999) for participants who were unable to perform the test allowed this important subgroup to be analyzed.[51,52] This approach contributed to the external validity of the clinical study. Both parametric and nonparametric ROC and AUC methods have been demonstrated as robust and accurate for a wide range of distributions in continuous data.[52] Similar statistical management of participants unable to perform locomotor tests has been documented in the spinal and stroke literature.[32,33,50]

Role of the Funding Source

This study was supported by an International Society for Prosthetics and Orthotics (ISPO) Australia Research Grant.

Results

A total of 201 consecutive participants were interviewed from November 2009 to December 2012 at a median of 1.5 years (interquartile range=1.2–2.2) after discharge. At 12 months after discharge, 18% (n=36) of the participants were prosthetic nonusers. Table 1 outlines cohort characteristics from the medical record abstraction for prosthetic users and nonusers at 12 months. Prosthetic users and nonusers were similar in terms of age, demographics, amputation cause, and comorbidities ($P \geq .055$). However, prosthetic nonusers had significantly higher rates of cardiac conditions, transfemoral amputation, and residing in a metropolitan area and lower rates of transtibial amputation level than prosthetic users ($P \leq .015$).

Figure 2 details the percentage of participants who were unable to perform the 10MWT, 6MWT, TUGT, and FSST at discharge, and the time locomotor tests were assessed before physical therapy discharge. The 10MWT, 6MWT, TUGT, and FSST ROCs for prosthetic users and nonusers are demonstrated in eFigures 2–5 (available at ptjournal.apta.org), respectively.

Table 2 details locomotor test results for participants who were prosthetic users and nonusers at 12 months after discharge. Thresholds, AUC, and associated accuracy statistics (95% CI) for prosthetic nonuse at 12 months postdischarge were as follows (full details are shown in Tab. 3).

10MWT

If walking speed was ≤ 0.44 ms^{-1} (AUC=0.743; 95% CI=0.675, 0.804), RR of prosthetic nonuse increased to 2.76 (95% CI=1.83, 3.79; $P<.0001$).

TUGT

If time was greater than 21.4 seconds (AUC=0.796; 95% CI=0.731, 0.851), RR of prosthetic nonuse increased to 3.17 (95% CI=2.17, 4.14; $P<.0001$).

6MWT

If distance was 191 m or lower (AUC=0.788; 95% CI=0.724, 0.843), RR of prosthetic nonuse increased to 2.84 (95% CI=2.05, 3.48; $P<.0001$).

FSST

A very high number of the total cohort (32%, n=65) were recorded as unable to perform the FSST by discharge, consisting of 72% (n=26) nonusers and 25% (n=39) users. If time was 36.6 seconds or greater (AUC=0.762; 95% CI=0.694, 0.820), RR of prosthetic nonuse increased to 2.76 (95% CI=1.99, 3.39; $P<.0001$).

Self-reported reasons for prosthetic nonuse were multifactorial, with both modifiable and nonmodifiable issues reported (full details are shown in Tab. 4).

Discussion

Clinical Utility of Locomotor Tests Predicting Prosthetic Nonuse

The primary finding of this study was that locomotor test performances while in rehabilitation were significantly associated with the likelihood of an individual sustaining prosthetic use 12 months after discharge. The 4 tests used in this study (10MWT, TUGT, 6MWT, and FSST) represent an ascending continuum of locomotor skill acquisition during rehabilitation for people with lower limb amputation. The 10MWT has the lowest locomotor and cognitive demand, as it involves fast walking in a straight line early in rehabilitation. The TUGT incorporates the indoor locomotor skills of sit-to-stand, walking, and turning.[27] The 6MWT assesses cardiovascular capacity, which is required for community ambulation.[16] In our study, locomotor skill progression was demonstrated by the 6MWT prosthetic nonuse criterion of 191 m having a slightly faster walking speed of 0.53 ms^{-1} than the 10MWT criterion of 0.44 ms^{-1}. The FSST has the greatest locomotor and cognitive demand, as participants need to perform dual tasks by simultaneously stepping over obstacles while changing directions, skills required for walking in challenging environmental contexts.[17,53]

Although these locomotor tests vary in physical and cognitive demand, they all require the ability to modulate walking speed and control center of mass.[54] This common functional domain may be reflected in the fact that all of the locomotor tests had similar AUC and RR scores that suggest all the tests were moderately predictive (ie, AUC >0.7 and <0.9).[48,49] Therefore, to select one test in preference over another, the clinician would need to consider other factors affecting overall clinical utility.[21] All tests on the locomotor continuum (10MWT, TUGT, 6MWT, and FSST) are low cost and require minimal training, equipment, and time for implementation in health care settings.[21] In the context of a test that can be used safely by clinicians on the highest proportion of clients at an

Table 1.
Demographic, Comorbidity, and Amputation Details Abstracted From the Medical Records of People Who Remained Prosthetic Users and Became Prosthetic Nonusers at 12 Months After Discharge From Rehabilitation[a]

Demographic, Comorbidity, and Amputation Details	Prosthetic Users at 12 mo After Discharge (n=165)	Prosthetic Nonusers at 12 mo After Discharge (n=36)	*z* or *t* Score	*P* (α=.05)
Sex, male, n (%)	135 (82)	26 (72)	1.31	.190
Age at amputation (y), $\bar{X}$ (SD)	55.5 (15.2)	55.6 (17.0)	0.03	.98
Aboriginal, n (%)	23 (14)	6 (17)	−0.42	.674
Accommodation after discharge from inpatient rehabilitation, n (%)				
Home (not residential care)	162 (98)	34 (94)	1.30	.194
Metropolitan (not country)	87 (53)	27 (75)	−2.44	.015
CCI, median (IQR)	2 (1–4)	3 (1–4.2)	1.17	.241
Combined age CCI, median (IQR)	4 (1–6)	4.5 (2.8–7)	1.23	.219
Comorbidities, n (%)				
Diabetes				
Type 1	8 (5)	4 (11)	−1.44	.150
Type 2	71 (43)	13 (36)	0.76	.447
Peripheral arterial disease	85 (52)	21 (58)	−0.74	.459
Cardiac condition	54 (33)	21 (58)	−2.88	.004
Renal failure	24 (15)	8 (22)	−1.14	.254
Cerebrovascular accident/transient ischemic attack	14 (8)	3 (8)	0.03	.98
Arthritis	56 (34)	13 (36)	−0.25	.803
Remaining lower limb pathology	128 (78)	33 (92)	−1.92	.055
Amputation cause, n (%)				
Circulatory	39 (24)	13 (36)	−1.55	.121
Infection	74 (45)	13 (36)	0.96	.337
Trauma	44 (27)	10 (28)	−0.14	.889
Cancer	8 (5)	0 (0)	1.35	.177
Amputation level, n (%)				
Transtibial	140 (85)	23 (64)	2.91	.004
Knee disarticulation	6 (4)	1 (3)	0.25	.803
Transfemoral	41 (25)	21 (58)	−3.94	<.0001
Major bilateral lower limb amputation	22 (13)	9 (25)	−1.76	.08
Minor amputation of remaining limb	18 (11)	3 (8)	0.46	.65
Upper limb amputation	17 (10)	3 (8)	0.36	.72

[a] CCI=Charlson Comorbidity Index, IQR=interquartile ratio.

early stage of gait retraining within the hospital setting, the 10MWT may be suggested as having greatest clinical utility as a single screening tool for prosthetic nonuse. The 10MWT is widely used and benchmarked in health care for performance of activities of daily living across a variety of clinical conditions.[11,12,29,32,39,40,55] Having repeated assessments of walking speed also may be a valuable gauge to progressing rehabilitation. Walking speed has been shown to be more important than balance for achieving longer walking distances following stroke,[56] whereas reduced walking speed is a marker of capacity to ambulate in the community and mortality in other clinical cohorts.[32,33,57]

Although the 10MWT is able to be used earlier and on more clients with lower limb amputation in the hospital setting, our study supports previous findings[16] that the 6MWT is an important tool for identifying risk of prosthetic nonuse in the mid to later stages of rehabilitation. The 6MWT had the highest sensitivity, correctly classifying 80.6% of individuals who became prosthetic nonusers. This

Table 2.
Median (IQR) and Mann-Whitney *U* Test Performance Results for People Who Remained Prosthetic Users and Became Nonusers at 12 Months After Discharge[a]

Locomotor Test	Prosthetic Users (n=165) Median (IQR)	Prosthetic Nonusers (n=36) Median (IQR)	*U* Score	*z* Score	*P*
10MWT	0.72 (0.46–0.95)	0.31 (0.16–0.56)	4,094	4.54	<.001
6MWT	274 (156–371)	86 (0–177)	4,596	5.40	<.001
TUGT	12.5 (9–20.8)	35.4 (21.2–999[b])	4,356	5.52	<.001
FSST	17.5 (12–999[b])	999[b] (100–999[b])	4,222	4.88	<.001

[a] IQR=interquartile range, 10MWT=10-Meter Walk Test, 6MWT=Six-Minute Walk Test, TUGT=Timed "Up & Go" Test, FSST=Four Square Step Test.
[b] 999 represents median and IQR of participants who were unable to perform the test.

finding is in contrast to the 10MWT, which had a lower overall accuracy. Therefore, clinicians need to understand the value of different locomotor tests in rehabilitation and progress the locomotor test protocol as clients improve. Future research should examine the association between the changes in the 10MWT and 6MWT to elucidate if there is a recognizable subgroup in the amputation cohort that both tests could identify as high risk. It is likely that if factors that have been shown to affect 6MWT performance (eg, bilateral lower limb amputation, body mass, height,[41] and symptoms such as dyspnea, claudication, and musculoskeletal pain[58]) also affect prosthetic use after discharge, then potentially a combined test protocol could be more predictive.

In contrast to the 10MWT, TUGT, and 6MWT was the difficult dual-task paradigm of the FSST.[53] Regardless of being a significant predictor of nonuse, the FSST has limited clinical utility due to the high number of individuals who were unable to perform the test in the late stages of rehabilitation. Participants who could perform the FSST were at low risk of prosthetic nonuse.

Comparison of Locomotor Performance in Lower Limb Amputation and Other Cohorts

10MWT

Comfortable gait speed in able-bodied participants ranges from 1.39 ms^{-1} for men and 1.41 ms^{-1} for women aged in their second decade and slows to 1.33 ms^{-1} for men and 1.27 ms^{-1} for women aged in their seventh decade.[11] An interesting finding was that our walking speed criterion for prosthetic nonuse of ≤0.44 ms^{-1} was identical to the criterion for not being a community ambulator in people with incomplete spinal cord injury.[32,33] This speed may represent a minimum criterion for efficient walking in amputation cohorts, given inability to walk outdoors has been identified as an early predictor of discontinuing prosthetic use.[1] Walking speeds up to 1.3 ms^{-1} have been reported for individuals following traumatic amputations,[15,39,40] and walking speeds up to 0.75 ms^{-1} have been reported for individuals with vascular causes of unilateral lower limb amputation.[15] Waters et al[15] reported that walking speed in participants with lower limb amputation was reduced by 13% to 66% compared with able-bodied participants. Previous studies have shown slower walking speeds for people with older ages and transfemoral, bilateral, and vascular amputations.[15,19,39,40]

TUGT. Times ranging from 7.2 to 102 seconds and slower performance for older people with transfemoral and vascular amputation have been reported in the literature for the TUGT.[3,6,17,18,25,59] However, ceiling effects also have been noted for the TUGT in individuals with lower limb amputation and a high level of functioning.[27] A criterion of ≥19 seconds was reported for people with transtibial amputation performing the TUGT who became multiple fallers,[17] which is similar to the prosthetic nonuse criterion of ≥21.4 seconds in our study.

Table 3.
Locomotor Test Thresholds From Receiver Operating Characteristic Curve Analysis and Associated Accuracy Statistics (95% Confidence Interval) for People Who Became Prosthetic Nonusers at 12 Months After Discharge[a]

Locomotor Test	Performance Threshold (Criteria) for Prosthetic Nonuse	Sensitivity (%)	Specificity (%)	Area Under the Curve	Youden Index J	Relative Risk of Prosthetic Nonuse	*P*
10MWT	≤0.44 ms^{-1}	66.7 (49.0, 81.4)	75.8 (68.2, 82.4)	0.743 (0.675, 0.804)	0.425	2.76 (1.83, 3.79)	<.0001
6MWT	≤191 m	80.6 (64.0, 91.8)	71.6 (64.0, 78.4)	0.788 (0.724, 0.843)	0.522	2.84 (2.05, 3.48)	<.0001
TUGT	≥21.4 s	75.0 (57.8, 87.9)	78.3 (70.9, 84.6)	0.796 (0.731, 0.851)	0.533	3.17 (2.17, 4.14)	<.0001
FSST	≥36.6 s	80.6 (64.0, 91.8)	71.4 (63.6, 78.4)	0.762 (0.694, 0.820)	0.520	2.76 (1.99, 3.39)	<.0001

[a] 10MWT=10-Meter Walk Test, 6MWT=Six-Minute Walk Test, TUGT=Timed "Up & Go" Test, FSST=Four Square Step Test.

Table 4.
Multifactorial Reasons for Prosthetic Nonuse Self-Reported by Participants Who Were Prosthetic Nonusers at 12 Months After Discharge From Rehabilitation[a]

Multifactorial Self-Reported Reasons for Prosthetic Nonuse at 12 Months After Discharge From Rehabilitation	n (%)
Issues with residual limb	13 (36)
Prosthetic issues	10 (28)
Medical comorbidities	10 (28)
Issues with remaining lower limb	9 (25)
Pain issues	9 (25)
Falls or fear of falling	5 (14)
High energy cost	3 (8)
Unmotivated	3 (8)
Unable to don prosthesis	2 (6)
Balance issues	2 (6)

[a] Participants were able to report more than one reason for not using their prosthesis; therefore, the cumulative percentage exceeds 100.

6MWT. The 6MWT distance has been reported as ranging from 4 to 858 m in cohorts with lower limb amputation.[16,20,25,37,40,41] Inability to walk 200 m nonstop using a prosthesis was identified as a potential barrier to efficient community ambulation.[60] Gailey et al[16] reported that participants in K-level 0 to 1 (ie, prosthetic nonusers or prosthesis used for transfers or household ambulation) had a mean 6MWT distance of 49.86 m (SD=29.82). The 6MWT prosthetic nonuse criterion (≤191 m) in our study was similar to the limited community ambulator (K-level 2), with a mean of 189.9 m (SD=111.3).[16] Previous studies[40,41] have shown that 6MWT distance was significantly greater in people with transtibial, unilateral, and traumatic amputations.

FSST. A criterion of ≥24 seconds for the FSST has been reported for individuals with unilateral transtibial amputation who have multiple falls,[17] which is lower than the prosthetic nonuse criterion of 36.6 seconds in this current study. In this study of a heterogeneous cohort with bilateral, unilateral, and differing amputation levels, 32% of participants were unable to perform the FSST by discharge. Consistent with our findings, a longitudinal study of patients with stroke revealed that up to 15% were unable to perform the FSST.[61]

High variance of locomotor test performance results for this and other studies[16,18,41] may be explained by the temporal relationship with prosthetic fitting and the commencement of gait retraining in cohorts with different causes of amputation. The starting point of prosthetic gait retraining following surgery is rarely uniform in heterogeneous amputation cohorts (ie, may range from 21 days to 6 months or greater depending on stump wound or fracture healing) and may be affected by variabilities in service delivery models.[4,5] If walking is delayed, greater functional impairments in locomotor and balance skills are expected, as preprosthetic rehabilitation programs may not be of sufficient intensity to counteract the physiological effects of being nonambulant.[1] Diversity in amputation cohorts with factors such as amputation level, cause, age, skill level (eg, military service personnel), and comorbidities also contributes to variance in locomotor test performance.[23]

Prosthetic Nonuse

In this study, issues with the residual limb (ie, stump wounds), prosthetic issues, high burden of comorbid disease, remaining lower limb pathology, and pain were reported most frequently by participants as their multifactorial reasons for discontinuing prosthetic use, which was consistent with the literature.[1–5,60,62,63] These self-reported issues were supported by the fact that a significantly higher proportion of prosthetic nonusers in our study had transfemoral amputation–level and cardiac conditions, which have both been demonstrated as factors contributing to abandonment of prosthetic use.[1–5,16,60] Prosthetic technologies such as gel liners, componentry, and suspension techniques may have the potential to improve prosthetic use and satisfaction by addressing wound or prosthetic issues that are often associated with higher amputation levels.[62–64] Impaired balance, falls, and fear of falling were reported less frequently by participants as reasons for prosthetic nonuse, which was surprising because other studies[17,60,65,66] have reported prosthetic gait limitations due to multiple falls and fear of falling. Furthermore, validated predictors of prosthetic nonuse, such as mobility aid use and inability to walk outdoors on concrete,[1] are often related to balance impairment. Reasons for prosthetic nonuse reported by clients were multifactorial and complex, so further research to examine the relationship of these factors to locomotor and balance function is indicated.

Clinical and Research Implications

From a clinical perspective, knowledge of prosthetic nonuse indicators from locomotor performance across a continuum of clinical tests increasing in difficulty is very useful for appropriate goal setting, guiding treatment plans, prosthetic intervention required, and discharge planning. If clients do not achieve the 10MWT, TUGT, 6MWT, or FSST thresholds identified in this study, specific strategies should be adopted to optimize managing the client's daily needs given the high risk of prosthetic nonuse. These strategies include targeted rehabilitation to address modifiable impairments. Interventions may include gait retraining to improve walking efficiency in different environmental contexts; strength, speed, endurance, and balance exercises; prosthetic intervention; mobility aids; and adaptive equipment for carrying objects while walking. Furthermore, poor performance on locomotor tests may reflect greater issues with the model of care for people with amputation, such as delay to rehabilitation or inadequate intervention intensity to overcome impairments in muscular strength, joint range of motion, cardiovascular fitness, and balance.

From a research perspective, performance criteria for future prosthetic nonuse raise the question of whether there should be minimum locomotor test performance standards to be achieved by clients during an interim prosthetic trial before progressing to a definitive prosthesis or accessing more expensive prosthetic componentry. Furthermore, the minimum clinically important difference has yet to be established for the 10MWT, TUGT, 6MWT, and FSST in cohorts with amputation, so the value of improved

locomotor and balance function from rehabilitation intervention remains undefined.[16,17,25] These performance criteria for prosthetic nonuse may support clinical decisions and resource allocation; however, caution should be exercised as further research to validate the tests in a new cohort with lower limb amputation is necessary.

Limitations

There were some limitations in this study that have implications in interpretation of the results. There were some missing retrospective performance measure data, and the interview relied on participant recall, which are potential sources of bias. Individuals who were unable to attempt, independently perform, or complete the tests were included, but although their inclusion did not affect the distribution-free statistical analysis,[52] this subgroup highlights the limitations of the more difficult performance measures in heterogeneous cohorts with amputation. Assessment time frames for locomotor tests varied, as they were dependent on the participants' individualized rehabilitation progress. Future studies may control assessment timeframes. As this was a retrospective study, these locomotor criteria for prosthetic nonuse warrant prospective validation.

This study demonstrated that progressive tests of increasing locomotor and cognitive demand (ie, 10MWT, TUGT, 6MWT, and FSST) may be predictive of future prosthetic nonuse when used during hospital rehabilitation. It is the first study, to our knowledge, to generate criteria for the functional domains of walking speed, distance, and balance. It may be implied that the 10MWT has the greatest clinical utility as a single screening tool for prosthetic nonuse, given the highest proportion of participants were able to perform this test early in rehabilitation. However, as locomotor skills improve, other tests on the continuum (in particular, the 6MWT) have specific clinical utility. To fully enable implementation of these locomotor criteria for prosthetic nonuse into clinical practice, validation is warranted.

All authors provided concept/idea/research design, writing, fund procurement, institutional liaisons, and consultation (including review of manuscript before submission). Ms Roffman and Professor Buchanan provided data collection, project management, participants, and facilities/equipment. Ms Roffman and Professor Allison provided data analysis. Ms Roffman provided administrative support.

The Royal Perth Hospital and Curtin University human research ethics committees approved this study.

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References

1 Roffman CE, Buchanan J, Allison GT. 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;60:224–231.

2 Taylor SM, Kalbaugh CA, Blackhurst DW, et al. Preoperative clinical factors predict postoperative functional outcomes after major lower limb amputation: an analysis of 553 consecutive patients. *J Vasc Surg.* 2005;42:227–234.

3 Schoppen T, Boonstra A, Groothoff JW, et al. Physical, mental, and social predictors of functional outcome in unilateral lower-limb amputees. *Arch Phys Med Rehabil.* 2003;84:803–811.

4 Sansam K, Neumann V, O'Connor R, Bhakta B. Predicting walking ability following lower limb amputation: a systematic review of the literature. *J Rehabil Med.* 2009;41:593–603.

5 Webster JB, Hakimi KN, Williams RM, et al. Prosthetic fitting, use, and satisfaction following lower-limb amputation: a prospective study. *J Rehabil Res Dev.* 2012;49:1493–1504.

6 van Eijk MS, van der Linde H, Buijck B, et al. Predicting prosthetic use in elderly patients after major lower limb amputation. *Prosthet Orthot Int.* 2012;36:45–52.

7 Davies B, Datta D. Mobility outcome following unilateral lower limb amputation. *Prosthet Orthot Int.* 2003;27:186–190.

8 Pohjolainen T, Alaranta H, Kärkäinen M. Prosthetic use and functional and social outcome following major lower limb amputation. *Prosthet Orthot Int.* 1990;14:75–79.

9 Jones WS, Patel MR, Dai D, et al. High mortality risks after major lower extremity amputation in Medicare patients with peripheral artery disease. *Am Heart J.* 2013;165:809–815, 815e801.

10 Fortington LV, Geertzen JH, van Netten JJ, et al. Short and long term mortality rates after a lower limb amputation. *Eur J Vasc Endovasc Surg.* 2013;46:124–131.

11 Bohannon RW. Comfortable and maximum walking speed of adults aged 20-79 years: reference values and determinants. *Age Ageing.* 1997;26:15–19.

12 Asher L, Aresu M, Falaschetti E, Mindell J. Most older pedestrians are unable to cross the road in time: a cross-sectional study. *Age Ageing.* 2012;41:690–694.

13 Casanova C, Celli BR, Barria P, et al. The 6-min walk distance in healthy subjects: reference standards from seven countries. *Eur Respir J.* 2011;37:150–156.

14 Dite W, Temple VA. A clinical test of stepping and change of direction to identify multiple falling older adults. *Arch Phys Med Rehabil.* 2002;83:1566–1571.

15 Waters R, Perry J, Antonelli D, Hislop H. Energy cost of walking of amputees: the influence of level of amputation. *J Bone Joint Surg Am.* 1976;58:42–46.

16 Gailey RS, Roach KE, Applegate EB, et al. The Amputee Mobility Predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate. *Arch Phys Med Rehabil.* 2002;83:613–627.

17 Dite W, Connor HJ, Curtis HC. Clinical identification of multiple fall risk early after unilateral transtibial amputation. *Archives Phys Med Rehabil.* 2007;88:109–114.

18 Schoppen T, Boonstra A, Groothoff JW, et al. The timed "up and go" test: reliability and validity in persons with unilateral lower limb amputation. *Arch Phys Med Rehabil.* 1999;80:825–828.

19 Franchignoni F, Orlandini D, Ferriero G, Moscato TA. Reliability, validity, and responsiveness of the Locomotor Capabilities Index in adults with lower-limb amputation undergoing prosthetic training. *Arch Phys Med Rehabil.* 2004;85:743–748.

20 Raya MA, Gailey RS, Fiebert IM, Roach KE. Impairment variables predicting activity limitation in individuals with lower limb amputation. *Prosthet Orthot Int.* 2010;34:73–84.

21 Smart A. A multi-dimensional model of clinical utility. *Int J Qual Health Care.* 2006;18:377–382.

22 Heinemann AW, Connelly L, Ehrlich-Jones L, Fatone S. Outcome instruments for prosthetics: clinical applications. *Phys Med Rehabil Clin North Am.* 2014;25:179–198.

23 Stevens PM. Clinimetric properties of timed walking events among patient populations commonly encountered in orthotic and prosthetic rehabilitation. *J Prosthet Orthot.* 2010;22:62–74.

24 Rehabilitation Institute of Chicago, Center for Rehabilitation Outcomes Research, Northwestern University Feinberg School of Medicine, Department of Medical Social Sciences Informatics Group. Rehabilitation Measures Database. Available at: http://www.rehabmeasures.org/rehabweb/allmeasures.aspx?PageView=Shared. 2010. Accessed December 6, 2013.

25 Resnik L, Borgia M. Reliability of outcome measures for people with lower-limb amputations: distinguishing true change from statistical error. *Phys Ther.* 2011;91:555–565.

26 Condie E, Scott H, Treweek S. Lower limb prosthetic outcome measures: a review of the literature 1995 to 2005. *J Prosthet Orthot.* 2006;18:P13–P45.

27 Deathe AB, Miller WC. The L Test of Functional Mobility: measurement properties of a modified version of the Timed "Up & Go" Test designed for people with lower-limb amputations. *Phys Ther.* 2005;85:626–635.

28 Gardner AW, Katzel LI, Sorkin JD, Goldberg AP. Effects of long-term exercise rehabilitation on claudication distances in patients with peripheral arterial disease: a randomized controlled trial. *J Cardiopulm Rehabil Prev.* 2002;22:192–198.

29 Tilson JK, Sullivan KJ, Cen SY, et al. Meaningful gait speed improvement during the first 60 days poststroke: minimal clinically important difference. *Phys Ther.* 2010;90:196–208.

30 Shumway-Cook A, Brauer S, Woollacott M. Predicting the probability for falls in community-dwelling older adults using the Timed Up & Go Test. *Phys Ther.* 2000;80:896–903.

31 Jenkins SC. 6-Minute walk test in patients with COPD: clinical applications in pulmonary rehabilitation. *Physiotherapy.* 2007;93:175–182.

32 van Hedel HJ. Gait speed in relation to categories of functional ambulation after spinal cord injury. *Neurorehabil Neural Repair.* 2009;23:343–350.

33 Forrest GF, Hutchinson K, Lorenz DJ, et al. Are the 10 meter and 6 minute walk tests redundant in patients with spinal cord injury? *PloS One.* 2014;9:e94108.

34 Aged Care Network. *Amputee Services and Rehabilitation Model of Care*. Perth, Western Australia, Australia: Department of Health, Western Australia; 2008.

35 Gaunaurd I, Spaulding SE, Amtmann D, et al. Use of and confidence in administering outcome measures among clinical prosthetists: results from a national survey and mixed-methods training program. *Prosthet Orthot Int.* 2015;39:314–321.

36 Jette DU, Halbert J, Iverson C, et al. Use of standardized outcome measures in physical therapist practice: perceptions and applications. *Phys Ther.* 2009;89:125–135.

37 Lin SJ, Bose NH. Six-Minute Walk Test in persons with transtibial amputation. *Arch Phys Med Rehabil.* 2008;89:2354–2359.

38 Lahiri S, Das PG. Reliability of the Six-Minute Walk Test in individuals with transtibial amputation. *Indian J Physiother Occup Ther.* 2012;6:100–102.

39 Tekin L, Safaz Ý, Göktepe AS, Yazýcýoðlu K. Comparison of quality of life and functionality in patients with traumatic unilateral below knee amputation and salvage surgery. *Prosthet Orthot Int.* 2009;33:17–24.

40 Akarsu S, Tekin L, Safaz I, et al. Quality of life and functionality after lower limb amputations: comparison between uni- vs bilateral amputee patients. *Prosthet Orthot Int.* 2013;37:9–13.

41 Linberg AA, Roach KE, Campbell SM, et al. Comparison of 6-minute walk test performance between male active duty soldiers and servicemembers with and without traumatic lower-limb loss. *J Rehabil Res Dev.* 2013;50:931–940.

42 US Department of Veterans Affairs, Department of Defense. VA/DoD clinical practice guidelines for rehabilitation of lower limb amputation. 2008. Available at: http://www.healthquality.va.gov/guidelines/rehab/amp/. Accessed July 27, 2014.

43 Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chron Dis.* 1987;40:373–383.

44 Charlson M, Szatrowski TP, Peterson J, Gold J. Validation of a combined comorbidity index. *J Clin Epidemiol.* 1994;47:1245–1251.

45 Hall WH, Ramachandran R, Narayan S, et al. An electronic application for rapidly calculating Charlson comorbidity score. *BMC Cancer.* 2004;4:94.

46 DeLong ER, DeLong DM, Clarke-Pearson DL. Comparing the areas under two or more correlated receiver operating characteristic curves: a nonparametric approach. *Biometrics.* 1988;44:837–845.

47 Kumar R, Indrayan A. Receiver operating characteristic (ROC) curve for medical researchers. *Indian Pediatr.* 2011;48:277–287.

48 Vanagas G. Receiver operating characteristic curves and comparison of cardiac surgery risk stratification systems. *Interact Cardiovasc Thorac Surg.* 2004;3:319–322.

49 Fawcett T. An introduction to ROC analysis. *Pattern Recognit Lett.* 2006;27:861–874.

50 Scrivener K, Schurr K, Sherrington C. Responsiveness of the ten-metre walk test, Step Test and Motor Assessment Scale in inpatient care after stroke. *BMC Neurol.* 2014;14:129.

51 Conover WJ, Iman RL. Rank transformations as a bridge between parametric and nonparametric statistics. *Am Stat.* 1981;35:124–129.

52 Hajian-Tilaki KO, Hanley JA, Joseph L, Collet JP. A comparison of parametric and nonparametric approaches to ROC analysis of quantitative diagnostic tests. *Med Decis Making.* 1997;17:94–102.

53 McKee KE, Hackney ME. The Four Square Step Test in individuals with Parkinson's disease: association with executive function and comparison with older adults. *NeuroRehabilitation.* 2014;35:279–289.

54 Gibson W, Campbell A, Allison G. No evidence hip joint angle modulates intrinsically produced stretch reflex in human hopping. *Gait Posture.* 2013;38:1005–1009.

55 Scivoletto G, Tamburella F, Laurenza L, et al. Validity and reliability of the 10-m walk test and the 6-min walk test in spinal cord injury patients. *Spinal Cord.* 2011;49:736–740.

56 Awad LN, Reisman DS, Wright TR, et al. Maximum walking speed is a key determinant of long distance walking function after stroke. *Top Stroke Rehabil.* 2014;21:502–509.

57 Studenski S, Perera S, Patel K, et al. Gait speed and survival in older adults. *JAMA.* 2011;305:50–58.

58 ATS Committee on Proficiency Standards for Cardiopulmonary Function Laboratories. ATS statement: guidelines for the six-minute walk test. *Am J Respir Crit Care Med.* 2002;166:111–117.

59 Salavati M, Mazaheri M, Khosrozadeh F, et al. The Persian version of Locomotor Capabilities Index: translation, reliability and validity in individuals with lower limb amputation. *Qual Life Res.* 2011;20:1–7.

60 Gauthier-Gagnon C, Grisé MC, Potvin D. Enabling factors related to prosthetic use by people with transtibial and transfemoral amputation. *Arch Phys Med Rehabil.* 1999;80:706–713.

61 Blennerhassett JM, Jayalath VM. The Four Square Step Test is a feasible and valid clinical test of dynamic standing balance for use in ambulant people poststroke. *Arch Phys Med Rehabil.* 2008;89:2156–2161.

62 Sherman RA. Utilization of prostheses among US veterans with traumatic amputation: a pilot survey. *J Rehabil Res Dev.* 1999;36:100–108.

63 Karmarkar AM, Collins DM, Wichman T, et al. Prosthesis and wheelchair use in veterans with lower-limb amputation. *J Rehabil Res Dev.* 2009;46:567–576.

64 Hoskins RD, Sutton EE, Kinor D, et al. Using vacuum-assisted suspension to manage residual limb wounds in persons with transtibial amputation: a case series. *Prosthet Orthot Int.* 2014;38:68–74.

65 Miller WC, Speechley M, Deathe B. The prevalence and risk factors of falling and fear of falling among lower extremity amputees. *Arch Phys Med Rehabil.* 2001;82:1031–1037.

66 Miller WC, Deathe AB, Speechley M, Koval J. The influence of falling, fear of falling, and balance confidence on prosthetic mobility and social activity among individuals with a lower extremity amputation. *Arch Phys Med Rehabil.* 2001;82:1238–1244.

eAppendix.

Procedures, Scoring, and Psychometric Properties for the Locomotor Tests[a]

Participants were tested using standardized methods and equipment for the locomotor tests. In this study, independent walking was defined as being able to walk without physical assistance from another person. No physical assistance was provided during the 10MWT, TUGT, 6MWT, and FSST. No encouragement was provided during the 10MWT, TUGT, and FSST; however, encouragement was provided for the 6MWT, as per the American Thoracic Society guidelines.[58] Type of mobility aid used and failure to perform the locomotor test were dated and recorded on the physical therapy data collection sheet for all test trials. Psychometric properties and methods of the 10MWT, 6MWT, TUGT, and FSST were as follows:

10MWT

In a cohort with unilateral lower limb amputation, 10MWT time was demonstrated as having concurrent validity with the LCI5 score ($r=-.708$, $P\leq.0001$)[19]and L test ($r=.97$).[27] Studies[19,27,39,40] using the 10MWT with lower limb amputation cohorts did not report reliability; however, good interrater and intrarater reliability up to .98 and .99, respectively, have been demonstrated in the spinal cord injury cohort.[55] The procedure for the 10MWT is outlined in the studies by Tilson et al[29] and van Hedel.[32] Four markers were placed on the 14-m walking track. Participants had 2 m of acceleration (flying start) and deceleration.[32] Time and number of steps were recorded for the middle 10 m. The 10MWT was not demonstrated to participants. Participants were instructed to walk as fast as they could for the whole distance.[32] Time to perform the 10MWT was recorded using a digital stopwatch. Participants performed the 10MWT 3 times, with rest between trials. The 3 time trials were recorded on the data collection sheet. To score participants, the average of the 2 best trials (in seconds) was calculated, and time (in seconds) was recorded as the score. This average time was used to calculate walking speed. Walking speed was calculated by dividing distance by time and recording speed as meters per second. Participants who were unable to attempt or walk 10 m independently with or without a mobility aid were scored as unable to perform the task. No time limit was set for completion of this test.

TUGT

The TUGT has been reported as a valid and reliable measure in individuals with unilateral lower limb amputation, with ICCs up to .96,[18,25] intrarater reliability of .93,[18] and interrater reliability of .96.[18] The procedure for the TUGT is outlined in Schoppen et al.[18] Participants were instructed to move from sitting in a standard chair (46-cm seat height, 76-cm armrest height), walk 3 m to a marker, turn around, walk back, and sit down. The TUGT was demonstrated to participants. Time to perform the TUGT was recorded using a digital stopwatch. No time limit was set for completion of this test. Participants performed the TUGT 3 times, with rest between trials. The 3 time trials were recorded on the data collection sheet. To score this test, the best trial was used for data analysis. Participants who were unable to attempt or independently walk 3 m, turn around, and walk back, with or without a mobility aid, were scored as unable to perform this task.

6MWT

The 6MWT has good retest reliability, with ICCs up to .97.[25,37] Intrarater and interrater reliability have been reported up to .83 and .88, respectively, for the 6MWT in individuals with unilateral transtibial amputation.[38] Concurrent validity has been demonstrated between 6MWT performance and the AMP with no prosthesis ($r=.69$, $P<.0001$) and AMP with prosthesis ($r=.82$, $P<.0001$).[16] The procedure for the 6MWT is outlined in the American Thoracic Society Guidelines[58] and Linberg et al.[41] Participants were instructed to walk as many laps as possible of a marked, rectangular walking track in 6 minutes.[41] A rectangular track (with a total distance of 100 m, length of 35 m, and width of 15 m) was used, so 180° pivot turns were not required to ensure the safety of participants with bilateral amputation or balance issues and minimize the impact of turning on cadence.[41] Participants were told that they could stop and rest as needed. Participants were not given a 6MWT demonstration and performed only one trial. Distance was measured using a handheld wheel pedometer while walking behind the participant to minimize the risk of pacing during the test.[16] Time to 6 minutes and the number and duration of rests were recorded using a digital stopwatch. Distance walked, rating of perceived exertion, and number and time of rests were recorded on the data collection sheet. To score this test, maximum walking distance for 6 minutes was used, and participants who were unable to attempt or independently walk with or without a mobility aid were scored as unable to perform the test. No minimum walking distance was set for this test.

FSST

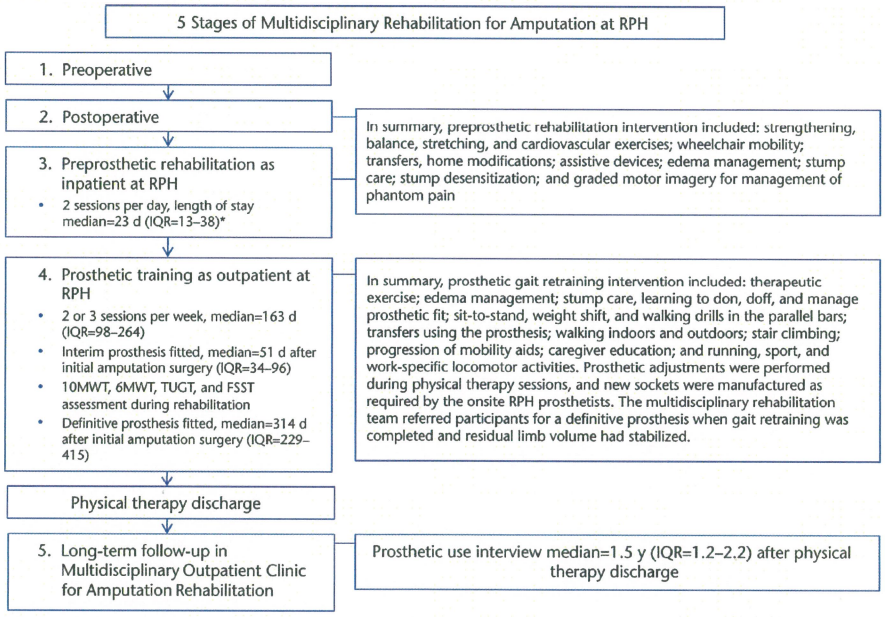
Reliability has not been established in cohorts with lower limb amputation.[17] However, in a geriatric cohort of multiple fallers, both ICC and interrater reliability of the FSST were reported as .99.[14] Construct validity has been demonstrated for the FSST, as it discriminates multiple faller classification in people with transtibial amputation and FSST time.[17] Concurrent validity of the FSST with the TUGT ($r=.88$, $P<.001$), Step Test ($r=-.83$, $P<.001$), and Functional Reach Test ($r=-.47$, $P<.001$) also were demonstrated in a geriatric cohort.[14] The full procedure and scoring for FSST are outlined in Dite and colleagues.[14,17] Four walking canes arranged to form a cross and a digital stopwatch were used to administer this test. Participants were instructed to step forward over the canes in a clockwise direction from square 1 so that both feet were in square 2, then to the right into square

(Continued)

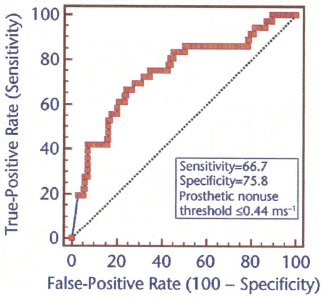
eAppendix.
Continued

3, backward into square 4 and to the left into square 1, and then in reverse order in an anticlockwise direction to step to the right into square 4, forward into square 3, to the left into square 2, and backward into square 1 to complete the task. The FSST was demonstrated to participants. No time limit was set for completion of this task. However, the participants were instructed to complete the task as fast as possible without touching a cane and to try to remain facing forward during the task.[14,17] If the participants touched a cane, the trial was scored as a failed attempt. Participants performed the FSST 3 times, with rest between trials. The 3 time trials were recorded on the data collection sheet, and the best time trial was used for data analysis. Participants who were unable to attempt, independently perform the test with or without a mobility aid, or step over without touching canes were scored as unable to perform the test.

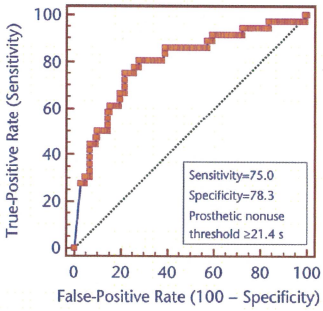
[a] 10MWT=10-Meter Walk Test, 6MWT=Six-Minute Walk Test, TUGT=Timed "Up & Go" Test, FSST=Four Square Step Test, LCI5=Locomotor Capabilities Index 5, ICC=intraclass correlation coefficient, AMP=Amputee Mobility Predictor.



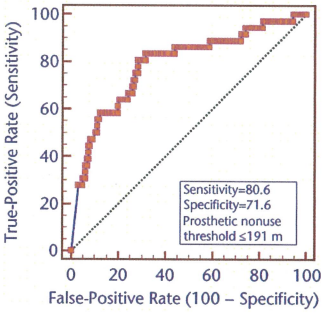
eFigure 1.
Multidisciplinary model of care at Royal Perth Hospital (RPH), the state center for rehabilitation after amputation, with 5 stages of rehabilitation, summary of rehabilitation interventions, and service demographics for participants.[1,42] IQR=interquartile range, 10MWT=10-Meter Walk Test, 6MWT=Six-Minute Walk Test, TUGT=Timed "Up & Go" Test, FSST=Four Square Step Test. *91% (n=182) of the participants had 237 inpatient rehabilitation episodes, 71% (n=142) had a single episode, 20% (n=40) had multiple-episode inpatient rehabilitation admissions, and 9% (n=19) did not have an RPH inpatient rehabilitation admission.



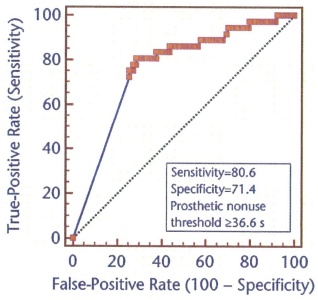
eFigure 2.
Receiver operating characteristic curve for 10-Meter Walk Test gait speed in prosthetic users and nonusers. Dashed line is the line of chance.



eFigure 4.
Receiver operating characteristic curve for Timed "Up & Go" Test time in prosthetic users and nonusers. Dashed line is the line of chance.



eFigure 3.
Receiver operating characteristic curve for Six-Minute Walk Test distance in prosthetic users and nonusers. Dashed line is the line of chance.



eFigure 5.
Receiver operating characteristic curve for Four Square Step Test time in prosthetic users and nonusers. Dashed line is the line of chance.

Chapter 7 Construct validity of locomotor tests

7. Construct validity of locomotor tests in people with lower limb amputation.

Introduction

There has been limited research on the psychometric properties of locomotor tests that may be used by health professionals during prosthetic rehabilitation and in the long term follow-up stage of rehabilitation for people with lower limb amputation (Heinemann et al., 2014; Resnik & Borgia, 2011). Validity is when a test accurately measures the domain it was designed to test (Hattie & Cooksey, 1984; Heale & Twycross, 2015). The 3 main categories of validity are content, construct and criterion validity (Hattie & Cooksey, 1984). An improved understanding of a test's validity contributes to clinical utility by assisting health professionals with interpretation of the test in the cohort of interest (Smart, 2006).

Predictive validity is a sub-type of criterion validity that is present if a test can identify a future outcome (Hattie & Cooksey, 1984). Chapter 6 of this thesis explored whether locomotor tests performed during rehabilitation had predictive validity, by developing performance thresholds for locomotor tests that identified increased risk of prosthetic non-use at 12 months after discharge (Roffman et al., 2016b).

Construct validity is a form of validity that is present when a test effectively measures a construct or abstract concept (Megens, Harris, Backman, & Hayes, 2007). The known groups method has been used to establish construct validity of a test by statistically distinguishing between 2 groups that are clinically known to differ and validated across multiple sources in the literature (Hattie & Cooksey, 1984; Megens et al., 2007). The known groups method has been used to test the scale of outcome measures in many clinical cohorts including lower limb amputation, stroke and infants with neuromotor delay (Gailey et al., 2002; Gailey et al., 2013; Golicki et al., 2015; Megens et al., 2007).

Gailey et al. (2002) used the known groups method to demonstrate the construct validity of the Amputee Mobility Predictor (AMP) for Medicare Functional Classification Levels (MFCL). Construct validity was tested in people with different levels of amputation for the Comprehensive High-Level Amputee Mobility Predictor (CHAMP) (Gailey et al., 2013).

Convergent validity is a sub-type of construct validity that is present when a test correlates with other tests that measure a similar domain (Heale & Twycross, 2015). Convergent validity can be calculated parametrically using the Pearson correlation and non-parametrically using the Spearman rank correlation depending on the data distribution (Golicki et al., 2015; Lin & Bose, 2008).

Part A

Balance and Locomotor function in known groups with lower limb amputation at high risk of prosthetic non-use.

Part B

Activity and participation levels after discharge from rehabilitation self reported by people with lower limb amputation.

Chapter 7 of this thesis investigated construct and convergent validity of locomotor tests that may be used following lower limb amputation. In **part A** of Chapter 7 the locomotor tests including the 10 metre walk test (10MWT), timed up and go test (TUGT), 6 minute walk test (6MWT) and Four Square Step Test (FSST) were analysed using the known groups method and for convergent validity. In **part B** the locomotor capabilities index 5 (LCI5) was analysed using the known groups method. Long term, self reported activity and participation levels of people with lower limb amputation were

also measured in **part B**. In these studies, the known groups that were identified from the literature as at high risk of prosthetic non-use include people with above transtibial amputation level, bilateral lower limb amputation, diabetes, Aboriginal ethnicity, older age (≥ 58), atraumatic cause and high comorbidities (≥ 19) (Roffman et al., 2014; Sansam et al., 2009; Schoppen et al., 2003; Taylor et al., 2005; van Eijk et al., 2012; Vos et al., 2009; Webster et al., 2012). In this study, part-time prosthetic users (people who functionally use their prosthesis < 7 days per week) were also included as a high risk group for prosthetic non-use in the known groups analysis. Key points from the studies in **part A and B** have been summarised in the **combined discussion** at the end of chapter 7.

Chapter 7-A

Part A

7.1. Balance and Locomotor function in known groups with lower limb amputation at high risk of prosthetic non-use.

Synopsis

This chapter reports findings of a known groups analysis for performance measures including the 10MWT, TUGT, 6MWT and FSST that may be used during rehabilitation of people with lower limb amputation. The chapter forms a manuscript being prepared for peer review submission.

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15thWorld Congress of the International Society for Prosthetics and Orthotics (ISPO), 22nd to 25th June 2015, Lyon, France.

Australian New Zealand Society for Vascular Surgery (ANZSVS), 13th to 16th October 2017, Perth, Western Australia

Momentum 2017 Physiotherapy Conference, Australian Physiotherapy Association, 19th to 21st October 2017, Sydney, Australia.

Abstract

Background: There is limited data for balance and locomotor performance of people with lower limb amputation who are undergoing rehabilitation to inform clinical decision making.

Objectives: To gain knowledge on the balance and locomotor skills of known groups at high risk of discontinuing prosthetic use and test the construct validity of the 10MWT, TUGT, 6MWT and FSST in these groups.

Design: Retrospective cohort study

Methods: Descriptive variables and 10m walk (10MWT), timed up and go (TUGT), 6 minute walk (6MWT) and four square step (FSST) tests were abstracted from the medical records for 201 consecutive participants with lower limb amputation. Participants were classified as in known high or low risk groups and the Mann Whitney U Test was used to analyse if there were differences in locomotor test performance.

Results: Performance on locomotor tests were significantly impaired for people in known groups at high risk of prosthetic non-use including those with above transtibial amputation level, older age, bilateral amputation and high comorbidities ($p \leq .025$). However, performance on locomotor tests, were not significantly different ($p \geq .449$) for Aboriginal people and on the 10MWT and TUGT for the diabetes and atraumatic sub-groups ($p \geq .075$).

Limitations: Missing data, low numbers of participants in some known groups and assessment times varied.

Conclusions: The 10MWT, TUGT, 6MWT and FSST have construct validity as they significantly differentiated between the locomotor performance of known groups at high risk of prosthetic non-use including above transtibial amputation level, older age, bilateral amputation and high comorbidities. However, it appears that the 6MWT was the best marker of locomotor performance during rehabilitation as it distinguished between all the groups at high and low risk of prosthetic non-use.

Key words: *Performance measures, lower extremity, amputation, leg prosthesis, rehabilitation outcome*

Balance and Locomotor function in known groups with lower limb amputation at high risk of prosthetic non-use.

7.1.1. Introduction

Locomotor tests may be used during prosthetic rehabilitation of people with lower limb amputation as they provide health professionals with objective information on a client's potential to walk indoors, outdoors and to negotiate obstacles in complex walking environments (Dite et al., 2007; Franchignoni et al., 2004; Gailey et al., 2002; Schoppen et al., 1999). Although locomotor tests measure rehabilitation outcome and enhance communication between clients, clinicians, administrators and funding organisations less than 50% of health professionals routinely use locomotor tests during rehabilitation (Gaunaurd et al., 2015; Jette et al., 2009; Wong et al., 2016a). Some commonly perceived barriers to the implementation of locomotor tests in clinical practice include lack of time, space, equipment, knowledge, training and confidence with test administration and difficulty with interpretation (Gaunaurd et al., 2015; Jette et al., 2009).

To assist with interpretation of locomotor tests in lower limb amputation cohorts Roffman et al. (2016b) developed performance criteria for the 10 metre walk test (10MWT), Timed up and go test (TUGT), 6 minute walk test (6MWT) and Four square step test (FSST) that were moderately predictive of prosthetic non-use after discharge (see Table 7.1A). This study established predictive validity and clinical utility for the 10MWT, TUGT, 6MWT and FSST during amputee rehabilitation as clients' locomotor skills progressed (Roffman et al., 2016b).

One of the gaps identified in the literature was the need for a known groups analysis to improve understanding of balance and locomotor skills in sub-groups at high risk of abandoning prosthetic use after rehabilitation discharge (Heinemann et al., 2014; Roffman et al., 2016b; Rogers & Stevens, 2015a, 2015b; Stevens, 2010; Wong et al., 2016a). Known groups analyses have been used to determine construct validity for tests

Table 7.1A: Performance measure thresholds from ROC curve analysis and associated accuracy statistics (95% CI) for people who become prosthetic non-users at 12 months after discharge

Performance Measure	Optimal Performance Threshold (Criteria) for Prosthetic Non-use (Roffman et al., 2016b)	Sensitivity (%)	Specificity (%)	Area Under the Curve	Youden Index J	Relative Risk of prosthetic non-use	p value
10MWT	$\leq$ 0.44 ms^{-1}	66.7 (49.0 to 81.4)	75.8 (68.2 to 82.4)	0.743 (0.675 to 0.804)	0.425	2.76 (1.83 to 3.79)	< .0001
6MWT	$\leq$ 191 m	80.6 (64.0 to 91.8)	71.6 (64.0 to 78.4)	0.788 (0.724 to 0.843)	0.522	2.84 (2.05 to 3.48)	< .0001
TUGT	$\geq$ 21.4 s	75.0 (57.8 to 87.9)	78.3 (70.9 to 84.6)	0.796 (0.731 to 0.851)	0.533	3.17 (2.17 to 4.14)	< .0001
FSST	$\geq$ 36.6 s	80.6 (64.0 to 91.8)	71.4 (63.6 to 78.4)	0.762 (0.694 to 0.820)	0.520	2.76 (1.99 to 3.39)	< .0001

(Roffman et al., 2016b).

by demonstrating ability to significantly distinguish between groups that are known to differ in the literature based on the presence or absence of a characteristic (Gailey et al., 2002; Gaunaurd, 2012; Hattie & Cooksey, 1984; Megens et al., 2007). Another form of construct validity is convergent validity which is demonstrated when a high level of correlation exists between tests that measure similar functional domains (Gailey et al., 2013; Gaunaurd, 2012). An example of convergent validity is increased 6MWT distance as time decreases for TUGT (Bhangu et al., 2009).

People at high risk of discontinuing prosthetic use include those with above transtibial amputation level, bilateral lower limb amputation, diabetes, Aboriginal ethnicity, older age, atraumatic cause and high comorbidities (Roffman et al., 2014; Sansam et al., 2009; Schoppen et al., 2003; Taylor et al., 2005; van Eijk et al., 2012; Vos et al., 2009; Webster et al., 2012). These high risk groups have impairments that potentially reduce walking speed, distance and balance limiting their ability to perform locomotor activities with a prosthesis but in contrast to other clinical populations (Asher, Aresu, Falaschetti, & Mindell, 2012; Dite & Temple, 2002; Forrest et al., 2014; Gardner, Katzel, Sorkin, & Goldberg, 2002; Jenkins, 2007; Shumway-Cook, Brauer, & Woollacott, 2000; Tilson et al., 2010; van Hedel, 2009) there is a paucity of performance data to assist with interpretation of locomotor tests in lower limb amputation cohorts (Akarsu, Tekin, Safaz, Goktepe, & Yazicioglu, 2013; Dite et al., 2007; Gailey et al., 2002; Heinemann et al., 2014; Resnik & Borgia, 2011; Stevens, 2010).

People with high level and bilateral lower limb amputation may have impaired locomotor and balance function due to the increased energy cost of walking, decreased lever length of their residual limb and lack of proprioception from multiple prosthetic joint components (Akarsu et al., 2013; Erjavec et al., 2014; Gailey et al., 2002; Gaunaurd, 2012; Starholm et al., 2016; Su, Gard, Lipschutz, & Kuiken, 2008). Asymmetrical movement patterns have been identified in biomechanical studies as contributing to slower performance of locomotor activities such as sit to stand in people with unilateral lower limb amputation (Agrawal, Gailey, Gaunaurd, Gailey, & O'Toole, 2011; Burger, Kuzelicki, & Marincek, 2005). Reduced walking speed, distance and

balance have been reported for older participants with atraumatic causes of amputation (Erjavec et al., 2014; Schoppen et al., 1999; Su et al., 2008; van Eijk et al., 2012; Waters et al., 1976). In many of these atraumatic cases of amputation the remaining limb is in a pre-amputation state with claudication pain or diabetic peripheral neuropathy limiting locomotor performance. It is unclear which locomotor tests are most valid in the clinical setting for assessment of heterogenous rehabilitation cohorts that have high variance in physical fitness, amputation cause, age and comorbidities. To date studies have been small, focused samples of convenience (e.g. military service personnel, experienced prosthetic users), specific groups (e.g. unilateral, transtibial) or have involved biomechanical analyses that are not easily replicated in busy clinical settings (Agrawal et al., 2011; Akarsu et al., 2013; Burger et al., 2005; Resnik & Borgia, 2011).

In Aboriginal people (who were the first inhabitants of Australia), poor health outcomes due to geographical isolation from health services, high diabetes related amputation and mortality rates have been well documented (Norman et al., 2010; Vos et al., 2009). Language barriers, cultural and health beliefs also have the potential to impact on access to healthcare and functional outcome following lower limb amputation (Schoen et al., 2010). However, amputation has been the primary endpoint of research and performance on locomotor tests using a prosthetic limb has not been investigated for Aboriginal people (Norman et al., 2010; Schoen et al., 2010; Vos et al., 2009).

The hypotheses for this generated study were:
1. That people with lower limb amputation in known groups at high risk of abandoning prosthetic use will have slower walking speeds, reduced distance and increased time for balance tasks on locomotor tests than those in lower risk groups during rehabilitation; and
2. That the 10MWT, TUGT, 6MWT and FSST will be highly correlated as they all test a common domain of locomotor function.

Therefore, the study objectives were to gain knowledge on the balance and locomotor skills of known groups at high risk of abandoning prosthetic use and test the construct validity of the 10MWT, TUGT, 6MWT and FSST.

7.1.2. Methods

Participants

The Royal Perth Hospital (RPH) and Curtin University Human Research Ethics Committees approved this study (full details in Appendix 3.1). A research assistant who was unknown to potential participants recruited and obtained informed verbal consent from participants to abstract details from the medical records.

Participants were included if: they had at least one recent major lower limb amputation (i.e. transtibial level or above) as their primary admission diagnosis, multiple limb amputation, lived in the community, were ambulant before amputation surgery, were Medicare Functional Classification Level (MFCL) K-level 1 to 4, had received prosthetic rehabilitation and been discharged from Royal Perth Hospital (RPH), the state centre for amputee rehabilitation. Recent major lower limb amputation was defined as surgery in the weeks or months preceding rehabilitation admission. This classification enabled identification of new amputee rehabilitation cases from multi-diagnostic cases with past medical history of amputation (e.g. fractured neck of femur and past amputation).

K-levels were assigned collaboratively in the post-operative period by the Rehabilitation Physician and Senior Physiotherapist (who had 10 years of clinical experience in amputee rehabilitation) as part of the RPH assessment procedure for rehabilitation admission based on criteria outlined in Roffman et al. (2014). K-levels have been defined by Gailey et al. (2002).

K-level 0 participants and those who did not consent were excluded from this study. K-level 0 participants were monitored through the multidisciplinary amputee outpatient clinic for the duration of this study and remained K-level 0.

The flow chart in Chapter 6 Figure 1 details participant eligibility and recruitment into this study. A total of 307 consecutive potential participants were identified from the Amputee Physiotherapy Service Database from June 2006 to July 2011 and 264 of these participants were K-level 1 to 4 however 37 participants were deceased. A total of 201 of the 211 eligible participants (95%) were recruited for this study.

Rehabilitation Intervention

RPH, the state centre for amputee rehabilitation, provides comprehensive multidisciplinary rehabilitation for approximately 85% of all individuals with lower limb amputation in Western Australia (Department of Health, 2008; Roffman et al., 2014). Chapter 6, eAppendix, eFigure 1 summarises the 5 stages of amputee rehabilitation at RPH (Department of Health, 2008; Department of Veterans Affairs, 2008), service demographics and rehabilitation interventions (see Chapter 2, Appendix 2.1 and Roffman et al. (2016b) for full intervention details). Physiotherapy commenced in the post-operative stage once participants were medically stable. To achieve discharge home to the community, K-level 0 to 4 participants received multidisciplinary inpatient rehabilitation. K-level 1 to 4 participants received approximately 2 to 3 sessions per week of outpatient physiotherapy with discharge determined by individualised rehabilitation goals.

Data Collection During Rehabilitation

The RPH amputee rehabilitation senior physiotherapist routinely assessed locomotor milestones to monitor rehabilitation progress and for patient goal setting. Once participants were able to walk outside the parallel bars they were assessed using the 10MWT, TUGT, 6MWT and FSST. Procedures, scoring and psychometric properties for these performance measures are reported in Chapter 6 e-appendix. The senior physiotherapist amputee rehabilitation trained all physiotherapy staff working in the amputee rehabilitation division in the standardised administration procedures for the 10MWT, TUGT, 6MWT and FSST. The physiotherapy staff trained in locomotor test administration, had 1 to 10 years of clinical experience. Standardised equipment was used to administer these tests for all participants. Type of mobility aids used and if

participants were unable to attempt, independently perform or complete any of the performance measures were recorded on the physiotherapy data collection sheet. The physiotherapist repeated performance measure assessments as participants progressed during rehabilitation from using mobility aids (e.g. walking frames, elbow crutches and sticks) to walking without aids.

Procedure

Performance measure data (i.e. date, results, mobility aid use) and cohort descriptive variables were retrospectively abstracted from the medical records by the senior physiotherapist. Chapter 6 Figure 2 details the abstracted descriptive variables, performance measure data and assessment timeframes relative to physiotherapy discharge.

In this study, above transtibial amputation level was defined as knee disarticulation level or above (Roffman et al., 2014). Major bilateral lower limb amputation was defined as transtibial amputation level or above of both lower limbs (Roffman et al., 2014). The type and number of medical comorbidities (including musculoskeletal pathology and mental health issues) were counted and recorded for each participant (Roffman et al., 2014). Charlson Comorbidity Index (CCI) and age adjusted CCI were calculated (Charlson et al., 1987; Charlson, Szatrowski, Peterson, & Gold, 1994; Hall et al., 2004) for each participant. 10MWT, 6MWT, TUGT and FSST performance assessed closest to discharge were analysed for this study.

Statistical analysis

Walking speed (ms^{-1}), distance (metres) and time (seconds) were derived from the 10MWT, 6MWT, TUGT and FSST data. In this study, the known groups at high risk of prosthetic non-use were identified from review of the literature (Roffman et al., 2014; Sansam et al., 2009; Schoppen et al., 2003; Taylor et al., 2005; van Eijk et al., 2012; Vos et al., 2009; Webster et al., 2012) and included: Aboriginal ethnicity, older age (≥58 years), above transtibial amputation level, bilateral lower limb amputation, atraumatic amputation cause, diabetes and high number of comorbidities (≥19). Full methodology

for the previously validated prosthetic non-use criteria of age (≥58 years) and high number of comorbidities (≥19) were reported by Roffman et al. (2014). These criteria were generated using receiver operating characteristic (ROC) curves with an equal balance of sensitivity and specificity and the chi squared test to determine likelihood ratio of prosthetic non-use (Roffman et al., 2014). From the medical record data participants were classified as in these known groups "yes" or "no". Using these binary classifications performance measure data were analysed.

Shapiro Wilk tests demonstrated that the performance measure data were not normally distributed $p < .01$. Non-parametric analyses using the Mann-Whitney U test (95% Confidence Intervals (CI)) were performed to determine if differences were significant between rankings of locomotor test performances for those in known groups at high or low risk of prosthetic non-use.

Spearman rank correlation coefficients were calculated for the total cohort to generate a correlation matrix and determine if there were any relationships between the 10MWT, TUGT, 6MWT and FSST.

The proportion of participants in high risk groups with the locomotor test prosthetic non-use criteria (Roffman et al., 2016b) (see table 7.1A for criteria) present were calculated. The descriptive amputation, demographic and comorbidity variables obtained from the medical record were analysed for the total cohort.

Data scoring and reduction

Chapter 6 Figure 2 details the percentage of participants with missing performance measure data who were excluded from the statistical analyses. Participants with missing data did not systematically differ from the tested cohort in terms of demographic or amputation details. The main reasons that performance measure data were missing included: participants being medically unfit to attempt the test (e.g. stump wound), declining to perform the test or not attending their outpatient appointment.

Participants who were unable to complete or perform the assessment during rehabilitation were included in the statistical analyses (see Chapter 6 Figure 2). These participants could not independently perform or attempt the locomotion tests (i.e. required physical assistance from another person or used their prosthesis for transfers only). To enable statistical analyses, these participants were scored as "0" for the 10MWT and 6MWT (tests where low scores reflect poor performance) (Forrest et al., 2014; Scrivener, Schurr, & Sherrington, 2014; van Hedel, 2009) and "999" for the TUGT and FSST (tests where high scores reflect poor performance). As non-parametric (distribution free) statistics were used in this study, assigning the lowest ("0") and highest ("999") scores for those unable to perform the test allowed this important sub-group to be analysed (Conover & Iman, 1981; Hajian-Tilaki, Hanley, Joseph, & Collet, 1997). This contributed to the external validity of the clinical study. Similar statistical management of participants unable to perform locomotor tests has been documented in the spinal and stroke literature (Forrest et al., 2014; Scrivener et al., 2014; van Hedel, 2009).

7.1.3. Results

Table 7.2A outlines demographic, comorbidity and amputation characteristics for the total cohort from the medical record abstraction.

Locomotor Performance of known groups

Table 7.3A details locomotor test results of the known groups at high and low risk of prosthetic non-use. High risk groups including above transtibial amputation, older age (≥58 years), bilateral amputation and high comorbidities had significantly poorer performances ($z \geq 2.23$, $p \leq .025$) on all of the locomotor tests. Locomotor performance of Aboriginal people was not significantly poorer ($z \leq 0.760$ $p \geq .449$) for the 10MWT, TUGT, 6MWT and FSST than non-Aboriginal people. In the diabetes and atraumatic groups, 10MWT and TUGT performance were not significantly poorer ($z \leq 1.77$, $p \geq .075$) than low risk groups.

Prosthetic non-use criteria and known groups

Table 7.4A demonstrates that people at high risk of prosthetic non-use including those with above transtibial amputation, bilateral amputation and high comorbidities had the greatest proportion of participants with prosthetic non-use criteria for the 10MWT, TUGT, 6MWT and FSST present.

Correlation Matrix

Relationships between performance measures are shown in a correlation matrix (See Appendix 7.1A, Table 7.5A). 10MWT velocity had strong negative correlations with TUGT ($r_s = - .84$, $p < .0001$) and FSST ($r_s = - .77$, $p < .0001$) and a strong positive correlation with 6MWT distance ($r_s = .79$, $p < .0001$). 6MWT distance had strong negative correlations with TUGT ($r_s = - .85$, $p < .0001$) and FSST ($r_s = - .86$, $p < .0001$). TUGT had a strong positive correlation with the FSST ($r_s = .85$, $p < .0001$).

Table 7.2A: Demographic, comorbidity and amputation details abstracted from the medical records for the total cohort.

Demographic, Comorbidity and Amputation Details	Total cohort (n = 201)
Gender, Male, n (%)	161 (80)
Age at amputation, mean (SD)	55.5 (15.5)
Aboriginal, n (%)	23 (14)
Accommodation after discharge from inpatient rehabilitation, n (%)	
Home (not residential care)	196 (98)
Metropolitan (not country)	114 (57)
Charlson Comorbidity Index (CCI), median (IQR)	2 (1 to 4)
Combined Age CCI, median (IQR)	4 (1 to 6)
Comorbidities, n (%)	
Diabetes Type I	12 (6)
Type II	84 (42)
Peripheral Arterial Disease	106 (53)
Cardiac Condition	75 (37)
Renal Failure	32 (16)
Cerebrovascular accident / Transient Ischemic Attack	17 (8)
Arthritis	69 (34)
Remaining Lower Limb Pathology	161 (80)
Amputation Cause, n (%)	
Circulatory	52 (26)
Infection	87 (43)
Trauma	54 (27)
Cancer	8 (4)
Amputation Level, n (%)	
Transtibial	163 (81)
Knee disarticulation	7 (3)
Transfemoral	62 (31)
Major Bilateral Lower Limb Amputation	31 (15.4)
Bilateral transtibial	19 (9.5)
Transtibial & transfemoral	8 (4)
Knee disarticulation & transfemoral	1 (0.5)
Bilateral transfemoral	3 (1.5)
Minor Amputation of Remaining Limb*	21 (10)
Toe amputation	18 (9)
Transmetatarsal amputation	2 (1)
Ankle disarticulation	1 (0.5)
Upper Limb Amputation/s	20 (10)

*Minor amputation of the remaining limb was defined as ankle disarticulation and below including partial foot and toe amputations.

Table 7.3A: Median, interquartile range and Mann Whitney U test performance measure results for known groups at high and low risk of prosthetic non-use.

Known Group Classifications for Performance measures		n1	n2	n1 median (IQR)	n2 median (IQR)	U score	Z score	p value
Aboriginal vs. Non-Aboriginal	10MWT (ms^{-1})	28	161	0.64 (0.26 to 0.91)	0.63 (0.36 to 0.94)	2370	0.432	.667
	6MWT (m)	28	170	262 (115 to 330)	240 (120 to 362)	2525	0.516	.609
	TUGT (s)	28	160	16.7 (10.8 to 31.6)	14.0 (9.2 to 27.3)	2442	0.760	.449
	FSST (s)	27	163	19.4 (13.9 to **999***)	19.8 (12.4 to **999***)	2204	0.013	.993
Age ≥ 58 vs. < 58 years	10MWT (ms^{-1})	87	102	0.54 (0.31 to 0.85)	0.72 (0.40 to 1.08)	5272	2.23	.025
	6MWT (m)	91	107	198 (107 to 294)	292 (168 to 410)	6442	3.92	< .001
	TUGT (s)	90	98	16.9 (10.5 to 31.0)	12.0 (8.1 to 21.9)	5266	2.30	.02
	FSST (s)	90	100	43.5 (15.7 to **999***)	14.7 (11.2 to 38.9)	6122	4.29	< .001
Above transtibial vs. transtibial amputation	10MWT (ms^{-1})	57	132	0.37 (0.21 to 0.64)	0.75 (0.48 to 1.0)	5494	5.02	< .001
	6MWT (m)	64	134	148 (77 to 243)	284 (169 to 405)	6161	4.97	< .001
	TUGT (s)	59	129	23.5 (15.4 to 44.6)	11.4 (8.03 to 19.1)	5752	5.62	< .001
	FSST (s)	57	133	999* (25.4 to **999***)	15.5 (11.5 to **999***)	5527	5.00	< .001
Bilateral vs. unilateral amputation	10MWT (ms^{-1})	30	159	0.42 (0.26 to 0.83)	0.67 (0.40 to 0.94)	3012	2.28	.022
	6MWT (m)	31	167	136 (44 to 360)	250 (127 to 359)	3269	2.32	.020
	TUGT (s)	29	159	29.5 (11.8 to 56)	13.1 (9.2 to 23)	3074	2.85	.004
	FSST (s)	29	161	999* (15.4 to **999***)	18.8 (12.1 to **999***)	2943	2.23	.025
Diabetes vs. no diagnosis	10MWT (ms^{-1})	89	100	0.63 (0.30 to 0.88)	0.66 (0.39 to 1.09)	5027	1.54	.121
	6MWT (m)	94	104	229 (117 to 312)	257 (134 to 400)	5724	2.08	.037
	TUGT (s)	92	96	14.8 (10.2 to 31.1)	13.2 (8.9 to 23.9)	4936	1.39	.160
	FSST (s)	93	97	28.2 (14.6 to **999***)	17.6 (10.9 to **999***)	5621	2.93	.003
High (≥19) vs. low (< 19) comorbidities	10MWT (ms^{-1})	18	171	0.29 (0.23 to 0.49)	0.69 (0.40 to 0.95)	2299	3.44	< .001
	6MWT (m)	18	180	126 (84.8 to 232)	248 (127 to 366)	2302	2.94	.003
	TUGT (s)	18	170	27.4 (19.3 to 44.5)	13.3 (9.19 to 24.5)	2177	2.95	.003
	FSST (s)	18	172	999* (55 to **999***)	18.6 (12.1 to **999***)	2326	3.50	< .001
Atraumatic vs. traumatic amputation	10MWT (ms^{-1})	50	139	0.60 (0.31 to 0.90)	0.76 (0.43 to 1.08)	4064	1.77	.075
	6MWT (m)	54	144	224 (113 to 330)	299 (216 to 405)	4975	3.03	.002
	TUGT (s)	47	141	15.4 (9.6 to 30)	12.3 (8.4 to 21.2)	3828	1.59	.109
	FSST (s)	49	141	28.2 (14.5 to **999***)	13 (10.5 to 30.2)	4724	3.83	< .001

***999** represents medians and IQR of participants who were unable to perform the FSST.

Table 7.4A: Proportion of participants in high risk groups for prosthetic non-use with the 10MWT, TUGT, 6MWT and FSST prosthetic non-use criteria.

Known Groups at high risk of prosthetic non-use	Prosthetic non-use criteria for locomotor tests			
	10MWT ($\leq$ 0.44ms^{-1})* % (n)	TUGT ($\geq$ 21.4s)* % (n)	6MWT ($\leq$ 191m)* % (n)	FSST ($\geq$ 36.6s)* % (n)
Aboriginal ethnicity	36 (10)	36 (10)	43 (12)	30 (8)
Age ($\geq$ 58 years)	37 (32)	40 (36)	49 (45)	51 (46)
Above transtibial amputation level	54 (31)	59 (35)	59 (38)	65 (37)
Bilateral lower limb amputation	53 (16)	55 (16)	61 (19)	55 (16)
Diabetes	37 (33)	37 (34)	40 (38)	44 (41)
High Comorbidities ($\geq$ 19)	67 (12)	67 (12)	72 (13)	83 (15)
Atraumatic amputation cause	35 (48)	36 (51)	44 (64)	44 (62)

*Thresholds by Roffman et al. (2016b)

7.1.5. Discussion

This study has demonstrated that people in groups at high risk of prosthetic non-use including those with above transtibial amputation, bilateral amputation, high comorbidities and older age have significantly slower walking speed, reduced walking distance and impaired balance compared to low risk groups. The locomotor tests have construct validity for use during rehabilitation as they distinguished between all groups at high and low risk of prosthetic non-use following lower limb amputation except the Aboriginal sub-group for 10MWT, TUGT, 6MWT and FSST; the diabetes and atraumatic sub-groups for 10MWT and TUGT.

The findings for Aboriginal participants support earlier research by Roffman et al. (2014) that there were environmental, sociocultural and model of care factors contributing to this positive locomotor outcome. This was important as rehabilitation models of care should manage potential barriers such as language, geographical isolation from services, cultural and health beliefs to optimise the outcomes of people regardless of ethnicity (Schoen et al., 2010).

Atraumatic and diabetic group findings for the 10MWT and TUGT were a major point of difference between our study and the literature as slower walking speeds and poor balance have been demonstrated for people with vascular causes of amputation (Schoppen et al., 2003; Schoppen et al., 1999; Su et al., 2008; Waters et al., 1976). However, ceiling effect has been reported for TUGT in people with lower limb amputation so this locomotor test may not be sensitive enough to discriminate between known groups during the later stages of rehabilitation (Deathe & Miller, 2005). Another potential rationale for the TUGT findings that requires further research is that participants with diabetic peripheral neuropathy may have adapted to walking without proprioception prior to their amputation and prosthetic gait retraining. McDermott et al. (2010) reported that walking speed was not associated with ankle brachial index and intermittent claudication symptoms in people with peripheral arterial disease however walking endurance in 6MWT was significantly associated. Consistent with this study (McDermott et al., 2010), our 10MWT results for the atraumatic and diabetic groups

may suggest that tests of walking endurance such as the 6MWT were better indicators of locomotor impairment.

10MWT

There have been limited studies of the 10MWT in lower limb amputation cohorts and the methodology used differed from our study (Akarsu et al., 2013; Franchignoni et al., 2004; Tekin, Safaz, Göktepe, & Yazýcýođlu, 2009). Soldiers from the Turkish armed forces with unilateral amputation (n = 15, median = 1.3ms^{-1}) had significantly slower ($p < .001$) walking speed than those with bilateral (n = 15, median = 1.0ms^{-1}) amputation (Akarsu et al., 2013). In our study, participants in the 75th quartile of the young, transtibial and traumatic groups performed at similar speeds to those reported by Akarsu et al. (2013) while all other participants had slower walking speeds. Franchignoni et al. (2004) reported gait speed as 1.11 ms^{-1} in people with transtibial amputation and 0.41 ms^{-1} in people with transfemoral amputation which was similar to the above transtibial amputation group in this study. Similar to past studies (Akarsu et al., 2013; Franchignoni et al., 2004; Su et al., 2008; Tekin et al., 2009; Waters et al., 1976; Wong et al., 2016a), our participants with above transtibial amputation, bilateral amputation, older age and high comorbidities walked at significantly slower speeds than those with unilateral transtibial amputation, low comorbidities and younger age.

TUGT

The TUGT has been used as a measure of dynamic balance function in amputation cohorts with a time of 19 seconds or greater associated with increased risk of multiple falls (Dite et al., 2007; Resnik & Borgia, 2011; Salavati et al., 2011; Schoppen et al., 2003; Schoppen et al., 1999; van Eijk et al., 2012). Consistent with the literature (Dite et al., 2007; Salavati et al., 2011; Schoppen et al., 2003; Schoppen et al., 1999; van Eijk et al., 2012), our study found significantly slower times in those with above transtibial amputation, bilateral amputation, high comorbidities and older age. In people with above transtibial and bilateral amputation slower times may be related to difficulty with sit to stand and turning when walking due to reduced proprioception, the need to control more

prosthetic joints and increased reliance on upper limb and trunk strength for locomotor activities (Burger et al., 2005; Linberg et al., 2013).

6MWT

6MWT was used by Gailey et al. (2002) to validate the Amputee Mobility Predictor and the 6MWT is a good test of endurance locomotor function in amputation cohorts. 6MWT distance for people with lower limb amputation varies widely in studies with distances over 800 metres reported in fit, young cohorts such as military service personnel who have traumatic amputation cause (Akarsu et al., 2013; Erjavec et al., 2014; Gailey et al., 2002; Gailey et al., 2013; Linberg et al., 2013; Tekin et al., 2009). Reduced walking distances have been reported in those who were older, had atraumatic amputation cause, high comorbidities, transfemoral and bilateral amputations (Erjavec et al., 2014; Gailey et al., 2002; Raya et al., 2010). In a study of participants with transfemoral amputation from vascular causes (n = 101), 6MWT distance ranged from 22 to 203 metres (median = 85 metres) which was lower than our study findings for the above transtibial and atraumatic amputation cause groups (Erjavec et al., 2014). Significant differences for the diabetes and atraumatic groups from their low risk groups supports the claudication research that tests of endurance such as 6MWT were more likely to reveal walking impairment (McDermott et al., 2010).

FSST

Ability to dual task and perform multidirectional movement is important for outdoors ambulation and to walk in complex contexts (Dite et al., 2007; Gailey et al., 2013; Gaunaurd, 2012). Although FSST performance was significantly different for all of the groups, floor effect was detected. A high proportion of the total cohort were unable to perform the FSST by discharge or were at greater risk of having multiple falls as they required $\geq$24 seconds to complete this test (Dite et al., 2007). Inability to perform the FSST was most pronounced in above transtibial amputation level, bilateral amputation and high comorbidities groups. An important part of this test is single prosthetic limb balance which may be a difficult task using a prosthetic knee joint, in people with bilateral lower limb amputation or comorbidities that affect balance. The results may

indicate that more high level balance skills need to be incorporated into the rehabilitation program. These findings suggest that the FSST has greatest utility in younger people with transtibial and traumatic amputation cause as these groups were able to perform the test.

Relationship between performance measures

This study has shown that tests of walking speed, distance and balance have convergent validity as they were highly correlated with strong positive or negative relationships (Gailey et al., 2013; Gaunaurd, 2012). This supports earlier findings by Roffman et al. (2016b) where the locomotor tests had similar AUC (Area Under the Curve) and RR (Relative Risk) for predicting prosthetic non-use and correlation coefficients reported in the literature between TUGT and 6MWT ($r = -.76$, $p = .004$) and FSST and TUGT ($r = .88$, $p < .001$) (Dite et al., 2007; Lin & Bose, 2008).

Prosthetic non-use criteria

A higher proportion of the performance thresholds for prosthetic non-use developed by Roffman et al. (2016b) were present in the groups with above transtibial amputation level, bilateral lower limb amputation and high comorbidities. These high risk groups have all been associated with prosthetic non-use in the literature (Roffman et al., 2014; Sansam et al., 2009; Schoppen et al., 2003; Taylor et al., 2005; Webster et al., 2012).

Clinical and Research Implications

These study findings have shown that locomotor tests distinguish between high risk groups including those with above transtibial amputation, bilateral amputation and high comorbidities and lower risk groups. In heterogenous lower limb amputation cohorts where physical skill levels vary it is important that locomotor tests are sensitive for low and high performance. These results highlight the locomotor skills that lower limb amputation cohorts with different characteristics have difficulty in performing and form the first stage in developing normative data for amputee rehabilitation cohorts and to guide physiotherapy and prosthetic interventions. As a large proportion of the case mix

have diabetes and atraumatic amputation it may be suggested that the 6MWT is the best locomotor test for distinguishing between high and low risk groups and defining capacity to walk outdoors however further research is required to validate these findings.

Limitations

There were some limitations with this study which have implications for interpretation of these results. There were missing retrospective locomotor test data and some known groups had small numbers which were a potential sources of bias. Individuals who were unable to attempt, independently perform or complete the tests were included and while their inclusion did not impact on the distribution free statistical analysis, this sub-group highlights the limitations of the more difficult performance measures in the heterogeneous cohorts with amputation (Roffman et al., 2016b). Performance measure assessment timeframes varied as it was dependent on the participants' individualised rehabilitation progress. Future studies may control assessment times. Low numbers in some of the sub-groups investigated. In addition, Australia has a very low proportion of military personnel that have sustained amputation. Veterans with amputation, their associated rehabilitation models of care and funding have some fundamental differences from the Western Australian public health context.

7.1.6. Conclusion

This study has demonstrated that tests of varying locomotor demand (i.e. 10MWT, 6MWT, TUGT and FSST) may have construct validity when used during rehabilitation to evaluate locomotor performance in people with lower limb amputation. The four tests effectively discriminated between locomotor performance of groups at high risk of prosthetic non-use including above transtibial amputation level, older age, bilateral amputation, high comorbidities and those with lower risk. The locomotor tests were highly correlated which suggests they all measure a common functional domain. However, it appears that the 6MWT was the most sensitive and therefore has some clinical utility as a locomotor test as it differentiated between all the known groups including people with diabetes and atraumatic amputation.

Chapter 7-B

Part B

7.2. Activity and participation levels after discharge from rehabilitation self reported by people with lower limb amputation.

Synopsis

Long term activity and participation (including locomotor function, return to driving and work) following lower limb amputation have been described in this chapter. A known groups analysis of the LCI5 has been performed. Components of this chapter form a paper for publication in the future and were presented at the:

International Society for Prosthetics and Orthotics (ISPO) 15th World Congress in Lyon, France, June 22nd to 25th June 2015.

ISPO 16th World Congress in Cape Town, South Africa, May 8 to 11 2017.

Abstract

Objectives: The objectives of this study were:

1. To describe activity and participation levels including transfers, wheelchair or motorised scooter use, hopping, locomotor activities using a prosthesis, return to driving and work after discharge from rehabilitation in people with lower limb amputation.

2. To determine if the locomotor capabilities index 5 (LCI5) has construct validity as a measure of long term locomotor function in known groups at high risk of prosthetic non-use and groups with lower risk.

3. To investigate if return to driving and work were associated with dichotomous variables including being a prosthetic user, transtibial amputation level, younger age, not having diabetes, traumatic amputation cause, metropolitan residence, unilateral lower limb amputation, self reported walking distance of $\geq$ 500m and male gender.

4. To describe complications of amputation including residual limb pathology, remaining lower limb pathology and falls after discharge from rehabilitation in people with lower limb amputation.

Method: 201 consecutive tertiary rehabilitation participants from Royal Perth Hospital were interviewed using the LCI5 and a questionnaire on complications of amputation, activity and participation levels. Medical records were abstracted and descriptive statistics generated for the cohort. Chi squared analysis was used to determine if the presence or absence of dichotomous variables were associated (Confidence Intervals (CI) 95%) with return to driving or work in sub-groups who were drivers and workers prior to their amputation. Mann Whitney U Tests were used to compare locomotor capabilities of the prosthetic users and non-users and prosthetic users in known high and lower risk groups of prosthetic non-use.

Results: At median, 1.5 (IQR, 1.2 to 2.2) years after discharge, 74% (n = 149) of participants were prosthetic users. Long term wheelchair use and residual limb pathology were 71% (n = 143) and 72% (n = 144) respectively.

LCI5 scores were significantly different ($z \geq 2.10$, $p \leq .036$) for all known groups at high risk of prosthetic non-use except the Aboriginal and above transtibial amputation level ($z \leq 1.56$, $p \leq .12$) groups. The maximum LCI5 score of 56 points was reported by 25% of the cohort and ceiling effect was demonstrated for the scale.

A total of 61% (n = 122) of participants were drivers and 45% (n = 91) of participants were workers prior to their amputation. The rates of return to driving and work were 91% (n = 111) and 62% (n = 56) respectively for these sub-groups. Return to driving was significantly associated being a prosthetic user (Positive likelihood ratio (+LR) = 1.59, p = .006). Return to work was significantly associated with being a prosthetic user and transtibial amputation level ($+LR \leq 2.36$, $p \leq .006$).

Conclusion: Rates of return to driving and work were similar to previous studies. The LCI5 has construct validity as a self reported locomotor outcome measure. However, 25% of the total cohort reported maximum LCI5 scores which suggests the LCI5 scale may be less sensitive when measuring long term locomotor function or once locomotor capabilities have improved above a specific threshold. Further investigation of locomotor outcome measures to implement in the long term follow-up phase of amputee rehabilitation is warranted.

Activity and participation levels after discharge from rehabilitation self reported by people with lower limb amputation.

7.2.1. Introduction

There is a paucity of information regarding outcomes of people with lower limb amputation following discharge from Australian rehabilitation centres (Hordacre et al., 2013b; Jones et al., 1993; Lim et al., 2006; Roffman et al., 2014; Wu et al., 2010). Australian research (Hordacre et al., 2013b; Lim et al., 2006; Wu et al., 2010) has focused on population demographics, institution specific variables (e.g. average length of stay, time to prosthetic fitting) and function at discharge. Therefore limited knowledge exists on long term functional outcomes in people with lower limb amputation for the domains of activity and participation including transfers, wheelchair or motorised scooter use, hopping, locomotor activities using a prosthesis, return to driving and work. Depending on the model of care and associated time frames, some of these activity and participation milestones may be achieved after rehabilitation discharge and not captured by current outcome measures (e.g. Functional Independence Measure (FIM)) or healthcare data collection systems. Comorbidities and complications of amputation such as falls, residual and remaining limb pathology have the potential to limit activity and participation levels (Burger, 2012; Gailey et al., 2008; Kulkarni, 2008). It is vital for health professionals, administrators and funding organisations to know if the functional outcomes of individuals selected for rehabilitation inventions are sustained after discharge for future resource utilisation, model of care planning and funding.

The FIM is used to report on inpatient rehabilitation outcomes of clinical cohorts (including amputation) and informs funding of health services (Eagar, 2011; Hordacre et al., 2013b). However, the FIM has limitations as an outcome measure for amputation cohorts due to lack of responsiveness and ceiling effect observed in the scale (Condie et

al., 2006; Franchignoni et al., 2004; Heinemann et al., 2014). The FIM is the main outcome measure used by Australian rehabilitation services and is only assessed at inpatient admission and discharge. In Western Australia, the FIM is only capturing pre-prosthetic locomotor function during the inpatient admission because prosthetic gait retraining is conducted as an outpatient rehabilitation service so due to the model of care, data on full locomotor capacity is not being collected (Department of Health, 2008; Roffman et al., 2014). These issues highlight a need for a locomotor outcome measure that is clinically relevant for amputation cohorts throughout the rehabilitation continuum and easy to administer in outpatient and community settings.

The Locomotor Capabilities Index (LCI) and Locomotor Capabilities Index 5 (LCI5) are amputee specific locomotor outcome measures that generate a score based on a person's self reported ability to complete basic and advanced locomotor activities (Agrawal, Skrabek, Embil, Gross, & Trepman, 2014; Condie et al., 2006; Gauthier-Gagnon et al., 1999; Gauthier-Gagnon & Grisé, 2006; Heinemann et al., 2014). Psychometric properties of the LCI (Gauthier-Gagnon & Grise, 1994) and LCI5 (Franchignoni et al., 2004; Larsson, Johannesson, Andersson, & Atroshi, 2009; Salavati et al., 2011) have been investigated during rehabilitation with limited studies on locomotor function post-discharge (Agrawal et al., 2014; Czerniecki et al., 2012a; Czerniecki et al., 2012b; Gauthier-Gagnon et al., 1999). Assessment of locomotor function post-discharge is important as prosthetic prescription involves long term costs to healthcare services, however capacity to safely ambulate with a prosthesis is not necessarily maintained as people age (Schoppen et al., 2003). Australian studies (Gordon et al., 2010; Stepien, Cavenett, Taylor, & Crotty, 2007) have not used the LCI5 to measure long term locomotor outcomes after discharge from rehabilitation in sub-groups with lower limb amputation.

Abandonment of prosthetic use after rehabilitation discharge and poorer locomotor function have been associated with high or multiple limb amputation, older age, atraumatic cause, comorbidities, impaired pre-morbid mobility and functional level achieved during rehabilitation (Roffman et al., 2014; Schoppen et al., 2003; Taylor et al.,

2005). Roffman et al. (2014) identified that diabetes, Aboriginal ethnicity and geographical isolation from health services were not predictors of prosthetic non-use after discharge. However, further research into self reported locomotor function is warranted because factors associated with poor health outcomes (i.e. diabetes, increased chronic disease burden) have been well documented in Aboriginal people (Norman et al., 2010; Vos et al., 2009).

Construct validity is demonstrated when the scale of an outcome measure has sensitivity to discriminate between low and high performance in sub-groups which are known to differ in the literature (Hattie & Cooksey, 1984; Megens et al., 2007). Knowledge of long term locomotor capabilities after rehabilitation discharge by sub-groups at high risk of prosthetic non-use including people with Aboriginal ethnicity, older age, amputation above transtibial level, bilateral lower limb amputation, diabetes, very high number of comorbidities, atraumatic amputation cause and part-time prosthetic users (< 7 days per week) would allow health professionals to develop targeted models of care to improve rehabilitation outcome and optimise allocation of resources.

The objectives of this study were:
1. To describe activity and participation levels including transfers, wheelchair or motorised scooter use, hopping, locomotor activities using a prosthesis, return to driving and work after discharge from rehabilitation in people with lower limb amputation.

2. To determine if the locomotor capabilities index 5 (LCI5) has construct validity as a measure of long term locomotor function in known groups at high risk of prosthetic non-use and groups with lower risk.

3. To investigate if return to driving and work were associated with dichotomous variables including being a prosthetic user, transtibial amputation level, younger age, not having diabetes, traumatic amputation cause, metropolitan residence, unilateral lower limb amputation, self reported walking distance of $\geq$ 500m and male gender.

4. To describe complications of amputation including residual limb pathology, remaining lower limb pathology and falls after discharge from rehabilitation in people with lower limb amputation.

7.2.2. Methods

Participants

Royal Perth Hospital and Curtin University Ethics approval were obtained for this study (see Appendix 3.1). Participants were recruited by an independent research assistant who obtained informed verbal consent for an interview.

Participants were included if: they had at least one recent major lower limb amputation (i.e. transtibial level or above), had multiple limb amputation, were community dwelling and ambulant prior to amputation, were Medicare Functional Classification Level (MFCL) K-level 1 to 4, had participated in and been discharged from prosthetic rehabilitation at Royal Perth Hospital, the state centre for amputee rehabilitation (Roffman et al., 2014). K-level classifications are defined in Gailey et al. (2002).

Participants were excluded if they did not meet the inclusion criteria, were K-level 0 (i.e. not prosthetic rehabilitation candidates), unable to communicate or did not consent (Roffman et al., 2014). K-level 0 participants were monitored in multidisciplinary outpatient clinic and remained K-level 0.

A total of 307 consecutive tertiary rehabilitation patients with lower limb amputation were identified as potential participants from the Amputee Physiotherapy Services Database from June 2006 to July 2011. A flow diagram (see Figure 7.1B) demonstrates the participant eligibility and recruitment into this study.

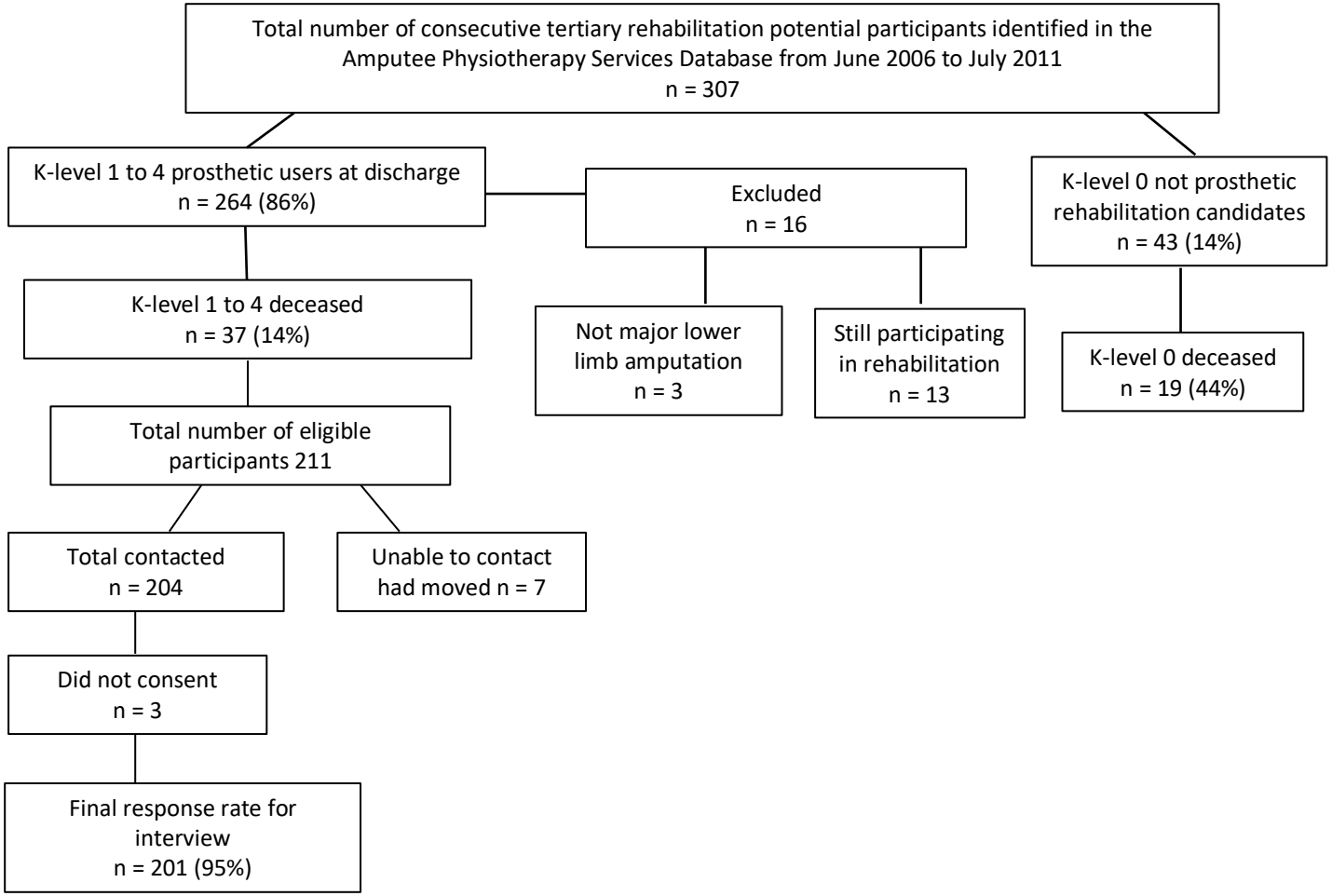

Figure 7.1B: Flow diagram of participant recruitment and eligibility for this study.

Rehabilitation Intervention

RPH provides a comprehensive multidisciplinary rehabilitation program for inpatients and outpatients. K-level 0 to 4 participants received inpatient rehabilitation to achieve independent wheelchair mobility, transfers and discharge home to the community. Prosthetic rehabilitation was performed by K-level 1 to 4 participants as an outpatient service at the dedicated state amputee rehabilitation service, Royal Perth Hospital (RPH) which rehabilitates approximately 85% of all individuals with lower limb amputation in Western Australia (Department of Health, 2008).

Details of physiotherapy and prosthetic interventions are reported in Roffman et al. (2014) (and reported in full detail in Chapter 2, appendix 2.1). Participants received 2 to 3 sessions per week of outpatient rehabilitation for median, 163 (IQR, 98 to 264) days and were fitted with an interim prosthesis at median, 51 (IQR, 34 to 96) days after initial amputation. Participants were progressed through a standardised gait retraining program and received prosthetic care during physiotherapy gait retraining sessions from onsite prosthetists. Participants were discharged from physiotherapy when they achieved their individualised rehabilitation goals. Once gait retraining was completed and residual limb volume had stabilised participants were referred by the multidisciplinary rehabilitation team for a definitive prosthesis at median, 314 days (IQR 229 to 415) after initial amputation surgery. Figure 7.2B details the timeframes from the post-operative stage of rehabilitation to interview including length of stay and time from initial amputation surgery until rehabilitation milestones (e.g. prosthetic casting, fitting and gait retraining) were achieved by the total cohort (n = 201).

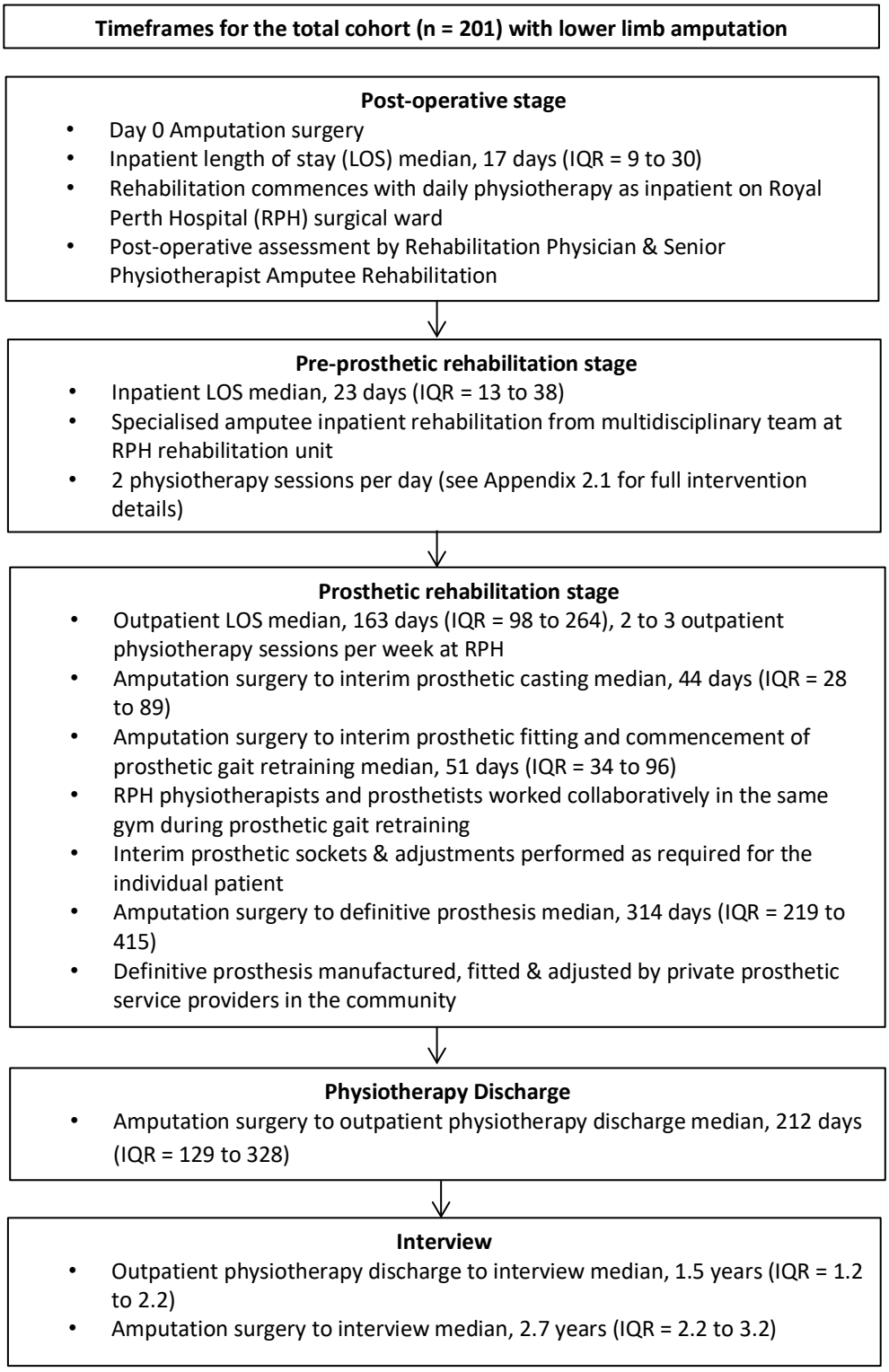

Figure 7.2B: Timeframes for the total cohort (n = 201) from the post-operative stage of rehabilitation to interview.

Study Instruments

The LCI5 is a 14 item questionnaire (Appendix 7.1B, Table 7.1B) that uses a 5 point ordinal scale (Franchignoni et al., 2007; Franchignoni et al., 2004). The scale range is as follows: 0 = No; 1 = Yes, if someone helps me; 2 = Yes if someone is near me; 3 = Yes, alone with ambulation aids; and 4 = Yes, alone without ambulation aids (Franchignoni et al., 2007; Franchignoni et al., 2004). This 5 point scale was developed to reduce the ceiling effects observed in the LCI (Franchignoni et al., 2007; Franchignoni et al., 2004; Gauthier-Gagnon et al., 1999). Participants can score a maximum of 28 for basic and advanced activities and total score of 56 (Franchignoni et al., 2007; Franchignoni et al., 2004). The LCI5 can be self administered, performed in person or as a telephone interview (Franchignoni et al., 2007; Franchignoni et al., 2004; Gauthier-Gagnon et al., 1999) and takes approximately 5 minutes to administer (Franchignoni et al., 2007; Franchignoni et al., 2004; Larsson et al., 2009).

A questionnaire (Appendix 7.2B) developed and previously piloted by the Senior Physiotherapist Amputee Rehabilitation (with 10 years clinical experience) was administered to measure demographic details, amputation details, general health, transfers, wheelchair and motorised scooter use, hopping, prosthetic use, mobility aid type and use, falls history since amputation surgery, pain, remaining and residual limb pathology, return to driving and work. The questionnaire was approximately 15 minutes in duration.

Procedure

Medical records were abstracted for medical history, demographic, amputation and rehabilitation details blind to participant interviews. Participants were interviewed using the questionnaire and LCI5.

In this study, participants were classified as prosthetic users if they used their prosthesis for locomotor activities (e.g. transfers, standing, walking) on one or more week days. Prosthetic users were asked on which days they used their prosthesis and for one day of normal activity how long they wore the prosthesis; how many sit to stands they

performed; and the duration they performed prosthetic walking and standing activities. Verbal prompts were used to improve recall accuracy of prosthetic wearing and use (e.g. *Do you put your prosthesis on when you first wake up? What time do you take off your prosthesis to go to bed?*). From this information normal prosthetic use over one week was calculated for each participant. Self reported maximum walking distance before resting (for a recovery time frame selected by the participant) was also recorded for participants. Participants were classified as full-time prosthetic users if the used their prosthesis on all 7 week days and part-time users if they used their prosthesis < 7 days.

Participants were prosthetic non-users if they did not use their prosthetic limb on any days for locomotor activities or wore their prosthesis for cosmesis only. Non-users were asked to recall how many months after physiotherapy discharge they ceased using their prosthesis and their reasons for non-use. Important calendar events (e.g. last amputee outpatient clinic, birthday, Christmas) were used as verbal prompts to assist with recall accuracy.

Participants were instructed to answer the LCI5 questions based on their current perceived level of locomotor function and were asked, *"Whether or not you use your prosthesis at the present time, would you say that you are able to do the following activities with your prosthesis on?"* (Franchignoni et al., 2007; Franchignoni et al., 2004; Gauthier-Gagnon et al., 1999). Basic, Advanced and Total LCI5 scores were calculated for all participants. Participants were interviewed from 4 months onwards after discharge and re-interviewed at approximately 6 monthly intervals until data were collected for 12 months. Participants were interviewed by telephone, in person and via telehealth videoconference. In remote Aboriginal communities, interviews were coordinated between the senior physiotherapist, country physiotherapists, community nurses and Aboriginal health workers.

From the questionnaire it was recorded if participants had returned to driving and the type of modifications (if required) that had been done to the motor vehicle. Occupation,

return to work, study, retirement and disability support pension details were obtained through the participant interview.

The Australian Standard Classification of Occupations (ASCO) (McLennan, 1997) were used to classify participant's occupations into 9 major groups including: managers and administrators; professionals; associate professionals; tradespersons and related workers; advanced clerical and service workers; intermediate clerical, sales and service workers; intermediate production and transport workers; elementary clerical, sales and service workers; and labourers and related workers.

Statistical Methods

Participants were classified as prosthetic users or non-users from the interview and LCI5 scores were recorded for these groups. The participants who had remained prosthetic users were further classified into known groups at high and lower risk of prosthetic non-use. Median and interquartile ranges were calculated for the LCI5 scores of the prosthetic non-users and users, prosthetic users in the known groups, prosthetic users who returned to driving and work.

In this study, known groups at high and lower risk of prosthetic non-use were determined from the literature (Roffman et al., 2014; Schoppen et al., 2003; Taylor et al., 2005) and the dichotomous classifications for statistical analyses were: Aboriginal and non-Aboriginal, age $\geq$ 58 and < 58 years, above transtibial and transtibial amputation level, diabetes and no diagnosis, part-time and full-time prosthetic users, very high number of comorbidities ($\geq$ 19) and low comorbidities (< 19), atraumatic and traumatic amputation causes and bilateral and unilateral lower limb amputation. The thresholds used to dichotomise the continuous variables of age and number of comorbidities were generated by Roffman et al. (2014) (see chapter 4) using receiver operator characteristic (ROC) curves with an equal weighting of sensitivity and specificity.

Shapiro-wilk tests demonstrated LCI5 data were not normally distributed ($p < .01$) so non-parametric analyses using the Mann-Whitney U tests (MWUT) were performed to determine if differences in locomotor function between known high and lower risk groups were significant. The distribution of Basic, Advanced and Total LCI5 scores (from minimum to maximum), were examined for the total cohort and individual known groups.

Descriptive statistics were calculated for the prosthetic user and non-user characteristics and questionnaire data on complications of amputation, activity and participation levels for the total cohort. Depending on the distribution of the data, cohort characteristics for prosthetic users and non-users were analysed using 2 proportion Z tests. Time from discharge to interview, time to prosthetic milestones and length of outpatient rehabilitation were calculated.

Participants who were drivers and workers prior to amputation were recorded. Age and Charlson Comorbidity Index (CCI) score were calculated for the sub-groups who were drivers, non-drivers, workers and non-workers prior to amputation. In participants who were drivers and workers prior to amputation, chi squared analysis was used to determine if the presence or absence of dichotomous variables including being a prosthetic user, having traumatic amputation cause, transtibial amputation level, no diabetes, younger age (< 58 years), metropolitan residence, unilateral lower limb amputation, self reported walking distance ≥ 500m and male gender were associated (Confidence Intervals 95%) with return to driving or work.

7.2.3. Results

Participants were interviewed at median, 1.5 years (IQR, 1.2 to 2.2) after discharge from rehabilitation (full details of timeframes for length of stay and rehabilitation milestones have been reported in figure 7.2B). The final interview response rate was 95% (n = 201). A total of 74% (n = 149) of participants reported being prosthetic users. The multifactorial self reported reasons for prosthetic non-use by the 52 participants classified as prosthetic nonusers have been detailed in Table 7.2B

Table 7.2B: Multifactorial reasons for prosthetic non-use reported by participants classified as prosthetic non-users (n = 52).

Multifactorial reasons for prosthetic non-use reported by prosthetic non-users (n = 52)	% (n)*
Issue with residual limb (stump)	40 (21)
Issue with remaining Limb	29 (15)
Prosthetic issue	25 (13)
Pain	25 (13)
Medical comorbidities	21 (11)
Balance issues	12 (6)
Fear of falling	8 (4)
Energy Cost or efficiency	6 (3)
Unmotivated	6 (3)
Amputation of remaining limb	6 (3)
Unable to don independently	6 (3)
Body Weight fluctuations	4 (2)
Falls	2 (1)

*Participants were able to report more than one reason for not using their prosthesis so the cumulative percentage exceeds 100.

Appendix 7.3B Table 7.3B details the characteristics of prosthetic users and non-users from the medical record abstraction.

Activity and participation levels without a prosthesis

Appendix 7.4B Table 7.4B details the frequency of mobility activities without a prosthesis such as transfers, hopping, wheelchair and motorised scooter use performed by a cohort with lower limb amputation after discharge from rehabilitation. A total of 71% (n = 143) of the cohort still used a wheelchair for activities of daily living and 64% (n = 91) of prosthetic users still used a wheelchair.

Activity and participation levels with a prosthesis

LCI5 for Prosthetic Non-users and Users

Basic locomotor capabilities reported by prosthetic non-users (median, 11 IQR, 3 to 21) were significantly lower ($z = 8.27$, $p < .001$) than users (median, 28 IQR, 22 to 28). Advanced locomotor capabilities reported by prosthetic non-users (median, 4 IQR, 1 to 11) were significantly lower ($z = 8.13$, $p < .001$) than users (median, 24 IQR, 18 to 28). Total locomotor capabilities reported by prosthetic non-users (median, 16 IQR, 6 to 31) were significantly lower ($z = 8.33$, $p < .001$) than users (median, 51 IQR, 41 to 56).

Known groups analysis of LCI5 in long term prosthetic users at high and low risk of prosthetic non-use

Locomotor capabilities were as follows for the participants that remained prosthetic users in the known high and lower risk groups for prosthetic non-use (full details in Table 7.5B):

Indigenous status

Basic, Advanced and Total Locomotor Capabilities reported by Aboriginal participants were not significantly lower ($z \leq 1.17$, $p \geq .25$) than non-Aboriginal participants.

Table 7.5B: Known user group median (IQR) and Mann-Whitney U Test results for LCI5 Basic, Advanced and Total scores.

Known Groups	n1 median (IQR)	n2 median (IQR)	U score	z score	p value
Aboriginal (n = 18) vs. Non-Aboriginal (n = 131)					
Basic LCI5 Score	28 (22 to 28)	28 (22 to 28)	1182	0.02	.99
Advanced LCI5 Score	22 (16 to 26)	25 (18 to 28)	1380	1.17	.25
Total LCI5 Score	48 (40 to 54)	52 (42 to 56)	1342	0.95	.34
Age ≥ 58 (n = 81) vs. < 58 years (n = 68)					
Basic LCI5 Score	26 (22 to 28)	28 (26 to 28)	3430	2.57	**.009***
Advanced LCI5 Score	22 (16 to 26)	28 (20 to 28)	3680	3.53	**< .001***
Total LCI5 Score	46 (39 to 54)	56 (46 to 56)	3704	3.62	**< .001***
Amputation level above transtibial (n = 35) vs. transtibial (n = 114)					
Basic LCI5 Score	23 (22 to 28)	28 (23 to 28)	2344	1.56	.12
Advanced LCI5 Score	22 (16 to 28)	25 (18 to 28)	2178	0.82	.41
Total LCI5 Score	44 (38 to 56)	52 (43 to 56)	2244	1.11	.27
Diabetes (n = 67) vs. no diagnosis (n = 82)					
Basic LCI5 Score	26 (22 to 28)	28 (24 to 28)	3498	2.86	**.004***
Advanced LCI5 Score	21 (16 to 26)	27 (21 to 28)	3774	3.92	**< .001***
Total LCI5 Score	45 (38 to 54)	55 (44 to 56)	3759	3.86	**< .001***
Part-time (n = 16) vs. Full-time User (n = 133)					
Basic LCI5 Score	22 (17 to 23)	28 (23 to 28)	1669	3.71	**< .001***
Advanced LCI5 Score	13 (9 to 20)	25 (19 to 28)	1790	4.45	**< .001***
Total LCI5 Score	34 (26 to 42)	53 (43 to 56)	1777	4.37	**< .001***
High comorbidities (n = 9) vs. Low comorbidities (n = 140)					
Basic LCI5 Score	21 (7 to 26)	28 (22 to 28)	975	2.75	**.005***
Advanced LCI5 Score	18 (2 to 24)	25 (18 to 28)	895	2.11	**.034***
Total LCI5 Score	39 (9 to 50)	52 (42 to 56)	926	2.36	**.017***
Amputation Cause Atraumatic (n = 106) vs. Traumatic (n = 43)					
Basic LCI5 Score	26 (22 to 28)	28 (28 to 28)	2926	2.71	**.006***
Advanced LCI5 Score	22 (17 to 27)	28 (26 to 28)	3230	3.98	**< .001***
Total LCI5 Score	47 (40 to 55)	56 (54 to 56)	3216	3.93	**< .001***
Bilateral (n = 13) vs. Unilateral Amputation (n = 136)					
Basic LCI5 Score	22 (17 to 26)	28 (23 to 28)	1282	2.68	**.006***
Advanced LCI5 Score	17 (12 to 21)	25 (18 to 28)	1292	2.75	**.005***
Total LCI5 Score	36 (29 to 47)	53 (43 to 56)	1292	2.74	**.005***

(* p < .05)

Age

Basic, Advanced and Total Locomotor Capabilities reported by older participants aged ≥ 58 years were significantly lower ($z \geq 2.57$, $p \leq .009$) than younger participants aged < 58 years.

Amputation level

Basic, Advanced and Total Locomotor Capabilities reported by participants with amputation level above transtibial were not significantly lower ($z \leq 1.56$, $p \geq .12$) than participants with transtibial amputation level.

Diabetes

Basic, Advanced and Total Locomotor Capabilities reported by participants with diabetes were significantly lower ($z \geq 2.86$, $p \leq .004$) than participants with no diagnosis.

Part-time and Full-time Prosthetic Users

Basic, Advanced and Total Locomotor Capabilities reported by part-time prosthetic users were significantly lower ($z \geq 3.71$, $p < .001$) than full-time prosthetic users.

Comorbidities

Basic, Advanced and Total Locomotor Capabilities reported by participants with very high comorbidities were significantly lower ($z \geq 2.11$, $p \leq .034$) than participants with low comorbidities.

Amputation Cause

Basic, Advanced and Total Locomotor Capabilities reported by participants with atraumatic amputation causes were significantly lower ($z \geq 2.71$, $p \leq .006$) than participants with traumatic amputation causes.

Bilateral and Unilateral Amputation

Basic, Advanced and Total Locomotor Capabilities reported by participants with bilateral lower limb amputation were significantly lower ($z \geq 2.68$, $p \leq .006$) than participants with unilateral lower limb amputation.

Scale of the LCI5 and observed ceiling effect

Maximum scores were reported by the total cohort (n = 201) for Basic LCI5 = 43% (n = 86), Advanced LCI5 = 25% (n = 51) and Total LCI5 = 25% (n = 51) with ceiling effects observed. Ceiling effects were observed for Basic LCI5 scores with maximal scores of 28 in the following sub-groups: prosthetic users, Aboriginal, non-Aboriginal, aged < 58 years, transtibial amputation level, no diagnosis of diabetes, full-time prosthetic users, low comorbidities, traumatic amputation, and unilateral amputation. For Basic LCI5 score, 100% of participants with traumatic amputation reported the maximum score of 28. Ceiling effects were also observed for Advanced and Total LCI5 scores in participants with traumatic amputation and age < 58 years scoring maximum scores of 28 and 56 respectively.

Mobility aid use and type of mobility aid used

A total of 50% (75) participants reported using a mobility aid when walking with their prosthesis. The use of mobility aids and type of mobility aids used indoors and outdoors by participants that remained prosthetic users have been detailed in Appendix 7.5B Table 7.6B.

Amputation level and self reported prosthetic usage

Appendix 7.6B Table 7.7B outlines the hours of reported prosthetic usage for locomotor activities of total prosthetic users (n = 149), transtibial (n = 114) and above transtibial (n = 35) prosthetic users and self reported maximal walking distance before resting. Users with transtibial amputation level reported wearing their prosthetic limb for significantly ($z = 3.90$, $p < .001$) more hours than those with above transtibial amputation. However, time walking, standing, number of sit to stands and maximal walking distance reported

were not significantly different ($z \leq 1.80$, $p \geq .07$) between users with transtibial and above transtibial amputation levels for weekly or daily usage.

Return to driving and work

Table 7.8B describes the self reported work and driving characteristics of the cohort. Appendix 7.7B Table 7.9B details the age and CCI scores for participants who reported being drivers, non-drivers, workers and non-workers prior to amputation. CCI scores and age were significantly higher ($p \leq .0274$) in participants who did not drive or work prior to amputation. Full details of the univariate analysis for return to driving and work have been reported in Table 7.10B.

Return to driving

A total of 39% (79) did not drive prior to amputation. A total of 61% (122) of participants were drivers prior to amputation and 91% (111) of this sub-group had returned to driving after rehabilitation discharge. The type of car modifications required by participants to drive, have been described in Table 7.8B. Return to driving was significantly associated with being a prosthetic user (+LR = 1.59, CI = 1.04 to 3.40, p = .006) (full details in Table 7.10B). The Total LCI5 score was median, 54 (IQR, 47 to 56) for prosthetic users who returned to driving (n = 96).

Table 7.8B: Return to driving and work characteristics for a cohort with lower limb amputation.

Return to driving and work characteristics	n (%)
Non-drivers before amputation	61 (39)
Drivers before amputation	122 (61)
Return to driving after amputation	111 (91)
Amputation details	
Right unilateral lower limb amputation	37 (33)
Bilateral lower limb amputation	6 (5)
Type of motor vehicle driven	
Manual transmission	5 (4)
Automatic transmission	84 (76)
Left foot accelerator	15 (14)
Hand controls	7 (6)
Occupational Details	
Paid work or studying prior to amputation surgery	91 (45)
Employed after amputation from cohort who worked before amputation	56 (62)
Study or retraining	3 (1.5)
Time spent working, studying or retraining	
Full-time	43 (73)
Part-time	16 (27)
Unemployed	9 (4.5)
Retired	108 (54)
Disability support pension or compensation	25 (12)
Australian Standard Classification of Occupations (ASCO) major groups for participants who returned to work (n = 56)	
1. Managers and Administrators	5 (9)
2. Professionals	15 (27)
3. Associate Professionals	6 (11)
4. Tradespersons and Related Workers	13 (23)
5. Advanced Clerical and Service Workers	3 (5)
6. Intermediate Clerical, Sales and Service Workers	4 (7)
7. Intermediate Production and Transport Workers	9 (16)
8. Elementary Clerical, Sales and Service Workers	1 (2)
9. Labourers and Related Workers	0 (0)

Table 7.10B: Variables associated with return to driving and work (95% confidence intervals).

	Return to driving		
Variables	**Chi Square (1 d.f.)**	**Positive Likelihood Ratio (LR+)**	**p value**
Prosthetic user	7.45	1.59 (1.04 to 3.40)	< .006*
Transtibial amputation level	0	1.00 (0.705 to 2.05)	.983
Younger age (≤ 58 years)	0.021	1.05 (0.60 to 2.71)	.884
Not having diabetes	2.93	1.67 (0.89 to 4.94)	.087
Traumatic amputation cause	1.31	1.39 (0.80 to 3.53)	.252
Unilateral amputation	2.67	1.16 (0.96 to 1.74)	.102
Metropolitan residence	0.141	1.11 (0.709 to 2.50)	.707
Walking distance ≥ 500m	1.71	1.81 (0.767 to 10.3)	.191
Male gender	0.475	0.932 (0.88 to 1.36)	.491
	Return to work		
Variables	**Chi Square (1 d.f.)**	**Positive Likelihood Ratio (LR+)**	**p value**
Prosthetic user	7.60	2.36 (1.12 to 7.15)	.006*
Transtibial amputation level	15.4	2.01 (1.33 to 3.08)	< .0001*
Younger age (≤ 58 years)	1.07	1.19 (0.84 to 1.75)	.301
Not having diabetes	3.05	1.58 (0.89 to 2.71)	.081
Traumatic amputation cause	1.29	0.76 (0.47 to 1.29)	.256
Unilateral amputation	0.78	1.08 (0.91 to 1.29)	.378
Metropolitan residence	0.25	0.91 (0.61 to 1.41)	.618
Walking distance ≥ 500m	1.42	1.25 (0.85 to 2.07)	.233
Male gender	0.68	0.93 (0.81 to 1.15)	.408

*p < .05

Return to work

A total of 54% (108) of participants were retired prior to amputation. A total of 45% (91) of participants worked prior to amputation and 62% (56) of this sub-group had returned to paid work after rehabilitation discharge. Return to work was significantly associated with being a prosthetic user (+LR = 2.36, CI = 1.12 to 7.15, p = .006) and transtibial amputation level (+LR = 2.01, CI = 1.33 to 3.08, p ≤ .0001) (full details in Table 7.10B). The Total LCI5 score was median, 56 (IQR, 54 to 56) for prosthetic users who returned to work (n = 52). The Australian Standard Classification of Occupations (ASCO) major groups for participants who returned to work (n = 56) have been detailed in Table 7.8B.

Complications of amputation

Appendix 7.8B Table 7.11B outlines pain, residual and remaining limb pathology for the cohort. Appendix 7.9B Table 7.12B details falls since amputation for the total cohort, prosthetic users and non-users.

7.2.4. Discussion

This is the first Australian study to describe long term activity and participation levels including locomotor outcome using the LCI5, mobility without a prosthesis, return to driving and work, and complications of amputation in a consecutive cohort of people with lower limb amputation following discharge from rehabilitation. To date Australian outcome research has reported on institution specific variables such as average length of stay, time to prosthetic casting, inpatient FIM score and function at discharge (Hordacre et al., 2013b; Lim et al., 2006; Wu et al., 2010) or on samples of convenience with high variation in time since discharge (Stepien et al., 2007).

Activity and participation levels without a prosthesis

Mobility without a prosthesis such as transfers, wheelchair mobility and hopping were sustained after rehabilitation discharge by participants in our study. A large proportion of the cohort (71%) still used a wheelchair for activities of daily living. Motorised

scooters were used for community access by 13% of participants. In contrast to our findings, Burger (2012) reported limitations in the activity and participation levels of participants with lower limb amputation who were 21.8 years post-amputation and had undergone comprehensive rehabilitation in Slovenia. These participants reported problems with transfers, locomotor activities, driving, transportation, community life and recreation (Burger, 2012). These activity and participation outcomes may potentially be related to differences in the Western Australian and Slovenian rehabilitation models of care. In Western Australia both wheelchairs and prostheses are funded for people with lower limb amputation however in Slovenia people with transfemoral amputation are funded for a prosthesis or wheelchair only (Erjavec et al., 2014).

Activity and participation levels with a prosthesis

LCI5 for Prosthetic Non-users and Users

This study has shown that 74% (n = 149) of participants continued using their prosthesis at median, 1.5 years (IQR, 1.2 to 2.2) after discharge from rehabilitation and that prosthetic non-users reported significantly lower locomotor capabilities than users. These results were similar to Gauthier-Gagnon et al. (1999) who reported that 85% of individuals sustained prosthetic use at 1 to 5 years after rehabilitation discharge and total LCI scores for non-users were significantly lower than users. Participants who became prosthetic non-users in our study reported multifactorial reasons for prosthetic non-use including: residual limb issues, remaining lower limb issues, prosthetic issues, pain, medical comorbidities and balance issues that have been identified in the literature (Gailey et al., 2010; Laferrier et al., 2010).

Functional level achieved during rehabilitation has been associated with prosthetic non-use after rehabilitation discharge (Roffman et al., 2014). It has been reported that the locomotor activities most likely to be performed independently using a prosthesis at discharge were rising from a chair, walking inside the house and outside on even ground; while the activities most difficult to perform were walking outside in inclement weather, going up and down steps without a handrail (Franchignoni et al., 2004;

Gauthier-Gagnon et al., 1999). Our study participants reported similar levels of ease and difficulty on these locomotor activities.

Known groups analysis of LCI5 in long term prosthetic users at high and low risk of prosthetic non-use

Indigenous Status

An interesting finding of this research was that locomotor capabilities reported by Australian Aboriginal participants were not significantly different from non-Aboriginal participants. This was the first study to report on Aboriginal locomotor capabilities so we were unable to compare it with other Australian research (Hordacre et al., 2013b; Lim et al., 2006; Wu et al., 2010). These results were surprising as Aboriginal participants generally reside remote from health services and poor health outcomes have been reported (Norman et al., 2010; Vos et al., 2009). Our findings were similar to Agrawal et al. (2014) who demonstrated that LCI and prosthetic use for Canadian Aboriginal participants were not significantly different from non-Aboriginal participants.

Diabetes and Comorbidities

In this study participants with diabetes reported significantly lower LCI5 scores than those with no diagnosis. Webster et al. (2012) and Meatherall et al. (2005) reported poorer locomotor function for individuals with diabetes. These results are in contrast to the findings of Roffman et al. (2014), who demonstrated that not having a diagnosis of diabetes was an early predictor of prosthetic non-use after discharge from rehabilitation. Those with high comorbidities were demonstrated to have lower LCI5 scores in our study. Severe comorbidities have been previously shown to reduce locomotor function for individuals with unilateral lower limb amputation in the literature (Schoppen et al., 2003).

Amputation cause

Czerniecki et al. (2012b) found in individuals with dysvascular amputation that LCI5 score was reduced from pre-amputation (Total LCI5 mean = 48, SD = 10.7, n = 86), at 12 months post-amputation surgery (Total LCI5 mean = 40.8, SD = 15.5, n = 75). However, there were limited details reported on participants' prosthetic use or non-use for the LCI5 interview time frames in this longitudinal study (Czerniecki et al., 2012b). In our study prosthetic users with atraumatic amputation reported higher total LCI5 scores than Czerniecki et al. (2012b) which may have been related to the later follow-up after discharge or the fact that only participants with dysvascular amputation were investigated by (Czerniecki et al., 2012b).

Prosthetic usage

Our study demonstrated that there was a sub-group who used their prosthesis < 7 days per week who had significantly lower LCI5 scores than the full-time users. In part-time users the prosthesis appears to be used more like an exercise device with recovery days required by participants after walking days. Meatherall et al. (2005) have also reported part-time prosthetic use. Self reported hours a prosthesis was worn has been reported as significantly different ($p < .001$) between transtibial (mean = 84.8, SD = 30.4 hours per week) and transfemoral prosthetic users (mean = 75.0, SD = 31.6 hours per week) (Gauthier-Gagnon et al., 1999). Our study findings for time the prosthesis was worn were similar to Gauthier-Gagnon et al. (1999). This behaviour may be related to the additional energy costs associated with transfemoral prosthetic gait or the fact that transfemoral prosthetic sockets may be uncomfortable in sitting. Other studies (Meatherall et al., 2005; Miller, Deathe, & Speechley, 2001) have reported consistent prosthetic use times for activities of walking, standing and wearing with those in our study.

Amputation level

In our study LCI5 scores were not significantly different for those with above transtibial and transtibial amputation levels. These findings were similar to past studies (Agrawal et

al., 2014; Czerniecki et al., 2012b; Gauthier-Gagnon et al., 1999) that reported no difference in Total LCI and LCI5 scores for individuals with transtibial and transfemoral amputation levels. However, other studies (Franchignoni et al., 2004; Salavati et al., 2011) have demonstrated lower LCI5 scores at rehabilitation discharge in individuals with transfemoral amputation. The prosthetic users with above transtibial amputation level in our investigation may represent a fitter sub-group than other studies (Franchignoni et al., 2004; Salavati et al., 2011) as they have sustained prosthetic use for an extended time after discharge.

Unilateral and bilateral amputation

Many studies (Czerniecki et al., 2012b; Franchignoni et al., 2004; Gauthier-Gagnon et al., 1999; Gordon et al., 2010) have reported on locomotor outcomes in sub-groups with unilateral or specific lower limb amputation levels while other studies (Agrawal et al., 2014; Parker, Kirby, Adderson, & Thompson, 2010; Salavati et al., 2011) have not performed separate analyses for bilateral amputation level data due to small numbers. Larsson et al. (2009) reported significantly lower LCI scores in individuals with bilateral lower limb amputation. Our study demonstrated similar results to this research (Larsson et al., 2009) with significantly lower LCI5 scores in those with major bilateral lower limb amputation.

Age

LCI5 scores were significantly lower in older participants aged $\geq$ 58 years in this study. This is consistent with other studies (Franchignoni et al., 2004; Larsson et al., 2009) which have reported poorer locomotor function in older participants. In a Persian cohort where 98.1% of participants had traumatic amputation, total LCI5 score was mean = 44.8, SD = 1.22 (Salavati et al., 2011). In our study total LCI5 score was higher (median, 56 IQR 54 to 56) for individuals with traumatic amputation. This may be explained by the fact that some Persian participants had only been using their prosthesis for 6 months and possibly had further functional goals to achieve.

Scale of the LCI5 and observed ceiling effect

The LCI5 was developed to address the ceiling effect that was observed in the scale of the LCI (Franchignoni et al., 2007). The frequency of maximum scores on the LCI5 has been reported as low as 5% (Franchignoni et al., 2007). In our study, maximum scores were demonstrated for the basic LCI5 scores in all the known groups but similar to the literature (Gauthier-Gagnon & Grisé, 2006) younger participants and those with traumatic causes of amputation had the highest frequency of maximum scores. Maximum total LCI5 scores were observed for 25% of the total cohort in our study. This was consistent with maximum scores of 23.6% or more reported by previous studies (Parker et al., 2010; Salavati et al., 2011). The PLUS-M (Prosthetic Limb Users Survey of Mobility) and CHAMP (Comprehensive High-level Activity Mobility Predictor) are amputee specific outcome measures that could potentially be implemented into future models of care for assessment of clients with capacity for higher level locomotor function (Gailey et al., 2013; Hafner et al., 2017).

Complications of amputation

Similar to past reviews (Gailey et al., 2008; Kulkarni, 2008), participants in our study reported a high frequency of falls, residual and remaining limb pathology. Participants in other studies (Burger, 2012; Radhakrishnan et al., 2017) have reported issues with pain and skin following amputation that were identified by our participants. Further research is required into complications of amputation because issues with skin breakdown on the residual limb may potentially explain the high rate of long term wheelchair use reported by our participants.

Return to driving and work

Our study demonstrated that return to driving and work both were significantly associated with participants who were prosthetic users. Future research may examine whether not fitting a prosthesis is an independent barrier to return to driving after amputation. High levels of locomotor function on the LCI5 were reported by participants who were prosthetic users and returned to driving or work. However, in contrast to

Schoppen et al. (2001b), self reported walking distance ≥ 500m was not significantly associated with return to driving or work. In our study, return to work was also significantly associated with transtibial amputation level but amputation level has not been significantly associated with return to work in previous studies (Fisher, Hanspal, & Marks, 2003; Schoppen et al., 2001b). This finding was interesting because prosthetic use has been associated with transtibial amputation level in the literature (Sansam et al., 2009). There was potential for male gender bias in the rates of return to driving and work due to the incidence of amputation in Australia being higher for males (Dillon et al., 2017b) and sociodemographic factors (e.g. caring for children may result in females leaving paid work for extended timeframes). Our study found that male gender was not associated with return to driving or work in the sub-groups who were drivers and workers prior to amputation. Similar to Schoppen et al. (2001a), the ASCO demonstrated that participants worked in less physically demanding occupations after amputation.

The rate of return to driving was 91% in the sub-group who were drivers prior to amputation. Rates of return to driving have been reported as high as 80.5% in people with lower limb amputation with variables including wearing a prosthesis and male gender significantly associated ability to drive after amputation (Boulias, Meikle, Pauley, & Devlin, 2006; Burger, 2012; Engkasan, Ehsan, & Chung, 2012). In our study, 61% of participants with left sided, unilateral amputation returned to driving. This higher proportion may be explained by the following:

1. No car modifications were required if the participants owned automatic transmission cars because their right lower limb remained intact.
2. It potentially reflects a pattern of right lower limb dominance in the cohort because more people with an intact right lower limb returned to driving and it was harder for participants with an amputated right lower limb to change dominance and learn to drive a car with a left foot accelerator.

Similar patterns of limb dominance have been noted in the literature by Boulias et al. (2006) however left sided unilateral amputation was not significantly associated with

return to driving in a study by Engkasan et al. (2012). Future studies should investigate the role of laterality in return to driving.

A total of 62% of participants who were employed prior to amputation, returned to paid work after amputation. Our findings were similar to previous studies that have reported rates up to 79% for return to work and job reintegration (Fisher et al., 2003; Penn-Barwell, 2011; Schoppen et al., 2001a; Schoppen et al., 2001b).
Issues with employment, driving, transportation and involvement in the community have been reported by participants with lower limb amputation in previous studies (Burger, 2012; Radhakrishnan et al., 2017). In our study, the sub-groups who were not drivers or workers prior to amputation had significantly higher age and CCI scores than participants in the sub-groups who were drivers and workers prior to amputation. A total of 54% of participants reported they were retired prior to amputation. While these findings reflect the impact of older age and comorbidities on activity and participation levels after amputation they also highlight that a large proportion of the cohort had pre-existing activity and participation limitations. Future research should include multivariate analysis and psychosocial variables including cognition, adjustment to amputation, educational level, family and financial support to assist in development of a rehabilitation model of care that facilitates return to work.

Limitations

Our study had some limitations. Firstly, there was potential for recall bias in the patient interview. This may have been an issue particularly with the prosthetic use (e.g. hours worn, standing and walking). Verbal prompts were used to improve recall accuracy and our study results for hours of prosthetic use were consistent past studies (Gauthier-Gagnon et al., 1999; Meatherall et al., 2005; Miller et al., 2001). However, some studies have found step activity monitors and GPS to be highly correlated with community ambulation (Hordacre, Barr, & Crotty, 2014) and poorly correlated with self reported estimates of step activity (Stepien et al., 2007). Although this is an area for future research as technology becomes more accessible in the clinical setting and device accuracy improves, there are potential ethical issues surrounding patient privacy with

this type of data collection (Maddison & Ni Mhurchu, 2009; McNamee, 2005; Michael, McNamee, & Michael, 2006). Secondly, some of the numbers were low in the known user groups (e.g. Aboriginal and high comorbidities) due to high mortality. However, our interviewed cohort of 201 participants (95% response rate) represents a large cohort for this area of research. The third limitation of this research was the observed ceiling effect for the LCI5 scale which suggests that the LCI5 may provide better locomotor activity discrimination early in rehabilitation for older participants with atraumatic amputation causes as previously reported (Condie et al., 2006; Gauthier-Gagnon & Grisé, 2006; Heinemann et al., 2014). Falls data was recorded from amputation surgery to the time of interview and not referenced to the time frame of 6 months from the date of interview.

7.2.5. Conclusion

This was the first study in a consecutive Australian cohort with lower limb amputation to describe long term activity and participation levels including mobility with and without a prosthesis, complications of amputation, return to driving and work after rehabilitation discharge. The LCI5 has construct validity as it identified significantly lower LCI5 scores for prosthetic users in known groups at high risk of prosthetic non-use including: age $\geq$ 58, diabetes, part-time prosthetic users, high comorbidities, atraumatic amputation cause and bilateral amputation. However, maximum scores and ceiling effects were observed for 25% of the total cohort. This suggests the LCI5 scale may be less sensitive when measuring long term locomotor function or once locomotor capabilities have improved above a specific threshold. Similar to previous studies participants who returned to driving and work were prosthetic users and reported high levels of locomotor function on the LCI5. Further investigation of outcome measures for clients with high levels of locomotor function that can be implemented into the long term follow-up phase of rehabilitation service models is warranted.

Chapter 7 Discussion

7.3. Discussion

Chapter 7 of this thesis has demonstrated that locomotor tests have construct validity and utility for assessment of people with lower limb amputation during prosthetic rehabilitation and the long term follow-up stages of rehabilitation. These studies have also contributed valuable performance data for locomotor tests by people with lower limb amputation.

Part A

Key findings from the known groups analysis of the locomotor tests were:

- 10MWT, TUGT, 6MWT and FSST were significantly different for all the known groups at high risk of prosthetic non-use including: above transtibial amputation, bilateral amputation, high comorbidities and older age
- People with Aboriginal ethnicity did not perform significantly different from non-Aboriginal people on the locomotor tests
- 10MWT and TUGT performance were not significantly different for the diabetes and atraumatic amputation groups
- 6MWT performance was significantly different for the diabetes and atraumatic amputation groups and the lower risk groups
- The 6MWT may be a more effective measure of locomotor function as it was better at discriminating between known groups at high and lower risk of prosthetic non-use
- The 10MWT, TUGT, 6MWT and FSST have convergent validity as they were all highly correlated suggesting a common functional domain is being measured by these locomotor tests. This confirms previous findings in Chapter 6 by Roffman et al. (2016b) where area under the curve for these locomotor tests was similar.

Part B

In the study of long term activity and participation:

- LCI5 scores were reported as significantly different by known groups including: older age, diabetes, part-time prosthetic users, high comorbidities, atraumatic amputation and bilateral amputation
- Aboriginal people and the above transtibial level of amputation group did not report significantly different locomotor function
- These findings support earlier work by Roffman et al. (2014) that Aboriginal ethnicity was not a predictor of prosthetic non-use
- The LCI5 may not be sensitive test of locomotor function in the long term follow-up phase of rehabilitation, due to the high ceiling effect observed for the lower limb amputation cohort.

In conclusion, these known groups studies provide evidence for the validity and utility of locomotor tests during prosthetic rehabilitation. The findings that locomotor performance was not significantly different for Aboriginal people during rehabilitation and in the long term follow-up stage of rehabilitation were important as this group of people have many risk factors (e.g. high rates of diabetes, geographical isolation from health services) that could potentially impact on functional outcome. Further research is recommended to develop an outcome measure for the long term follow-up stage of rehabilitation due to high ceiling effect observed for the LCI5.

Chapter 8

Comorbidity Burden in a cohort with lower limb amputation

Synopsis

This chapter explores comorbidity in a cohort with lower limb amputation. Construct validity for the Functional Comorbidity Index, Charlson Comorbidity Index and Combined Age Charlson Comorbidity Index is investigated using the known groups method. The manuscript in Appendix 8.1 published in Journal of Physiotherapy on the psychometric properties of the Charlson Comorbidity Index was an output of this chapter:

Roffman, Caroline E., Buchanan, John, & Allison, Garry T. (2016). Charlson Comorbidities Index. *Journal of Physiotherapy, 62*(3), 171. doi: 10.1016/j.jphys.2016.05.008

8. Comorbidity Burden in a cohort with lower limb amputation

8.1. Introduction

The global incidence of lower limb amputation ranges from 5.8 to 31 per 100 000 total population and increases to 46.1 to 9600 per 100 000 population with diabetes (Moxey et al., 2011). Dillon et al. (2014) reported that between 2000 to 2010 the absolute number of lower limb amputations in Australia had increased 14% from 7000 to 8000 per annum while the age standardised incidence of lower limb amputations remained stable at 37.41 ± 1.01 procedures per 100 000 population per annum. During this decade there was a significant increase ($p = .001$) in the incidence of minor lower limb amputation with a concomitant decrease in major lower limb amputation (Dillon et al., 2014). The ratio of minor lower limb amputations was 3 times higher than major lower limb amputations (Dillon et al., 2014).

People who undergo lower limb amputation for atraumatic causes have comorbidities that increase mortality; with 1 year mortality up to 48.3%. These comorbidities include systemic diseases such as diabetes, renal failure, cardiovascular and chronic obstructive pulmonary disease (COPD) and chronic disease risk factors such as physical inactivity, obesity and smoking. They also have non-life threatening musculoskeletal disorders such as arthritis, back, knee and shoulder pathology sometimes reported at a greater incidence for people with diabetes (Mueller, 2016).

As a result of the chronic disease and comorbidities individuals with atraumatic lower limb amputations have significantly greater healthcare costs and poorer functional outcome (Fortington et al., 2013; Hoffstad, Mitra, Walsh, & Margolis, 2015; Jones et al., 2013; Malone et al., 2014; Roffman et al., 2014; Schoppen et al., 2003; Taylor et al., 2005; van Netten, Fortington, Hinchliffe, & Hijmans, 2016).

In the presence of such high mortality and extensive comorbidity burden it would seem logical that within the lower limb amputee patient cohort, models of care in the tertiary hospital setting would document the incidence of musculoskeletal disorders, mental health issues and systemic diseases. However, it appears that in many situations the presence of these conditions is poorly defined at hospital admission. Identification of musculoskeletal disorders is important for understanding functional potential in people with lower limb amputation. To date, the literature has focused on musculoskeletal disorders being sequelae to amputation due to asymmetrical movement patterns during activities of daily living and prosthetic gait (Devan, Hendrick, Ribeiro, Hale, & Carman, 2014; Gailey et al., 2008; Kulkarni, 2008).

Comorbidities are a major consideration by multidisciplinary teams for rehabilitation interventions such as wheelchair prescription, prosthetic gait retraining, return to driving and work. Moreover, a high number of comorbidities have been associated with poorer functional outcome and self reported by people with lower limb amputation as reasons for abandonment of prosthetic use (Agrawal et al., 2014; Roffman et al., 2014, 2016b). However, within the literature there is little consensus on the most valid method of measuring comorbidity in people with lower limb amputation (Agrawal et al., 2014; Davie-Smith et al., 2016; Gailey et al., 2002; Melchiorre, Findley, & Boda, 1996; Roffman et al., 2014; van Eijk et al., 2012; Webster et al., 2012). Early methodological processes undertaken within this thesis (see Roffman et al. (2014)) counted number of comorbidities in participants with amputation. From this comorbidity estimation a threshold was derived using receiver operating characteristic curve. It was demonstrated that having a very high number of comorbidities ($\geq$ 19) was predictive of prosthetic non-use at 4 months after discharge from rehabilitation. However, it is acknowledged that this method may not be generalisable to other international settings as all conditions were included even though some were not related to mortality or functional outcome. In busy clinical settings, counting comorbidities has limited utility as it is time consuming (Roffman et al., 2014). Furthermore, the use of a validated composite index that reduces a patient's diseases into a single numeric score, based on a standardised list of comorbidities may be able to be used across multiple health contexts including

predicting mortality or functional outcome (Charlson et al., 1987; de Groot, Beckerman, Lankhorst, & Bouter, 2003; Groll et al., 2005; Roffman et al., 2014).

The Charlson Comorbidity Index (CCI) and Combined Age-CCI (CA-CCI) have been widely used in clinical research including cohorts with lower limb amputation, to measure mortality risk and burden of disease (Charlson et al., 1987; Charlson et al., 1994; Fortington et al., 2013; Hall et al., 2004; Hoffstad et al., 2015; Quan et al., 2011; Roffman et al., 2014; van Eijk et al., 2012; Webster et al., 2012; Wu, Hsu, Chang, Yu, & Lee, 2015). However, while the CCI and CA-CCI provide insight into mortality risk it is unclear whether these indices have adequate sensitivity to measure functional outcome following lower limb amputation (Gailey et al., 2002; Melchiorre et al., 1996; van Eijk et al., 2012; Webster et al., 2012).

The Functional Comorbidity Index (FCI) has been proposed as the measure of comorbidity to use when physical function is the primary outcome of interest (Groll, Heyland, Caeser, & Wright, 2006; Groll et al., 2005; Haines, Berney, Warrillow, & Denehy, 2014). The FCI includes diseases that impact on function such as arthritis, obesity, visual impairment and mental illness but do not necessarily increased mortality (Groll et al., 2005). FCI is highly correlated with the physical function section of the SF36 (Spearman Rho up to 0.6) (Groll et al., 2006; Groll et al., 2005; Haines et al., 2014) but there has been limited use in amputation cohorts (Davie-Smith et al., 2016; de Laat et al., 2014).

In the literature, high comorbidities have been reported in sub-groups with lower limb amputation including atraumatic amputation cause, older age, diabetes, Aboriginal ethnicity, above transtibial amputation level, bilateral lower limb amputation and people who abandon using a prosthesis (Fortington et al., 2013; Jones et al., 2013; van Netten et al.; Vos et al., 2009). The "known groups" method has been used to evaluate construct validity of tests by demonstrating their capacity to significantly discriminate between groups that are known to differ in the literature (Hattie & Cooksey, 1984; Megens et al., 2007). However, construct validity of comorbidity indices has been rarely investigated

(Hall, 2006; Kiefe, Funkhouser, Fouad, & May, 1998; Moltó & Dougados, 2014; Spaetgens, Wijnands, van Durme, & Boonen, 2015). A known groups analysis in lower limb amputation sub-groups with high and low comorbidities would provide important knowledge on the level of sensitivity for the FCI, CCI and CA-CCI and clinical utility of comorbidity indices in amputation cohorts.

The aims of this study were:
1. To map comorbidities (including musculoskeletal pathology and mental illness) that were present at hospital admission in a cohort with lower limb amputation.
2. To describe the relationship between number of comorbidities and FCI, CCI and CA-CCI scores.
3. To evaluate the construct validity of using comorbidity indices in people with lower limb amputation in known groups with high and low comorbidities.

The hypotheses generated for this study were:

1. Known groups reported in the literature as having high comorbidities including those with atraumatic amputation cause, diabetes, Aboriginal ethnicity, above transtibial amputation level, bilateral lower limb amputation, older age and those who become prosthetic non-users will have significantly higher scores on the FCI, CCI and CA-CCI than the groups with lower comorbidities.
2. The FCI will identify lower limb amputation groups with known high and low comorbidities with greater sensitivity than the CCI and CA-CCI.

8.2. Methods

Participants

This study was approved by the Royal Perth Hospital (RPH) and Curtin University Human Research Ethics Committees (see Appendix 3.1). An independent research assistant recruited and obtained informed verbal consent from participants.

Inclusion criteria for participants were: at least one recent major lower limb amputation (i.e. transtibial level or above), multiple limb amputation, lived in the community,

ambulant before amputation surgery, Medicare Functional Classification Level (MFCL) K-level 1 to 4 (Gailey et al., 2002), had undergone prosthetic rehabilitation and been discharged from Royal Perth Hospital (RPH), the state centre for amputee rehabilitation. K-levels were assigned collaboratively in the post-operative period by the Rehabilitation Physician and Senior Physiotherapist Amputee Rehabilitation (with 10 years of clinical experience) as part of the RPH assessment procedure for rehabilitation admission based on criteria outlined in Roffman et al. (2014).

K-level 0 participants, those unable to communicate or who did not consent were excluded from this study. Participants were assessed as K-level 0 due to: comorbidities (e.g. heart failure, COPD, Parkinson's disease), medications (e.g. warfarinisation), cognitive impairment, high level or multiple limb amputation, remaining limb pathology, increased body weight, mental health issues, poor motivation, no social support, poor premorbid mobility and falls history (Roffman et al., 2014). The multidisciplinary amputee outpatient clinic was used to monitor K-level 0 participants and K-level of these participants did not change during this study.

Participant eligibility and recruitment into this study is outlined in Figure 8.1. A total of 201 participants were recruited out of the 211 eligible participants for this study. The final response rate was 95%.

Procedure

The Senior Physiotherapist developed and implemented a standardised physiotherapy assessment form for people with lower limb amputation to record data on comorbidity and rehabilitation outcome at RPH (see appendix 8.2). Medical records were abstracted for 201 consecutive participants with lower limb amputation by the Senior Physiotherapist Amputee Rehabilitation using a previously piloted and standardised data collection form (see appendix 8.3). Comorbidities at hospital admission for amputation were recorded for each participant. The operational definition of comorbidity in this study was any condition that was documented in the medical record including musculoskeletal pathology and mental illness (de Groot et al., 2003; Groll et al., 2005).

The comorbidities were given a numerical code and entered into a database. Comorbidities were totalled for each participant. Cohort characteristics including amputation, demographic and admission details were also abstracted from the medical records (figure 8.1).

Table 8.1 summarises the comorbidities and scoring for the FCI, CCI and CA-CCI. The FCI is scored by binary classification (yes = 1, no = 0) of comorbidities, summed to a maximum score of 18 (Groll et al., 2005). The CCI consists of 17 comorbidities, with 2 subcategories for diabetes and liver disease that have been weighted from 1 to 6 for mortality risk and disease severity (Charlson et al., 1987; Charlson et al., 1994; Roffman et al., 2014). The CA-CCI adds additional 1 point for each decade of age over 40 years to the CCI score to account for age being an independent predictor of mortality (Charlson et al., 1987; Charlson et al., 1994; Roffman et al., 2014). In this study, total CCI and CA-CCI scores were generated using the electronic calculator developed by Hall et al. (2004). Higher scores in the FCI, CCI and CA-CCI indicate increased disease severity (Charlson et al., 1987; Groll et al., 2005). One year mortality of 85% has been reported for CCI score $\geq$ 5 and 10 year survival of 34% for CA-CCI scores of 5 (Charlson et al., 1987).

Inter-rater reliability has been reported as moderate to good for the FCI and CCI, with intraclass correlations (ICC) up to 0.91 and 0.945 respectively (Fan et al., 2012). The CCI has high test re-test reliability with an ICC of .92 ($p < .0001$) (Katz, Chang, Sangha, Fossel, & Bates, 1996). Criterion validity for comorbidity indices has generally been demonstrated through comparison to other indices (Hall, 2006). Strong correlation between the FCI and CCI has been reported for patients with Acute Respiratory Distress Syndrome (ARDS) (Spearman Rho = 0.62, $p < .001$) (Groll et al., 2006).

Participants were interviewed after the medical record abstraction to determine if they were prosthetic users or non-users, their general health, condition of residual and remaining limbs, demographic, amputation, falls, physical function, return to driving and work details.

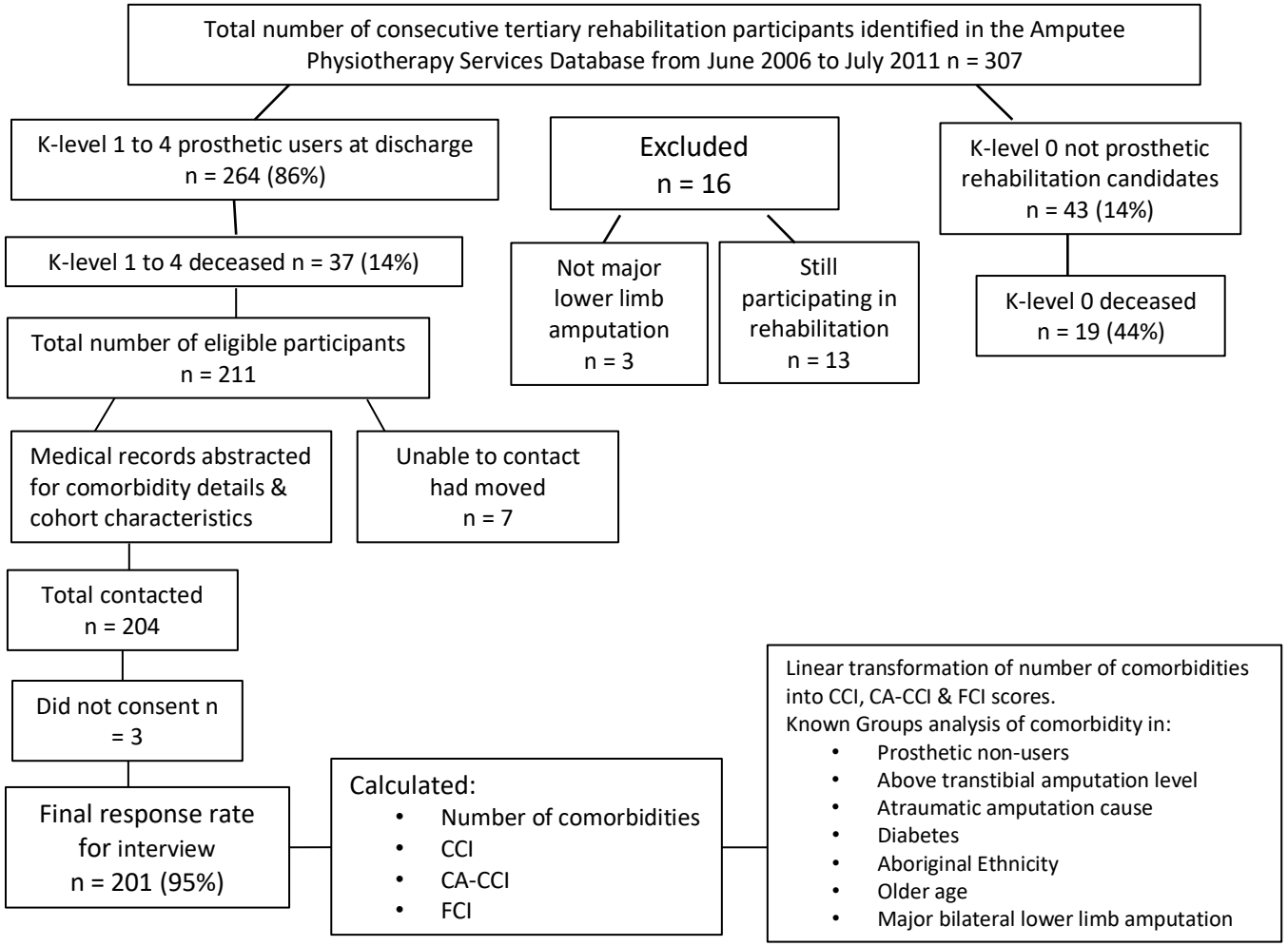

Figure 8.1: Flow chart for participants and study methodology.

Table 8.1: Scoring and comorbidities for the Functional Comorbidity Index (FCI), Charlson Comorbidity Index (CCI) and Combined Age - Charlson Comorbidity Index (CA-CCI).

Functional Comorbidity Index (FCI)	Charlson Comorbidity Index (CCI)	Combined Age - Charlson Comorbidity Index (CA-CCI)
1. Arthritis 2. Osteoporosis 3. Asthma 4. Chronic Obstructive Pulmonary Disease (COPD), acquired respiratory distress syndrome (ARDS) or emphysema 5. Angina 6. Congestive heart failure (or heart disease) 7. Heart attack (myocardial infarct) 8. Neurological disease (such as multiple sclerosis or Parkinson's disease) 9. Stroke or TIA 10. Peripheral vascular disease 11. Diabetes type I or II 12. Upper gastrointestinal disease (ulcer, hernia, reflux) 13. Depression 14. Anxiety or panic disorders 15. Visual impairment (such as cataracts, glaucoma or macular degeneration) 16. Hearing impairment (hard of hearing or even with hearing aids) 17. Degenerative disc disease (back disease, spinal stenosis or severe back pain) 18. Obesity and or body mass index > 30	1. Myocardial infarct 2. Congestive heart failure 3. Peripheral vascular disease 4. Cerebrovascular disease 5. Dementia 6. Chronic pulmonary disease 7. Connective tissue disease 8. Ulcer disease 9. Stroke or transient ischemic attack 10. Diabetes 11. Hemiplegia 12. Moderate or severe renal disease 13. Diabetes with end organ damage 14. Any tumour 15. Leukaemia 16. Lymphoma 17. Moderate or severe liver disease 18. Metastatic solid tumour 19. AIDS	1. Myocardial infarct 2. Congestive heart failure 3. Peripheral vascular disease 4. Cerebrovascular disease 5. Dementia 6. Chronic pulmonary disease 7. Connective tissue disease 8. Ulcer disease 9. Stroke or transient ischemic attack 10. Diabetes 11. Hemiplegia 12. Moderate or severe renal disease 13. Diabetes with end organ damage 14. Any tumour 15. Leukaemia 16. Lymphoma 17. Moderate or severe liver disease 18. Metastatic solid tumour 19. AIDS Age range categories by decade: 0 to 49 years 50 to 59 years 60 to 69 years 70 to 79 years 80 to 89 years 90 to 99 years 100 years +
Scored by simple count of No = 0 & Yes = 1 for each comorbidity. Sum of scores equals total FCI out of 18.	Comorbidities have weighted scores if present. Numbers 1 to 10 score = 1. Numbers 11 to 16 score = 2. Number 17 score = 3. Numbers 18 to 19 score = 6. Maximum total score = 37.	Comorbidities are scored the same as the CCI. An extra 1 point is added for every decade the person is aged over 40 years up to 6 points for 100 years + Maximum total score = 43.

Statistical Methods

Descriptive statistics were generated for the comorbidities data abstracted from the medical records and participant interview. Number of comorbidities, FCI, CCI and AC-CCI were calculated for each participant. Comorbidities were assigned to the following categories: diabetes, cardiovascular, pulmonary, musculoskeletal, neurological, renal, cancer, urological, falls, vision, skin, gastrointestinal, endocrine, substance abuse, psychological, cognitive, infectious diseases and frequencies were calculated.
Data were analysed in sub-groups using a known groups analysis methodology.

The known high comorbidity groups for analysis were:

- prosthetic non-users,
- atraumatic amputation cause,
- diabetes,
- Aboriginal ethnicity,
- older age ($\geq$ 58 years),
- above transtibial amputation, and
- bilateral lower limb amputation

(Fortington et al., 2013; Jones et al., 2013; Roffman et al., 2014; Schoppen et al., 2003; Taylor et al., 2005; van Netten et al.; Vos et al., 2009; Webster et al., 2012).

Sharpiro Wilk tests demonstrated that the comorbidity data were not normally distributed so non-parametric analyses were performed using the Mann-Whitney U Test (MWUT) to determine the statistical separation between the known groups with high and low comorbidities (two tailed, 95% Confidence Intervals (CI)). The effect size was plotted for the each of the known groups analyses to demonstrate the effect size of the individual comorbidity indices. Effect size was calculated by dividing the Z score with the square root of the number of participants, using the following equation:

$$r = \frac{Z}{\sqrt{N}}$$

Effect size of comorbidity indices was plotted for the known groups. The following values were used to define effect size of comorbidity indices: small effect = 0.1, medium effect = 0.3 and large effect = 0.5 (Field, 2009). Since the effect sizes were derived from the same cohort (split by the known group dichotomy) the sample size and degrees of freedom were identical for each statistical analysis. Therefore the 95% confidence limit for each analysis was identified for each of the group comparisons.

To improve the generalisability and utility of the comorbidity count by Roffman et al. (2014) the threshold of $\geq$19 comorbidities was cross-validated with the FCI, CCI and CA-CCI. Number of comorbidities was plotted against FCI, CCI and CA-CCI scores to determine if there was a relationship between these measures of comorbidity. Bubble plots were used so that high frequency data points could be visualized (i.e. the higher the frequency of the data point the larger the bubble size). R^2 and linear transformations were calculated for these bubble plots. Using the equation generated from the bubble plots FCI, CCI and CA-CCI score were calculated for having a very high number of comorbidities ($\geq$19).

8.3. Results

A total of 26% (52) of participants were prosthetic non-users when interviewed at median, 1.5 (IQR, 1.2 to 2.2) years after discharge from rehabilitation. Table 8.2 shows the median and interquartile range of comorbidity index scores, age categories amputation and demographic details for the total cohort (n = 201). Appendix 8.4 Table 8.3 summarises the frequency of common comorbidities including musculoskeletal pathology and mental illness in the total cohort. The rate of diabetes was significantly higher ($z = 4.66$, $p < .0001$) in participants of Aboriginal ethnicity at 86% (n = 25) in contrast to 40% (n = 68) for non-Aboriginal participants. A total of 33% (n = 67) had both the diagnoses of diabetes and peripheral arterial disease. Of the people with bilateral lower limb amputation, 61% (n = 19) had bilateral transtibial amputation levels.

Table 8.2: Median and interquartile range of number comorbidities, Functional Comorbidity Index (FCI), Charlson Comorbidity Index (CCI) and Combined Age - Charlson Comorbidity Index (CA-CCI), age categories and demographics for total cohort (n = 201).

Comorbidity Index	Median (interquartile range) Total Cohort (n = 201)
Number of comorbidities	10 (5 to 15)
Functional Comorbidity Index (FCI)	3 (1 to 5)
Charlson Comorbidity Index (CCI)	2 (1 to 4)
Combined Age - Charlson Comorbidity Index (CA-CCI)	4 (1 to 6)
Gender, males, n (%)	161 (80)
Age at amputation, Mean (SD)	55.5 (15.5)
Age Categories for CA-CCI, n (%)	
0 to 49 years	63 (31)
50 to 59 years	47 (23)
60 to 69 years	50 (25)
70 to 79 years	29 (14)
80 to 89 years	12 (6)
90 to 99 years	0 (0)
100 years +	0 (0)
Amputation Level, n (%)	
Transtibial	163 (81)
Knee disarticulation	7 (3)
Transfemoral	62 (31)
Minor amputation of remaining lower limb, n (%)	21 (10)
Major Bilateral amputation, n (%)	31 (15)
Bilateral transtibial	19 (9)
Transtibial and transfemoral	8 (4)
Knee disarticulation and transfemoral	1 (0.5)
Bilateral transfemoral	3 (2)
Upper limb amputation, n (%)	20 (10)
Amputation Cause, n (%)	
Circulatory	52 (26)
Infection	87 (43)
Trauma	54 (27)
Cancer	8 (4)
Ethnicity, Aboriginal, n (%)	29 (14)
Accommodation, n (%)	
Home (not residential care)	194 (96)
Metropolitan (not country)	127 (63)
Social Support, lives with others (not alone), n (%)	160 (80)

Figures 8.2 to 8.4 demonstrate bubble plots with the linear transformations and R^2 for number of comorbidities versus FCI, CCI and CA-CCI. Figures 8.5 to 8.7 demonstrate bubble plots between the comorbidity indices. A total of 9% (18) had ≥19 comorbidities. The equations generated from bubble plots in Figures 8.2 to 8.3 demonstrate that having 19 comorbidities were associated with CCI = 5, FCI 6 and CA-CCI 7 (algebraic estimations were CCI = 4.95, FCI = 5.95, and CA-CCI = 7.05).

Of the total cohort, 14% (29) scored ≥ 6 on the FCI, 19% (39) scored ≥ 5 on the CCI and 20% (41) scored ≥ 7 on the Aged Adjusted CCI.

The FCI had the best model fit explaining 71% of the variance for number of comorbidities.

Known Groups Analysis

Table 8.4 details the median, interquartile range (IQR) and Mann Whitney U Test results for measures of comorbidity in known groups with high comorbidity including prosthetic non-users, atraumatic amputation, Aboriginal ethnicity, older age (≥58 years), above transtibial amputation and bilateral amputation. Figures 8.8 to 8.14 demonstrate the effect size of the comorbidity indices for the known groups. The alpha level of .05 that occurred at an effect size of 0.138 was plotted on the graphs to demonstrate the magnitude of effect size for comorbidity indices in the known groups.

Prosthetic non-users had significantly higher number of comorbidities, FCI and CCI scores than users ($p \leq .0414$) and effect size was greatest for number of comorbidities. The atraumatic, diabetes and older age (≥ 58 years) groups had significantly higher number of comorbidities, FCI, CCI and CA-CCI scores than the traumatic, no diabetes and younger groups ($p < .0001$). The Aboriginal group had significantly higher CCI than non-Aboriginal group ($p = .0147$). The above transtibial amputation group had significantly lower CCI and CA-CCI scores than the transtibial amputation group ($p \leq .0203$). Comorbidity scores for the bilateral lower limb amputation group were not significantly different from the unilateral amputation group ($p \geq .0949$).

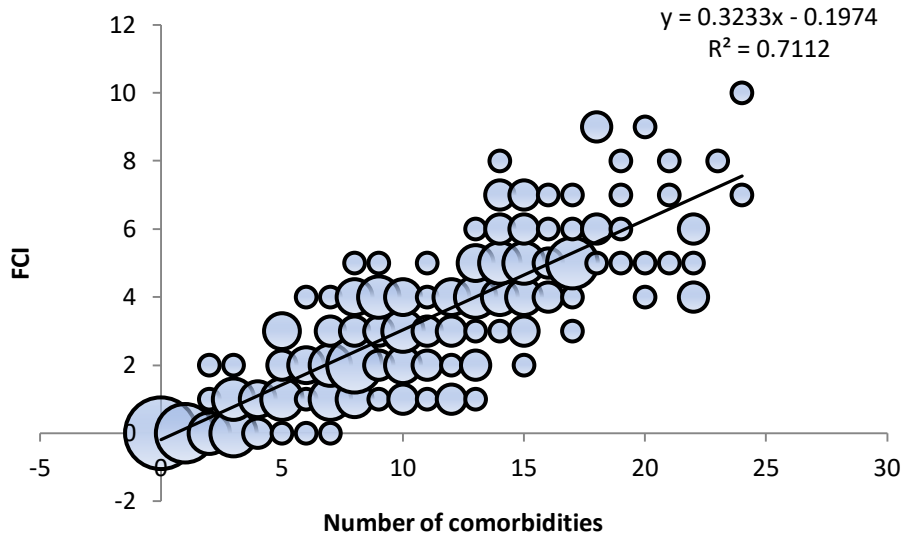

Figure 8.2: Bubble plot of number of comorbidities versus Functional Comorbidity Index (FCI) scores for people with lower limb amputation (n = 201).

The bubble size corresponds to frequency of the data point (i.e. larger bubbles for higher frequency data points).

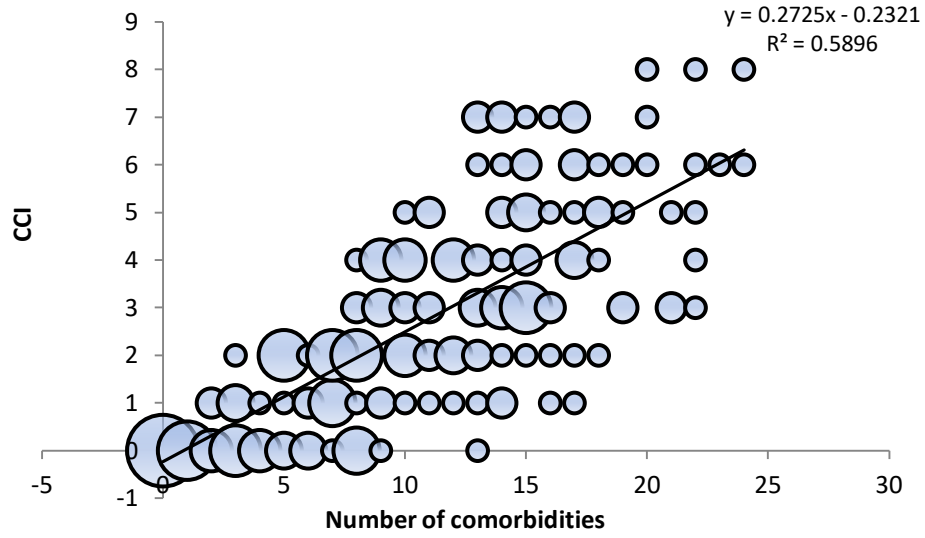

Figure 8.3: Bubble plot of number of comorbidities versus Charlson Comorbidity Index (CCI) scores for people with lower limb amputation (n = 201).

The bubble size corresponds to frequency of the data point (i.e. larger bubbles for higher frequency data points).

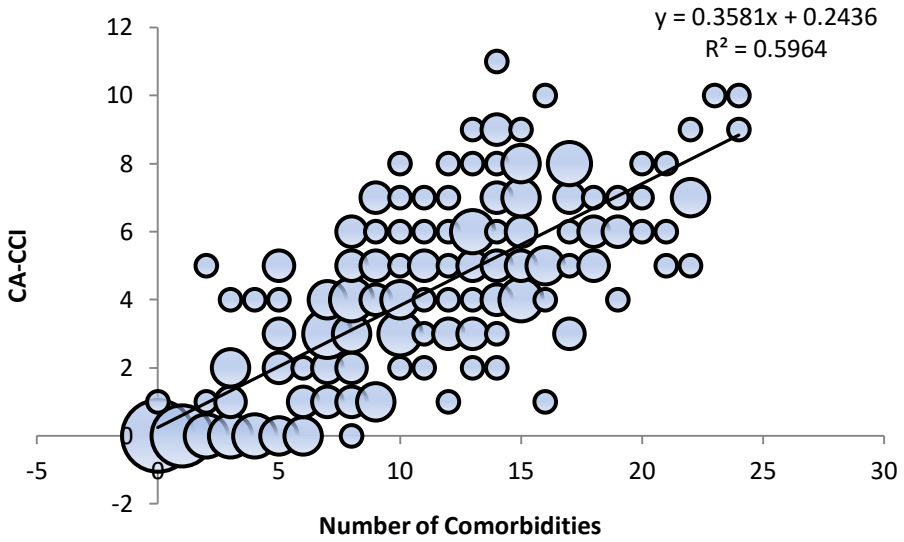

Figure 8.4: Bubble plot of number of comorbidities versus Combined Age Charlson Comorbidity Index (CA-CCI) scores for people with lower limb amputation (n = 201).

The bubble size corresponds to frequency of the data point (i.e. larger bubbles for higher frequency data points).

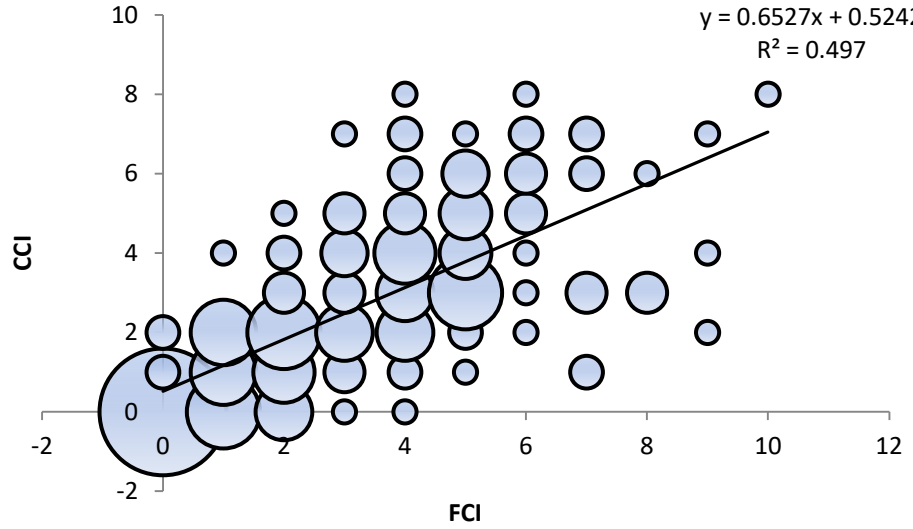

Figure 8.5: Bubble plot of Functional Comorbidity Index (FCI) versus Charlson Comorbidity Index (CCI) scores for people with lower limb amputation (n = 201).

The bubble size corresponds to frequency of the data point (i.e. larger bubbles for higher frequency data points).

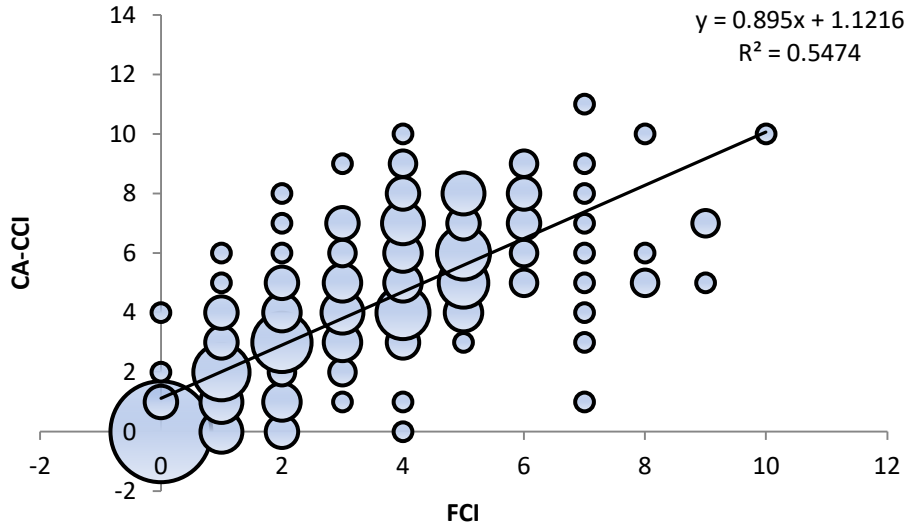

Figure 8.6: Bubble plot of Functional Comorbidity Index (FCI) versus Combined Age Charlson Comorbidity Index (CA-CCI) scores for people with lower limb amputation (n = 201).

The bubble size corresponds to frequency of the data point (i.e. larger bubbles for higher frequency data points).

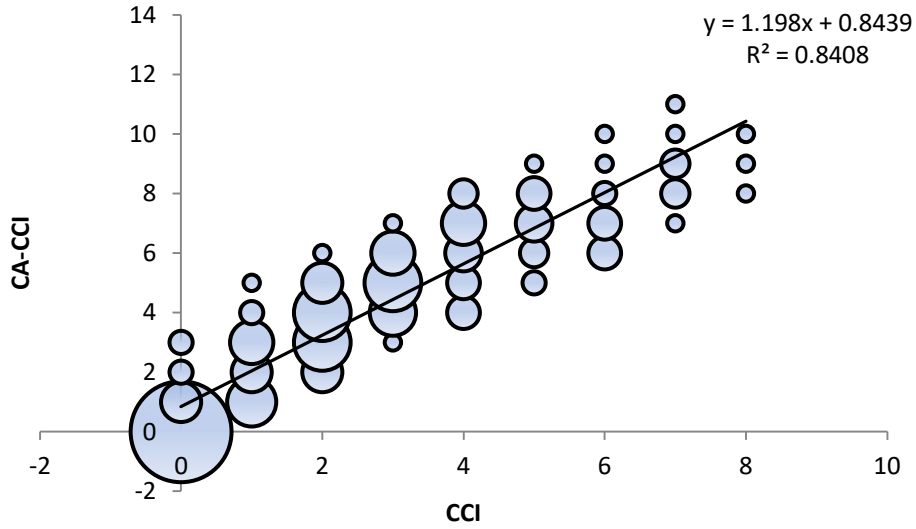

Figure 8.7: Bubble plot of Charlson Comorbidity Index (CCI) versus Combined Age Charlson Comorbidity Index (CA-CCI) scores for people with lower limb amputation (n = 201).

The bubble size corresponds to frequency of the data point (i.e. larger bubbles for higher frequency data points).

Table 8.4: Median, Interquartile Range (IQR) and Mann Whitney U Test for measures of comorbidity in known groups with high and low comorbidity (95% CI).

Known groups & measures of comorbidity	n1	n2	n1 median (IQR)	n2 median (IQR)	U score	Z score	p value	Effect size
Prosthetic non-users vs. users	52	149						
No. of comorbidities			14 (7.75 to 17)	9 (5 to 14)	5026	-3.19	.0014	-0.225
FCI			4 (2 to 5)	2 (1 to 4)	4778	-2.5	.0124	-0.176
CCI			3 (1 to 5)	2 (0 to 4)	4612	-2.04	.0414	-0.144
CA-CCI			4 (3 to 7)	4 (1 to 5)	4584	-1.96	0.05	-0.138
Atraumatic vs. Traumatic	147	54						
No. of comorbidities			12 (8 to 15)	4 (1 to 9)	1740	6.1	< .0001	0.430
FCI			4 (2 to 5)	0 (0 to 2)	1774	6	< .0001	0.423
CCI			3 (2 to 5)	0 (0 to 1)	1138	7.74	< .0001	0.546
CA-CCI			5 (3 to 7)	0 (0 to 2)	1158	7.69	< .0001	0.542
Diabetes vs. No diabetes	93	108						
No. of comorbidities			13 (9 to 17)	7 (3 to 12)	2330	6.55	< .0001	0.462
FCI			4 (3 to 5)	1 (0 to 4)	2244	6.75	< .0001	0.476
CCI			4 (2 to 5)	1 (0 to 2)	1304	9.04	< .0001	0.638
CA-CCI			5 (4 to 7)	2 (0 to 4)	1904	7.58	< .0001	0.535
Age $\geq$ 58 vs. < 58 years	92	109						
No. of comorbidities			13 (8 to 15)	8 (3 to 13)	6986	-4.8	< .0001	-0.339
FCI			4 (2 to 5)	2 (0 to 4)	7382	-5.76	< .0001	-0.406
CCI			3 (2 to 4)	1 (0 to 3)	6796	-4.33	< .0001	-0.305
CA-CCI			5 (4 to 7)	2 (0 to 4)	8240	-7.85	<. 0001	-0.554
Aboriginal vs. Non-Aboriginal	29	172						
No. of comorbidities			10 (7 to 15)	10 (5 to 15)	2648	-0.53	.5961	-0.037
FCI			3 (1 to 5)	3 (1 to 5)	2606	-0.39	.6965	-0.028
CCI			3 (2 to 5)	2 (0 to 4)	3201	-2.44	.0147	-0.172
CA-CCI			4 (3 to 6)	4 (1 to 6)	2793	-1.03	.303	-0.073

Known groups & measures of comorbidity	n1	n2	n1 median (IQR)	n2 median (IQR)	U score	Z score	p value	Effect size
Above transtibial vs. transtibial	65	136						
No. of comorbidities			8 (4 to 15)	11 (7 to 15)	3836	1.51	.131	0.107
FCI			2 (1 to 4)	3 (1 to 5)	3830	1.53	.126	0.108
CCI			2 (0 to 3)	2.5 (1 to 4)	3524	2.32	.0203	0.164
CA-CCI			3 (0 to 5)	4 (2 to 6)	3426	2.57	.0102	0.181
Bilateral vs. unilateral	31	170						
No. of comorbidities			10 (6 to 16.5)	10 (5 to 14)	2942	-1.03	.303	-0.073
FCI			4 (2 to 5)	3 (1 to 5)	3118	-1.62	.1052	-0.114
CCI			3 (1 to 6)	2 (1 to 4)	3133	-1.67	.0949	-0.118
CA-CCI			5 (2.5 to 7)	4 (1 to 6)	3085	-1.51	.131	-0.107

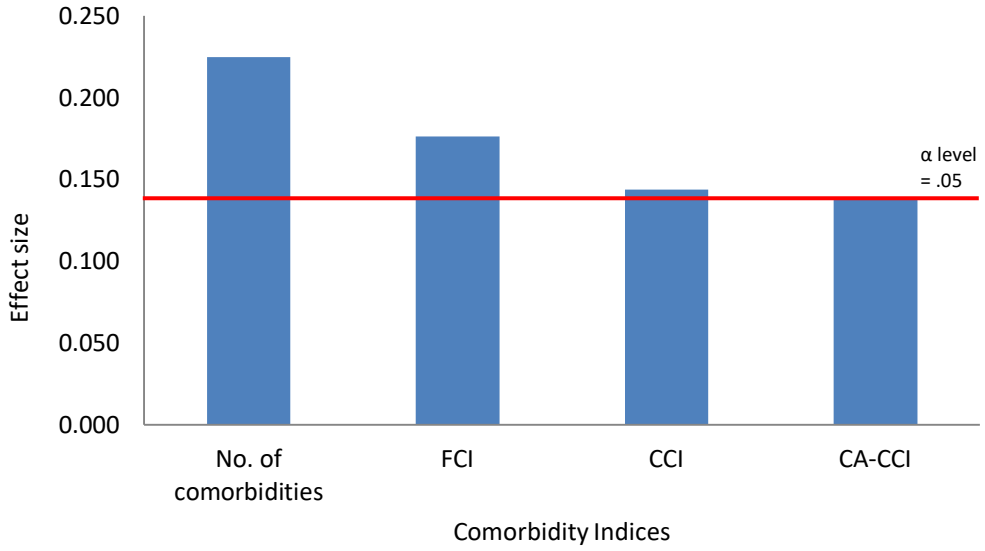

Figure 8.8: Effect size of comorbidity indices for people who become prosthetic users and non-users.

Effect sizes above the line (alpha =0.05) identify significant differences between groups. The number of comorbidities separates the user and non-user groups showing greater sensitivity for this known dichotomy.

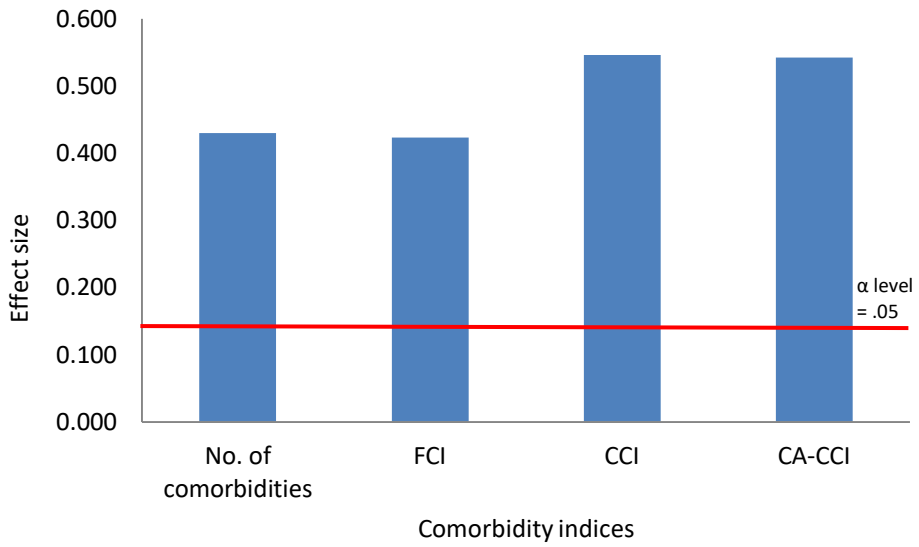

Figure 8.9: Effect size of comorbidity indices for people with atraumatic & traumatic amputation causes.

All comorbidity scales are well above the line (alpha =0.05) identifying significant differences between groups. The CCI and Age adjusted CCI showed greater sensitivity for this known dichotomy.

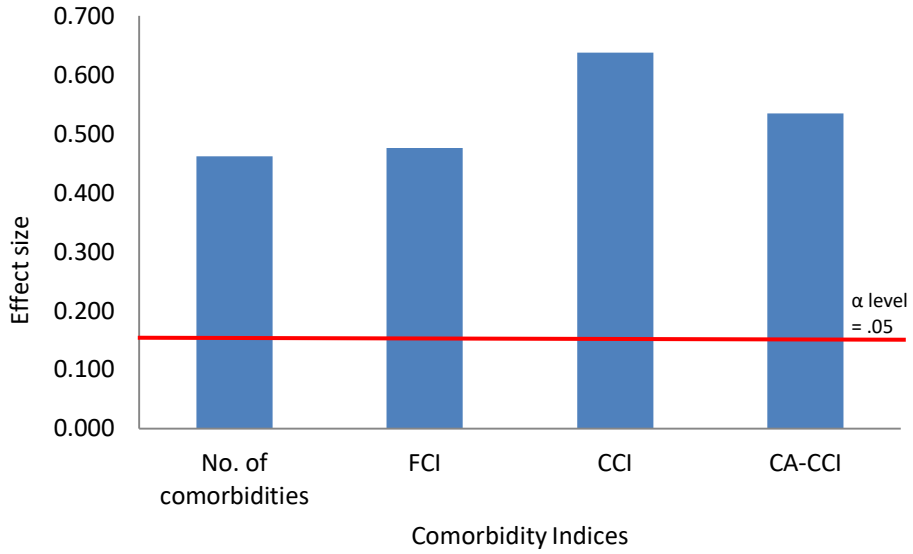

Figure 8.10: Effect size of comorbidity indices in people with and without diabetes.

All comorbidity scales are well above the line (alpha =0.05) identifying significant differences between groups. The CCI showed greater sensitivity for this known dichotomy.

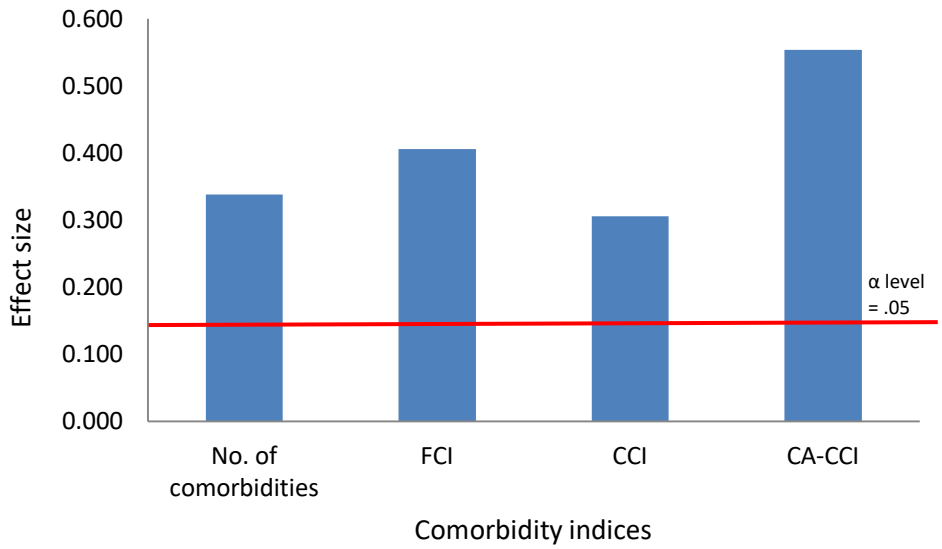

Figure 8.11: Effect size of comorbidity indices for people with amputation who are older and younger.
All comorbidity scales are above the line (alpha =0.05) identifying significant differences between groups. As expected the Combined Age CCI had the greatest sensitivity for this known dichotomy.

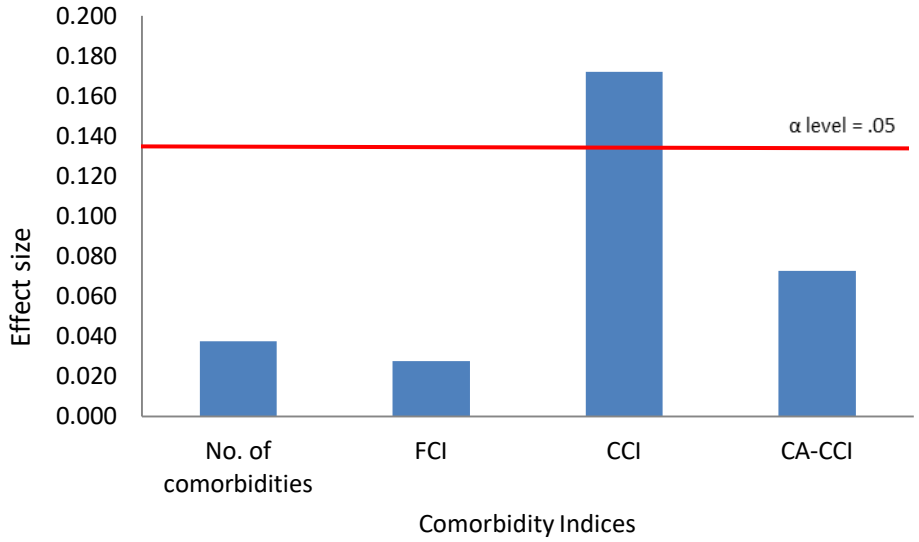

Figure 8.12: Effect size of comorbidity indices for people with Aboriginal and non-Aboriginal ethnicity. The only index to be sensitive to this known group dichotomy was the CCI. All other comorbidity scales failed to statistically separate the known groups.

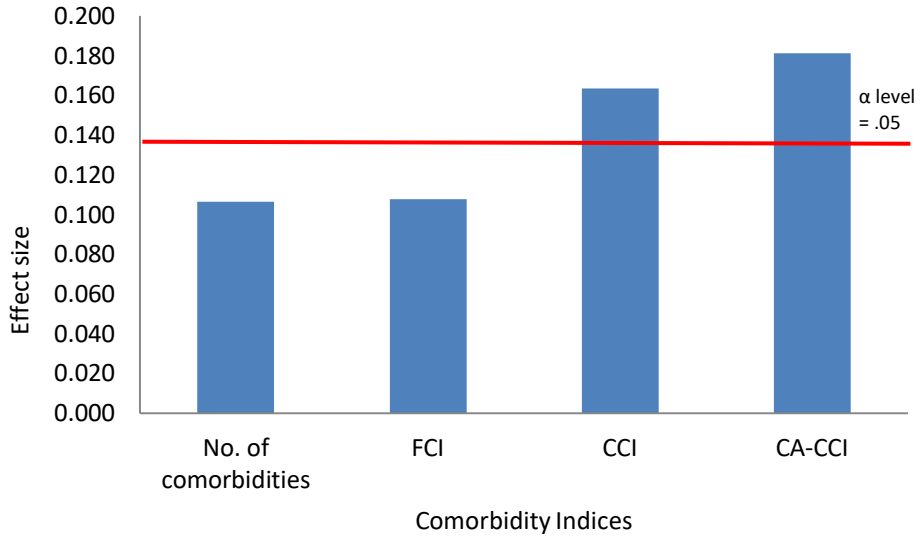

Figure 8.13: Effect size of comorbidity indices for people with above transtibial and transtibial amputation. The CCI and the age adjusted version of the CCI were the only scales able to separate the groups statistically.

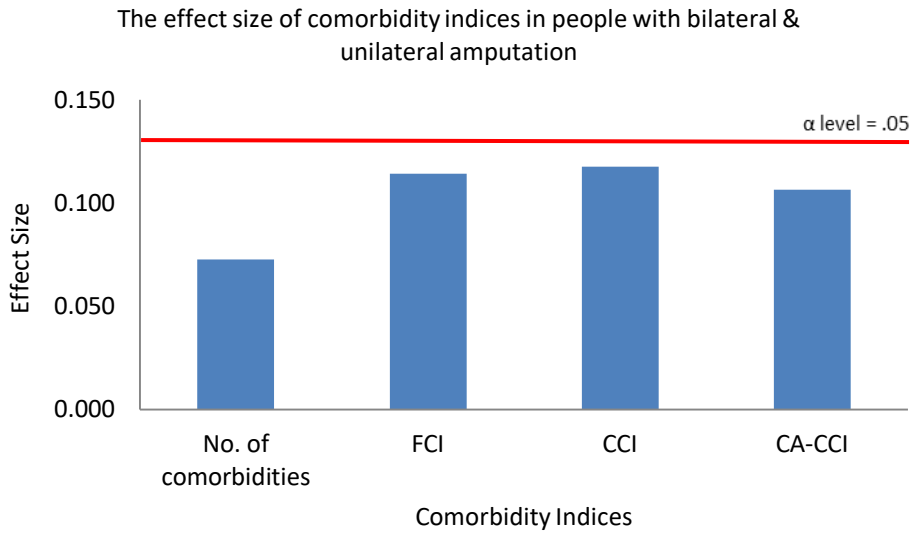

Figure 8.14: Effect size of comorbidity indices for people with unilateral and bilateral lower limb amputation. No comorbidity scale was able to separate the two known groups suggesting that there may not be any observable systematic differences between the known groups.

The CCI had the greatest effect size in the diabetes, atraumatic amputation, transtibial and Aboriginal known groups analyses of the comorbidity indices. Effect size was greatest for the CA-CCI for the older age known groups analysis.

8.4. Discussion

This study has mapped comorbidities associated with function and mortality in a heterogeneous cohort with lower limb amputation who underwent prosthetic rehabilitation. The study has demonstrated that in people with lower limb amputation, FCI, CCI and CA-CCI scores all had strong positive correlations with number of comorbidities. From the known groups analysis, the CCI had the greatest construct validity which may be due to its stronger link to mortality.

The FCI had the strongest relationship to number of comorbidities explaining 71% of variance in the model. A FCI score of 6 was equivalent to ≥ 19 comorbidities reported by Roffman et al. (2014) as a predictor of prosthetic non-use at 4 months after rehabilitation discharge. This stronger relationship may have been related to the fact that FCI and number of comorbidities scales were both summed totals while scales for the CCI and CA-CCI had comorbidities that were weighted based on mortality risk, disease severity and age. Therefore, a known groups analysis was performed to determine which comorbidity index separated the scale most effectively in high and low comorbidity groups with lower limb amputation.

It is difficult to compare CCI scores from the literature (Fortington et al., 2013; Hoffstad et al., 2015; van Eijk et al., 2012; Webster et al., 2012) due to different methodology used in amputation cohort studies, as some researchers have included or excluded diabetes and peripheral arterial disease while others have used the CCI to generate a standardised list of comorbidities and not reported scores. Webster et al. (2012) used the CCI to stratify 87 participants with transmetatarsal, transtibial and transfemoral amputation into low (0 to 3 points), moderate (3.1 to 5.9 points), high (6 to 7.9 points) and very high (≥ 8 points) burden of disease. In this study a total of 49% of participants

with transtibial and transfemoral amputation had moderate to very high CCI scores (Webster et al., 2012).

The FCI scores in our study were similar to those reported in the literature for cohorts with amputation (Davie-Smith et al., 2016; de Laat et al., 2014). de Laat et al. (2014) reported that 39% of a cohort with both atraumatic and traumatic causes of amputation had an FCI $\geq$ 4. In a cohort with amputation from vascular and diabetic causes, the mean FCI was 3.2 (SD = 1.9) (Davie-Smith et al., 2016).

Known Groups analysis

The known groups analysis in our study has improved understanding of the scale for common comorbidity indices and provided representative scores for lower limb amputation in the WA health context. The magnitude of significance or effect size of comorbidity indices tested (as demonstrated by p and *r* values) was greatest for the atraumatic, diabetes and older age subgroups with high comorbidity and their associated lower comorbidity sub-groups with medium to large effect demonstrated.

Prosthetic non-users

In the prosthetic non-user known group analysis, number of comorbidities was validated as having the greatest effect size and FCI was the second most sensitive method for analysing comorbidity. Comorbidity has been the main reason reported in the literature for not fitting a prosthetic limb and proceeding with gait retraining in people with lower limb amputation (Davie-Smith et al., 2016; Fletcher et al., 2001; Fletcher et al., 2002; Webster et al., 2012). People with 5 to 10 comorbidities have been shown to score significantly lower for functional prosthetic use on the Houghton Scale and LCI (Agrawal et al., 2014). de Laat et al. (2014) demonstrated that participants with higher FCI scores reported significantly greater difficulty performing rising activities using a prosthetic limb from the Locomotor Capabilities Index (LCI) including rising from a chair, picking up an object and floor transfers. Past studies (Gailey et al., 2002; Melchiorre et al., 1996) have also shown that as score on the Melchiorre Comorbidity

Index (a modified version of the CCI) increases, ability to walk using a prosthetic limb decreases.

Atraumatic amputation

In our study participants with atraumatic amputation had significantly higher number of comorbidities, FCI, CCI and CA-CCI scores compared to those with traumatic amputation. Large effect was demonstrated by the CCI and CA-CCI. These findings were supported by Schoppen et al. (2003) who demonstrated that functional outcome could be predicted at 2 weeks after surgery in people with atraumatic causes of lower limb amputation through age at amputation, single limb balance on unaffected limb, cognitive impairment and the presence of severe comorbidity. In atraumatic amputation cohorts, poor functional outcome has been associated with comorbidities including end staged renal failure (ESRF), ischaemic heart disease, cerebrovascular disease, diabetes, depression, dementia and previous arterial revascularisation surgery (Schoppen et al., 2003; Taylor et al., 2005; Webster et al., 2012). Webster et al. (2012) demonstrated that the number of hours people with atraumatic amputation walk using a prosthesis was significantly reduced in people with a history of end stage renal failure and major depressive episodes. However in contrast to our study, Webster et al. (2012) reported that CCI was not sensitive enough as a measure of disease burden to identify people with atraumatic amputation who were fitted with prosthesis.

Older age

Similar to past studies (Schoppen et al., 2003; Taylor et al., 2005; van Eijk et al., 2012) we found participants with older age ($\geq$ 58 years) had significantly higher number of comorbidities FCI, CCI and CA-CCI scores compared to younger participants. The CA-CCI was validated as the most sensitive comorbidity index because it had the largest effect size. Independent association of older age with mortality has been demonstrated following lower limb amputation in the presence of heart failure, renal disease, cancer and COPD with every 5 year incremental increase of age (Jones et al., 2013). Studies (Roffman et al., 2014; Webster et al., 2012) have demonstrated ages of 55 years or greater and comorbidities were associated with prosthetic non-use or fewer hours of

prosthetic walking. In a geriatric lower limb amputation cohort where the median age was 79.7 years, only 36% of participants were successfully fitted with a prosthetic limb (Fletcher et al., 2001). In this study, advanced age, cerebrovascular disease, dementia and transfemoral amputation level were significantly associated with failure to fit a prosthetic limb (Fletcher et al., 2001).

Diabetes

In our study people with a diagnosis of diabetes had significantly higher number of comorbidities, FCI, CCI and CA-CCI scores than those without diabetes. A large effect was demonstrated for the CCI. Higher comorbidity has been demonstrated in people with amputation that have diabetes than those with cardiovascular disease alone (Kurowski et al., 2015). In contrast to our study, Davie-Smith et al. (2016) reported that FCI was not significantly different between people with and without diabetes that had atraumatic causes of amputation. Many patients with diabetes who undergo amputation have end organ disease due to the macrovascular and microvascular complications of diabetes (Bate & Jerums, 2003; Hoffstad et al., 2015) which potentially explains the significant results and large effect size in CCI and CA-CCI scores. Some researchers (Davie-Smith et al., 2016; Webster et al., 2012) have demonstrated that diabetes is an independent factor associated with functional outcome as people with diabetes and transfemoral amputation were less likely to be fitted with a prosthesis. However other studies (Roffman et al., 2014; van Eijk et al., 2012) have reported that diabetes was not predictive of abandonment of prosthetic use. Studies (Davie-Smith et al., 2016; Fortington et al., 2013; Kurowski et al., 2015) have reported higher rates of distal amputation and contralateral lower limb amputation in people with diabetes. In our cohort 46.3% (n = 93) of participants had diabetes which was similar to rates reported in other studies (Davie-Smith et al., 2016; Fortington et al., 2013; van Eijk et al., 2012). There was significantly higher representation of diabetes in people with Aboriginal ethnicity which was similar to past demographic studies of Australian Aboriginal cohorts (Baba et al., 2015; Norman et al., 2010; Vos et al., 2009). Higher representation of diabetes has also been identified in ethnic groups with amputation in the USA,

Canada and New Zealand (Agrawal et al., 2014; Jones et al., 2013; Moxey et al., 2011; Schoen & Norman, 2014).

Aboriginal Ethnicity

In 2003, a study of Disability Adjusted Life Years (DALYs) revealed a health gap of 59% for Aboriginal people with 70% of the health gap explained by non-communicable diseases (i.e. diabetes, cardiovascular disease) and poorer health outcomes in remote regions of Australia (Vos et al., 2009). In our study, CCI score was significantly higher with a small effect size for participants of Aboriginal ethnicity. However, number of comorbidities, FCI and CA-CCI were not significantly different. These findings support previous research that Aboriginal people have higher mortality from chronic disease at a younger age while functional outcomes following lower limb amputation were not significantly different (Baba et al., 2015; Roffman et al., 2014; Schoen & Norman, 2014; Vos et al., 2009).

Above Transtibial Amputation Level

The relationship between disease burden and level of amputation is unclear in the literature (Davie-Smith et al., 2016; Fortington et al., 2013; Jones et al., 2013). We hypothesised that people with above transtibial amputation would have higher comorbidity because it is often performed as a lifesaving procedure in older people. However, in our study participants with transtibial amputation had significantly higher CCI and CA-CCI scores than those with above transtibial amputation levels. Jones et al. (2013) reported significantly higher mortality rate for people with transfemoral amputation. Studies (Davie-Smith et al., 2016; Fortington et al., 2013) have reported higher rates of transtibial amputation in people with diabetes due to peripheral arterial disease in the distal arterial supply. Increased burden of disease and mortality risk have been associated with this diabetes sub-group (Bate & Jerums, 2003; Hoffstad et al., 2015; Mueller, 2016).

Bilateral Amputation

There were no differences in comorbidity scores between bilateral and unilateral participants in this study. This was unexpected as other studies (Davie-Smith et al., 2016; Fortington et al., 2013; Kurowski et al., 2015) demonstrated that progression to bilateral lower limb amputation was more frequent in the diabetes sub-group which have significantly higher comorbidity. Fitting and capacity to walk using prostheses has also been reported as reduced in people with bilateral lower limb amputation (Davie-Smith et al., 2016; Sansam et al., 2009). Therefore, people who were selected and underwent prosthetic gait retraining after bilateral amputation in our study may represent a healthier cohort. These results highlight a need for longitudinal studies of bilateral lower limb amputation cohorts as there is potential to develop higher comorbidity over time due to the associated reduction in physical activity and quality of life.

Prevalence of Comorbidities

Similar to past studies (Devan et al., 2014; Fortington et al., 2013; Jones et al., 2013) the most frequently occurring comorbidities were peripheral arterial disease, diabetes, ischaemic heart disease, hypertension, hypercholesterolaemia, renal failure, arthritis, back pain and obesity. A large proportion of the study cohort with diabetes had a history of peripheral neuropathy, toe, foot or leg ulcers prior to amputation. In people with diabetes, a triad of peripheral neuropathy, structural deformity and minor trauma have been identified as a causal pathway to ulceration that potentially leads to amputation (Reiber et al., 1999). In terms of disease risk factors many participants were ex-smokers (30.3%, n = 61) or continued to smoke (25.4%, n = 51) following lower limb amputation which has been reported by past studies (Agrawal et al., 2014; Baba et al., 2015; van Netten et al.). In this study depression was present in 13.4% (n = 27) of the cohort prior to amputation. Pre-existing mental illness may impact on adjustment to lower limb amputation, motivation, ability to manage chronic disease or engage in the rehabilitation.

Osteoarthritis, osteoporosis of the residual limb, back and shoulder pathology have been recognised as some of the musculoskeletal sequelae developed by people with lower limb amputation that affect long term ability to sustain prosthetic gait (Devan et al., 2014; Gailey et al., 2008; Kulkarni, 2008). However, an important finding from our study was that many participants had musculoskeletal pathology including osteoarthritis, back, knee and shoulder pathology before they underwent amputation. Mueller (2016) identified higher rates of musculoskeletal pathology in people with diabetes and the potential for musculoskeletal injury with lower force. Knowledge of musculoskeletal pathology prior to rehabilitation commencing is useful for planning physiotherapy and rehabilitation interventions (e.g. prosthetic gait retraining, wheelchair prescription and driving).

Limitations and Future Research

There were some limitations with this study that potentially impacted on the results. This was a single centre, retrospective study so possible sources of bias were missing data from the medical record and the interview relied on participant recall. However, accuracy of this study was improved through the auditing of individual medical records instead of using de-identified administrative health databases. Standardised physiotherapy assessment and data retrieval forms were also used to improve quality of the data abstracted from the medical record (see Appendices 8.2 and 8.3). The sample size in this study is relatively large in terms of amputation cohorts however a high proportion of the cohort were deceased and small numbers in some of the known groups have the potential to influence results. Therefore further research to validate these results is warranted. The interaction of comorbidities with capacity for prosthetic gait has not been directly measured by this study so it is unknown whether the increased exercise intensity of prosthetic gait offers any protective benefits or deleterious side effects for the management of chronic diseases such as diabetes, cardiovascular disease and renal failure in people with lower limb amputation.

8.5. Conclusion

This study has demonstrated high burden of disease in sub-groups with lower limb amputation who were selected for prosthetic rehabilitation. Comorbidity indices of both function and mortality have construct validity in people with lower limb amputation. The FCI had the strongest relationship with number of comorbidities however the CCI was more sensitive and had greater effect size for more sub-groups in the known groups analysis. This was the first study to map the frequency of musculoskeletal pathology and mental illness at hospital admission prior to rehabilitation intervention. This study highlights a need to standardise measurement of comorbidity in clinical practice to enable comparison of long term outcome and plan resource allocation for amputation cohorts. Further research to validate these results and understand how disease progression is modified by physical activity through sustained prosthetic use is indicated.

Chapter 9 Discussion

9. Discussion and future research directions

This thesis has made an original and significant contribution to rehabilitation outcomes following lower limb amputation that will be translated into future models of care, interventions, funding and social policy. At the time of submission in July 2017 for this thesis, the findings have been crossed referenced in most recent research clinical reports[3].

This thesis has achieved the following objectives:

- Development of clinical prediction rules (CPRs) for prosthetic non-use
- Validation of clinical prediction rules for prosthetic non-use
- Development of performance thresholds for locomotor tests during rehabilitation that identify increased risk of prosthetic non-use at 12 months after discharge
- Measurement of construct validity of locomotor tests in a cohort with lower limb amputation
- Mapping of comorbidities at admission and measurement of the construct validity of using comorbidity indices in a cohort with lower limb amputation
- The first study to report rehabilitation outcomes in (Australian) Aboriginal people with amputation
- Determined long term self reported outcomes of people with lower limb amputation after rehabilitation discharge including sociodemographic characteristics, complications of amputation, prosthetic locomotor function using the locomotor capabilities index 5 (LCI5), mobility without a

[3] (Rogers and Stevens 2015a, Rogers and Stevens 2015b, Stevens 2015, Joubert 2016, Kahle, Klenow et al. 2016, Šrubařová and Stašková 2016, Felice, Kerekes et al. 2017, Ioannidis, Kitsikosta et al. 2017, Jakobsen, Biering et al. 2017, Kelly, Pedersen et al. 2017, McCabe, Butler et al. 2017, Rossiter, Knoop et al. 2017, Seng, Traore et al. 2017)

prosthesis, use of wheelchair and assistive devices, return to driving and work.

To date amputee rehabilitation models of care and clinical practice guidelines have been predominantly based on the lowest level (level 5) of evidence such as expert clinical opinion (Broomhead et al., 2006; Department of Health, 2008; Highsmith, 2013; Schaffalitzky et al., 2012; US Department of Veterans Affairs, 2008; van der Linde et al., 2005). The knowledge gaps in the literature, key findings and limitations of the studies in this thesis are discussed in this chapter to demonstrate how this research has contributed to evolution of the evidence base and areas for future scientific investigation. The levels of evidence used to appraise the research in this thesis were based on the criteria reported by Childs and Cleland (2006) for the clinical prediction rule studies and the Oxford Centre for Evidenced-Based Medicine (OCEBM) (Howick, 2009) for the cohort studies.

9.1. Clinical Prediction Rules developed and validated for prosthetic non-use

9.1.1. Knowledge Gaps

The CPR development and validation studies in this thesis have addressed the following knowledge gaps that were identified in the literature (Cumming et al., 2006; Department of Health, 2008; Gailey et al., 2002; Jones et al., 1993; Lim et al., 2006; Sansam et al., 2009; Schaffalitzky et al., 2012; Schoppen et al., 2003; Taylor et al., 2005):

- No CPRs to identify people with lower limb amputation at risk of prosthetic non-use after discharge from rehabilitation existed
- Studies have focused on factors associated with not fitting a prosthesis, surgical outcomes and people with limited rehabilitation potential
- There were mainly literature reviews, univariate and descriptive studies with limited multivariate studies or randomised controlled trials
- Studies have used sub-groups with lower limb amputation (e.g. unilateral amputation, transfemoral level, atraumatic cause, geriatric) or samples of

convenience (e.g. peer support groups, military service personnel) that were several years post-amputation reducing generalisability to the early rehabilitation context

- Rehabilitation outcomes in Western Australia were unknown.

9.1.2. Similarities and differences with the literature

This was the first study to develop and validate clinical prediction rules (CPRs) for prosthetic non-use at 4 (& 6), 8 and 12 months after discharge from rehabilitation in a heterogeneous cohort with lower limb amputation (Roffman et al., 2014). Although many CPRs have been developed in the health literature, the second stage of validation requires a substantial and sustained second phase of research that often tests the validity of the first research project. It is unclear if the lack of follow-up is related to the research question changing or the possibility of a publication bias but in the clinical context there is a very small conversion of CPRs being reported in second phase validation studies (Stiell et al., 1993; Stiell et al., 1996). Based on criteria for rating levels of evidence in CPRs our research represents level 3 evidence (Beneciuk et al., 2009; Childs & Cleland, 2006; Cleland et al., 2007). The OCEBM appraisal system (used to determine levels of evidence for the other studies in this thesis) rates the retrospective CPR development study as level 2b and the prospective CPR validation study as level 1b evidence (Howick, 2009). Although randomised controlled trials (RCTs) are the gold standard for treatment efficacy studies, for complex models of care in cases where there is substantial therapeutic opinion that the best practice methods are being used – CPR studies often form the basis to change decision pathways and practices in the model to facilitate evidence based change or additional options for clients (Beneciuk et al., 2009; Childs & Cleland, 2006; Cleland et al., 2007).

The majority of studies in lower limb amputation cohorts have focused on variables associated with *"not fitting prostheses"* (i.e. choosing not to proceed to prosthetic rehabilitation) rather than predictors for discontinuing prosthetic use after a patient has been discharged from prosthetic rehabilitation (Davie-Smith et al., 2016; Fletcher et al., 2001; Fletcher et al., 2002; Resnik & Borgia, 2015; Webster et al., 2012).

These studies have answered a different research question to our CPR study making comparison or generalisation difficult because they are not testing effectiveness of the prosthetic rehabilitation intervention or variables associated with sub-groups who have undergone this rehabilitation. However, both lines of research provide important insight into patient selection for prosthetic rehabilitation.

Prior to the CPR studies reported in this thesis (Roffman et al., 2014), there were limited studies using multivariate statistical methods with the majority of evidence coming from descriptive studies, univariate association and interpretative summaries of these sources in literature reviews (Cumming et al., 2006; Gauthier-Gagnon et al., 1999; Jones et al., 1993; Lim et al., 2006; Sansam et al., 2009; Schoppen et al., 2003; Taylor et al., 2005; Webster et al., 2012). Furthermore, studies focused on sub-groups with limited potential to rehabilitate and surgical outcomes limiting external validity of the findings (Lim et al., 2006; Taylor et al., 2005).

Our research has investigated a broad range of amputation, intrinsic and functional predictor variables from the literature that influence prosthetic use and non-use in people with lower limb amputation who have undergone prosthetic rehabilitation (see Chapter 4, figure 4.1). Similar to the literature review by Sansam et al. (2009), the univariate analysis in our CPR development study demonstrated that many variables had univariate association with prosthetic non-use. These variables were further reduced to key variables or flags using backwards stepwise logistic regression to generate the CPRs for different time points. The variables in the final CPRs were considered to be parsimonious and acting in combination to predict the outcome of prosthetic non-use (e.g. 4 out of 5 variables at 4 months, 3 out of 3 variables at 8 months, 2 out of 3 variables for 12 months). Therefore, it is important to consider these variables in combination for the CPR timeframes, rather than in isolation because the combined effect of different variables represents different sub-groups at risk of prosthetic non-use who may benefit from different clinical decision making (Childs & Cleland, 2006).

9.2. Amputation Predictor Variables

9.2.1. Amputation level and energy cost of prosthetic gait

Similar to the many studies, above transtibial amputation level and using a mobility aid at discharge were significant predictors across all time frames. Higher levels of amputation have been consistently associated with reduced capacity to walk using a prosthesis (Davies & Datta, 2003; Dillon, Major, Kaluf, Balasanov, & Fatone, 2017a; Gauthier-Gagnon et al., 1999; Moore et al., 1989; Nehler et al., 2003; Sansam et al., 2009; Taylor et al., 2005; Webster et al., 2012). Higher energy cost has been reported for walking with a transfemoral prosthesis compared to walking with a transtibial prosthesis or in able bodied participants (Waters et al., 1976; Wezenberg et al., 2013). Waters et al. (1976) demonstrated significantly higher heart rate in people with atraumatic transfemoral amputation in contrast to able bodied participants. Chin et al. (2002) demonstrated that predicted VO_{2max} derived from an incremental 1 leg cycle test was significantly higher in people who were able to walk 100m with a transfemoral prosthesis than those who did not achieve this milestone during rehabilitation. From this study it was suggested that people with atraumatic amputation and a working capacity of 50% predicted VO_{2max} or greater were more likely to be successful at walking 100m with a transfemoral prosthesis.

Erjavec et al. (2014) reported that people with atraumatic transfemoral amputation who performed an intermittent, incremental, submaximal arm ergometry test at a working capacity of 30 Watts (W) or greater were able to complete a 6MWT using a prosthesis. Participants performed 2 minutes of arm ergometry at 10W and 50 to 55 RPM, with 1 minute rest between increments that increased by 10W. An interesting finding of the study by Erjavec et al. (2014) was the high number of participants with detected cardiovascular complications (e.g. electrocardiogram changes, coronary ischaemia, hypertension) resulting in the exercise test being ceased before steady state was achieved. The cardiac load of prosthetic gait is a major clinical decision for rehabilitation teams when selecting clients for prosthetic rehabilitation that remains important during the other phases of rehabilitation because health professionals may need to advise clients to stop using their prosthesis due to progression of cardiac conditions such as ischaemic heart disease, heart failure or arrhythmias.

Wezenberg et al. (2013) demonstrated that the predicted relative aerobic load VO_{2rel} walking on a treadmill with a prosthesis, was significantly higher in people atraumatic amputation compared to those with traumatic causes of amputation. However, while studies of energy cost in people with varying levels and causes of lower limb amputation have demonstrated the importance of physical fitness for walking performance, there have been no longitudinal studies of VO_{2rel} and VO_{2max} to quantify if energy cost is the primary causative factor for abandoning use of a prosthesis. This line of research assumes there is a central limitation (e.g. ischaemic heart disease, chronic obstructive pulmonary disease) to function as opposed to the peripheral limitation or impairment (e.g. peripheral arterial disease, motor peripheral neuropathy). In clinical practice, a combination of central and peripheral limitations may be present during exercise testing of sub-groups with atraumatic amputation. This may result in fatigue or claudication pain in lower limb muscles before shortness of breath and at a lower anaerobic threshold than sub-groups with traumatic amputation. It also contributes to the cycle of physical deconditioning (i.e. person does not walk due to fatigue resulting in decreased muscle strength, muscle mass and VO_{2max}).

Research is required to determine if the difference between atraumatic and traumatic outcomes following lower limb amputation relate to the differences in central and peripheral limitations to exercise. Future studies may investigate whether prosthetic non-use is related to individual relative capacity or absolute capacity following lower limb amputation. For example, walking efficiency in a sedentary, overweight person with ischaemic heart disease and an atraumatic transtibial amputation is potentially lower than an athlete of normal weight without ischaemic heart disease and a traumatic transfemoral amputation. Furthermore, research is required to validate whether attrition of prosthetic use correlates with a decline in ambulation efficiency. This research could improve rehabilitation models of care through development of screening protocols, targeted exercise guidelines and prosthetic gait retraining strategies as well as enhance understanding of the relationship between physical fitness and prosthetic non-use.

9.2.2. Amputation level and other factors impacting on prosthetic use

Other factors such as inability to independently don the prosthesis, automaticity or cognitive load of prosthetic gait, socket discomfort, muscle biomechanics, residual limb length, skin or soft tissue issues, hip joint range of movement, weight of the prosthesis and physical impairments of balance and strength have been associated with poor prosthetic outcome for people with above transtibial amputation level in the literature (Brånemark et al., 2014; Dillingham et al., 2001; Gailey et al., 2010; Gailey et al., 2002; Gauthier-Gagnon et al., 1999; Gottschalk, 2002; Hagberg, Haggstrom, Uden, & Branemark, 2005; Laferrier & Gailey, 2010; Legro, Reiber, del Aguila, & Ajax, 1999; Lusardi, 2013; Meier & Melton, 2014; Schoppen et al., 2003; Waters et al., 1976). Prosthetic and surgical technologies such as microprocessor knee components, brimless sockets, vacuum assisted suspension and osseointegration are examples of clinical research that aim to improve efficiency of gait, balance and prosthetic use in people with higher levels of amputation (Brånemark et al., 2014; Frossard, Merlo, Quincey, Burkett, & Berg, 2017; Hafner, Willingham, Buell, Allyn, & Smith, 2007; Hagberg et al., 2005; Hagberg et al., 2014; Kahle & Highsmith, 2014; Kaufman et al., 2008; Laferrier & Gailey, 2010). However, although these technologies may potentially improve prosthetic outcome they are currently not funded in the WA public health context (or the majority of Australian public health service systems). Frossard et al. (2017) recently reported on the development of a procedure for government provision of bone anchored prosthesis using osseointegration in 18 people with transfemoral amputation from Queensland, Australia.

There are some key anatomical differences between transtibial, knee disarticulation and transfemoral amputation levels that have been associated with functional outcome in the literature (Gottschalk, 2002; Knapp, 2013; Lusardi, 2013; Lusardi & Pepe, 2013; Meier & Melton, 2014; Psonak, 2013; Ries & Vaughan, 2013). Absence of the plantar flexors is the main muscle group that people with transtibial amputation have to compensate for during prosthetic gait by using the hip abductor and extensor muscle groups (Ries & Vaughan, 2013). Preservation of the knee joint in people with transtibial amputation means that the quadriceps, hamstrings, satorius, tensor fasciae latae/iliotibial band and hip adductor muscle groups remain functional

and the longer lever length of the transtibial residual limb allows greater force generation when performing locomotor activities (Lusardi, 2013). In contrast, muscle group insertions including quadriceps, hamstrings, satorius, hip adductors (in particular adductor magnus) and tensor fasciae latae/iliotibial band have undergone myodesis, myoplasty or been completely transected in people with transfemoral amputation level (Gottschalk, 2002; Lusardi, 2013; Lusardi & Pepe, 2013). Transfemoral amputation surgery results in hip muscle imbalance and reduced muscle mass that changes the biomechanical line of pull so the residual femur is abducted (Gottschalk, 2002; Lusardi, 2013). This may cause lateral shift of the pelvis and impact on the efficiency of transfemoral prosthetic gait because the normal anatomical alignment of the human femur in able bodied people, is in adduction with the femoral shaft axis at 9 degrees from the vertical (Gottschalk, 2002; Lusardi, 2013). People with knee disarticulation level of amputation have the functional advantages of a residual limb with longer lever length, preservation of the thigh musculature including the hip adductor muscle group and proprioception during prosthetic gait (due to weight bearing through the femoral condyles) that are not present in people with transfemoral amputation (Baumgartner, 1979; Psonak, 2013).

From a functional perspective the transtibial prosthesis assists people with transtibial amputation during seated transfers (e.g. wheelchair to bed) while the knee disarticulation and transfemoral prostheses with prosthetic knee joints are only functionally useful once standing or walking (Meier & Melton, 2014). The human knee joint anatomically has a combination of flexion and extension (i.e. hinge) and rotational movements that are challenging to replicate in a prosthetic knee joint (Psonak, 2013). Stability of the prosthetic knee joint during the stance phase of gait and trusting the prosthetic knee have been reported as major concerns that may affect prosthetic use in people with transfemoral amputation (Hafner & Smith, 2009; Kaufman et al., 2008; Mundell et al., 2017; Psonak, 2013). Furthermore, the cognitive load of learning to control and stabilise the mechanical prosthetic knee joint has been identified as challenging for some sub-groups with transfemoral amputation level (Lee & Costello, 2018; Sansam et al., 2009; Schoppen et al., 2003). This need for improved stability during the stance phase of prosthetic gait (especially walking down ramps and on uneven terrain) has led the design evolution from

mechanical to microprocessor prosthetic knees (Hafner & Smith, 2009; Laferrier & Gailey, 2010; Psonak, 2013).

Proprioception is not present at the ankle or knee joint for people with transfemoral amputation using conventional socket prostheses so the balance compensatory strategies used are at the hip joint level. This lack of proprioception in people with tranfemoral amputation contributes to the difficulty of controlling the prosthetic knee during locomotor activities. Restoration of proprioception referred to as *'osseoperception'* has been reported in people with transfemoral amputation who have undergone osseointegration (Brånemark et al., 2014; Frossard et al., 2010; Laferrier & Gailey, 2010). Osseoperception occurs because the bony anchoring of the prosthesis to the femur and suspension of the prosthetic components from this bony anchor provides vibratory feedback when weight bearing through the prosthetic foot, that is not present in people who use conventional transfemoral prosthetic sockets (Brånemark et al., 2014; Laferrier & Gailey, 2010).

Frossard et al. (2010) investigated the temporal gait characteristics of 12 people with transfemoral amputation who had undergone osseointegration and then compared these characteristics to the normative data reported in the literature for people with transfemoral amputation who use conventional socket prostheses and able bodied people. The cadence of people with osseointegrated prostheses was 46 ± 4 strides per minute, duration of gait cycle was 1.29 ± 0.11 seconds, support phase was 0.73 ± 0.07 seconds, 57% ± 3% of the cadence cycle and swing phase was 0.56 ± 0.07 seconds, 43% ± 3% of the gait cycle. These gait cycle characteristics for people with osseointegration were 2% faster, 3% and 6% shorter, and 1% longer respectively than people who used conventional transfemoral prosthetic sockets. The gait cycle characteristics for people with osseointegration were 11% slower and 9%, 6% and 13% longer than able bodied people respectively. Although further longitudinal and cross-sectional studies were recommended, this study demonstrated that osseointegration enabled people with transfemoral amputation to walk with a biomechanically more efficient gait pattern than conventional prosthetic sockets (Frossard et al., 2010).

Prosthetic socket designs for people with transtibial and knee disarticulation levels of amputation generally do not cause any functional limitations during sitting. However, restriction of hip range of movement and socket discomfort in sitting positions have been reported as issues by people with transfemoral amputation who use conventional prosthetic sockets (Hagberg et al., 2005). Hagberg et al. (2005) compared hip range of movement and socket comfort in people with transfemoral amputation who used conventional transfemoral sockets (n = 43) and people with transfemoral amputation who had undergone osseointegration (n = 20). Hip range of movement was significantly reduced in all directions (i.e. flexion, extension, abduction, adduction, internal and external rotation) for people who used conventional transfemoral prosthetic sockets (Hagberg et al., 2005). A total of 37% (16) of subjects in the conventional transfemoral socket group had less than 90 degrees hip flexion while none of the subjects in the osseointegration group had less than 90 degrees hip flexion (Hagberg et al., 2005). A discomfort level of moderate to a great deal of trouble when sitting were reported by 44% (19) in the conventional transfemoral socket group and 5% (1) in the osseointegration group (Hagberg et al., 2005). This study demonstrated that conventional transfemoral prosthetic sockets limited active hip range of movement in users of conventional transfemoral prosthetic sockets and that active hip range of movement was not restricted in any direction for people who used osseointegrated prostheses (Hagberg et al., 2005).

9.2.3. Bilateral lower limb amputation

Studies (Bhangu et al., 2009; Datta, Nair, & Payne, 1992; Moore et al., 1989) have demonstrated reduced capacity to walk in people with bilateral lower limb amputation however bilateral lower limb amputation was not a predictor of prosthetic non-use in our study. This may reflect the high number of participants with bilateral transtibial amputation in our study. In a review of ideal functional outcomes for different amputation levels, Meier and Melton (2014) reported that people with bilateral amputation were more likely to use their prostheses than people with unilateral amputation.

9.2.4. Delays after amputation surgery to prosthetic rehabilitation

Delay after amputation surgery to prosthetic fitting of >160 days was a predictor of prosthetic non-use at 12 months after discharge in our study. Studies (Pohjolainen & Alaranta, 1991; Traballesi et al., 1998) have made a clear association between delays from surgery to prosthetic rehabilitation negatively impacting on mobility. The factors that underpin delays in systems or client complications may be a significant focus for future health systems research.

9.2.5. Amputation cause

Past studies (Davies & Datta, 2003; Geertzen, Bosmans, van der Schans, & Dijkstra, 2005; Pohjolainen & Alaranta, 1991; Schoppen et al., 2003; Webster et al., 2012) have reported poorer prosthetic outcome in people with atraumatic causes of amputation. In contrast to these studies, atraumatic amputation cause was not a predictor of prosthetic non-use in our study. A recent study by Dillon et al. (2017a) demonstrated that atraumatic amputation cause was not an independent predictor of MFCL K-level.

9.3. Functional Predictor Variables

9.3.1. Use of a mobility aid

The role of the mobility aid would seem paradoxical in various contexts for predicting future prosthetic outcomes. For example, it could be suggested that people with greater levels of ambulatory impairment or higher amputation levels may need a mobility aid and yet the compensatory value of the mobility aid has been identified in the literature as a major factor that enables prosthetic gait in the community or challenging environments (Franchignoni et al., 2004; Gauthier-Gagnon et al., 1999; Pohjolainen & Alaranta, 1991; Wong et al., 2016b). Furthermore, the type of mobility aid used has the potential to enhance or reduce the functionality of prosthetic gait by impacting on the person's capacity to carry objects (e.g. four wheeled walking frame with carry basket versus elbow crutches). In regression analyses by Gauthier-Gagnon et al. (1999) using a mobility aid was one of the significant variables associated with duration a prosthesis was worn and capacity to

walk indoors and outdoors with a prosthesis. Capacity to walk indoors using a prosthesis was associated with being able to carry an object while walking and the type of mobility aid used (i.e. crutches, cane or walking frame) (Gauthier-Gagnon et al., 1999). Some participants in this study by Gauthier-Gagnon et al. (1999) reported that they did not use their prosthesis to walk inside their home because they required a mobility aid and could not carry objects while walking.

The dichotomous classification of using a mobility aid at discharge (i.e. yes or no) was used as a variable in our CPR study. The type of mobility aid used by participants was not statistically weighted for the amount of support provided and the environment or tasks in which it was required. However, our study in Chapter 7 part B on long term self reported activity and participation highlighted that the 50% (75) of participants who used a mobility aid may choose to use different types of mobility aids depending on the walking environment or task (e.g. indoors, outdoors, stairs) (see appendix 7.5B, table 7.6B). Schoppen et al. (2003) used an eight point mobility scale that incorporated mobility aids (i.e. walking stick, crutches, walking frame, wheelchair) and walking environment (i.e. indoors, outdoors) to score participants who were prosthetic users and non-users at 1 year post-amputation. In this study functional prosthetic use was only achieved by 49% (18) participants (Schoppen et al., 2003). To improve clinical utility, future CPR studies may statistically weight the type of mobility aid for the level of assistance it provides or develop a cut-off score from an amputee specific mobility scale using receiver operating characteristic (ROC) curves.

9.3.2. Mobility without a prosthesis

The univariate phase of our study analysed functional variables related to both low and high functioning people with lower limb amputation because this was representative of milestones achieved by heterogeneous rehabilitation cohorts. Rehabilitation teams may use achievement of the lowest level of functional milestones early during pre-prosthetic rehabilitation such as independence with wheelchair mobility, transfers, standing and hopping before progressing onto prosthetic gait retraining (Roffman et al., 2014, 2016b). Hopping is a method of assessing functional lower limb strength, balance and aerobic capacity in people with

unilateral amputation. Waters et al. (1976) demonstrated that the energy cost of hopping with crutches was equivalent to walking with a transfemoral prosthesis. Therefore, hopping is one of the quick screening tests used by our rehabilitation team for clients with unilateral transfemoral amputation before prescribing a prosthesis. However, after analysing the pre-prosthetic locomotor variables (i.e. wheelchair mobility, transfers and hopping) in our study, inability to hop was the only univariate predictor of prosthetic non-use at 8 and 12 months. The ability to hop is a factor that may be mediated by the level of peripheral limitation in function (e.g. claudication, peripheral neuropathy, impaired muscle strength and balance) present as an independent factor within lower limb amputation cohorts. Future research may investigate the 6 minute wheelchair propulsion test or other tests of peripheral impairment (e.g. muscle strength, balance, proprioception) to determine their association with prosthetic non-use.

9.3.3. Mobility with a prosthesis

Ability to don, doff and monitor prosthetic fit and mobility level achieved using a prosthesis at discharge from rehabilitation were examined to assess the whole continuum of locomotor skill and association with prosthetic non-use. The following prosthetic gait variables were analysed: walking indoors, outdoors, stairs, slopes, grass, gravel, uneven terrain, high-level balance activities and running. Dependence or inability to perform these locomotor milestones, were univariate predictors of prosthetic non-use for 4, 8 and 12 months. These functional variables confirmed that people who achieved low locomotor skill levels during rehabilitation were at greater risk of becoming prosthetic non-users (e.g. unable to walk outdoors on grass) while those who achieved high locomotor skill levels (e.g. able to run which represents an extremely high level of locomotor skill achieved by a small proportion of clients) continued to use their prosthesis. The other studies in this thesis have quantified these locomotor outcomes associated with prosthetic non-use using performance based locomotor tests (i.e. 10MWT, TUGT, 6MWT, FSST) and self reported function (i.e. LCI5).

In our final CPR model, dependence walking outdoors on concrete was the functional milestone that predicted prosthetic non-use at 4 and 8 months after

discharge. This finding in the CPR was consistent with the work of Taylor et al. (2005) who reported that being unable to ambulate outdoors prior to amputation surgery was a predictor of prosthetic non-use. This CPR variable validates the indoors and outdoors walking dichotomy associated with prosthetic use and non-use in the literature (Gailey et al., 2002; Gauthier-Gagnon et al., 1999; Taylor et al., 2005). Gauthier-Gagnon et al. (1999) demonstrated that capacity to walk outdoors using a prosthesis was associated with being able to independently don a prosthesis, climb stairs with a handrail, the type of mobility aid used and absence of stairs in the outdoors walking environment. In contrast to Gauthier-Gagnon et al. (1999) dependence with donning the prosthesis and walking up and down stairs were only univariate predictors of prosthetic non-use for the timeframes in our study.

9.4. Intrinsic Predictor Variables

9.4.1. Comorbidities

In our study the cumulative effect of having a very high number of comorbidities was a predictor of prosthetic non-use at 4 months post-discharge this is consistent with well reported findings showing that as comorbidities increase, capacity to walk with a prosthesis decreases (Gailey et al., 2002; Schoppen et al., 2003; Taylor et al., 2005). Diabetes is a major comorbidity of high prevalence in the lower limb amputation population. However, at 4 months after discharge from rehabilitation in the presence of the other parsimonious variables, not having a diagnosis of type 2 diabetes was a predictor of prosthetic non-use in our study. The impact of diabetes on prosthetic outcome is unclear in the literature, as some studies have reported that diabetes was not associated with prosthetic outcome (Moore et al., 1989; Taylor et al., 2005) while other studies have demonstrated poorer functional outcomes in people with diabetes and lower limb amputation (Davie-Smith et al., 2016; Geertzen et al., 2005; Webster et al., 2012). Our findings suggest that there may be a sub-group without type 2 diabetes but with high chronic disease burden and other CPR variables that increase the risk of becoming an early prosthetic non-user at 4 months. Future research may focus on developing models of care that optimise chronic disease management, exercise and rehabilitation strategies in this sub-group.

The presence of cardiac disease was another comorbidity that has been associated with prosthetic non-use in the literature (Moore et al., 1989; Pohjolainen & Alaranta, 1991; Taylor et al., 2005) however in our study having a cardiac condition was only a univariate predictor of prosthetic non-use at the 8 and 12 months. Heart failure is one of the common cardiac conditions in people with atraumatic lower limb amputation. Ejection fraction may be reduced or preserved in clients with heart failure and this influences response to exercise and physical activity (De Maeyer, Beckers, Vrints, & Conraads, 2013). Further research is required to develop exercise, prosthetic prescription and user guidelines for sub-groups with lower limb amputation and cardiac conditions such as heart failure. Other comorbidities including peripheral arterial disease, type 1 diabetes, renal failure, stroke, arthritis and remaining lower limb pathology were not predictors of prosthetic non-use in our study. This was an interesting finding because clients with these comorbidities may be less physically active and therefore at higher risk of becoming prosthetic non-users. For example, clients with renal failure who undergo haemodialysis are inactive up to 15 hours per week during their haemodialysis sessions which may impair physical fitness and capacity to use a prosthesis.

9.4.2. Sociodemographic variables

Resnik and Borgia (2015) reported that prosthetic prescription rates were significantly lower in people of African American ethnicity and the southern regions of the USA. Important findings of our study were that geographical isolation from health services and Aboriginal ethnicity were not predictors of prosthetic non-use. Health care services are centralised to Perth the capital city in Western Australia however 43% of our cohort reside in country regions. A large proportion of people with Aboriginal ethnicity live in country or remote regions of WA. These findings suggest that the long established Telemedicine and service linkage strategies with local health professionals that form part of our model of care were successful in addressing any issues that may lead to prosthetic non-use in these clients.

9.4.3. Age

Older age (55 years and over) has been a predictor of poor prosthetic outcome in past studies (Davies & Datta, 2003; Dillon et al., 2017a; Pohjolainen & Alaranta, 1991; Schoppen et al., 2003; Taylor et al., 2005; Webster et al., 2012). Age $\geq$ 58 years was only a univariate predictor of prosthetic non-use in our study. These findings suggest there may be critical factors related to human mobility (e.g. physical fitness, comorbidities) as people enter the 6th decade of life that warrant further investigation.

9.5. Multifactorial reasons for prosthetic non-use reported by participants who became prosthetic non-users

Multifactorial reasons for prosthetic non-use were reported by participants who became prosthetic non-users in the CPR development and validation studies. The main reasons reported for prosthetic non-use were similar between the retrospective and prospective cohorts and included: issue with the residual limb (stump), issue with the remaining limb, prosthetic issue, pain, medical comorbidities and balance issues. Similar reasons for abandoning prosthetic use have been reported in the literature and associated with transfemoral (or higher) and bilateral lower limb amputations (Chamlian, 2014; Gailey et al., 2010; Karmarkar et al., 2009; Laferrier et al., 2010). Single limb balance at 2 weeks after amputation has been associated with prosthetic non-use (Schoppen et al., 2003). In our CPR study, participants reported that medical comorbidities were one of the main reasons for prosthetic non-use which corresponds with the significant variables associated with prosthetic non-use in the univariate and multivariate regression analyses. Although falls and fear of falling have been reported as contributing to prosthetic non-use and morbidity in the literature (Gauthier-Gagnon et al., 1999; Hafner & Smith, 2009; Mundell et al., 2017), balance issues were reported more frequently than falls as reasons for prosthetic non-use by our participants. Prosthetic issues (e.g. socket discomfort or difficulty controlling the mechanical prosthetic knee) have led to important clinical research into prosthetic design and surgical techniques such as osseointegration (Brånemark et al., 2014; Fatone & Caldwell, 2017; Hafner & Smith, 2009; Hafner et al., 2007; Laferrier & Gailey, 2010; Mundell et al., 2017). However, Gallagher, O'Donovan, Doyle, and Desmond (2011) noted that there has been limited literature

on how the type of prosthesis contributes to environmental, activity and participation restrictions.

Our study did not report the individualised prosthetic components used by each participant in the interim and definitive prostheses which is a limitation of this research. Instead we provided detailed definitions of the interim and definitive prostheses funded and supplied to participants through RPH amputee rehabilitation model of care in WA (refer to Chapter 2, section 2.5). Due to the funding model in WA, only participants who were compensable due to motor vehicle accidents and worker's compensation claims were fitted with microprocessor knees for their definitive prostheses. In our study, the majority of participants with above transtibial amputation levels had mechanical prosthetic knee joints. To improve comparison of clinical outcomes, future research may classify prostheses as being advanced technology, mechanical and speciality as defined by Gailey et al. (2010). Higher rates of prosthetic abandonment were reported by US veterans from the Vietnam war (11%) who used mechanical prostheses in contrast to veterans from Operation Iraqi Freedom (OIF) / Operation Enduring Freedom (OEF) (4%) who had trialled and abandoned a range of advanced, mechanical and speciality prosthetic devices (Gailey et al., 2010). The most common reasons for prosthetic abandonment reported by the Vietnam veterans were: short residual limb, prosthetic device too heavy and pain (Gailey et al., 2010). Issues with the remaining lower limb (from cumulative trauma associated with prosthetic use) were present in 50% (Gailey et al., 2010). The OIF / OEF veterans abandoned prosthetic use most frequently due to combat injuries and cumulative trauma injuries to the remaining lower limb (Gailey et al., 2010). Issues with the remaining lower limb were one of the main reasons participants in our study reported becoming prosthetic non-users. An interesting finding by Gailey et al. (2010) was that the OIF / OEF veterans abandoned prosthetic use in significantly shorter time frames (mean = 7 months, SD = 5 months, $p = .03$) than Vietnam veterans (mean = 13 years, SD = 13.5 years). Similar to Karmarkar et al. (2009), these findings by Gailey et al. (2010) highlight that the use of advanced or specialised prosthetic technologies may not translate into a person using a prosthetic limb as their primary mobility aid.

The other limitations of our research were that the multifactorial reasons were not ranked in order of importance by the participants, objective measures of prosthetic satisfaction, adjustment to amputation, locus of control, health literacy and quality of life were not used in the CPR development or validation models. As prosthetic issues were reported by participants as one of the main reasons for prosthetic non-use in our CPR research, there is the potential that prosthetic dissatisfaction may have been a significant predictor variable of prosthetic non-use. Above transtibial amputation level was a significant predictor of prosthetic non-use for all the CPR timeframes, therefore future research may examine the impact of prosthetic componentry (such as mechanical versus microprocessor knees) on longitudinal outcomes to validate the self reported reasons for prosthetic non-use identified by this research.

Dunne, Coffey, Gallagher, Desmond, and Ryall (2015) demonstrated that the way people with lower limb amputation perceive and experience assistive technologies has meaning beyond functional restoration and may influence use of the device. The socket comfort score, Trinity Amputee Prosthetic Experience Scale (TAPES) and TAPES revised (TAPES-R) are examples of objective measures of prosthetic satisfaction, adjustment to amputation and quality of life that could be implemented into future research and models of care (Gallagher, Franchignoni, Giordano, & MacLachlan, 2010; Gallagher & Maclachlan, 2004; Gallagher & MacLachlan, 2000; Hanspal, Fisher, & Nieveen, 2003). The inclusion of psychosocial variables such as adjustment to amputation, locus of control and health literacy in combination with prosthetic satisfaction scales provides important insight into the experiences of the prosthetic user and consumer expectations of prostheses.

9.6. CPR Validation

The survival curves for prosthetic non-use demonstrated a high level of concordance between the retrospective and prospective cohorts and identified there was a sub-group of early prosthetic non-users who abandoned prosthetic use almost immediately after discharge. One of the main reasons why researchers do not undertake the second phase CPR validation study is that the model of care changes during the phase 1 CPR development study (i.e. the system changes). The second reason is that the population changes the primary outcome or there is contamination

of practice by health professionals who are informed of the studies. This is a major source of bias in model of care research and specifically in complex long term rehabilitation protocol studies where development and validation phases are performed sequentially. The similarity of the curves in two concurrent cohorts demonstrates that there was limited contamination of the model of care and the rehabilitation intervention was stable during the studies (Roffman et al., 2014).

An alternative rehabilitation pathway focusing on optimisation of wheelchair seating, physical fitness, mental health and community access may be best for the sub-group who are at risk of becoming early prosthetic non-users. If prosthetic gait retraining is undertaken in this sub-group at risk of early prosthetic non-use the physiotherapy time frames should be clearly set prior to commencing this phase of rehabilitation. For example, an initial outpatient rehabilitation time frame of 8 weeks (with 3 physiotherapy sessions per week) for prosthetic gait retraining may be set, with the client discharged from physiotherapy or rehabilitation lengthened based on functional progress with locomotor milestones at this assessment time frame. Improved standardisation of time frames for assessment of locomotor function in the model of care would also assist in identifying complications of amputation that impact on functional progress (e.g. residual limb pathology such as stump blisters, back pain, falls). This sub-group of early prosthetic non-users also provide evidence for having an interim prosthetic phase in our model of care, to trial if someone will sustain prosthetic use prior to progressing to more expensive definitive prosthetic components (Department of Health, 2008; Roffman et al., 2014). A limitation of our CPR study was that many of the functional variables were at the end of rehabilitation reducing the ability to use them as early screening tools. However, using a mobility aid and not walking outdoors are functional variables that can be easily determined prior to prosthetic rehabilitation from the physiotherapy subjective assessment of pre-amputation mobility. Future CPR research may incorporate pre-amputation mobility as well as focus on impairments and locomotor tests that can be assessed post-operatively or early in rehabilitation and correlate with prosthetic non-use.

9.6.1. Other CPR for ambulation in people with lower limb amputation

Since development and validation of clinical prediction rules for prosthetic non-use described within this thesis, a second CPR has been developed by Wong et al. (2016b) for determining ability of people with lower limb amputation to ambulate using a prosthesis in the community at 1 year. A total of 40 out of 54 participants initially assessed participated in this study (74.1% follow-up rate). The participants were an average of 6.6 (11.0) years post-amputation and recruited from local peer support groups and prosthetic clinics.

The 8 variables investigated for the outcome of ability to ambulate in the community using a prosthesis were: age, amputation level, amputation cause, years since amputation, number of lower limbs amputated (unilateral or bilateral), initial Houghton score, Activities-specific Balance Confidence (ABC) score and Berg Balance Score (Wong et al., 2016b). A CPR for predicting community ambulation at 1 year was generated with the following 4 criteria included: initial Houghton cut off score $\leq$ 7, ABC cut off score $\leq$ 65, Berg Balance task 9 (retrieve an object from the floor) cut off score $\leq$ 3 and Berg Balance task 10 (look behind shoulders) cut off score $\leq$ 3 (Wong et al., 2016b). The number of lower limbs amputated (unilateral or bilateral) was not included in the final CPR because it did not have the prediction accuracy (Wong et al., 2016b). The post-test probability was 90% or higher for not becoming a community ambulator using a prosthesis at 1 year in participants who did not exceed 2 or more of the criteria cut off scores (Wong et al., 2016b). Amputation level, amputation cause and age of participants were not significant predictor variables in the logistic regression analysis (Wong et al., 2016b).

The key differences between Wong et al. (2016b) and our CPR studies were:

1. Our CPR studies investigated variables associated with prosthetic outcome of a consecutive cohort of participants who recently underwent tertiary rehabilitation. Wong et al. (2016b) had a non-consecutive, sample of convenience recruited from community organisations that were several years post-amputation. Therefore, walking capacity was defined prior to the study.

2. We validated the CPRs that were developed for prosthetic non-use in a new cohort of people with lower limb amputation. Wong et al. (2016b) have not validated their CPRs.
3. Amputation level was not a predictor of prosthetic walking capacity in the study by Wong et al. (2016b). This result reflects a cohort of prosthetic users that have been recruited several years after their amputation surgery resulting in people at risk of becoming prosthetic non-users already being excluded from the study.

The research reported in this thesis informs clinical decision making of health professionals by assisting them to stratify patients for inventions based on the future risk of prosthetic non-use and with developing targeted amputee rehabilitation models of care. The CPR research represents the first 2 stages of CPR research development (Childs & Cleland, 2006). Multi-centre prospective validation of the CPRs and implementation followed by impact analysis (which represents the third stage of CPR methodology) would improve the generalisability and levels of evidence for this research (Childs & Cleland, 2006).

9.7. Locomotor Performance Measures

9.7.1. Knowledge Gaps

The following knowledge gaps were identified from the literature (Deathe & Miller, 2005; Dite et al., 2007; Gailey et al., 2002; Heinemann et al., 2014; Raya et al., 2010; Resnik & Borgia, 2011; Schoppen et al., 2003; Stevens, 2010) as having implications for the use of locomotor tests in cohorts with lower limb amputation:

- No consensus on whether a single locomotor test during rehabilitation could identify increased risk of prosthetic non-use at 12 months after discharge
- The clinical utility of locomotor tests during rehabilitation was unknown
- Limited studies and performance data to assist interpretation of locomotor tests in amputation cohorts
- Past studies have used samples of convenience which has limited the generalisability of results
- The psychometric properties of some locomotor tests (including construct validity) had not been established in lower limb amputation cohorts

9.7.2. Similarities and differences with the literature

There have been few studies to assist with interpretation of locomotor tests in people with lower limb amputation and it was unknown whether performance on a single test can be used to predict future issues with prosthetic gait (Gailey et al., 2002; Resnik & Borgia, 2011; Roffman et al., 2016b). In comparison to other clinical populations (e.g. COPD, neurological) there was limited performance data on locomotor tests in people with lower limb amputation and as samples of convenience have been used, the results cannot be easily generalised to populations participating in amputee rehabilitation (Resnik & Borgia, 2011; Roffman et al., 2016b).

In amputee rehabilitation, Medicare Functional Classification Level (MFCL) K-levels are the main subjective criteria used by rehabilitation services to classify functional status of people with lower limb amputation and allocate prosthetic components (Borrenpohl et al., 2016; Gailey et al., 2002; Gaunaurd et al., 2015; Roffman et al., 2016b). There has been limited implementation of performance based outcome measures in clinical practice with recent surveys of health professionals calling for the K-level system to be supplemented with locomotor performance measures (Borrenpohl et al., 2016; Gaunaurd et al., 2015). Prior to our study there was minimal published data on locomotor test performance in people with lower limb amputation to guide clinical decision making during rehabilitation (Gailey et al., 2002; Resnik & Borgia, 2011; Roffman et al., 2016b).

Ambulation is a multifactorial domain and there are well known locomotor tests used in rehabilitation that are considered to assess different sub-domains such as aerobic capacity, balance, speed, dual tasking and other ambulatory factors. Our study examined multiple locomotor tests to see if they were sensitive enough to detect prosthetic non-use at 12 months after discharge. The majority of rehabilitation assessments and studies have been used to describe thresholds for functional outcomes such as crossing the road, falls, mortality or psychometric properties of new outcome measures (e.g. concurrent validity, construct validity). The following discussion speaks to the literature about the thresholds determined in our study on prosthetic non-use and the concordant literature for other functional thresholds.

This was the first study to develop performance thresholds that identified increased risk of prosthetic non-use in people with lower limb amputation from locomotor tests commonly used during rehabilitation including the 10 metre walk test (10MWT), timed up and go test (TUGT), 6 minute walk test (6MWT) and four square step test (FSST). Area under the curve (AUC) demonstrated that performance thresholds were all moderately predictive of prosthetic non-use at 12 months. This suggests the locomotor tests were all measuring a similar functional domain. Based on these findings, health professionals can select the test that is most appropriate for the client, situation and healthcare setting.

9.7.3. 10MWT

The 10MWT can be performed early in rehabilitation when people with lower amputation first walk out of the parallel bars. Gait speeds ranging from 0.75 ms^{-1} to 1.3 ms^{-1} have been reported for people with atraumatic and traumatic causes of lower limb amputation (Akarsu et al., 2013; Tekin et al., 2009; Waters et al., 1976). Although studies have used the 10MWT in cohorts with lower limb amputation (Akarsu et al., 2013; Deathe & Miller, 2005; Franchignoni et al., 2004; Tekin et al., 2009) there were no studies examining the relationship between gait speed from the 10MWT and prosthetic non-use.

van Hedel (2009) used gait speed derived from the 10MWT to determine mobility categories for 886 people with incomplete spinal cord injury. The 10MWT threshold for not being a community ambulator in people with incomplete spinal cord injury of 0.44 ms^{-1} was identical to the 10MWT threshold for prosthetic non-use in people with lower amputation from our study (Roffman et al., 2016b; van Hedel, 2009). A minimum gait speed of 0.70 ms^{-1} was required by people with incomplete spinal cord injury to walk without mobility aids in the community (van Hedel, 2009). Since mobility aid use was a predictor of prosthetic non-use in our CPR studies, future studies should investigate the relationship between gait speed and the need for mobility aids in people with lower limb amputation. Salbach et al. (2014) reported that gait speeds ranging from 0.44 ms^{-1} to 1.32 ms^{-1} were required to safely walk across the road at pedestrian crossings in the community.

A gait speed of 0.53 ms^{-1} was derived from the 6MWT threshold of ≤ 191 m in our study which was faster than 0.44 ms^{-1}. This increase in gait speed suggests progression of locomotor skills in participants who were able to perform the 6MWT during rehabilitation. The gait speeds derived from 6MWT distance for MFCL K levels in a study by Gailey et al. (2002) were: K0 to 1 = 0.138 ms^{-1}; K2 = 0.528 ms^{-1}; K3 = 0.805 ms^{-1} and K4 = 1.16 ms^{-1}. The K0 to 1 gait speed of 0.138 ms^{-1} for prosthetic non-users and people who use their prosthesis for transfers or household ambulation only by Gailey et al. (2002) was slower than our threshold of 0.44 ms^{-1} for prosthetic non-use. The findings from our study validate the literature (Salbach et al., 2014; van Hedel, 2009) that gait speed is a marker of ability to ambulate in the community and increased risk of prosthetic non-use.

The 10MWT has utility as a measure that can be performed early in rehabilitation by the greatest number of participants to detect increased risk of prosthetic non-use. It does not require extensive training, is efficient and easy to administer in a small space. The 10MWT can be performed by clients with low and high levels of locomotor function. The 10MWT can be adapted to enable video gait analysis and progressed to a 10 metre running test for clients with sport and recreational goals. However, further research is required to determine the psychometric properties of the 10MWT and 10 metre running test in people with lower limb amputation.

9.7.4. 6MWT

Capacity to walk distances of 200 m or greater have been proposed as important for community ambulation following lower limb amputation (Gauthier-Gagnon et al., 1999; Salbach et al., 2014). The 6MWT is a performance measure that provides insight into a person's capacity for community ambulation with distances ranging from 4 m to 858 m in people with lower limb amputation (Akarsu et al., 2013; Gailey et al., 2002; Lin & Bose, 2008; Linberg et al., 2013; Raya et al., 2010; Resnik & Borgia, 2011). In our study, the 6MWT threshold for prosthetic non-use of ≤ 191m was similar to the distance reported for MFCL K level 2 (limited community ambulator) of average, 189.9 m (SD = 111.3) reported by Gailey et al. (2002). A shorter 6MWT distance average of 49.86 m (SD = 29.82) was reported by Gailey et al. (2002) for people who were K level 0 to 1 (non-prosthetic, prosthesis for transfers

only or household ambulators). In our study, 6MWT had the highest sensitivity out of all the locomotor tests investigated, correctly classifying 80.6% of participants who became prosthetic non-users.

Raya et al. (2010) demonstrated that hip extensor strength of the residual limb was the strongest predictor of 6MWT distance in 72 participants with atraumatic and traumatic lower limb amputation. Hip extensor muscle strength explained 30.9% of the variance in the regression model. Single limb balance was also associated with 6MWT distance in this study. These findings were important because muscle strength and balance can be modified through exercise and prosthetic gait retraining to increase 6MWT distance and improve functional outcome.

Resnik and Borgia (2011) reported that minimal detectable change (MDC) for the 6MWT was 45 m in people with lower limb amputation. This is a large improvement in walking distance to be made by clients during rehabilitation so the distance is not considered statistical error or variance. However further research is required because minimal clinically important difference (MCID) is yet to be determined for 6MWT distance of people with lower limb amputation and improvements of < 45 m may increase capacity to progress from walking indoors to community ambulation using a prosthesis (Resnik & Borgia, 2011).

Similar to the literature, findings from our study suggest that the 6MWT has utility as a measure of capacity to ambulate in the community. The 6MWT requires a large, rectangular space to be performed effectively in amputation cohorts (Linberg et al., 2013). While the 10MWT can be performed early in rehabilitation once the client with lower limb amputation is walking outside the parallel bars, the 6MWT may need to be performed later in rehabilitation once the locomotor skills have improved. This highlights the importance of progressing assessments as a client's locomotor function improves during rehabilitation. Future studies may investigate a combined testing protocol of the 10MWT and 6MWT to determine factors associated with prosthetic non-use.

9.7.5. TUGT

The TUGT incorporates the frequently used locomotor tasks of sit to stand, walking and turning with times reported as ranging from 7.2 s to 102 s in people with lower limb amputation. The locomotor tasks associated with the TUGT reflect skills required by an indoors ambulator with lower limb amputation. Increased risk of multiple falls by people with transtibial amputation, have been associated with a criterion of $\geq$ 19 s on the TUGT (Dite et al., 2007). Schoppen et al. (2003) reported that the 18 elderly, participants who were able to perform the TUGT at 1 year post-amputation completed the test in average 23.9 s (SD = 13.2). These times were similar to our threshold for identifying increased risk of prosthetic non-use of $\geq$ 21.4 s.

Deathe and Miller (2005) have identified ceiling effect for the TUGT in high functioning people with lower limb amputation. Therefore, the TUGT identifies increased risk of falls in lower functioning clients but is not sensitive enough to detect change in high functioning clients. Resnik and Borgia (2011) reported that MDC was 3.6 s for the TUGT in people with lower limb amputation. Due to reported ceiling effect and an MDC of 3.6 s, the TUGT has greatest utility when performed as a locomotor test early in rehabilitation, in domiciliary settings to identify increased risk of falling and prosthetic non-use.

9.7.6. FSST

The FSST provides information on high level balance, ability to negotiate obstacles, change direction and dual task (Dite et al., 2007; Dite & Temple, 2002). Dite et al. (2007) reported that people with transtibial amputation who were at risk of multiple falls performed this test in $\geq$ 24 s. Studies of people with transfemoral amputation testing different styles of prosthetic socket and knee components have reported faster times on the FSST than our study with averages ranging between 13.2 s (SD = 2.2) to 18.1 s (SD = 11.5) (Highsmith et al., 2016b; Lythgo, Marmaras, & Connor, 2010). The threshold for prosthetic non-use was $\geq$ 36.6 s in our study which included people with all levels of amputation (i.e. transtibial and above) and bilateral lower limb amputation. This threshold was generated from balanced sensitivity and specificity with the extreme score of 999 used so that people unable to perform the FSST were

included in the ROC analysis. As a non-parametric ROC analysis was used, the inclusion of people unable to perform the FSST with an extreme 999 score did not bias our results. However, the FSST had limited utility because 32% of the cohort could not perform this test. The participants who could perform this test were unlikely to become prosthetic non-users therefore this test is better suited to high functioning clients and determining the effectiveness of components that enable high level function.

9.8. Known Groups Analysis

Slower walking speed, reduced walking distance and increased time to complete balance tasks have been associated with older age, transfemoral amputation level, atraumatic amputation cause, bilateral lower limb amputation and comorbidities in people with lower limb amputation (Akarsu et al., 2013; Christiansen, Fields, Lev, Stephenson, & Stevens-Lapsley, 2015; Dite et al., 2007; Dite & Temple, 2002; Franchignoni et al., 2004; Gailey et al., 2002; Raya et al., 2010; Schoppen et al., 2003; Tekin et al., 2009). Our known groups analysis validated that locomotor performance on the 10MWT, TUGT, 6MWT and FSST was poorer for people in known groups at high risk of prosthetic non-use including: above transtibial amputation, bilateral amputation, high comorbidities and older age. Locomotor performance of people with Aboriginal ethnicity was not significantly different from non-Aboriginal people. An important finding from our study was that the 6MWT discriminated difference in locomotor performance more effectively for the atraumatic and diabetes sub-groups from lower risk sub-groups than the 10MWT and TUGT. This was similar to findings for locomotor tests in cohorts with intermittent claudication (McDermott et al., 2010).

Investigating the outcome of prosthetic non-use at 12 months after discharge and variation in the assessment times for performance measures were limitations of our research. To improve the power of our study, prosthetic non-use at 12 months after discharge from physiotherapy was the primary outcome instead of investigating time intervals such as 4, 6, 8 and 12 months. However, at 12 months after discharge there were potentially multiple variables in addition to locomotor test performance associated with prosthetic non-use and our CPR research (Chapters 4 and 5)

demonstrated that a sub-group of early prosthetic non-users existed. Future research may investigate time intervals to identify locomotor performance limitations of this sub-group or test the effects of interventions on outcome. In the literature timeframes have been censored since amputation surgery rather than discharge therefore we have provided supplementary information (see Chapters 4, 5 and 7.2B) on time since amputation to enable comparison with other research and health care facilities.

Locomotor tests were assessed as patients progressed with their individualised rehabilitation goals. A future system change could be standardisation of the assessment time frames for the locomotor tests in the prosthetic and long term follow-up phases of rehabilitation. Standardisation of assessment time frames (i.e. repeated measures design) is important to implement in the model of care because the locomotor tests do not measure the activity and participation limitation related to lower limb amputation in isolation and reflect limitations of the individual client's other comorbidities (e.g. heart failure, back or claudication pain). This approach may identify sub-groups who progress slower or faster with rehabilitation, enable research on change in locomotor performance during rehabilitation and identify functional decline in the long term follow-up phase that potentially responds to physiotherapy or prosthetic interventions.

Our study findings for performance on locomotor tests highlight there is an indoors and outdoors walking dichotomy similar to that identified in our CPR studies. The 10MWT, TUGT, 6MWT and FSST represent a continuum of locomotor tests with increasing physical and cognitive demand. Clinical utility was similar for all the locomotor tests in terms of cost, time, training and equipment. The 10MWT is a good locomotor test early in rehabilitation and could be adapted for high level performance later in rehabilitation. The 6MWT is most accurate in detecting prosthetic non-use and was more effective at separating high and low level locomotor performance in the known groups study compared to the 10MWT and TUGT. The TUGT provides information about falls risk, sit to stand and turning but is better suited to domiciliary settings or healthcare facilities with limited space. The FSST has utility for high functioning clients and research settings because it is attained by few participants. In public healthcare settings with time and resource limitations, a combined testing protocol of the 10MWT and 6MWT has high

interpretive value for identifying increased risk of prosthetic non-use. Future studies may investigate improvements during rehabilitation on locomotor test performance.

This research on locomotor test represents level 2b evidence (Howick, 2009). The performance thresholds and data from the known groups analyses of locomotor tests in this thesis may be used to inform clinical decision making however before they can be implemented into policy and funding models, validation is required in a prospective cohort. In summary, locomotor tests assess multiple domains within the ambulatory framework including functional balance and community participation. The findings in this thesis concur that at the time of rehabilitation they are also a marker for prosthetic non-use. Future studies would need to investigate if this is an independent predictive factor or a concordant element of overall functional outcomes. Furthermore, are the domains of gait speed, balance and endurance modifiable after discharge to alter the attrition seen over time for prosthetic use? From a hypothetical perspective, the answer to this question is yes with the rehabilitation program of appropriate intensity gait speed, balance and endurance are variables that can be maintained or improved. However, rehabilitation teams, administrators, funding and peer support organisations need to develop and fund community based models of care that target these functional domains. It has been identified in the literature that many patient cohorts find it challenging to transition from tertiary to community based rehabilitation, sports or recreation resulting in high rates of physical inactivity (Bragaru et al., 2013; de Oliveira et al., 2016; Jaarsma, Dijkstra, Geertzen, & Dekker, 2014; Kars, Hofman, Geertzen, Pepping, & Dekker, 2009; Langford, Dillon, Granger, & Barr, 2018).

9.9. Comorbidity in people with lower limb amputation

9.9.1. Knowledge Gaps

The following knowledge gaps were identified from the literature (Charlson et al., 1987; Charlson et al., 1994; Davie-Smith et al., 2016; de Laat et al., 2014; Fortington et al., 2013; Gailey et al., 2002; Groll et al., 2006; Hall, 2006; Hall et al., 2004; Hoffstad et al., 2015; Jones et al., 2013; Melchiorre et al., 1996; van Eijk et al., 2012;

Webster et al., 2012) for measuring comorbidity in people with lower limb amputation:

- Comorbidity is a major consideration for clinical pathway decisions in rehabilitation interventions e.g. prosthetic prescription, return to driving and work. However, there is no commonly used measure of comorbidity in people with amputation.
- Construct validity has not been tested for comorbidity indices in amputation cohorts
- A limitation of past studies was the incidence of musculoskeletal pathology and mental health issues prior to admission have not been reported.

9.9.2. Similarities and differences with the literature

It is well known that various comorbidities exist in the population with atraumatic amputation and that these are strongly correlated to high mortality, burden of disease and healthcare costs (Fortington et al., 2013; Hoffstad et al., 2015; Jones et al., 2013; Lazzarini, Gurr, Rogers, Schox, & Bergin, 2012; van Netten et al., 2016). Similar to these aforementioned studies, investigation of comorbidity in this thesis has demonstrated high burden of disease and mortality risk in sub-groups with atraumatic cause of amputation. Comorbidities such as diabetes, peripheral arterial disease, cardiovascular disease, renal failure and back pain consistently reported in the literature (Fortington et al., 2013; Gailey et al., 2008; Jones et al., 2013) as being of high frequency for lower limb amputation cohorts were identified by our study.

Our CPR research demonstrated that the cumulative effect of having a very high number of comorbidities was predictive of prosthetic non-use at 4 months after discharge from rehabilitation rather than specific comorbid conditions (Roffman et al., 2014). Comorbidity was also one of the multi-factorial, self reported reasons for abandoning prosthetic use by participants in our study (Roffman et al., 2016b). However, counting number of comorbidities lacked external validity and clinical utility.

Comorbidity indices provide a standardised method of measuring the cumulative effect of having multiple comorbidities in clinical populations. FCI and CCI scores in our study were similar to past studies of people with lower limb amputation (Davie-Smith et al., 2016; de Laat et al., 2014; Webster et al., 2012). Our study demonstrated that the FCI, CCI and CA-CCI significantly discriminated between the scores of lower limb amputation groups with known high comorbidity including: prosthetic non-users, atraumatic amputation, diabetes and age $\geq$ 58 years and groups with low comorbidity. However, analysis of effect size for these comorbidity indices in the known groups revealed that separation of the scores was greatest by the CCI for the diabetes, atraumatic amputation, transtibial amputation level and Aboriginal sub-groups. CA-CCI was validated as it was most effective at separating scores for the older and younger groups – which is inherently obvious as the scale is age corrected. Number of comorbidities from our CPR study was validated as having the greatest effect size in prosthetic non-users and FCI was the second most effective method of analysing comorbidity in this group. Therefore, the CCI was the best indicator of comorbidity in lower limb amputation cohorts probably due to its stronger link with mortality. The findings within this known groups analysis are the first to demonstrate such construct validity for this patient cohort.

The incidence of musculoskeletal pathology and mental health issues (e.g. depression) at hospital admission were unknown for people with lower limb amputation as research has been limited to investigating these comorbidities as complications of amputation (Gailey et al., 2008; Webster et al., 2012). Webster et al. (2012) reported that having a major depressive episode after amputation was one of the predictors of poor prosthetic outcome at 12 months after amputation. Past studies have reported musculoskeletal issues as secondary complications of amputation with asymmetrical movement patterns (Devan et al., 2014; Gailey et al., 2008; Kulkarni, 2008). Our study demonstrated high rates of musculoskeletal pathology and mental health issues present at hospital admission. These pre-existing musculoskeletal problems such as back and shoulder pathology may be exacerbated by activities including propelling a manual wheelchair, asymmetry of locomotor activities and using a mobility aid. Mueller (2016) reported that people with diabetes (a common comorbidity in amputation cohorts) had increased frequency of musculoskeletal pathology and were at risk of musculoskeletal injury at lower forces

than other sub-groups. These findings have implications for exercise prescription in amputation cohorts.

Single tracking of public hospital notes was a methodological limitation of our comorbidity study. However, a standardised physiotherapy assessment form was implemented for our study to improve the quality of comorbidity data collected from the medical records and subjective interviews of participants. This comorbidity research will assist with future service model planning and resource allocation. This thesis provides evidence for standardised methods of measuring comorbidity in cohorts with lower limb amputation. This research represents level 2b evidence (Howick, 2009). Prospective validation of this study is warranted. Future studies may investigate whether participants with different sub-clusters of comorbidities benefit from alternative models of care, exercise prescription guidelines and chronic disease management strategies.

9.10. Outcomes for Aboriginal people with lower limb amputation

9.10.1. Knowledge Gaps

The following knowledge gaps on lower limb amputation in people with Aboriginal ethnicity were identified from the literature (Baba et al., 2015; Norman et al., 2010; Schoen et al., 2010; Schoen & Norman, 2014; Vos et al., 2009):

- High diabetes related amputation rates and mortality risk due to chronic disease has been the primary end point of research with no investigation of rehabilitation outcomes
- The impact of residing in geographically isolated regions of Western Australia on rehabilitation outcome was unknown
- Performance on locomotor tests during rehabilitation for amputation were unknown for people of Aboriginal ethnicity
- Self reported function after amputation was unknown for people of Aboriginal ethnicity.

9.10.2. Similarities and differences with the literature

Rehabilitation outcomes have not been reported for Aboriginal people with lower limb amputation high rates of diabetes related amputation and mortality have been the primary endpoint of health outcomes research (Baba et al., 2015; Norman et al., 2010; Schoen & Norman, 2014; Vos et al., 2009). This is the first research to demonstrate that rehabilitation outcomes including prosthetic use, locomotor performance and self reported functional ability in people of Aboriginal ethnicity with lower limb amputation were not significantly different from non-Aboriginal people. Similar to past Australian studies (Baba et al., 2015; Norman et al., 2010; Schoen & Norman, 2014; Vos et al., 2009), we found significantly higher representation of diabetes in people with Aboriginal ethnicity.

Armstrong, Gillespie, Leeder, Rubin, and Russell (2007) identified that innovation and improved links were required between primary, acute and rehabilitation healthcare services in Australia to manage to the challenges of chronic disease and health outcomes of Aboriginal people residing in rural and remote communities. Our CPR studies validated that Aboriginal ethnicity and geographical isolation from health services were not predictors of prosthetic non-use. These findings were important because it suggests that the long term model of care strategies (i.e. Telemedicine, linkage with local health professionals) to provide equity of access to health services for people residing in rural and remote regions have been successful in addressing any issues (e.g. socket fit, residual limb wound, health professional skills training) that may lead to prosthetic non-use in these clients. However, further research is required to analyse the psychosocial, cultural, lifestyle and environmental factors that contribute to these positive rehabilitation outcomes. For example, Aboriginal people from rural and remote areas generally lead a physically active lifestyle that involves camping and transferring on and off the floor using anti-gravity muscles and balance skills that may contribute to locomotor performance using a prosthesis. Cultural factors such as inclusion and not wanting to be different from their community may increase prosthetic use, activity and participation levels of Aboriginal people. Health beliefs regarding amputation, disease, healing and death warrant further investigation to identify factors that may improve the model of care for Aboriginal people. Schoen et al. (2010) consulted 60 Aboriginal people from

Western Australia on diabetic foot health promotion and education resources. Participants preferred real pictures of foot problems rather than cartoons and to develop their own messages for resources so that they were used by and inclusive of the whole community (Schoen et al., 2010).

Performance on locomotor tests during rehabilitation and long term self reported function after rehabilitation discharge on the LCI5 by Aboriginal participants were not significantly different from non-Aboriginal participants. There were no Australian studies (Hordacre et al., 2013b) to compare functional outcomes for Aboriginal participants. However, our study results were consistent with Agrawal et al. (2014) who demonstrated that locomotor function using the LCI and prosthetic use for Canadian Aboriginal participants was not significantly different from non-Aboriginal participants.

This research represents level 2b evidence (Howick, 2009). A limitation of our study was small numbers of Aboriginal participants. Future multicentre research may increase the number of participants recruited to studies and address the need for innovative models of care that are culturally sensitive and facilitate rehabilitation closer to rural and remote areas.

9.11. Self reported outcomes and sociodemographic characteristics

9.11.1. Knowledge Gaps

The following knowledge gaps were identified from the literature (Department of Health, 2008; Dillon et al., 2014; Hordacre et al., 2013a; Hordacre et al., 2013b; Jones et al., 1993; Lim et al., 2006; Wu et al., 2010):

- Limited reporting of long term outcomes following discharge from rehabilitation in Australia
- Rehabilitation outcomes including sociodemographic characteristics, mobility without a prosthesis, mobility with a prosthesis, return to work, return driving and complications of amputation (e.g. stump pathology, falls) were unknown in Western Australia

- It is unknown whether rehabilitation outcomes achieved during rehabilitation are sustained after discharge. Therefore, the effectiveness of intervention with comprehensive multidisciplinary rehabilitation program for people with lower limb amputation in Western Australia is unknown
- The FIM is used for reporting outcomes in Australia however it has limitations with observed ceiling effect and lack of responsiveness in amputation cohorts The FIM is performed at inpatient rehabilitation admission and discharge so many rehabilitation outcomes (e.g. locomotor function with a prosthesis) are not captured in Western Australia because prosthetic gait retraining is performed as an outpatient service[4].

9.11.2. Similarities and differences with the literature

Our study has reported on sociodemographics, complications of amputation, functional outcomes with and without a prosthesis, return to driving and work for a consecutive cohort with lower limb amputation. We used the locomotor capability index 5 (LCI5) because it is a self reported, amputee specific measure of basic and advanced locomotor function that has been administered throughout the rehabilitation continuum in past studies (Czerniecki et al., 2012b; Franchignoni et al., 2007; Franchignoni et al., 2004; Gauthier-Gagnon et al., 1999).

In the context of high 1 year mortality for people with atraumatic amputation our interview time frame of median, 1.5 (IQR, 1.2 to 2.2) years after rehabilitation discharge as opposed to the censor date of 12 months after amputation surgery reported in the literature, represents long term follow-up in this cohort with lower limb amputation. In our study, the actual time from amputation surgery to interview was median, 2.7 years (IQR = 2.2 to 3.2) and timeframe data from amputation surgery has been reported in Figure 7.2B (see Chapter 7 Part B) to enable comparison with other research and healthcare facilities. Rehabilitation outcomes were unknown in WA so this timeframe was selected to answer the global research question of: *What outcomes were sustained after discharge from amputee*

[4] This was the endorsed rehabilitation model of care for duration of studies in this thesis.

rehabilitation? Furthermore, the outcomes of return to driving and work represented long term rehabilitation goals for the majority of patients so this timeframe was selected to capture this data. This survey methodology provided a snapshot of function and was only valid for that particular point in time however functional ability may fluctuate. Amputee models of care may implement longitudinal follow-up interviews at regular time intervals (e.g. 6, 12, 18, 24 months) during the rehabilitation continuum to identify changes in function and measure the reliability of self reported data for future research.

There have been limited studies on long term functional outcomes following lower limb amputation in Australia (Hordacre et al., 2013a; Hordacre et al., 2013b; Jones et al., 1993; Lim et al., 2006; Roffman et al., 2014; Wu et al., 2010). Studies have focused on institution specific variables such as length of stay and despite major limitations with ceiling effect and timing of this assessment the Functional Independence Measure (FIM) has been the main outcome measure reported (Hordacre et al., 2013a; Hordacre et al., 2013b; Wu et al., 2010).

This is the first study of consecutive Australian participants to measure construct validity of the LCI5 in known groups who were at high risk of future prosthetic non-use including people with Aboriginal ethnicity, older age, above transtibial amputation, bilateral lower limb amputation, atraumatic amputation cause, diabetes, very high number of comorbidities, part-time prosthetic users and lower risk groups. Participants in our study reported higher LCI5 scores than Czerniecki et al. (2012b). The difference in findings was most likely due to the fact that only participants with dysvascular causes of amputation were investigated by Czerniecki et al. (2012b). Similar to past studies (Parker et al., 2010; Salavati et al., 2011), our study demonstrated maximum scores for 25% of the total cohort and ceiling effect of the LCI5 scale. These results suggest that the LCI5 has construct validity but due to the observed ceiling effect it lacks sensitivity as a measure of long term locomotor function. The PLUS-M (Prosthetic Limb Users Survey of Mobility) is a new self reported outcome measure with good psychometric properties that may have utility in the long term follow-up phase of rehabilitation (Hafner et al., 2017).

Long term wheelchair use for mobility activities and rates of residual limb pathology were high in our cohort. This is consistent with the literature where both prostheses and wheelchairs have been used for functional activities and wheelchairs used as a primary mobility device by people who abandon prosthetic use (Gailey et al., 2010; Karmarkar et al., 2009). Functional activities such as sit to stand, time the prosthesis was used and maximal walking distance were by self report so recall bias was a limitation of our study. Future amputee models of care and research may incorporate the use of wearable technology such as step activity monitors to objectively measure functional activity.

Participants who were non-drivers and non-workers prior to amputation had significantly higher Charlson Comorbidity Index (CCI) scores and ages than participants who were drivers and workers prior to amputation reflecting high burden of disease. Return to work and driving were both significantly associated with being a prosthetic user and participants reported high levels of locomotor function on the LCI5. Rates up to 80.5% and 79% have been reported for return to driving and work respectively in people with lower limb amputation by other countries (Boulias et al., 2006; Burger, 2012; Engkasan et al., 2012; Fisher et al., 2003; Penn-Barwell, 2011; Schoppen et al., 2001a; Schoppen et al., 2001b). These were consistent with our findings of 91% and 62% for return to driving and work respectively. Similar to past studies (Fisher et al., 2003; Schoppen et al., 2001a; Schoppen et al., 2001b), participants in our study worked in less physically demanding occupations after their amputation. A self reported walking distance of $\geq$ 500m has been associated with return to work following lower limb amputation (Schoppen et al., 2001b). However, self reported walking distance of $\geq$ 500m was not validated as a variable significantly associated with return to driving or work in our univariate analysis. Future research on return to work and driving should include multivariate analysis and psychosocial variables such as cognition, adjustment, family and financial support to address the limitations of our study and enable improvements to the model of care.

This research represents level 2b evidence (Howick, 2009). This research will assist with planning models of care and future service utilisation of people with lower limb amputation in Australia and internationally (Armstrong et al., 2007; Department of Health, 2008). Due to high ceiling effect observed on the LCI5 scale, future studies

should focus on development and implementation of self reported outcome measures such as the PLUS-M that can be easily administered in the long term follow-up phase of rehabilitation for people with lower limb amputation.

9.12. Reform to the Western Australian Amputee Rehabilitation Model of Care in 2014

In October 2014 the Western Australian State Amputee Rehabilitation Service moved to the newly commissioned State Rehabilitation Service campus of Fiona Stanley Hospital. The 4 major changes to the model of care were: introduction of Activity Based Funding, implementation of policy by hospital administrators that clients were only permitted to receive 6 occasions of service (OOS) for outpatient physiotherapy with a total of 15 OOS permitted for outpatient physiotherapy per week for the service, restrictions on issue of stump shrinkers for oedema management and trial of the National Disability Insurance Scheme. The prognostic research in this thesis identifies sub-groups who would potentially benefit from alternative models of care so that health professionals can improve the match of client to intervention and modify the clinical decision pathway earlier in rehabilitation which is important in resource limited healthcare settings. However, the intensity and time frames reported in this thesis for outpatient prosthetic gait retraining were higher than the new model of care. The Activity Based Funding model has led to prosthetic gait retraining being provided as an inpatient service over an approximately 3 to 4 week time frame which is different to the outpatient based service delivery model reported for prosthetic gait retraining in this thesis. During the studies in this thesis intensive oedema management with stump shrinkers was performed in combination with other oedema management interventions to expedite client recovery and minimise costs associated with manufacture of multiple prosthetic sockets. In the trial suburbs, the National Disability Insurance Scheme has funded definitive prosthetic components which may improve functional outcome of clients that were not funded by WALSA in the previous model of care. Therefore, comparative effectiveness research is warranted to determine the impact of changes to the model of care in October 2014 on outcomes for people with lower limb amputation, systems efficiency and cost to public health.

9.13. General limitations of this research

The research in this thesis had the following limitations:

- The thesis represents the Western Australian health context. It is valid to say that the models of care and pathway trajectory may be different in different contexts
- The thesis is relevant for western models of care and aetiologies of amputation and therefore does not reflect areas of warfare, civil unrest or terrorism
- The literature review includes grey literature from health services and clinical practice guidelines
- The health systems changes were true at the time of this study
- As the clinical prediction rule study was validated at a single centre it lacks generalisability until future validation in other health contexts
- Our research questions investigated what happened with prosthetic use for timeframes after physiotherapy discharge, which contributed to the originality of this thesis. However, this may be a potential limitation as the literature has focused on time since amputation surgery. To enable benchmarking between healthcare settings and research projects, we have provided supplementary data on time frames for significant rehabilitation milestones from date of initial amputation surgery (see Chapters 4, 5 and 7.2B)
- The timeframes for measurement of the locomotor tests were individualised to the patient's progress and not standardised during rehabilitation; and the survey of activity and participation in people with lower limb amputation was only valid for the point in time the participant was interviewed. Future models of care and research should implement longitudinal follow-up at standardised timeframes throughout the rehabilitation continuum
- Mobility aids were not statistically weighted for the level of assistance that they provided the patient in our CPR study. Future CPR studies may consider statistically weighting the mobility aid for the level of assistance or using an amputee specific mobility scale
- Recall bias was a limitation of the research in this thesis. No objective measures such as a step activity monitor or GPS monitoring were used to

ensure that the self reported mobility data in Chapter 7.2B were reliable. The use of wearable technology may be implemented in future studies and rehabilitation models of care to measure the reliability of self reported functional activity, support prescription of prosthetic components and achievement of mobility goals during rehabilitation

- Prosthetic componentry was not reported for the participants in this research instead we provided a detailed summary of the prosthetic componentry that were funded for participants in Chapter 2. Prosthetic prescription was stable during this research and access to advanced technologies (e.g. microprocessor knees) in the definitive stage was limited to participants who were compensable. To facilitate comparison between health care and research facilities, future studies should classify prosthetic components as advanced technology, mechanical and specialised as reported by Gailey et al. (2010)
- Participants reported multifactorial reasons for becoming prosthetic non-users. Prosthetic issues were one of the most frequent reasons reported by participants for abandoning prosthetic use. We did not enter prosthetic issues and types of prosthetic componentry as variables into the CPR or use objective measures of prosthetic satisfaction. Future research and models of care may incorporate the socket comfort score, TAPES or TAPES-R because it is important to consider prosthetic satisfaction in combination with the patient's adjustment to amputation.

Future research and amputee rehabilitation models of care should aim to address the limitations identified for the research in this thesis to improve the quality of evidence for clinical practice.

9.14. Conclusion

In conclusion, this thesis has contributed to evidence based assessment and treatment of people with lower limb amputation across the rehabilitation continuum. It is recognised that rehabilitation models of care for people with lower limb amputation vary widely in developed and developing countries. Rehabilitation interventions for prosthetic gait retraining may be a few days, months or many years depending on the social and political context of the health service (Rau et al., 2007; Roffman et al., 2014). However, limited health resources (e.g. budget, staffing, equipment and infrastructure) and matching of clients to interventions are universal challenges experienced by all health professionals in contemporary practice. This thesis may assist with guiding clinical decision making, resource allocation and development of future amputee rehabilitation models of care. It also directs future research to optimise outcomes following lower limb amputation.

10. References

Adams, E., Flynn, K., Alligood, E. (2005). A systematic review of clinical predictors of outcomes in adults with recent major lower limb amputation - Final report. VA Technology Assessment Program., 1-23.

Agrawal, V., Gailey, R., Gaunaurd, I., Gailey, R., 3rd, & O'Toole, C. (2011). Weight distribution symmetry during the sit-to-stand movement of unilateral transtibial amputees. *Ergonomics, 54*(7), 656-664. doi: 10.1080/00140139.2011.586060

Agrawal, Veena R, Skrabek, Ryan Q, Embil, John M, Gross, Patrick, & Trepman, Elly. (2014). Effect of Socioeconomic and Health Factors on Prosthetic Use after Lower-Limb Amputation. *JPO: Journal of Prosthetics and Orthotics, 26*(2), 79-86.

AIHW, Australian Institute of Health and Welfare (2008). *Diabetes Australian Facts 2008*. Canberra, Australia: Australian Government, AIHW.

Akarsu, S., Tekin, L., Safaz, I., Goktepe, A. S., & Yazicioglu, K. (2013). Quality of life and functionality after lower limb amputations: comparison between uni- vs. bilateral amputee patients. *Prosthetics and Orthotics International, 37*(1), 9-13. doi: 10.1177/0309364612438795

Ali, Sadeeq, Abu Osman, Noor Azuan, Arifin, Nooranida, Gholizadeh, Hossein, Abd Razak, Nasrul Anwar, & Wan Abas, Wan Abu Bakar. (2014). Comparative Study between Dermo, Pelite, and Seal-In X5 Liners: Effect on Patient’s Satisfaction and Perceived Problems. *The Scientific World Journal, 2014*, 8. doi: 10.1155/2014/769810

Armstrong, Bruce K, Gillespie, James A, Leeder, Stephen R, Rubin, George L, & Russell, Lesley M. (2007). Challenges in health and health care for Australia. *Medical Journal of Australia, 187*(9), 485.

Asher, L., Aresu, M., Falaschetti, E., & Mindell, J. (2012). Most older pedestrians are unable to cross the road in time: a cross-sectional study. *Age Ageing, 41*(5), 690-694. doi: 10.1093/ageing/afs076

Baba, M., Davis, W. A., Norman, P. E., & Davis, T. M. (2015). Temporal changes in the prevalence and associates of foot ulceration in type 2 diabetes: the Fremantle diabetes study. *Journal of Diabetes and its Complications, 29*. doi: 10.1016/j.jdiacomp.2015.01.008

Bachmann, Lucas M, Kolb, Esther, Koller, Michael T, Steurer, Johann, & Riet, Gerben ter. (2003). Accuracy of Ottawa ankle rules to exclude fractures of the ankle and mid-foot: systematic review. *BMJ, 326*(7386), 417. doi: 10.1136/bmj.326.7386.417

Bailey, Maggie J., & MacWhannell, Caroline. (1997). Clinical Monitoring of Dysvascular Lower Limb Amputees During Initial Gait Training. *Physiotherapy, 83*(6), 278-283. doi: http://dx.doi.org/10.1016/S0031-9406(05)66174-3

Basu, N. N., Fassiadis, N., & McIrvine, A. (2008). Mobility one year after unilateral lower limb amputation: a modern, UK institutional report. *Interactive Cardiovascular and Thoracic Surgery, 7*(6), 1024-1026. doi: 10.1510/icvts.2008.180422

Bate, Katherine L, & Jerums, George. (2003). 3: Preventing complications of diabetes. *Medical journal of Australia, 179*(9), 498-505.

Batten, Heather R., Kuys, Suzanne S., McPhail, Steven M., Varghese, Paulose N., & Nitz, Jennifer C. (2015). Demographics and discharge outcomes of dysvascular and non-vascular lower limb amputees at a subacute rehabilitation unit: a 7-year series. *Australian Health Review, 39*(1), 76-84. doi: http://dx.doi.org/10.1071/AH14042

Baumgartner, RF. (1979). Knee disarticulation versus above-knee amputation∗. *Prosthetics and Orthotics International, 3*(1), 15-19.

Beneciuk, Jason M., Bishop, Mark D., & George, Steven Z. (2009). Clinical Prediction Rules for Physical Therapy Interventions: A Systematic Review. *Physical Therapy, 89*(2), 114-124. doi: 10.2522/ptj.20080239

Bergin, S. M., Alford, J. B., Allard, B. P., Gurr, J. M., Holland, E. L., Horsley, M. W., . . . Wraight, P. R. (2012). A limb lost every 3 hours: can Australia reduce amputations in people with diabetes? *Medical Journal of Australia, 197*(4), 197-198.

Bhangu, S., Devlin, M., & Pauley, T. (2009). Outcomes of individuals with transfemoral and contralateral transtibial amputation due to dysvascular etiologies. *Prosthetics and Orthotics International, 33*(1), 33-40. doi: 10.1080/03093640802492434

Blough, D. K., Hubbard, S., McFarland, L. V., Smith, D. G., Gambel, J. M., & Reiber, G. E. (2010). Prosthetic cost projections for servicemembers with major limb loss from Vietnam and OIF/OEF. *Journal of Rehabilitation Research and Development, 47*(4), 387-402.

Borrenpohl, Dylan, Kaluf, Brian, & Major, Matthew J. (2016). Survey of U.S. Practitioners on the Validity of the Medicare Functional Classification Level System and Utility of Clinical Outcome Measures for Aiding K-Level Assignment. *Archives of Physical Medicine and Rehabilitation, 97*(7), 1053-1063. doi: http://dx.doi.org/10.1016/j.apmr.2016.02.024

Boulias, C., Meikle, B., Pauley, T., & Devlin, M. (2006). Return to driving after lower-extremity amputation. *Archives of Physical Medicine and Rehabilitation, 87*(9), 1183-1188. doi: 10.1016/j.apmr.2006.06.001

Bragaru, Mihai, van Wilgen, C. P., Geertzen, Jan H. B., Ruijs, Suzette G. J. B., Dijkstra, Pieter U., & Dekker, Rienk. (2013). Barriers and Facilitators of Participation in Sports: A Qualitative Study on Dutch Individuals with Lower Limb Amputation. *PLOS ONE, 8*(3), e59881. doi: 10.1371/journal.pone.0059881

Brånemark, R., Berlin, Ö., Hagberg, K., Bergh, P., Gunterberg, B., & Rydevik, B. (2014). A novel osseointegrated percutaneous prosthetic system for the treatment of patients with transfemoral amputation. *The Bone & Joint Journal, 96-B*(1), 106-113. doi: 10.1302/0301-620x.96b1.31905

Brodersen, Kay Henning, Ong, Cheng Soon, Stephan, Klaas Enno, & Buhmann, Joachim M. (2010). *The balanced accuracy and its posterior distribution.* Paper presented at the Pattern Recognition (ICPR), 2010 20th International Conference on.

Brooks, D., Parsons, J., Hunter, J. P., Devlin, M., & Walker, J. (2001). The 2-minute walk test as a measure of functional improvement in persons with lower limb amputation. *Archives of Physical Medicine and Rehabilitation, 82*(10), 1478-1483. doi: 10.1053/apmr.2001.25153

Broomhead, P. , Clark, K. , Dawes, D. , Hale, C. , Lambert, A. , Quinlivan, D. , . . . Withpetersen, J. (2012). *Evidence Based Clinical Guidelines for the Managements of Adults with Lower Limb Prostheses 2nd Edition.* . London: Retrieved from http://www.csp.org.uk/publications/evidence-based-clinical-guidelines-physiotherapy-management-adults-lower-limb-prosthese.

Broomhead, P. , Dawes, D. , Hancock, A. , Unia, P. , Blundell, A. , & Davis, V. (2006). *Clinical guidelines for the pre and post operative physiotherapy managment of adults with lower limb amputation.* London: Chartered Society of Physiotherapy Retrieved from http://bacpar.csp.org.uk/publications/clinical-guidelines-pre-post-operative-physiotherapy-management-adults-lower-li.

Broomhead, Penny, Dawes, Diana, Hale, Carolyn, Lambert, Amanda, Quinlivan, Di, & Shepherd, Robert. (2003). *Evidence based clinical guidelines for the physiotherapy management of adults with lower limb prostheses*: Chartered Society of Physiotherapy London.

Burger, H., Kuzelicki, J., & Marincek, C. (2005). Transition from sitting to standing after trans-femoral amputation. *Prosthetics and Orthotics International, 29*(2), 139-151.

Burger, Helena. (2012). Functioning of persons following lower limb amputation–patients' perspective. *Medicina Fluminensis, 48*(4), 471-479.

Butler, David S, & Moseley, G Lorimer. (2013). Explain Pain 2nd Edn: Noigroup Publications.

Campbell, W. B., & Ridler, B. M. (1996). Predicting the use of prostheses by vascular amputees. *European Journal of Vascular and Endovascular Surgery : The Official Journal of the European Society for Vascular Surgery, 12*(3), 342-345.

Carroll, Kevin, Rheinstein, John, & Pollard, Elicia. (2013). Understanding Prosthetic Feet. In M. M. Lusardi, M. Jorge & C. C. Nielsen (Eds.), *Orthotics & Prosthetics in Rehabilitation* (3rd ed., pp. 595-602). USA: Elsevier.

Chamlian, Therezinha Rosane. (2014). Use of prostheses in lower limb amputee patients due to peripheral arterial disease. *Einstein (São Paulo), 12*, 440-446.

Charlson, Mary E, Pompei, Peter, Ales, Kathy L, & MacKenzie, C Ronald. (1987). A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *Journal of chronic diseases, 40*(5), 373-383.

Charlson, Mary, Szatrowski, Ted P, Peterson, Janey, & Gold, Jeffrey. (1994). Validation of a combined comorbidity index. *Journal of clinical epidemiology, 47*(11), 1245-1251.

Childs, J.D., & Cleland, J.A. (2006). Development and application of clinical prediction rules to improve decision making in physical therapist practice. *Physical Therapy, 86*(1), 122-131.

Chin, Dr T., Sawamura, S., Fujita, H., Ojima, I., Oyabu, H., Nagakura, Y., . . . Nakagawa, A. (2002). %VO2max as an indicator of prosthetic rehabilitation outcome after dysvascular amputation. *Prosthetics and Orthotics International, 26*(1), 44-49. doi: doi:10.1080/03093640208726620

Christiansen, C. L., Fields, T., Lev, G., Stephenson, R. O., & Stevens-Lapsley, J. E. (2015). Functional Outcomes After the Prosthetic Training Phase of Rehabilitation After Dysvascular Lower Extremity Amputation. *PM&R, 7*(11), 1118-1126. doi: 10.1016/j.pmrj.2015.05.006

Clasper, Jon, & Ramasamy, Arul. (2013). Traumatic amputations. *British Journal of Pain, 7*(2), 67-73. doi: 10.1177/2049463713487324

Cleland, J. A., Childs, J. D., Fritz, J. M., Whitman, J. M., & Eberhart, S. L. (2007). Development of a clinical prediction rule for guiding treatment of a subgroup of patients with neck pain: use of thoracic spine manipulation, exercise, and patient education. *Physical Therapy, 87*(1), 9-23. doi: 10.2522/ptj.20060155

Cleland, J. A., Fritz, J. M., Kulig, K., Davenport, T. E., Eberhart, S., Magel, J., & Childs, J. D. (2009). Comparison of the effectiveness of three manual physical therapy techniques in a subgroup of patients with low back pain who satisfy a clinical prediction rule: a randomized clinical trial. *Spine (Phila Pa 1976), 34*(25), 2720-2729. doi: 10.1097/BRS.0b013e3181b48809

Cleland, J.A., Mintken, P.E., Carpenter, K., Fritz, J.M., Glynn, P., Whitman, J., & Childs, J.D. (2010). Examination of a clinical prediction rule to identify patients with neck pain likely to benefit from thoracic spine thrust manipulation and a general cervical range of motion exercise: multi-center randomized clinical trial. *Physical Therapy, 90*(9), 1239-1250.

Cohen, Jacob. (1992). Statistical Power Analysis. *Current Directions in Psychological Science, 1*(3), 98-101. doi: 10.1111/1467-8721.ep10768783

Condie, Elizabeth, Scott, Helen, & Treweek, Shaun. (2006). Lower limb prosthetic outcome measures: a review of the literature 1995 to 2005. *JPO: Journal of Prosthetics and Orthotics, 18*(6), P13-P45.

Condie, M. E., McFadyen, A. K., Treweek, S., & Whitehead, L. (2011). The trans-femoral fitting predictor: a functional measure to predict prosthetic fitting in transfemoral amputees--validity and reliability. *Archives of Physical Medicine and Rehabilitation, 92*(8), 1293-1297. doi: 10.1016/j.apmr.2011.03.021

Conover, W. J., & Iman, Ronald L. (1981). Rank Transformations as a Bridge Between Parametric and Nonparametric Statistics. *The American Statistician, 35*(3), 124-129. doi: 10.2307/2683975

Cumming, Jane, Barr, Steve, & Howe, Tracey E. (2006). Prosthetic rehabilitation for older dysvascular people following a unilateral transfemoral amputation. *The Cochrane Library*.

Cumming, Jane, Barr, Steve, & Howe, Tracey E. (2015). Prosthetic rehabilitation for older dysvascular people following a unilateral transfemoral amputation. *Cochrane Database of Systematic Reviews*(1). doi: 10.1002/14651858.CD005260.pub3

Czerniecki, J. M., Turner, A. P., Williams, R. M., Hakimi, K. N., & Norvell, D. C. (2012a). The effect of rehabilitation in a comprehensive inpatient rehabilitation unit on mobility outcome after dysvascular lower extremity amputation. *Archives of Physical Medicine and Rehabilitation, 93*(8), 1384-1391. doi: 10.1016/j.apmr.2012.03.019

Czerniecki, Joseph M., Turner, Aaron P., Williams, Rhonda M., Hakimi, Kevin N., & Norvell, Daniel C. (2012b). Mobility changes in individuals with dysvascular amputation from the pre-surgical period to 12 months post amputation. *Archives of Physical Medicine and Rehabilitation, 93*(10), 1766-1773.

Datta, D., Nair, P. N., & Payne, J. (1992). Outcome of prosthetic management of bilateral lower-limb amputees. *Disabil Rehabil, 14*(2), 98-102.

Davie-Smith, Fiona, Paul, Lorna, Nicholls, Natalie, Stuart, Wesley P, & Kennon, Brian. (2016). The impact of gender, level of amputation and diabetes on prosthetic fit rates following major lower extremity amputation. *Prosthetics and Orthotics International, 41*(1), 19-25. doi: 10.1177/0309364616628341

Davies, B., & Datta, D. (2003). Mobility outcome following unilateral lower limb amputation. *Prosthetics and orthotics international, 27*(3), 186-190.

Davis, WA, Norman, PE, Bruce, DG, & Davis, TME. (2006). Predictors, consequences and costs of diabetes-related lower extremity amputation complicating type 2 diabetes: the Fremantle Diabetes Study. *Diabetologia, 49*(11), 2634-2641.

de Groot, V., Beckerman, H., Lankhorst, G. J., & Bouter, L. M. (2003). How to measure comorbidity. a critical review of available methods. *Journal of Clinical Epidemiology, 56*(3), 221-229.

de Laat, F. A., Dijkstra, P. U., Rommers, G. M., Geertzen, J. H., & Roorda, L. D. (2014). Perceived independence and limitations in rising and sitting down after rehabilitation for a lower-limb amputation. *Journal of Rehabilitation Medicine, 46*(8), 824-827. doi: 10.2340/16501977-1834

De Maeyer, Catherine, Beckers, Paul, Vrints, Christiaan J, & Conraads, Viviane M. (2013). Exercise training in chronic heart failure. *Therapeutic advances in chronic disease, 4*(3), 105-117.

de Oliveira, B. I. R., Howie, E. K., Dunlop, S. A., Galea, M. P., McManus, A., & Allison, G. T. (2016). SCIPA Com: outcomes from the spinal cord injury and physical activity in the community intervention. *Spinal Cord, 54*, 855. doi: 10.1038/sc.2015.235

https://www.nature.com/articles/sc2015235#supplementary-information

Deathe, A. B., & Miller, W. C. (2005). The L test of functional mobility: measurement properties of a modified version of the timed "up & go" test designed for people with lower-limb amputations. *Physical Therapy, 85*(7), 626-635.

Department of Health, Western Australia. (2010). *High Risk Foot Model of Care*. Perth, Western Australia: Department of Health.

Department of Health, Western Australia. . (2008). *Amputee Services and Rehabilitation Model of Care.* Perth, Western Australian: Department of Health.

Department of Veterans Affairs, Department of Defense. (2008). *VA/DoD Clinical practice guideline for rehabilitation of lower limb amputation.* USA.

Deutsch, Anneke, English, Rowan D., Vermeer, Tammy C., Murray, Pamela S., & Condous, Michael. (2005). Removable rigid dressings versus soft dressings: A randomized, controlled study with dysvascular, trans-tibial amputees. *Prosthetics and Orthotics International, 29*(2), 193-200. doi: 10.1080/03093640500224295

Devan, H., Hendrick, P., Ribeiro, D. C., Hale, L. A., & Carman, A. (2014). Asymmetrical movements of the lumbopelvic region: is this a potential mechanism for low back pain in people with lower limb amputation? *Medical Hypotheses, 82*(1), 77-85. doi: 10.1016/j.mehy.2013.11.012

Dillingham, T. R., Pezzin, L. E., & Shore, A. D. (2005). Reamputation, mortality, and health care costs among persons with dysvascular lower-limb amputations. *Archives of Physical Medicine and Rehabilitation, 86*(3), 480-486. doi: 10.1016/j.apmr.2004.06.072

Dillingham, Timothy R., Pezzin, Liliana E., MacKenzie, Ellen J., & Burgess, Andrew R. (2001). Use and Satisfaction with Prosthetic Devices Among Persons with Trauma-Related Amputations: A Long-Term Outcome Study. *American Journal of Physical Medicine & Rehabilitation, 80*(8), 563-571.

Dillon, M. (2010). Comment on: An interim prosthesis program for lower limb amputees. *Prosthetics and Orthotics International, 34*(4), 495-497; author reply 498-501. doi: 10.3109/03093646.2010.520061

Dillon, M. P., Kohler, F., & Peeva, V. (2014). Incidence of lower limb amputation in Australian hospitals from 2000 to 2010. *Prosthetics and Orthotics International, 38*(2), 122-132. doi: 10.1177/0309364613490441

Dillon, M. P., Major, M. J., Kaluf, B., Balasanov, Y., & Fatone, S. (2017a). Predict the Medicare Functional Classification Level (K-level) using the Amputee Mobility Predictor in people with unilateral transfemoral and transtibial amputation: A pilot study. *Prosthetics and Orthotics International*, 309364617706748. doi: 10.1177/0309364617706748

Dillon, Michael P., Fortington, Lauren V., Akram, Muhammad, Erbas, Bircan, & Kohler, Friedbert. (2017b). Geographic Variation of the Incidence Rate of Lower Limb Amputation in Australia from 2007-12. *PLOS ONE, 12*(1), e0170705. doi: 10.1371/journal.pone.0170705

Dite, W., Connor, H. J., & Curtis, H. C. (2007). Clinical identification of multiple fall risk early after unilateral transtibial amputation. *Archives of Physical Medicine and Rehabilitation, 88*(1), 109-114. doi: 10.1016/j.apmr.2006.10.015

Dite, W., & Temple, V. A. (2002). A clinical test of stepping and change of direction to identify multiple falling older adults. *Archives of Physical Medicine and Rehabilitation, 83*(11), 1566-1571.

Dunne, S., Coffey, L., Gallagher, P., Desmond, D., & Ryall, N. (2015). Beyond function: Using assistive technologies following lower limb loss. *J Rehabil Med, 47*(6), 561-568. doi: 10.2340/16501977-1962

Eagar, Kathy. (2011). What is activity-based funding? ABF Information Series No. 1.

Edwards, D. S., Phillip, Rhodri D., Bosanquet, Nick, Bull, Anthony M. J., & Clasper, Jon C. (2015). What Is the Magnitude and Long-term Economic Cost of Care of the British Military Afghanistan Amputee Cohort? *Clinical Orthopaedics and Related Research®, 473*(9), 2848-2855. doi: 10.1007/s11999-015-4250-9

Engkasan, J. P., Ehsan, F. M., & Chung, T. Y. (2012). Ability to return to driving after major lower limb amputation. *Journal of Rehabilitation Medicine, 44*(1), 19-23. doi: 10.2340/16501977-0904

Erjavec, Tatjana, Vidmar, Gaj, & Burger, Helena. (2014). Exercise testing as a screening measure for ability to walk with aprosthesis after transfemoral amputation due to peripheral vascular disease. *Disability and rehabilitation, 36*(14), 1148-1155.

Esquenazi, A. (2004). Amputation rehabilitation and prosthetic restoration. From surgery to community reintegration. *Disabil Rehabil, 26*(14-15), 831-836.

Everitt, Brian S. (1992). *The analysis of contingency tables* (Vol. 45): CRC Press.

Fan, Eddy, Gifford, Jeneen M., Chandolu, Satish, Colantuoni, Elizabeth, Pronovost, Peter J., & Needham, Dale M. (2012). The functional comorbidity index had high inter-rater reliability in patients with acute lung injury. *BMC Anesthesiology, 12*(1), 1-8. doi: 10.1186/1471-2253-12-21

Fatone, S., & Caldwell, R. (2017). Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation: Part 2 Description and Preliminary evaluation. *Prosthet Orthot Int, 41*(3), 246-250. doi: 10.1177/0309364616685230

Felice, Peter A, Kerekes, David T, & Mast, Bruce A. (2017). Identifying Risk Factors Leading to Unanticipated Postoperative Readmission. *Annals of Plastic Surgery, 78*(6S), S322-S324.

Field, Andy. (2009). *Discovering statistics using SPSS*: Sage publications.

Fisher, K., Hanspal, R. S., & Marks, L. (2003). Return to work after lower limb amputation. *Int J Rehabil Res, 26*(1), 51-56. doi: 10.1097/01.mrr.0000054806.81886.d7

Fletcher, D. D., Andrews, K. L., Butters, M. A., Jacobsen, S. J., Rowland, C. M., & Hallett, J. W., Jr. (2001). Rehabilitation of the geriatric vascular amputee patient: a population-based study. *Archives of Physical Medicine and Rehabilitation, 82*(6), 776-779. doi: 10.1053/apmr.2001.21856

Fletcher, D. D., Andrews, K. L., Hallett, J. W., Jr., Butters, M. A., Rowland, C. M., & Jacobsen, S. J. (2002). Trends in rehabilitation after amputation for geriatric patients with vascular disease: implications for future health resource allocation. *Archives of Physical Medicine and Rehabilitation, 83*(10), 1389-1393.

Forrest, G. F., Hutchinson, K., Lorenz, D. J., Buehner, J. J., Vanhiel, L. R., Sisto, S. A., & Basso, D. M. (2014). Are the 10 meter and 6 minute walk tests redundant in patients with spinal cord injury? *PLOS ONE, 9*(5), e94108. doi: 10.1371/journal.pone.0094108

Fortington, L. V., Geertzen, J. H., van Netten, J. J., Postema, K., Rommers, G. M., & Dijkstra, P. U. (2013). Short and long term mortality rates after a lower limb amputation. *European Journal of Vascular and Endovascular Surgery : The Official Journal of the European Society for Vascular Surgery, 46*(1), 124-131. doi: 10.1016/j.ejvs.2013.03.024

Franchignoni, Franco, Giordano, Andrea, Ferriero, Giorgio, Muñoz, Susana, Orlandini, Duccio, & Amoresano, Amedeo. (2007). Rasch analysis of the Locomotor Capabilities Index-5 in people with lower limb amputation. *Prosthetics and Orthotics International, 31*(4), 394-404.

Franchignoni, Franco, Orlandini, Duccio, Ferriero, Giorgio, & Moscato, Tancredi A. (2004). Reliability, validity, and responsiveness of the locomotor capabilities index in adults with lower-limb amputation undergoing prosthetic training. *Archives of Physical Medicine and Rehabilitation, 85*(5), 743-748.

Fritz, J. M. (2009). Clinical prediction rules in physical therapy: coming of age? *Journal of Orthopaedic and Sports Physical Therapy, 39*(3), 159-161. doi: 10.2519/jospt.2009.0110

Frossard, Laurent, Hagberg, Kerstin, Häggström, Eva, Gow, David Lee, Brånemark, Rickard, & Pearcy, Mark. (2010). Functional outcome of transfemoral amputees fitted with an osseointegrated fixation: temporal gait characteristics. *JPO: Journal of Prosthetics and Orthotics, 22*(1), 11-20.

Frossard, Laurent, Merlo, Gregory, Quincey, Tanya, Burkett, Brendan, & Berg, Debra. (2017). Development of a Procedure for the Government Provision of Bone-Anchored Prosthesis Using Osseointegration in Australia. *PharmacoEconomics - Open, 1*(4), 301-314. doi: 10.1007/s41669-017-0032-5

Gailey, R., Allen, K., Castles, J., Kucharik, J., & Roeder, M. (2008). Review of secondary physical conditions associated with lower-limb amputation and long-term prosthesis use. *Journal of Rehabilitation Research and Development, 45*(1), 15-29.

Gailey, R., McFarland, L. V., Cooper, R. A., Czerniecki, J., Gambel, J. M., Hubbard, S., . . . Reiber, G. E. (2010). Unilateral lower-limb loss: prosthetic device use and functional outcomes in servicemembers from Vietnam war and OIF/OEF conflicts. *J Rehabil Res Dev, 47*(4), 317-331.

Gailey, R. S., Roach, K. E., Applegate, E. B., Cho, B., Cunniffe, B., Licht, S., . . . Nash, M. S. (2002). The amputee mobility predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate. *Arch Phys Med Rehabil, 83*(5), 613-627.

Gailey, R. S., Scoville, C., Gaunaurd, I. A., Raya, M. A., Linberg, A. A., Stoneman, P. D., . . . Roach, K. E. (2013). Construct validity of Comprehensive High-Level Activity Mobility Predictor (CHAMP) for male servicemembers with traumatic lower-limb loss. *Journal of Rehabilitation Research and Development, 50*(7), 919-930. doi: 10.1682/jrrd.2012.05.0100

Gailey, R.S., and Clark, C. R. (2004). Physical Therapy Management of Adult Lower-Limb Amputees. In J. B. D Smith, and JW Micheal (Ed.), Academy of Orthopaedic Surgeons, Atlas of Prosthetics: Surgical, Prosthetic, and Rehabilitation Principles. (pp. 589-619): Mosby Company. Retrieved from http://www.oandplibrary.org/alp/.

Gailey, R.S., Gailey, A.M., & Angulo, F. (1989). *Prosthetic Gait Training Program for Lower Extremity Amputees*: Advanced Rehabilitation Therapy, Incorporated.

Gailey, R.S., Gailey, A.M., & Angulo, F. (1994a). *The Rehabilitation Series for Lower Extremity Amputees*: Advanced Rehabilitation Therapy, Incorporated.

Gailey, R.S., Gailey, A.M., & Angulo, F. (1994b). *Stretching and Strengthening for Lower Extremity Amputees*: Advanced Rehabilitation Therapy, Incorporated.

Gailey, R.S., Gailey, A.M., Sendelbach, S.J., & Angulo, F. (1995). *Home Exercise Guide for Lower Extremity Amputees*: Advanced Rehabilitation Therapy, Incorporated.

Gallagher, P., Franchignoni, F., Giordano, A., & MacLachlan, M. (2010). Trinity amputation and prosthesis experience scales: a psychometric assessment using classical test theory and rasch analysis. *Am J Phys Med Rehabil, 89*(6), 487-496. doi: 10.1097/PHM.0b013e3181dd8cf1

Gallagher, P., & Maclachlan, M. (2004). The Trinity Amputation and Prosthesis Experience Scales and quality of life in people with lower-limb amputation. *Archives of Physical Medicine and Rehabilitation, 85*(5), 730-736.

Gallagher, P., O'Donovan, M. A., Doyle, A., & Desmond, D. (2011). Environmental barriers, activity limitations and participation restrictions experienced by people with major limb amputation. *Prosthet Orthot Int, 35*(3), 278-284. doi: 10.1177/0309364611407108

Gallagher, Pamela, & MacLachlan, Malcolm. (2000). Development and psychometric evaluation of the Trinity Amputation and Prosthesis Experience Scales (TAPES). *Rehabilitation Psychology, 45*(2), 130.

Gardner, Andrew W., Katzel, Leslie I., Sorkin, John D., & Goldberg, Andrew P. (2002). Effects of Long-term Exercise Rehabilitation on Claudication Distances in Patients With Peripheral Arterial Disease: A Randomized Controlled Trial. *Journal of Cardiopulmonary Rehabilitation and Prevention, 22*(3), 192-198.

Gaunaurd, I., Spaulding, S. E., Amtmann, D., Salem, R., Gailey, R., Morgan, S. J., & Hafner, B. J. (2015). Use of and confidence in administering outcome measures among clinical prosthetists: Results from a national survey and mixed-methods training program. *Prosthetics and Orthotics International, 39*(4), 314-321. doi: 10.1177/0309364614532865

Gaunaurd, Ignacio A. (2012). *The Comprehensive High-level Activity Mobility Predictor (CHAMP): A Performance-based Assessment Instrument to Quantify High-level Mobility in Service Members with Traumatic Lower Limb Loss.* (Doctoral thesis), University of Miami, USA. Retrieved from http://scholarlyrepository.miami.edu/cgi/viewcontent.cgi?article=1714&context=oa_dissertations (Paper 712)

Gauthier-Gagnon, C., & Grise, M. C. (1994). Prosthetic profile of the amputee questionnaire: validity and reliability. *Archives of Physical Medicine and Rehabilitation, 75*(12), 1309-1314.

Gauthier-Gagnon, C., Grisé, M.C., & Potvin, D. (1999). Enabling factors related to prosthetic use by people with transtibial and transfemoral amputation. *Archives of Physical Medicine and Rehabilitation, 80*(6), 706-713.

Gauthier-Gagnon, Christiane, & Grisé, Marie-Claude. (2006). Tools to measure outcome of people with a lower limb amputation: Update on the PPA and LCI. *JPO: Journal of Prosthetics and Orthotics, 18*(6), P61-P67.

Geertzen, J. H., Bosmans, J. C., van der Schans, C. P., & Dijkstra, P. U. (2005). Claimed walking distance of lower limb amputees. *Disability & Rehabilitation, 27*(3), 101-104. doi: 10.1080/09638280400009345

Geertzen, J., van der Linde, H., Rosenbrand, K., Conradi, M., Deckers, J., Koning, J., . . . Voesten, H. (2015a). Dutch evidence-based guidelines for amputation and prosthetics of the lower extremity: Rehabilitation process and prosthetics. Part 2. *Prosthetics and Orthotics International, 39*(5), 361-371. doi: 10.1177/0309364614542725

Geertzen, J., van der Linde, H., Rosenbrand, K., Conradi, M., Deckers, J., Koning, J., . . . Voesten, H. (2015b). Dutch evidence-based guidelines for amputation and prosthetics of the lower extremity: Amputation surgery and postoperative management. Part 1. *Prosthetics and Orthotics International, 39*(5), 351-360. doi: 10.1177/0309364614541460

Goktepe, A. S., Cakir, B., Yilmaz, B., & Yazicioglu, K. (2010). Energy expenditure of walking with prostheses: comparison of three amputation levels. *Prosthetics and Orthotics International, 34*(1), 31-36. doi: 10.3109/03093640903433928

Golicki, Dominik, Niewada, Maciej, Buczek, Julia, Karlińska, Anna, Kobayashi, Adam, Janssen, MF, & Pickard, A Simon. (2015). Validity of EQ-5D-5L in stroke. *Quality of Life Research, 24*(4), 845-850.

Gordon, R., Magee, C., Frazer, A., Evans, C., & McCosker, K. (2010). An interim prosthesis program for lower limb amputees: comparison of public and private models of service. *Prosthetics and Orthotics International, 34*(2), 175-183. doi: 10.3109/03093640903510980

Gottschalk, Frank. (2002). Transfemoral Amputation: Surgical Procedures. In H. Bowker & J. Michael (Eds.), Atlas of Limb Prosthetics: Surgical, Prosthetic, and Rehabilitation Principles (2nd ed.). Rosemont, IL: American Academy of Orthopedic Surgeons. Retrieved from http://www.oandplibrary.org/alp/.

Groll, D. L., Heyland, D. K., Caeser, M., & Wright, J. G. (2006). Assessment of long-term physical function in acute respiratory distress syndrome (ARDS) patients: comparison of the Charlson Comorbidity Index and the Functional Comorbidity Index. *American Journal of Physical Medicine & Rehabilitation, 85*(7), 574-581. doi: 10.1097/01.phm.0000223220.91914.61

Groll, D. L., To, T., Bombardier, C., & Wright, J. G. (2005). The development of a comorbidity index with physical function as the outcome. *Journal of Clinical Epidemiology, 58*(6), 595-602. doi: 10.1016/j.jclinepi.2004.10.018

Guirao, L., Samitier, C. B., Costea, M., Camos, J. M., Majo, M., & Pleguezuelos, E. (2016). Improvement in walking abilities in transfemoral amputees with a distal weight

bearing implant. *Prosthetics and Orthotics International, 41*(1), 26-32. doi: 10.1177/0309364616633920
Hafner, B. J., Gaunaurd, I. A., Morgan, S. J., Amtmann, D., Salem, R., & Gailey, R. S. (2017). Construct Validity of the Prosthetic Limb Users Survey of Mobility (PLUS-M) in Adults With Lower Limb Amputation. *Archives of Physical Medicine and Rehabilitation, 98*(2), 277-285. doi: 10.1016/j.apmr.2016.07.026
Hafner, B. J., & Smith, D. G. (2009). Differences in function and safety between Medicare Functional Classification Level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control. *J Rehabil Res Dev, 46*(3), 417-433.
Hafner, B. J., Willingham, L. L., Buell, N. C., Allyn, K. J., & Smith, D. G. (2007). Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee. *Archives of Physical Medicine and Rehabilitation, 88*(2), 207-217. doi: 10.1016/j.apmr.2006.10.030
Hagberg, K., Haggstrom, E., Uden, M., & Branemark, R. (2005). Socket versus bone-anchored trans-femoral prostheses: hip range of motion and sitting comfort. *Prosthet Orthot Int, 29*(2), 153-163. doi: 10.1080/03093640500238014
Hagberg, Kerstin, Hansson, Elisabeth, & Brånemark, Rickard. (2014). Outcome of percutaneous osseointegrated prostheses for patients with unilateral transfemoral amputation at two-year follow-up. *Archives of physical medicine and rehabilitation, 95*(11), 2120-2127.
Haggstrom, E. E., Hansson, E., & Hagberg, K. (2013). Comparison of prosthetic costs and service between osseointegrated and conventional suspended transfemoral prostheses. *Prosthetics and Orthotics International, 37*(2), 152-160. doi: 10.1177/0309364612454160
Haines, K, Berney, S, Warrillow, S, & Denehy, L. (2014). Predicting Physical Function and Health Related Quality of Life Following Intensive Care. *International Journal of Physical Medicine & Rehabilitation, 2*(180), 1-6.
Hajian-Tilaki, K. O., Hanley, J. A., Joseph, L., & Collet, J. P. (1997). A comparison of parametric and nonparametric approaches to ROC analysis of quantitative diagnostic tests. *Medical Decision Making 17*(1), 94-102. doi: 10.1177/0272989x9701700111
Hall, S. F. (2006). A user's guide to selecting a comorbidity index for clinical research. *Journal of Clinical Epidemiology, 59*(8), 849-855. doi: 10.1016/j.jclinepi.2005.11.013
Hall, W. H., Ramachandran, R., Narayan, S., Jani, A. B., & Vijayakumar, S. (2004). An electronic application for rapidly calculating Charlson comorbidity score. *BMC Cancer, 4*, 94. doi: 10.1186/1471-2407-4-94
Hanspal, R. S., Fisher, Keren, & Nieveen, Richard. (2003). Prosthetic socket fit comfort score. *Disability and Rehabilitation, 25*(22), 1278-1280. doi: 10.1080/0963828031000160398 3
Hattie, John, & Cooksey, Ray W. (1984). Procedures for assessing the validities of tests using the" known-groups" method. *Applied Psychological Measurement, 8*(3), 295-305.
Heale, Roberta, & Twycross, Alison. (2015). Validity and reliability in quantitative studies. *Evidence Based Nursing, 18*(3), 66-67.
Heinemann, A. W., Connelly, L., Ehrlich-Jones, L., & Fatone, S. (2014). Outcome instruments for prosthetics: clinical applications. *Physical Medicine and Rehabilitation Clinics of North America, 25*(1), 179-198. doi: 10.1016/j.pmr.2013.09.002
Heinemann, A. W., Ehrlich-Jones, L., Connelly, L., Semik, P., & Fatone, S. (2016). Enhancing quality of prosthetic services with process and outcome information. *Prosthetics and Orthotics International, 41*(2), 164-170. doi: 10.1177/0309364616637957
Highsmith, M Jason. (2013). Comparative Effectiveness Research in Prosthetics and Amputee Rehabilitation at the University of South Florida Contemplating New

Interventions for Contractures in Amputees. *Journal of Yoga & Physical Therapy, 3*(4), 1-2.
Highsmith, M Jason, Kahle, Jason T, Lewandowski, Amanda, Klenow, Tyler D, Orriola, John J, Miro, Rebecca M, . . . Highsmith, James T. (2016a). Economic Evaulations of Interventions For Transtibial Amputees: A Scoping Review of Comparative Studies. *Technology & Innovation, 18*(2-3), 85-98.
Highsmith, M Jason, Kahle, Jason T, Wernke, Matthew M, Carey, Stephanie L, Miro, Rebecca M, Lura, Derek J, & Sutton, Bryce S. (2016b). Effects of the Genium Knee System on Functional Level, Stair Ambulation, Perceptive and Economic Outcomes In Transfemoral Amputees. *Technology & Innovation, 18*(2-3), 139-150.
Hoffstad, O., Mitra, N., Walsh, J., & Margolis, D. J. (2015). Diabetes, lower-extremity amputation, and death. *Diabetes Care, 38*(10), 1852-1857. doi: 10.2337/dc15-0536
Hordacre, B., Birks, V., Quinn, S., Barr, C., Patritti, B. L., & Crotty, M. (2013a). Physiotherapy rehabilitation for individuals with lower limb amputation: a 15-year clinical series. *Physiotherapy Research International, 18*(2), 70-80. doi: 10.1002/pri.1529
Hordacre, B. G., Stevermuer, T., Simmonds, F., Crotty, M., & Eagar, K. (2013b). Lower-limb amputee rehabilitation in Australia: analysis of a national data set 2004-10. *Australian Health Review, 37*(1), 41-47. doi: 10.1071/ah11138
Hordacre, Brenton, Barr, Christopher, & Crotty, Maria. (2014). Use of an Activity Monitor and GPS Device to Assess Community Activity and Participation in Transtibial Amputees. *Sensors, 14*(4), 5845-5859.
Howick, J. (2009). Oxford Centre for Evidence-based Medicine – Levels of Evidence (March 2009). Retrieved 31/07/2016, 2016, from http://www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/
ICRC. (2015). International Committee of the Red Cross (ICRC). Physical Rehabilitation Programme Annual Report 2014. (pp. 1-92). Geneva, Switzerland.
Ioannidis, Orestis, Kitsikosta, Loukiani, Tatsis, Dimitris, Skandalos, Ioannis, Cheva, Aggeliki, Gkioti, Aikaterini, . . . Tsalis, Konstantinos George. (2017). Fournier's Gangrene: Lessons Learned from Multimodal and Multidisciplinary Management of Perineal Necrotizing Fasciitis. *Frontiers in Surgery, 4*(36), 1-12. doi: 10.3389/fsurg.2017.00036
Jaarsma, E. A., Dijkstra, P. U., Geertzen, J. H. B., & Dekker, R. (2014). Barriers to and facilitators of sports participation for people with physical disabilities: A systematic review. *Scandinavian Journal of Medicine & Science in Sports, 24*(6), 871-881. doi: doi:10.1111/sms.12218
Jaeschke, R., Guyatt, G., & Sackett, D. L. (1994). Users' guides to the medical literature. III. How to use an article about a diagnostic test. A. Are the results of the study valid? Evidence-Based Medicine Working Group. *JAMA, 271*(5), 389-391.
Jakobsen, Emma Lise Thorlund, Biering, Karin, Kærgaard, Anette, & Andersen, Johan Hviid. (2017). Neck–Shoulder Pain and Work Status among Former Sewing Machine Operators: A 14-year Follow-up Study. *Journal of Occupational Rehabilitation*, 1-9.
Jenkins, Sue C. (2007). 6-Minute walk test in patients with COPD: clinical applications in pulmonary rehabilitation. *Physiotherapy, 93*(3), 175-182. doi: http://dx.doi.org/10.1016/j.physio.2007.02.001
Jette, Diane U, Halbert, James, Iverson, Courtney, Miceli, Erin, & Shah, Palak. (2009). Use of standardized outcome measures in physical therapist practice: perceptions and applications. *Physical Therapy, 89*(2), 125-135.
Jones, L., Hall, M., & Schuld, W. (1993). Ability or disability? A study of the functional outcome of 65 consecutive lower limb amputees treated at the Royal South Sydney Hospital in 1988-1989. *Disability & Rehabilitation, 15*(4), 184-188.
Jones, W. S., Patel, M. R., Dai, D., Vemulapalli, S., Subherwal, S., Stafford, J., & Peterson, E. D. (2013). High mortality risks after major lower extremity amputation in Medicare

patients with peripheral artery disease. *American Heart Journal, 165*(5), 809-815, 815 e801. doi: 10.1016/j.ahj.2012.12.002
Joubert, Pip. (2016). 1year post amputee rehab.
Kahle, Jason T, & Highsmith, M Jason. (2014). Transfemoral interfaces with vacuum assisted suspension comparison of gait, balance, and subjective analysis: ischial containment versus brimless. *Gait & posture, 40*(2), 315-320.
Kahle, Jason T, Highsmith, M Jason, Schaepper, Hans, Johannesson, Anton, Orendurff, Michael S, & Kaufman, Kenton. (2016a). Predicting Walking Ability Following Lower Limb Amputation: An Updated Systematic Literature Review. *Technology & Innovation, 18*(2-3), 125-137.
Kahle, Jason T, Klenow, Tyler D, & Highsmith, M Jason. (2016b). Comparative Effectiveness of an Adjustable Transfemoral Prosthetic Interface Accommodating Volume Fluctuation: Case Study. *Technology and innovation, 18*(2-3), 175.
Karmarkar, A. M., Collins, D. M., Wichman, T., Franklin, A., Fitzgerald, S. G., Dicianno, B. E., . . . Cooper, R. A. (2009). Prosthesis and wheelchair use in veterans with lower-limb amputation. *Journal of Rehabilitation Research and Development, 46*(5), 567-576.
Kars, Cojanne, Hofman, Marianne, Geertzen, Jan H. B., Pepping, Gert-Jan, & Dekker, Rienk. (2009). Participation in Sports by Lower Limb Amputees in the Province of Drenthe, the Netherlands. *Prosthetics and Orthotics International, 33*(4), 356-367. doi: 10.3109/03093640902984579
Katz, J. N., Chang, L. C., Sangha, O., Fossel, A. H., & Bates, D. W. (1996). Can comorbidity be measured by questionnaire rather than medical record review? *Med Care, 34*(1), 73-84.
Kaufman, Kenton R, Levine, James A, Brey, Robert H, McCrady, Shelly K, Padgett, Denny J, & Joyner, Michael J. (2008). Energy expenditure and activity of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. *Archives of physical medicine and rehabilitation, 89*(7), 1380-1385.
Kelly, D. A., Pedersen, S., Tosenovsky, P., & Sieunarine, K. (2017). Major Lower Limb Amputation: Outcomes are Improving. *Ann Vasc Surg, 45*(Nov), 29-34. doi: 10.1016/j.avsg.2017.05.039
Kiefe, Catarina I., Funkhouser, Ellen, Fouad, Mona N., & May, Daniel S. (1998). Chronic disease as a barrier to breast and cervical cancer screening. *Journal of General Internal Medicine, 13*(6), 357-365. doi: 10.1046/j.1525-1497.1998.00115.x
Knapp, David. (2013). Transtibial Prosthetics. In M. M. Lusardi, M. Jorge & C. C. Nielsen (Eds.), *Orthotic & Prosthetics in Rehabilitation* (3rd ed., pp. 622-651). USA: Elsevier.
Kohler, F. (2010). Re: Article by Gordon et al. on interim prosthesis programme for lower limb amputees--comparison of public and private model of services. *Prosthetics and Orthotics International, 34*(2), 221-222. doi: 10.3109/03093646.2010.493046
Kulkarni, J. (2008). Post amputation syndrome. *Prosthetics and Orthotics International, 32*(4), 434-437. doi: 10.1080/03093640802258637
Kulkarni, J., Pande, S., & Morris, J. (2006). Survival rates in dysvascular lower limb amputees. *International Journal of Surgery, 4*(4), 217-221. doi: 10.1016/j.ijsu.2006.06.027
Kurichi, J. E., Kwong, P. L., Reker, D. M., Bates, B. E., Marshall, C. R., & Stineman, M. G. (2007). Clinical factors associated with prescription of a prosthetic limb in elderly veterans. *Journal of the American Geriatrics Society, 55*(6), 900-906. doi: 10.1111/j.1532-5415.2007.01187.x
Kurichi, Jibby E., Small, Dylan S., Bates, Barbara E., Prvu-Bettger, Janet A., Kwong, Pui L., Vogel, W. Bruce, . . . Stineman, Margaret G. (2009). Possible Incremental Benefits of Specialized Rehabilitation Bed Units Among Veterans After Lower Extremity Amputation. *Medical care, 47*(4), 457-465. doi: 10.1097/MLR.0b013e31818b08c6

Kurowski, J. R., Nedkoff, L., Schoen, D. E., Knuiman, M., Norman, P. E., & Briffa, T. G. (2015). Temporal trends in initial and recurrent lower extremity amputations in people with and without diabetes in Western Australia from 2000 to 2010. *Diabetes Research and Clinical Practice, 108*(2), 280-287. doi: 10.1016/j.diabres.2015.02.008

Laferrier, J. Z., & Gailey, R. (2010). Advances in lower-limb prosthetic technology. *Phys Med Rehabil Clin N Am, 21*(1), 87-110. doi: 10.1016/j.pmr.2009.08.003

Laferrier, J. Z., McFarland, L. V., Boninger, M. L., Cooper, R. A., & Reiber, G. E. (2010). Wheeled mobility: factors influencing mobility and assistive technology in veterans and servicemembers with major traumatic limb loss from Vietnam war and OIF/OEF conflicts. *J Rehabil Res Dev, 47*(4), 349-360.

Langford, J., Dillon, M. P., Granger, C. L., & Barr, C. (2018). Physical activity participation amongst individuals with lower limb amputation. *Disabil Rehabil*, 1-8. doi: 10.1080/09638288.2017.1422031

Larsson, B., Johannesson, A., Andersson, I. H., & Atroshi, I. (2009). The Locomotor Capabilities Index; validity and reliability of the Swedish version in adults with lower limb amputation. *Health and Quality of Life Outcomes, 7*, 44.

Laupacis, A., Sekar, N., & Stiell, I. G. (1997). Clinical prediction rules. A review and suggested modifications of methodological standards. *JAMA, 277*(6), 488-494.

Lazzarini, P. A., Gurr, J. M., Rogers, J. R., Schox, A., & Bergin, S. M. (2012). Diabetes foot disease: the Cinderella of Australian diabetes management? *Journal of Foot and Ankle Research, 5*(1), 24. doi: 10.1186/1757-1146-5-24

Lee, D. J., & Costello, M. C. (2018). 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, 42*(2), 144-152. doi: 10.1177/0309364617695883

Legro, Marcia W, Reiber, Gayle, del Aguila, Michael, & Ajax, Megan J. (1999). Issues of importance reported by persons with lower limb amputations and protheses. *Journal of rehabilitation research and development, 36*(3), 155.

Lesher, J. D., Sutlive, T. G., Miller, G. A., Chine, N. J., Garber, M. B., & Wainner, R. S. (2006). Development of a clinical prediction rule for classifying patients with patellofemoral pain syndrome who respond to patellar taping. *Journal of Orthopaedic and Sports Physical Therapy, 36*(11), 854-866.

Leung, E. C., Rush, P. J., & Devlin, M. (1996). Predicting prosthetic rehabilitation outcome in lower limb amputee patients with the functional independence measure. *Archives of Physical Medicine and Rehabilitation, 77*(6), 605-608.

Lim, T. S., Finlayson, A., Thorpe, J. M., Sieunarine, K., Mwipatayi, B. P., Brady, A., . . . Angel, D. (2006). Outcomes of a contemporary amputation series. *ANZ Journal of Surgery, 76*(5), 300-305. doi: 10.1111/j.1445-2197.2006.03715.x

Lin, S. J., & Bose, N. H. (2008). Six-minute walk test in persons with transtibial amputation. *Archives of Physical Medicine and Rehabilitation, 89*(12), 2354-2359. doi: 10.1016/j.apmr.2008.05.021

Linberg, A. A., Roach, K. E., Campbell, S. M., Stoneman, P. D., Gaunaurd, I. A., Raya, M. A., . . . Gailey, R. S. (2013). Comparison of 6-minute walk test performance between male Active Duty soldiers and servicemembers with and without traumatic lower-limb loss. *Journal of Rehabilitation Research and Development, 50*(7), 931-940. doi: 10.1682/jrrd.2012.05.0098

Lusardi, Michelle M. (2013). Postoperative and Preprosthetic Care. In M. M. Lusardi, M. Jorge & C. C. Nielsen (Eds.), *Orthotics & Prosthetics in Rehabilitation* (3rd ed., pp. 532-594). USA: Elsevier.

Lusardi, Michelle M, & Pepe, Judith L. (2013). Amputation Surgeries for the Lower Limb. In M. M. Lusardi, M. Jorge & C. C. Nielsen (Eds.), *Orthotics & Prosthetics in Rehabilitation* (3rd ed., pp. 498-531). USA: Elsevier.

Lythgo, Noel, Marmaras, Bill, & Connor, Helen. (2010). Physical function, gait, and dynamic balance of transfemoral amputees using two mechanical passive prosthetic knee devices. *Archives of physical medicine and rehabilitation, 91*(10), 1565-1570.

Ma, V. Y., Chan, L., & Carruthers, K. J. (2014). Incidence, prevalence, costs, and impact on disability of common conditions requiring rehabilitation in the United States: stroke, spinal cord injury, traumatic brain injury, multiple sclerosis, osteoarthritis, rheumatoid arthritis, limb loss, and back pain. *Archives of Physical Medicine and Rehabilitation, 95*(5), 986-995 e981. doi: 10.1016/j.apmr.2013.10.032

MacLachlan, Malcolm, McDonald, Dympna, & Waloch, Justine. (2004). Mirror treatment of lower limb phantom pain: A case study. *Disability and Rehabilitation, 26*(14-15), 901-904. doi: doi:10.1080/09638280410001708913

Maddison, Ralph, & Ni Mhurchu, Cliona. (2009). Global positioning system: a new opportunity in physical activity measurement. *International Journal of Behavioral Nutrition and Physical Activity, 6*(1), 73.

Malone, M., Lau, N. S., White, J., Novak, A., Xuan, W., Iliopoulos, J., . . . Dickson, H. G. (2014). The Effect of Diabetes Mellitus on Costs and Length of Stay in Patients with Peripheral Arterial Disease Undergoing Vascular Surgery. *European Journal of Vascular and Endovascular Surgery, 48*(4), 447-451. doi: 10.1016/j.ejvs.2014.07.001

McCabe, N., Butler, J., Dunbar, S. B., Higgins, M., & Reilly, C. (2017). Six-minute walk distance predicts 30-day readmission after acute heart failure hospitalization. *Heart Lung, 46*(4), 287-292. doi: 10.1016/j.hrtlng.2017.04.001

McDermott, M. M., Ferrucci, L., Guralnik, J. M., Dyer, A. R., Liu, K., Pearce, W. H., . . . Criqui, M. H. (2010). The ankle-brachial index is associated with the magnitude of impaired walking endurance among men and women with peripheral arterial disease. *Vascular medicine 15*(4), 251-257. doi: 10.1177/1358863x10365181

McLennan, W. (1997). *ASCO Australian Standard Classification of Occupations 2nd Edition*. Canberra: Australian Bureau of Statistics Retrieved from http://www.ausstats.abs.gov.au/ausstats/free.nsf/0/A86A0162E6F672DFCA256ADB001D10D4/$File/asco.pdf.

McNamee, Andrew. (2005). *Ethical Issues arising from the Real Time Tracking and Monitoring of People Using GPS-based Location Services.* (Bachelor of Information and Communication Technology (Honours) Honours Thesis), University of Wollongong, Australia. Retrieved from http://ro.uow.edu.au/thesesinfo/4/

McWhinnie, D. L., Gordon, A. C., Collin, J., Gray, D. W., & Morrison, J. D. (1994). Rehabilitation outcome 5 years after 100 lower-limb amputations. *Br J Surg, 81*(11), 1596-1599.

Meatherall, B. L., Garrett, M. R., Kaufert, J., Martin, B. D., Fricke, M. W., Arneja, A. S., . . . Embil, J. M. (2005). Disability and quality of life in Canadian aboriginal and non-aboriginal diabetic lower-extremity amputees. *Archives of Physical Medicine and Rehabilitation, 86*(8), 1594-1602. doi: 10.1016/j.apmr.2004.11.026

Megens, A. M., Harris, S. R., Backman, C. L., & Hayes, V. E. (2007). Known-groups analysis of the harris infant neuromotor test. *Physical Therapy, 87*(2), 164-169. doi: 10.2522/ptj.20060096

Meier Iii, Robert H., & Heckman, Jeffrey T. (2014). Principles of Contemporary Amputation Rehabilitation in the United States, 2013. *Physical Medicine and Rehabilitation Clinics of North America, 25*(1), 29-33. doi: http://dx.doi.org/10.1016/j.pmr.2013.09.004

Meier, R. H., 3rd, & Melton, D. (2014). Ideal functional outcomes for amputation levels. *Physical Medicine and Rehabilitation Clinics of North America, 25*(1), 199-212. doi: 10.1016/j.pmr.2013.09.011

Melchiorre, Philip J., Findley, Thomas, & Boda, Wanda. (1996). Functional outcome and comorbidity indexes in the rehabilitation of the traumatic versus the vascular

unilateral lower limb amputee. *American Journal of Physical Medicine & Rehabilitation, 75*(1), 9-14.
Michael, Katina, McNamee, Andrew, & Michael, MG (2006). *The Emerging Ethics of Humancentric GPS Tracking and Monitoring*. Paper presented at the Proceedings of the International Conference on Mobile Business.
Miller, W. C., Deathe, A. B., & Speechley, M. (2001). Lower extremity prosthetic mobility: a comparison of 3 self-report scales. *Archives of Physical Medicine and Rehabilitation, 82*(10), 1432-1440. doi: 10.1053/apmr.2001.25987
Moltó, A, & Dougados, M. (2014). Comorbidity indices. *Clinical and experimental rheumatology, 32*(5), S131-S134.
Moore, T. J., Barron, J., Hutchinson, F., 3rd, Golden, C., Ellis, C., & Humphries, D. (1989). Prosthetic usage following major lower extremity amputation. *Clinical Orthopaedics and Related Research, Jan*(238), 219-224.
Moseley, G Lorimer. (2012). *The graded motor imagery handbook*: Noigroup publications.
Moxey, PW, Gogalniceanu, P, Hinchliffe, RJ, Loftus, IM, Jones, KJ, Thompson, MM, & Holt, PJ. (2011). Lower extremity amputations—a review of global variability in incidence. *Diabetic Medicine, 28*(10), 1144-1153.
Mueller, Michael J. (2016). Musculoskeletal Impairments Are Often Unrecognized and Underappreciated Complications From Diabetes. *Physical Therapy, 96*(12), 1861-1864. doi: 10.2522/ptj.20160326
Mulvey, M. R., Radford, H. E., Fawkner, H. J., Hirst, L., Neumann, V., & Johnson, M. I. (2013). Transcutaneous electrical nerve stimulation for phantom pain and stump pain in adult amputees. *Pain Practice 13*(4), 289-296. doi: 10.1111/j.1533-2500.2012.00593.x
Mundell, B. F., Kremers, H. M., Visscher, S., Hoppe, K. M., & Kaufman, K. R. (2016). Predictors of Receiving a Prosthesis for Adults With Above-Knee Amputations in a Well-Defined Population. *PM&R, 8*(8), 730-737. doi: 10.1016/j.pmrj.2015.11.012
Mundell, B., Maradit Kremers, H., Visscher, S., Hoppe, K., & Kaufman, K. (2017). Direct medical costs of accidental falls for adults with transfemoral amputations. *Prosthet Orthot Int, 41*(6), 564-570. doi: 10.1177/0309364617704804
Murphy, Douglas P. (2013). *Fundamentals of amputation care and prosthetics*: Demos Medical Publishing.
Nehler, M. R., Coll, J. R., Hiatt, W. R., Regensteiner, J. G., Schnickel, G. T., Klenke, W. A., . . . Krupski, W. C. (2003). Functional outcome in a contemporary series of major lower extremity amputations. *Journal of Vascular Surgery, 38*(1), 7-14.
Nielsen, Caroline C, & Jorge, Milagros. (2013). Etiology of Amputation. In M. M. Lusardi, M. Jorge & C. C. Nielsen (Eds.), *Orthotics & Prosthetics in Rehabilitation* (3rd ed., pp. 455-468). USA: Elsevier.
Norman, P. E., Schoen, D. E., Gurr, J. M., & Kolybaba, M. L. (2010). High rates of amputation among Indigenous people in Western Australia. *Med J Aust, 192*(7), 421.
North, R. (2010). Second comment on: An interim prosthesis program for lower limb amputees. *Prosthetics and Orthotics International, 34*(4), 497-498; author reply 498-501.
O'Neill, B.F., & Evans, J.J. (2009). Memory and executive function predict mobility rehabilitation outcome after lower-limb amputation. *Disability & Rehabilitation, 31*(13), 1083-1091.
Parker, Kim, Kirby, R. Lee, Adderson, James, & Thompson, Kara. (2010). Ambulation of People With Lower-Limb Amputations: Relationship Between Capacity and Performance Measures. *Archives of Physical Medicine and Rehabilitation, 91*(4), 543-549. doi: 10.1016/j.apmr.2009.12.009
Pasquina, P. F. (2010). DOD paradigm shift in care of servicemembers with major limb loss. *Journal of Rehabilitation Research and Development, 47*(4), xi-xiv.

Penn-Barwell, J. G. (2011). Outcomes in lower limb amputation following trauma: a systematic review and meta-analysis. *Injury, 42*(12), 1474-1479. doi: 10.1016/j.injury.2011.07.005

Pohjolainen, T., & Alaranta, H. (1991). Predictive factors of functional ability after lower-limb amputation. *Annales chirurgiae et gynaecologiae, 80*(1), 36-39.

Pohjolainen, T., & Alaranta, H. (1998). Ten-year survival of Finnish lower limb amputees. *Prosthetics and Orthotics International, 22*(1), 10-16.

Pohjolainen, T., Alaranta, H., & Kärkäinen, M. (1990). Prosthetic use and functional and social outcome following major lower limb amputation. *Prosthetics and Orthotics International, 14*(2), 75-79.

Psonak, Richard. (2013). Transfemoral Prostheses. In M. M. Lusardi, M. Jorge & C. C. Nielsen (Eds.), *Orthotics & Prosthetics in Rehabilitation* (3rd ed., pp. 652-684). USA: Elsevier.

Quan, H., Li, B., Couris, C. M., Fushimi, K., Graham, P., Hider, P., . . . Sundararajan, V. (2011). Updating and validating the Charlson comorbidity index and score for risk adjustment in hospital discharge abstracts using data from 6 countries. *American Journal of Epidemiology, 173*(6), 676-682. doi: 10.1093/aje/kwq433

Radhakrishnan, S., Kohler, F., Gutenbrunner, C., Jayaraman, A., Li, J., Pieber, K., & Schiappacasse, C. (2017). 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. *Prosthetics and Orthotics International, 41*(4), 412-419. doi: 10.1177/0309364616652016

Rau, B., Bonvin, F., & de Bie, R. (2007). Short-term effect of physiotherapy rehabilitation on functional performance of lower limb amputees. *Prosthetics and Orthotics International, 31*(3), 258-270. doi: 10.1080/03093640600994615

Raya, M.A., Gailey, R.S., Fiebert, I.M., & Roach, K.E. (2010). Impairment variables predicting activity limitation in individuals with lower limb amputation. *Prosthetics and orthotics international, 34*(1), 73-84.

Reiber, G. E., McFarland, L. V., Hubbard, S., Maynard, C., Blough, D. K., Gambel, J. M., & Smith, D. G. (2010). Servicemembers and veterans with major traumatic limb loss from Vietnam war and OIF/OEF conflicts: survey methods, participants, and summary findings. *Journal of Rehabilitation Research and Development, 47*(4), 275-297.

Reiber, G. E., Vileikyte, L., Boyko, E. J., del Aguila, M., Smith, D. G., Lavery, L. A., & Boulton, A. J. (1999). Causal pathways for incident lower-extremity ulcers in patients with diabetes from two settings. *Diabetes Care, 22*(1), 157-162.

Resnik, L., & Borgia, M. (2011). Reliability of outcome measures for people with lower-limb amputations: distinguishing true change from statistical error. *Physical Therapy, 91*(4), 555-565. doi: 10.2522/ptj.20100287

Resnik, L., & Borgia, M. (2015). Predicting prosthetic prescription after major lower-limb amputation. *Journal of Rehabilitation Research and Development, 52*(6), 641-652. doi: 10.1682/jrrd.2014.09.0216

Ries, Julies D, & Vaughan, Victor. (2013). Early Rehabilitation in Lower-Extremity Dysvascular Amputation In M. M. Lusardi, M. Jorge & C. C. Nielsen (Eds.), *Orthotics & Prosthetics in Rehabilitation* (pp. 697-734). USA: Elsevier.

Roffman, Caroline E., Buchanan, John, & Allison, Garry T. (2014). Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules. *Journal of Physiotherapy, 60*(4), 224-231. doi: 10.1016/j.jphys.2014.09.003

Roffman, Caroline E., Buchanan, John, & Allison, Garry T. (2016a). Charlson Comorbidities Index. *Journal of Physiotherapy, 62*(3), 171. doi: 10.1016/j.jphys.2016.05.008

Roffman, Caroline E., Buchanan, John, & Allison, Garry T. (2016b). Locomotor Performance During Rehabilitation of People With Lower Limb Amputation and Prosthetic

Nonuse 12 Months After Discharge. *Physical Therapy, 96*(7), 985-994. doi: 10.2522/ptj.20140164

Rogers, Helen L, & Stevens, Phil. (2015a). Restrictive Devices: Penalizing Patients for Their Use of Assistive Devices after Lower Extremity Amputation.

Rogers, Helen L, & Stevens, Phil. (2015b). Using Cognitive Capability, Cardio-pulmonary Capacity and Neuromuscular Control as a Basis to Disqualify Amputees for Definitive Prosthetic Care in Proposed LCD: By What Standards and With What Rationale?

Rossiter, Jonathan, Knoop, Espen, & Nakamura, Yuichi. (2017). Affective Touch and Low Power Artificial Muscles for Rehabilitative and Assistive Wearable Soft Robotics *Wearable Robotics: Challenges and Trends* (pp. 101-106): Springer.

Salavati, M., Mazaheri, M., Khosrozadeh, F., Mousavi, S. M., Negahban, H., & Shojaei, H. (2011). The Persian version of locomotor capabilities index: translation, reliability and validity in individuals with lower limb amputation. *Quality of Life Research, 20*(1), 1-7. doi: 10.1007/s11136-010-9716-3

Salbach, Nancy M, O'Brien, Kelly, Brooks, Dina, Irvin, Emma, Martino, Rosemary, Takhar, Pam, . . . Howe, Jo-Anne. (2014). Speed and distance requirements for community ambulation: A systematic review. *Archives of physical medicine and rehabilitation, 95*(1), 117-128. e111.

Samuelsson, K. A., Toytari, O., Salminen, A. L., & Brandt, A. (2012). Effects of lower limb prosthesis on activity, participation, and quality of life: a systematic review. *Prosthet Orthot Int, 36*(2), 145-158. doi: 10.1177/0309364611432794

Sansam, K., Neumann, V., O'Connor, R., & Bhakta, B. (2009). Predicting walking ability following lower limb amputation: a systematic review of the literature. *Journal of Rehabilitation Medicine, 41*(8), 593-603. doi: 10.2340/16501977-0393

Sansam, Kate, O'Connor, Rory J, Neumann, Vera, & Bhakta, Bipin. (2014). Clinicians' Perspectives on Decision Making in Lower Limb Amputee Rehabilitation. *Journal of Rehabilitation Medicine, 46*(5), 447-453.

Schaffalitzky, Elisabeth, Gallagher, Pamela, MacLachlan, Malcolm, & Wegener, Stephen T. (2012). Developing consensus on important factors associated with lower limb prosthetic prescription and use. *Disability and rehabilitation, 34*(24), 2085-2094.

Schoen, D., Balchin, D., & Thompson, S. (2010). Health promotion resources for Aboriginal people: lessons learned from consultation and evaluation of diabetes foot care resources. *Health Promotion Journal of Australia, 21*(1), 64-69.

Schoen, Deborah E., & Norman, Paul E. (2014). Diabetic foot disease in Indigenous people. *Diabetes Management, 4*(6), 489-500. doi: 10.2217/dmt.14.43

Schoppen, T., Boonstra, A., Groothoff, J. W., de Vries, J., Goeken, L. N., & Eisma, W. H. (2001a). Employment status, job characteristics, and work-related health experience of people with a lower limb amputation in The Netherlands. *Archives of Physical Medicine and Rehabilitation, 82*(2), 239-245. doi: 10.1053/apmr.2001.18231

Schoppen, T., Boonstra, A., Groothoff, J. W., de Vries, J., Goeken, L. N., & Eisma, W. H. (2003). Physical, mental, and social predictors of functional outcome in unilateral lower-limb amputees. *Archives of Physical Medicine and Rehabilitation, 84*(6), 803-811.

Schoppen, T., Boonstra, A., Groothoff, J. W., van Sonderen, E., Goeken, L. N., & Eisma, W. H. (2001b). Factors related to successful job reintegration of people with a lower limb amputation. *Archives of Physical Medicine and Rehabilitation, 82*(10), 1425-1431.

Schoppen, Tanneke, Boonstra, Annemarijke, Groothoff, Johan W, de Vries, Jaap, Göeken, Ludwig NH, & Eisma, Willem H. (1999). The Timed “up and go” test: reliability and validity in persons with unilateral lower limb amputation. *Archives of Physical Medicine and Rehabilitation, 80*(7), 825-828.

Scrivener, K., Schurr, K., & Sherrington, C. (2014). Responsiveness of the ten-metre walk test, Step Test and Motor Assessment Scale in inpatient care after stroke. *BMC Neurol, 14*(Jun 16), 129. doi: 10.1186/1471-2377-14-129

Seng, Piseth, Traore, Madou, Lavigne, Jean-Philippe, Maulin, Laurence, Lagier, Jean-Christophe, Thiery, Jean-François, . . . Sotto, Albert. (2017). Staphylococcus lugdunensis: a neglected pathogen of infections involving fracture-fixation devices. *International Orthopaedics, 41*(6), 1085-1091.

Shumway-Cook, A., Brauer, S., & Woollacott, M. (2000). Predicting the probability for falls in community-dwelling older adults using the Timed Up & Go Test. *Physical Therapy, 80*(9), 896-903.

Singh, R., Ripley, D., Pentland, B., Todd, I., Hunter, J., Hutton, L., & Philip, A. (2009). Depression and anxiety symptoms after lower limb amputation: the rise and fall. *Clinical Rehabilitation, 23*(3), 281-286. doi: 10.1177/0269215508094710

Smart, Andrew. (2006). A multi-dimensional model of clinical utility. *International Journal for Quality in Health Care, 18*(5), 377-382.

Spaetgens, B., Wijnands, J. M., van Durme, C., & Boonen, A. (2015). Content and construct validity of the Rheumatic Diseases Comorbidity Index in patients with gout. *Rheumatology (Oxford), 54*(9), 1659-1663. doi: 10.1093/rheumatology/kev030

Šrubařová, Mgr Simona, & Stašková, Bc Petra. (2016). HODNOTENIE CHÔDZE PACIENTOV PO AMPUTÁCII NA DOLNÝCH KONČATINÁCH PO LIEČEBNEJ REHABILITÁCII.

Starholm, I. M., Mirtaheri, P., Kapetanovic, N., Versto, T., Skyttemyr, G., Westby, F. T., & Gjovaag, T. (2016). Energy expenditure of transfemoral amputees during floor and treadmill walking with different speeds. *Prosthetics and Orthotics International, 40*(3), 336-342. doi: 10.1177/0309364615588344

Stepien, Jacqueline M, Cavenett, Sally, Taylor, Leigh, & Crotty, Maria. (2007). Activity levels among lower-limb amputees: self-report versus step activity monitor. *Archives of physical medicine and rehabilitation, 88*(7), 896-900.

Stevens, P. (2015). Polishing the Crystal Ball: Predicting Prosthetic Usage after Lower-Limb Amputation. *The O & P Edge*(March).

Stevens, Phillip M. (2010). Clinimetric properties of timed walking events among patient populations commonly encountered in orthotic and prosthetic rehabilitation. *JPO: Journal of Prosthetics and Orthotics, 22*(1), 62-74.

Stiell, I. G., Greenberg, G. H., McKnight, R. D., Nair, R. C., McDowell, I., Reardon, M., . . . Maloney, J. (1993). Decision rules for the use of radiography in acute ankle injuries. Refinement and prospective validation. *JAMA, 269*(9), 1127-1132.

Stiell, I. G., Greenberg, G. H., Wells, G. A., McDowell, I., Cwinn, A. A., Smith, N. A., . . . Sivilotti, M. L. (1996). Prospective validation of a decision rule for the use of radiography in acute knee injuries. *JAMA, 275*(8), 611-615.

Stineman, M. G., Kwong, P. L., Xie, D., Kurichi, J. E., Ripley, D. C., Brooks, D. M., . . . Bates, B. E. (2010). 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, 2*(4), 232-243. doi: 10.1016/j.pmrj.2010.01.012

Stineman, Margaret G, Kwong, Pui L, Kurichi, Jibby E, Prvu-Bettger, Janet A, Vogel, W Bruce, Maislin, Greg, . . . Reker, Dean M. (2008). 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. *Archives of physical medicine and rehabilitation, 89*(10), 1863-1872.

Stokes, D, Curzio, J, Bacon, E, Barker, L, Berry, A, & Morten, M. (2008). A UK survey of therapists' perspectives on post-amputation hopping. *International Journal of Therapy & Rehabilitation, 15*(12).

Stokes, D, Curzio, J, Berry, A, Bacon, E, Morten, M, & Barker, L. (2009). Pre prosthetic mobility: The amputees' perspectives. *Disability and rehabilitation, 31*(2), 138-143.

Struyf, Pieter A., van Heugten, Caroline M., Hitters, Minou W., & Smeets, Rob J. (2009). The Prevalence of Osteoarthritis of the Intact Hip and Knee Among Traumatic Leg Amputees. *Archives of Physical Medicine and Rehabilitation, 90*(3), 440-446. doi: 10.1016/j.apmr.2008.08.220

Su, Po-Fu, Gard, Steven A., Lipschutz, Robert D., & Kuiken, Todd A. (2008). Differences in Gait Characteristics Between Persons With Bilateral Transtibial Amputations, Due to Peripheral Vascular Disease and Trauma, and Able-Bodied Ambulators. *Archives of Physical Medicine and Rehabilitation, 89*(7), 1386-1394. doi: 10.1016/j.apmr.2007.10.050

Taylor, S.M., Kalbaugh, C.A., Blackhurst, D.W., Hamontree, S.E., Cull, D.L., Messich, H.S., . . . Carsten III, C.G. (2005). Preoperative clinical factors predict postoperative functional outcomes after major lower limb amputation: an analysis of 553 consecutive patients. *Journal of vascular surgery, 42*(2), 227-234.

Tekin, Levent, Safaz, Ýsmail, Göktepe, Ahmet Salim, & Yazýcýođlu, Kamil. (2009). Comparison of quality of life and functionality in patients with traumatic unilateral below knee amputation and salvage surgery. *Prosthetics and Orthotics International, 33*(1), 17-24. doi: doi:10.1080/03093640802482542

Tilson, J. K., Sullivan, K. J., Cen, S. Y., Rose, D. K., Koradia, C. H., Azen, S. P., & Duncan, P. W. (2010). Meaningful gait speed improvement during the first 60 days poststroke: minimal clinically important difference. *Physical Therapy, 90*(2), 196-208. doi: 10.2522/ptj.20090079

Traballesi, M., Brunelli, S., Pratesi, L., Pulcini, M., Angioni, C., & Paolucci, S. (1998). Prognostic factors in rehabilitation of above knee amputees for vascular diseases. *Disability & Rehabilitation, 20*(10), 380-384.

Trewin, Dennis. (2005). Australian Standard Geographical Classification (ASGC) 2005. *1216.0*, 1 to 240.

US Department of Veterans Affairs, Department of Defense. (2008). *VA/DoD clinical practice guidelines for rehabilitation of lower limb amputation.* USA: Retrieved from http://www.healthquality.va.gov/amputation/amp_sum_508.pdf.

Van Brakel, Wim H, Poetsma, Peter A, Tam, Phan Thanh, & Verhoeff, Theo. (2010). User satisfaction and use of prostheses in ICRC's Special Fund for the Disabled project in Vietnam. *Disability, CBR and Inclusive Development, 21*, 70-91.

Van der Linde, H, Geertzen, JHB, Hofstad, CJ, Van Limbeek, J, & Postema, K. (2003). Prosthetic prescription in the Netherlands: An observational study. *Prosthetics and Orthotics International, 27*(3), 170-178.

van der Linde, Harmen, Hofstad, Cheriel J, Van Limbeek, J, Postema, Klaas, & Geertzen, Jan HB. (2005). Use of the Delphi Technique for developing national clinical guidelines for prescription of lower-limb prostheses. *Journal of Rehabilitation Research and Development, 42*(5), 693-704.

van Eijk, M. S., van der Linde, H., Buijck, B., Geurts, A., Zuidema, S., & Koopmans, R. (2012). Predicting prosthetic use in elderly patients after major lower limb amputation. *Prosthetics and Orthotics International, 36*(1), 45-52. doi: 10.1177/0309364611430885

van Hedel, H. J. (2009). Gait speed in relation to categories of functional ambulation after spinal cord injury. *Neurorehabilitation and Neural Repair, 23*(4), 343-350. doi: 10.1177/1545968308324224

van Netten, J. J., Fortington, L. V., Hinchliffe, R. J., & Hijmans, J. M. (2016). Early Post-operative Mortality After Major Lower Limb Amputation: A Systematic Review of Population and Regional Based Studies. *European Journal of Vascular and*

Endovascular Surgery, 51(2), 248-257. doi: http://dx.doi.org/10.1016/j.ejvs.2015.10.001

Van Velzen, JM, van Bennekom, C AM, Polomski, W, Slootman, JR, van der Woude, L HV, & Houdijk, H. (2006). Physical capacity and walking ability after lower limb amputation: a systematic review. *Clinical Rehabilitation, 20*(11), 999-1016.

Vos, Theo, Barker, Bridget, Begg, Stephen, Stanley, Lucy, & Lopez, Alan D. (2009). Burden of disease and injury in Aboriginal and Torres Strait Islander Peoples: the Indigenous health gap. *International Journal of Epidemiology, 38*(2), 470-477. doi: 10.1093/ije/dyn240

Wallace, Duncan. (2012). Trends in traumatic limb amputation in Allied Forces in Iraq and Afghanistan. *Journal of Military and Veterans Health, 20*(2), 31-35.

WALSA. (2016). *Manual on Western Australian Limb Service for Amputees (WALSA). For use by Clinicians, Prosthetists and Prosthetic Service Providers*. Perth, Western Australia: Government of Western Australia, Department of Health.

Waters, RL, Perry, Jacquelin, Antonelli, Daniel, & Hislop, Helen. (1976). Energy cost of walking of amputees: the influence of level of amputation. *Journal of Bone & Joint Surgery American Volume, 58*(1), 42-46.

Webster, Joseph B, Hakimi, Kevin N, Williams, Rhonda M, Turner, Aaron P, Norvell, Daniel C, & Czerniecki, Joseph M. (2012). Prosthetic fitting, use, and satisfaction following lower-limb amputation: A prospective study. *Journal of Rehabilitation Research and Development, 49*(10), 1493-1504.

Wezenberg, Daphne, van der Woude, Lucas H, Faber, Willemijn X, de Haan, Arnold, & Houdijk, Han. (2013). Relation between aerobic capacity and walking ability in older adults with a lower-limb amputation. *Archives of physical medicine and rehabilitation, 94*(9), 1714-1720.

Wong, C. K., Ehrlich, J. E., Ersing, J. C., Maroldi, N. J., Stevenson, C. E., & Varca, M. J. (2016a). Exercise programs to improve gait performance in people with lower limb amputation: A systematic review. *Prosthetics and Orthotics International, 40*(1), 8-17. doi: 10.1177/0309364614546926

Wong, C. K., Young, R. S., Ow-Wing, C., & Karimi, P. (2016b). Determining 1-Yr Prosthetic Use for Mobility Prognoses for Community-Dwelling Adults with Lower-Limb Amputation: Development of a Clinical Prediction Rule. *American Journal of Physical Medicine & Rehabilitation, 95*(5), 339-347. doi: 10.1097/phm.0000000000000383

World Health Organisation, (WHO). (2016). Global report on diabetes. Geneva: World Health Organization

World Health Organization, (WHO). (2001). *International Classification of Functioning, Disability and Health: ICF* World Health Organization.

Wu, Chin-Chia, Hsu, Ta-Wen, Chang, Chun-Ming, Yu, Chia-Hui, & Lee, Ching-Chih. (2015). Age-Adjusted Charlson Comorbidity Index Scores as Predictor of Survival in Colorectal Cancer Patients Who Underwent Surgical Resection and Chemoradiation. *Medicine, 94*(2), e431. doi: 10.1097/MD.0000000000000431

Wu, Jane, Chan, Tik Shun, & Bowring, Greg. (2010). Functional outcomes of major lower limb amputation 1994–2006: a modern series. *JPO: Journal of Prosthetics and Orthotics, 22*(3), 152-156.

Yamato, Tie P., Maher, Chris G., Saragiotto, Bruno T., Moseley, Anne M., Hoffmann, Tammy C., & Elkins, Mark R. (2016). The TIDieR checklist will benefit the physiotherapy profession. *Journal of Physiotherapy, 62*(2), 57-58. doi: http://dx.doi.org/10.1016/j.jphys.2016.02.015

Ziegler-Graham, Kathryn, MacKenzie, Ellen J, Ephraim, Patti L, Travison, Thomas G, & Brookmeyer, Ron. (2008). Estimating the prevalence of limb loss in the United

States: 2005 to 2050. *Archives of physical medicine and rehabilitation, 89*(3), 422-429.

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List of Appendices

Appendix 2.1: Physiotherapy and other important interventions during amputee rehabilitation.

Appendix 2.1: Physiotherapy and other important interventions during amputee rehabilitation.

There are many complex pathway elements in the rehabilitation model of care for people with lower limb amputation. Although the literature refers to these elements in the explicit terms and activities, when it comes to the final outcome of prosthetic use after discharge, many of these variations on care have not been considered.

Mobility retraining without a prosthesis

The person with lower limb amputation is taught how to move safely without a prosthetic limb (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Geertzen et al., 2015a; Lusardi, 2013; Meier & Melton, 2014). This includes propelling and manipulating parts of a wheelchair for mobility, transfers and if appropriate hopping (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Geertzen et al., 2015a; Lusardi, 2013; Meier & Melton, 2014). Pivot, slide board, lift, car and floor transfers are the types of transfers taught to patients after an amputation (Gailey, 2004; Geertzen et al., 2015a; Lusardi, 2013). Sit to stand and standing balance are functional exercises performed with people who have unilateral lower limb amputation (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Geertzen et al., 2015a; Lusardi, 2013; Meier & Melton, 2014). Although not documented clearly as a functional milestone in the literature (Broomhead et al., 2012; Broomhead et al., 2006; Department of Health, 2008; Geertzen et al., 2015a; Meier & Melton, 2014; US Department of Veterans Affairs, 2008), people with unilateral knee disarticulation or higher levels of amputation need to have standing endurance holding onto parallel bars or a mobility aid for a minimum of 20 minutes at Royal Perth Hospital as this is the duration it takes prosthetists to cast these types of prostheses with the patient in standing. In people with unilateral lower limb amputation where the remaining foot is not at high risk of amputation due to ulcer, diabetes related complications (e.g. Charcot foot, peripheral neuropathy) or peripheral arterial disease, hopping using a mobility aid may be taught as a form of locomotion and to maintain cardiovascular fitness (Geertzen et al., 2015a; Meier & Melton, 2014; Stokes et al., 2008; Stokes et al., 2009; US Department of Veterans Affairs, 2008). As hopping increases the risk of falls the patients selected also must

have adequate balance and muscle strength (Stokes et al., 2008; Stokes et al., 2009; US Department of Veterans Affairs, 2008).

Oedema management

There many factors that are critical in the management of the residual limb (stump) but these have not been well integrated into studies for predicting future rehabilitation outcomes. The literature focuses on oedema (swelling) of the residual limb as this has been shown to have major clinical and cost implications for wound healing and prosthetic rehabilitation (Broomhead et al., 2012; Broomhead et al., 2006; Deutsch, English, Vermeer, Murray, & Condous, 2005; Gailey, 2004; Geertzen et al., 2015a; Geertzen et al., 2015b; Knapp, 2013; Lusardi, 2013; Meier & Melton, 2014; Psonak, 2013; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008).

The residual limb has oedema following amputation surgery (Broomhead et al., 2012; Broomhead et al., 2006; Deutsch et al., 2005; Gailey, 2004; Geertzen et al., 2015a; Geertzen et al., 2015b; Knapp, 2013; Lusardi, 2013; Meier & Melton, 2014; Psonak, 2013; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Residual limb oedema is managed by a physiotherapist trained in amputee rehabilitation to: facilitate wound healing, shape the residual limb for the prosthesis, stabilise the residual limb volume in order to maintain the prosthetic fit and minimise complications such as stump blisters (Broomhead et al., 2012; Broomhead et al., 2006; Deutsch et al., 2005; Gailey, 2004; Geertzen et al., 2015a; Geertzen et al., 2015b; Knapp, 2013; Lusardi, 2013; Meier & Melton, 2014; Psonak, 2013; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Lusardi (2013) and Psonak (2013) report that oedema management is generally required for approximately 6 to 12 months following surgery until the oedema stabilises however some patients have comorbidities (e.g. renal failure, heart failure) resulting in long term volume fluctuations of the residual limb.

The literature uses colloquial terms that reflect the devices and systems that are used in rehabilitation to reflect strategies to manage oedema (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Geertzen et al., 2015a; Geertzen et al., 2015b;

Meier & Melton, 2014). Oedema management involves the use of stump bandaging, stump shrinkers or other compressive garments, rigid removable dressings (for people with a transtibial amputation level), positioning of residual limb so it is not dependent and the use of intermittent pneumatic compression pump therapy (Broomhead et al., 2012; Broomhead et al., 2006; Deutsch et al., 2005; Gailey, 2004; Geertzen et al., 2015a; Geertzen et al., 2015b; Knapp, 2013; Lusardi, 2013; Meier & Melton, 2014; Psonak, 2013; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Progression of the oedema management program is individualised for the patient depending on their residual limb wound, circulation and comorbidities (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Geertzen et al., 2015a; Geertzen et al., 2015b; Knapp, 2013; Lusardi, 2013; Meier & Melton, 2014; Psonak, 2013; Ries & Vaughan, 2013). Rigid removable dressings can be applied to patients with transtibial amputation in the operating theatre or in the days after surgery by a physiotherapist or prosthetist (Broomhead et al., 2012; Broomhead et al., 2006; Deutsch et al., 2005; Geertzen et al., 2015b; Lusardi, 2013). The rigid removable dressing assists with reducing oedema and protects the residual limb from injury that may occur if a patient falls or knocks their residual limb (Broomhead et al., 2012; Broomhead et al., 2006; Deutsch et al., 2005; Geertzen et al., 2015b; Knapp, 2013; Lusardi, 2013). However, the timing of rigid dressing application depends on the residual limb wound, size and shape of the residual limb, patient's comorbidities and surgeon preference (Broomhead et al., 2012; Broomhead et al., 2006; Deutsch et al., 2005; Geertzen et al., 2015b; Lusardi, 2013). Gailey (2004) notes that the compression from the stump bandaging or stump shrinker also assists with management of phantom limb pain and desensitisation of the residual limb.

Densensitisation of the residual limb

Desensitisation of the nerves supplying the residual limb is performed after amputation surgery to facilitate normal movement during activities of daily living and in preparation for using a prosthetic limb (Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). The main desensitisation techniques that patients are taught by the physiotherapist include touch, massage and compression of the residual limb tissues by the patient while looking at the residual limb (Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan,

2013; US Department of Veterans Affairs, 2008). Stump shrinker use, exercise and movement during activities of daily living also help to desensitise the residual limb (Gailey, 2004).

Scar tissue and wound management

Patients are taught by the physiotherapist about hygiene and how to care for their residual limb with massage using moisturiser and scar tissue mobilisation to the suture line (Broomhead et al., 2012; Gailey, 2004; Geertzen et al., 2015b; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). The residual limb massage and scar tissue mobilisation improves the patient's skin integrity, minimises complications such as hypertrophic scarring and adherent scar tissue which are associated with residual limb blistering during prosthetic gait retraining (Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013). Patients are educated by the physiotherapist during prosthetic gait retraining on how to protect fragile skin and manage stump blisters using protective dressings (Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013).

Therapeutic exercise

Therapeutic exercise is performed by patients after amputation to enable return to activities of daily living without a prosthesis, locomotor activities with a prosthesis and to prevent complications such as contracture of the lower limb joints, deconditioning, loss of muscle strength and mass (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Gailey, Gailey, & Angulo, 1989, 1994a, 1994b; Gailey, Gailey, Sendelbach, & Angulo, 1995; Geertzen et al., 2015a; Geertzen et al., 2015b; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Strength, range of movement, stretching, cardiovascular and balance exercises are prescribed to patients and individualised to their needs (Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013). Strength exercises targeting the quadriceps, hip abductor and extensors muscle groups are important for prosthetic gait retraining (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Gailey et al., 1989, 1994a, 1994b; Gailey et al., 1995; Geertzen et al., 2015a; Geertzen et al., 2015b; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs,

2008). Upper limb, abdominal and trunk muscle strengthening exercises, sitting and standing balance exercise are performed to improve functional ability at activities with and without a prosthesis (Gailey, 2004; Gailey et al., 1989, 1994a, 1994b; Gailey et al., 1995; Geertzen et al., 2015a; Geertzen et al., 2015b; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013).

Strengthening exercises involve isometric, isotonic and isokintetic exercises using a combination of no weights, body weight, free weights, theraband, weight machines (e.g. leg press, seated rowing, latissimus dorsi pull down) and exercise equipment including rolls, theradiscs and fitballs (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Gailey et al., 1989, 1994a, 1994b; Gailey et al., 1995; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Muscle length in the hip flexor and hamstring muscle groups are improved through stretching and positioning (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Gailey et al., 1989, 1994a, 1994b; Gailey et al., 1995; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Arm ergometry, propelling the wheelchair and hopping (in patients without a high risk remaining foot) are the main types of cardiovascular exercise performed until a patient is fitted with a prosthesis (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Gailey et al., 1989, 1994a, 1994b; Gailey et al., 1995; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Hydrotherapy is used as indicated when the residual limb wound is healed to improve strength, cardiovascular fitness and for return to aquatic activities such as swimming (Ries & Vaughan, 2013). All exercises are progressively overloaded by the physiotherapist as the patient's muscle strength, muscle length and cardiovascular fitness improves (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Gailey et al., 1989, 1994a, 1994b; Gailey et al., 1995; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Hip and knee strengthening exercises, treadmill walking and cycling are performed using a prosthetic limb by patients who do prosthetic gait retraining as part of their rehabilitation program (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Gailey et al., 1989, 1994a, 1994b; Gailey et al., 1995; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Full intervention and exercise details are

outlined in Gailey (2004); Gailey et al. (1989, 1994a, 1994b); Gailey et al. (1995) Lusardi (2013) and Ries and Vaughan (2013).

Pain management

Patients may have residual limb pain, phantom limb pain and phantom sensation after amputation surgery (Broomhead et al., 2012; Broomhead et al., 2006; Butler & Moseley, 2013; Geertzen et al., 2015a; Geertzen et al., 2015b; Lusardi, 2013; MacLachlan, McDonald, & Waloch, 2004; Meier & Melton, 2014; Moseley, 2012; Mulvey et al., 2013). In addition to the medical management of phantom limb pain with medications, the physiotherapist may prescribe interventions including graded motor imagery and transcutaneous electrical nerve stimulation (TENS) to manage phantom limb pain (Butler & Moseley, 2013; Lusardi, 2013; MacLachlan et al., 2004; Moseley, 2012; Mulvey et al., 2013). Graded motor imagery is a 3 staged process which involves left - right discrimination, explicit motor imagery through mental rehearsal of movements and mirror box therapy (Butler & Moseley, 2013; MacLachlan et al., 2004; Moseley, 2012; Mulvey et al., 2013). Mirror box therapy uses the reflection of the patient's remaining lower limb in a mirror to reduce phantom limb pain by retraining the messages between the nerves and somatosensory cortex in the brain (Butler & Moseley, 2013; MacLachlan et al., 2004; Moseley, 2012; Mulvey et al., 2013). Full details of this graded motor imagery including mirror box therapy are outlined by Moseley (2012), Butler and Moseley (2013) and MacLachlan et al. (2004). TENS is applied using a machine and re-useable gel electrodes on the skin of either the residual or remaining limb. TENS assists with managing phantom limb pain by inhibiting the pain signals from the nerves in the lower limbs to the brain (Lusardi, 2013; Mulvey et al., 2013).

Prosthetic casting and fitting by the Prosthetist

The onsite prosthetists at Royal Perth Hospital (RPH) take a cast of the patient's residual limb, manufacture and then fit the interim prosthetic limb (Department of Health, 2008; Meier & Melton, 2014; WALSA, 2016). Prosthetic adjustments and modifications are performed during physiotherapy gait retraining sessions and the RPH Prosthetists work collaboratively with the physiotherapists (Department of Health, 2008). New prosthetic sockets are manufactured as required when a patient's residual limb volume has significantly reduced and the old socket and liner is too large (i.e. cannot be packed) to address the reduced volume (Department of Health, 2008). When residual limb volume has stabilised (usually at 6 to 9 months after prosthetic gait retraining commences) and the patient has achieved their full locomotor capacity they are prescribed a definitive prosthesis by the multidisciplinary team which is manufactured by private prosthetic companies in the community (Department of Health, 2008; Meier & Melton, 2014; WALSA, 2016). Patients receive some additional prosthetic gait retraining from the physiotherapist to optimise their use of new definitive prosthetic components.

Prosthetic gait retraining

The goal of prosthetic gait retraining is to restore locomotor function, achieve a symmetrical gait pattern and prevent or minimise gait deviations (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Gailey et al., 1989, 1994a; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Patients with lower limb amputation are progressed through a standardised gait retraining program by a physiotherapist trained in amputee rehabilitation (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Gailey et al., 1989, 1994a; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Prosthetic gait retraining includes: care and hygiene of the residual and remaining limbs; learning to don, doff and manage the fit of the prosthesis; how to optimally use the features of their prosthetic foot or knee components; sit to stand; weight shift and walking drills in the parallel bars using the prosthesis; transfers using the prosthesis; walking indoors and outdoors on a range of terrains and environmental conditions (e.g. tiles, grass, gravel, slopes, concrete, different weather conditions); stair climbing; progression of mobility aids to walking without aids (if

safe); strengthening, balance, stretching and cardiovascular exercises using the prosthesis; running, sports and work-specific locomotor skills and education of carers or family members on how to assist with prosthetic activities if the patient is not independent with the activity (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Gailey et al., 1989, 1994a; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Full details of prosthetic gait retraining programs following lower limb amputation are outlined by Gailey et al. (1989, 1994a, 1994b) and Ries and Vaughan (2013).

Mobility aids and assistive devices

Mobility aids including slide boards, wheeled or non-wheeled Zimmer frames, four wheeled walking frames, elbow crutches, axillary crutches and single point walking sticks may be prescribed by the physiotherapist to assist the person with lower limb amputation to safely mobilise when transferring, hopping or walking with a prosthetic limb (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008).

Home modifications and equipment

The Occupational therapist assesses the patient's ability to perform activities of daily living and access their home (Lusardi, 2013; Meier & Melton, 2014; US Department of Veterans Affairs, 2008). Assistive devices such as wheelchairs, slide boards, commodes, shower benches and stools may be prescribed by the Occupational therapist for mobility during activities of daily living such as showering, toileting and cooking (Lusardi, 2013; Meier & Melton, 2014; US Department of Veterans Affairs, 2008). The patient's home may be modified with grab rails and ramps to enable wheelchair accessibility to house (Lusardi, 2013; Meier & Melton, 2014; US Department of Veterans Affairs, 2008).

Return to driving

A full assessment by the Rehabilitation medicine physician and Occupational therapist is performed to enable the patient with lower limb amputation to return to driving (Department of Health, 2008; Meier & Melton, 2014; US Department of Veterans Affairs, 2008). The laws vary throughout the Australia and the world regarding the type of vehicle that a person may drive after a lower limb amputation (Department of Health, 2008; Meier & Melton, 2014; US Department of Veterans Affairs, 2008). Patients may be required to have car modifications and a driving examination, depending on their comorbidities, number, side and level of limb amputation (Meier & Melton, 2014; US Department of Veterans Affairs, 2008).

Return to work, sport and recreational activities

Specific work, sport and recreational activities are incorporated into the physiotherapy rehabilitation program based on the patient's individualised rehabilitation goals (Gailey, 2004; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). This may include activities such as lifting or carrying objects, climbing ladders or running (Gailey, 2004; Meier & Melton, 2014; Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). In WA return to work after lower limb amputation, requires an assessment and medical clearance by the Rehabilitation Medicine Physician which is similar to the USA model of care (Meier & Melton, 2014). The patient may also be required to have a return to work assessment by their employer depending on their occupation. Prosthetic components have weight limitations that the Prosthetist educates the patient about as this can impact on return to work or sports (Ries & Vaughan, 2013; US Department of Veterans Affairs, 2008). Sports and recreational prostheses (e.g. running and aquatic prostheses) are not funded by the Western Australian Limb Service for Amputees (WALSA). In some cases, people with lower limb amputation may retrain or seek alternative employment due to the physical demands of their former occupation (Geertzen et al., 2015a; Meier & Melton, 2014).

Education

The patient, family members and carers are educated on the amputee rehabilitation process, falls prevention, care of the remaining limbs and residual limb by the physiotherapist (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Geertzen et al., 2015a; Geertzen et al., 2015b; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013). Family and carers are also taught by the physiotherapist (if required) how to assist the patient with transfers, prosthetic gait and exercise programs (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Geertzen et al., 2015a; Geertzen et al., 2015b; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013). The physiotherapist assists with linkage of the patient with peer support and disabled sporting associations (Broomhead et al., 2012; Broomhead et al., 2006; Gailey, 2004; Geertzen et al., 2015a; Geertzen et al., 2015b; Lusardi, 2013; Meier & Melton, 2014; Ries & Vaughan, 2013).

Appendix 3.1: Royal Perth Hospital and Curtin Ethics approval.

Department of Health
Government of Western Australia
South Metropolitan Area Health Service

Royal Perth Hospital

ETHICS COMMITTEE

Prof F M van Bockxmeer PhD MHGSA, ARCPA, FAHA
PathWest Laboratory Medicine
Tel: 9224 2322 Fax: 9224 2491
Email Frank.VB@health.wa.gov.au

Room 4112 Level 4, Kirkman House
Tel: 9224 2292

Ref: EC 2009/090
(This number must be quoted on all correspondence)

8th September 2009

A/Prof Garry Allison
Physiotherapy
Royal Perth Hospital

Dear Garry

EC 2009/090 Optimising outcomes in rehabilitation of lower limb amputees

Thank you for your responses to the Committee's queries about the above study which I am pleased to advise is now **APPROVED**.

The following general conditions apply to all approvals by this Committee, and starting a trial or research project following the issue of ethics approval will be deemed to be an acceptance of them by all investigators:

1. The submission of an application for Ethics Committee approval will be deemed to indicate that the investigator and any sponsor recognises the Committee as a registered (with AHEC) Health Research Ethics Committee and that it complies in all respects with the National Statement on Ethical Conduct Research Involving Humans and all other national and international ethical requirements. **The Committee will not enter into further correspondence on this point.**

2. All income arising from the study must be lodged in a hospital special purposes account. Performance of a clinical trial for a sponsor is a service for tax purposes and all GST obligations must be met.

3. The investigator will report adverse events accompanied by a statement as to whether or not the trial should continue. The Committee reserves the right to not receive reports whose complexity or level of detail requires the expenditure of unreasonable time and effort. The Committee receives voluminous paperwork relating to adverse event reporting. From time to time the Committee chairman may require these reports to be summarised and approval is granted subject to the agreement of the investigator that he or she will prepare such a summary on request.

4. The Committee has decided that, as the responsibility for the conduct of trials lies with the investigator, all correspondence should be signed by the investigator.

5. All trial drugs must be dispensed by the Pharmacy Department. A fee is levied for this service and investigators must regard this fee as an item requiring a budget allocation. Alternatively, if a sponsor agrees, separate direct funding of pharmacy services may be undertaken. There are provisions for this fee to be waived for locally-inspired unfunded studies not having an external sponsor.

6. Though state institutions are outside the jurisdiction of the Privacy Act and related legislation, the Committee will assume that the privacy provisions of that Act will be the minimum standards applying during the conduct of a trial at Royal Perth Hospital. Traditional standards of patient confidentiality will apply.

7. The Committee will not acknowledge trial communications as a matter of course, unless they relate to a matter requiring Committee approval. Evidence of dispatch of a letter will be deemed to be evidence of receipt. This rule may be waived at the Committee's discretion on provision of a *pro forma* receipt by the investigator for the Chairman's signature and return. However, trivial correspondence (as judged by the Committee) will not be acknowledged even if a *pro forma* receipt is provided. Where an investigator requests written approval or written record of a matter for special purposes (say at the request of a sponsor), the investigator should prepare the required letter for the chairman's signature rather than expect the Committee secretary to prepare it. This mechanism increases the probability that the trial details in the letter are correct.

8. The Committee will provide the names and representative affiliation of members on request, but will not provide personal details or voting records.

9. A brief annual report on each project approved will be required at the end of each fiscal year, in default of which approval for the study may be suspended. Ethics approvals at RPH do not carry an expiry date so the annual report is an important part of Ethics Committee procedure.

10. The Committee has the authority to audit the conduct of any trial without notice. Exercise of this authority will only be considered if there are grounds to believe that some irregularity has occurred or if a complaint is received from a third party, or the Committee wishes to undertake an audit for QA purposes.

11. Complaints relating to the conduct of a clinical trial should be directed to the Chairman and will be promptly investigated. Complaints about the Ethics Committee decisions or policies that cannot be resolved by discussion with the Chairman or about any actions of a particular member including the Chairman, should be directed to the Director of Clinical Services. Only written complaints (not e-mail) will be accepted for investigation.

Investigators of sponsored studies are advised to draw the above conditions to the attention of the sponsor. Investigators are reminded that records of consent or authorisation for participation in special studies (including clinical trials) form part of the Acute Hospital Patient Record and should be stored with that record in accordance with the WA *Health Patient Information Retention and Disposal Schedule (Version 2) 2000.* A copy of the 'Patient Information Sheet' should also be included in the medical records as part of informed consent documentation.

Yours sincerely

Prof Frank M van Bockxmeer
Chairman, Royal Perth Hospital Ethics Committee

The Royal Perth Hospital Ethics Committee is constituted and operates in accordance with NH&MRC Guidelines.

memorandum

To	Associate Professor Garry Allison, Physiotherapy
From	A/Professor Stephan Millett, Chair, Human Research Ethics Committee
Subject	Protocol Approval HR 138/2009
Date	4 November 2009
Copy	Caroline Roffman, Unit 14/19 Sorrento Street, North Beach, 6020, Graduate Studies Officer, Faculty of Health Sciences

Curtin University of Technology
Office of Research and Development

Human Research Ethics Committee

TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL hrec@curtin.edu.au

Thank you for your application submitted to the Human Research Ethics Committee (HREC) for the project titled "*Optimising Outcomes in Rehabilitation of Lower Limb Amputees*". Your application has been reviewed by the HREC and is **approved**.

- You have ethics clearance to undertake the research as stated in your proposal.
- The approval number for your project is **HR 138/2009.** *Please quote this number in any future correspondence.*
- Approval of this project is for a period of twelve months **03-11-2009** to **03-11-2010**. To renew this approval a completed Form B (attached) must be submitted before the expiry date **03-11-2010.**
- If you are a Higher Degree by Research student, data collection must not begin before your Application for Candidacy is approved by your Faculty Graduate Studies Committee.
- The following standard statement **must be** included in the information sheet to participants:

  This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 138/2009). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

Applicants should note the following:

It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

The attached **FORM B** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development:
When the project has finished, or

- If at any time during the twelve months changes/amendments occur, or
- If a serious or unexpected adverse event occurs, or
- 14 days prior to the expiry date if renewal is required.
- An application for renewal may be made with a Form B three years running, after which a new application form (Form A), providing comprehensive details, must be submitted.

Regards,

A/Professor Stephan Millett
Chair Human Research Ethics Committee

Curtin University

Memorandum

To	Associate Professor Garry Allison, Physiotherapy
From	Miss Linda Teasdale, Manager, Research Ethics
Subject	Protocol Extension Approval **HR 138/2009**
Date	21 July 2011
Copy	Caroline Roffman, Physiotherapy

Office of Research and Development

Human Research Ethics Committee

TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL hrec@curtin.edu.au

Thank you for keeping us informed of the progress of your research. The Human Research Ethics Committee acknowledges receipt of your Form B progress report and indication of modifications / changes for the project *"OPTIMISING OUTCOMES IN REHABILITATION OF LOWER LIMB AMPUTEES"*. Your application has been ***approved***.

The Committee notes the following amendments have been approved:

1. Changed the cohort of the research to look at a cross sectional cohort (more subjects) as opposed to a longitudinal cohort analysis (same subjects tested ion repeated occasions).

Approval for this project is extended for the year to **03-11-2011.**

Your approval number remains **HR138/2009.** Please quote this number in any further correspondence regarding this project.

Please note: An application for renewal may be made with a Form B three years running, after which a new application form (Form A), providing comprehensive details, must be submitted.

Thank you.

Teasdale

Miss Linda Teasdale
Manager, Research Ethics
Office of Research and Development

Appendix 4.1 CPR manuscript and appendices

Journal of Physiotherapy 60 (2014) 224–231

Journal of PHYSIOTHERAPY

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Research

Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules

Caroline E Roffman, John Buchanan, Garry T Allison

School of Physiotherapy and Exercise Science, Faculty of Health Sciences, Curtin University and Royal Perth Hospital, Perth, Australia

KEY WORDS

Clinical prediction rule
Lower extremity
Amputation
Leg prosthesis
Rehabilitation outcome

ABSTRACT

Questions: Can rules be developed to predict the risk of non-use of prostheses by people with lower limb amputation following discharge from rehabilitation? Are these clinical prediction rules valid? **Design**: Retrospective and prospective cohort study designs. **Participants**: Consecutive tertiary rehabilitation patients: 135 retrospective (103 males, mean age = 56 years, SD 15) and 66 prospective (58 males, mean age = 54 years, SD 16). **Method**: Medical records were audited for potential predictor variables. Retrospective participants were interviewed at a median of 1.9 years after discharge (IQR 1.4 to 2.5) and prospective participants at a median of 1.3 years (IQR 1.1 to 1.4). **Results**: Clinical prediction rules were identified at 4, 8 and 12 months after discharge, and validated. Amputation levels above transtibial and mobility-aid use were common predictors for all three time frames. At 4 months, if four out of five predictor variables were present (LR+ = 43.9, 95% CI 2.73 to 999+), the probability of non-use increased from 12 to 86% ($p < 0.001$). At 8 months, if all three predictor variables were present (LR+ = 33.9, 95% CI 2.1 to 999+), the probability of non-use increased from 15 to 86% ($p < 0.001$). At 12 months, if two out of three predictor variables were present (LR+ = 2.8, 95% CI 0.9 to 6.6), the probability of non-use increased from 17 to 36% ($p < 0.031$). **Conclusions**: These validated clinical prediction rules have implications for rehabilitation and service model development. **[Roffman CE, Buchanan J, Allison GT (2014) Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules. *Journal of Physiotherapy* 60: 224–231]**

Introduction

Multidisciplinary rehabilitation following lower limb amputation plays an important role in restoring function for activities of daily living, work and recreation. Amputee rehabilitation service models and clinical practice guidelines for prosthetic prescription vary widely throughout the world and have been developed largely from expert consensus.[1,2] In Western Australia, patients achieve independent transfers and wheelchair mobility during inpatient rehabilitation while prosthetic gait retraining is performed as an outpatient service.[3]

Limited research exists on long-term outcomes in relation to prostheses following discharge from rehabilitation. In particular, there is a lack of quality evidence to inform clinical decisions that may impact on the continued use of prostheses following lower limb amputation.[4–9] In their literature review, Sansam et al[5] called for further investigation of predictive factors to more accurately estimate walking potential because the studies they reviewed reported different predictors; this was probably due to differences in methodology, outcome measures and definitions of prosthetic rehabilitation success.

Some studies have quantified prosthetic rehabilitation success relative to surgery-related outcomes, the duration that the prosthesis is worn as opposed to functional use, or short-term outcomes while individuals were still participating in rehabilitation; other studies have limited their analyses to cohorts with limited rehabilitation potential.[8–11] None of these quantify long-term functional prosthetic use following discharge, which is important in understanding the quality of life of these people. In general, for those with atraumatic causes of amputation there is a decline in health status following discharge and 5-year mortality as high as 77%.[9,12–14] In some cases, prosthetic gait may impair health and wellbeing through associated morbidity (eg, falls, myocardial infarction) and many individuals stop using their prosthesis within 12 months of discharge.[12,15]

Factors associated with prosthetic outcome have been considered in univariate analyses. Pre-operative factors such as comorbidities, age, pre-morbid mobility, medications, skin integrity, ethnicity, socioeconomic status, cognition and social support have been reported as being associated with outcome.[5,6,11,15–18] Weak evidence supports an association between psychological factors, self-efficacy, motivation and outcome.[5] Prosthetic outcome has also

http://dx.doi.org/10.1016/j.jphys.2014.09.003

been associated with postoperative factors including high-level or multiple limb amputation, postoperative complications, wound healing, oedema, contractures, pain, delay to prosthesis, falls, energy cost of gait, and functional factors.[5,6,9,19–26]

Prosthetic outcome is therefore multifactorial and complex. To date, no studies have examined the factors that in combination are able to identify individuals at risk of prosthetic non-use following discharge from rehabilitation. A methodological approach of developing clinical prediction rules has been used in similar prognostic studies (eg, ankle fractures, neck pain)[27,28] and is yet to be established in the area of lower limb amputation. Clinical prediction rules are tools that assist clinicians to make evidence-based decisions and assign patients to interventions and targeted models of care using a parsimonious subset of predictor variables.[27–30] If clinical prediction rules could be generated to accurately identify individuals at risk of early prosthetic non-use, then rehabilitation teams could intervene with targeted models of care and prosthetic innovations to optimise functional outcome and allocation of healthcare resources. Therefore the research questions for this study were:

1. Can rules be developed to predict the risk of non-use of prostheses by people with lower limb amputation following discharge from rehabilitation?
2. Are these clinical prediction rules valid?

Methods

Participants

Inclusion criteria were: at least one recent major lower limb amputation (ie, transtibial level or above); community dwelling and ambulant prior to amputation; Medicare Functional Classification K-level 1 to 4 (from Gailey et al[24]); and had participated in and been discharged from prosthetic rehabilitation at Royal Perth Hospital, which is the state centre for amputee rehabilitation. Royal Perth Hospital rehabilitates 85% of all individuals with lower limb amputation in Western Australia.[3] Individuals with multiple limb amputations were included, as this was important for validity of the clinical prediction rules.

Participants were excluded if they were unable to communicate, did not consent, or were not prosthetic candidates (ie, K-level 0) as assessed collaboratively by the rehabilitation physician and senior physiotherapist. Reasons for K-level 0 categorisation included comorbidities, cognitive impairment, high-level amputation, multiple limb amputation, remaining limb pathology, increased body weight, mental health issues, poor motivation, no social support, poor premorbid mobility or falls history. These participants were monitored through amputee outpatient clinic but remained at K-level 0.

K-level 0 to 4 participants underwent inpatient rehabilitation to achieve independent transfers, wheelchair mobility and discharge home. K-level 1 to 4 participants received the standardised outpatient prosthetic rehabilitation service, as detailed in Appendix 1 (see eAddenda).

An independent research assistant contacted potential participants from the Amputee Physiotherapy Service database to obtain informed verbal consent for the interview. The interview process involved coordinating telephone interviews with country physiotherapists on remote community visits, Aboriginal Health workers, nurses, and the use of telehealth.

Procedure

Clinical prediction rules development

Medical records were audited for potential predictor variables and this was undertaken blind to the interviews. Box 1 outlines the predictor variable domains investigated. All potential variables were dichotomised (eg, amputation cause: atraumatic or traumatic). Receiver Operator Characteristic (ROC) curves were used to generate a threshold for dichotomous classification of continuous variables (eg, age). This was performed with an equal weighting for sensitivity and specificity. Table 1 in the eAddenda details the dichotomous variable classifications.

Medical comorbidities (including mental health issues and musculoskeletal pathology) were recorded and counted for each participant. Charlson Comorbidity Index and Combined Age Charlson Comorbidity Index were calculated from medical comorbidities data.[31]

In the present study, amputation level was classified as transtibial or above transtibial. Bilateral lower limb amputation was defined as having undergone two major lower limb amputations. Participants were classified as able to independently perform the locomotor skill or being dependent (ie, required assistance or unable to perform). Mobility aids were either used or not used, and the aid type was not statistically weighted for its level of support.

The operational definition of a successful prosthetic user was use of the prosthesis for locomotor activities (eg, transfers, standing, walking) on one or more week days. Participants were asked on which days they used their prosthesis and for one day of normal activity how long they wore the prosthesis, how many sit to stands they performed, and the duration they performed prosthetic walking and standing activities.

Prosthetic non-users did not use their prosthesis for locomotor activities on any days. Individuals who only wore their prosthesis for cosmesis were classified as non-users. Non-users were asked

Box 1. Predictor variable domains for prosthetic users and non-users investigated by this study.

Intrinsic predictor variables	Amputation predictor variables	Functional predictor variables
• gender • age • indigenous status • metropolitan versus country • accommodation at discharge: home versus residential care • medical comorbidities: diabetes type I or II, peripheral arterial disease, cardiac condition, renal failure, stroke, transient ischaemic attack, lower limb pathology • number of medical comorbidities, including mental health issues and musculoskeletal pathology	• amputation cause • amputation level • bilateral lower limb amputation • time to second lower limb amputation • time from amputation to prosthetic milestones: casting, fitting and definitive prosthesis	• mobility level achieved without a prosthesis: wheelchair mobility, transfers, hopping • independence with donning and doffing prosthesis, and monitoring prosthetic fit at discharge • mobility aid use at discharge • mobility level achieved using a prosthesis at discharge: walking indoors, outdoors, stairs, slopes, grass, gravel, uneven terrain, high-level balance activities and running

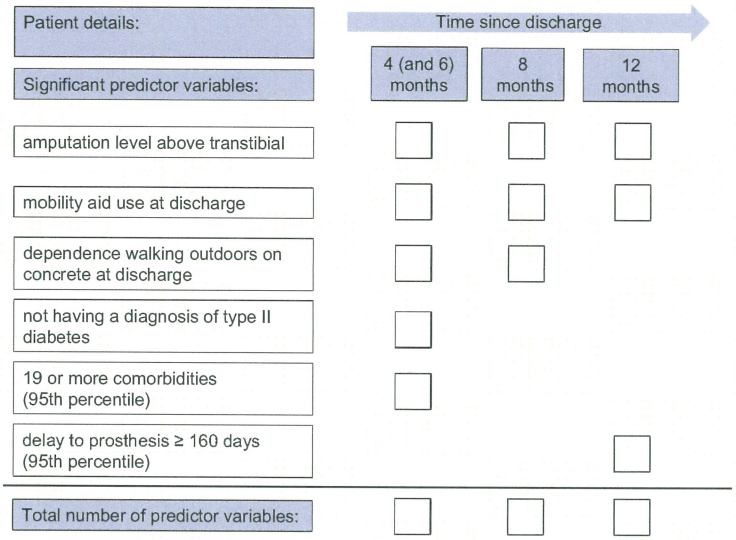

Figure 1. Validated clinical prediction rules for prosthetic non-use in individuals with lower limb amputation at 4, 8 and 12 months after discharge from rehabilitation. If the participant has the predictor variable, they score 1, which is written in the white box, and if they do not have the predictor variable, they score 0. At 4 (and 6) months, scores total out of 5, and at 8 and 12 months, scores total out of 3. Total score (below the line) is used for the risk estimates at each time point. For full details on use, see Appendix 2.

their reasons for prosthetic non-use and to recall how many months after physiotherapy discharge they stopped using their prosthesis. Important calendar events (eg, last amputee outpatient clinic, birthday, Christmas) were used as verbal prompts to assist with recall accuracy. Participants were interviewed with a previously piloted survey on their prosthetic use from 4 months onwards after discharge and re-interviewed approximately at 2-monthly intervals until data were collected for 12 months.

Clinical prediction rules validation

The procedure used for clinical prediction rules validation were the same as for the development procedure, except that data were prospectively collected during the participants' rehabilitation using a physiotherapy assessment form. This form was developed and implemented by the senior physiotherapist during clinical prediction rules development.

Statistical analyses

Clinical prediction rules development

The statistical models used in the present study are consistent with clinical prediction rules reports[27–30] and are not equivalent to a regression analysis. The primary outcome variable was prosthetic non-use at 4, 6, 8 and 12 months post-discharge. Descriptive statistics were generated.

The univariate relationship between categorical variables and prosthetic users and non-users was analysed using the chi-square test. For each of the continuous variables, ROC curves were used to determine the threshold at which specificity and sensitivity were equal to generate dichotomous classification for the univariate analyses. Univariate contingency tables were used to identify a smaller subset of variables related to prosthetic non-use that had a significance level of 10% (chi-square $p < 0.10$). This conservative significance level was selected to avoid missing critical variables. Sensitivity, specificity, and positive and negative likelihood ratios were calculated for the variables.

A backwards stepwise logistic regression model was used to reduce these variables to a set of flags or key variables that contributed to predicting non-use. To generate clinical prediction rules for the time frames, the set of variables from the regression was used to establish cumulative numbers of items present for any one individual at discharge. A list of likelihood ratios (negative and positive, 95% CI) were calculated to determine the cumulative effect of having a number of these predictors (1, 2, 3, etc) on non-use.

Clinical prediction rules validation

Prospective participants were classified as prosthetic users or non-users at 4, 6, 8 and 12 months after discharge. Descriptive statistics were generated. Participants were analysed for the absence (score = 0) or presence (score = 1) of significant clinical prediction rules variables at 4, 6, 8 and 12 months (see Figure 1, and the clinical prediction rules instructions in Appendix 2 in the eAddenda). Validity and cohort contamination effects of prosthetic use behaviours were compared by plotting pattern of non-use over time for the retrospective and prospective cohorts.

The retrospective study's continuous variable thresholds were used to generate dichotomous classification of these continuous variables in the present prospective study. To validate the clinical prediction rules for each of the time frames, chi-square tests were calculated to generate a progressive list of likelihood ratios (negative and positive, 95% CI) to determine the cumulative effect of having a number (ie, 1, 2, 3 etc) of these non-use predictors. Sensitivity, specificity, positive prediction value, accuracy and balanced accuracy were calculated to define the accuracy and precision of clinical prediction rules in the prospective cohort.[32]

For both the retrospective and prospective statistical analyses, in circumstances where zero cases were present in frequency cells of the 2 x 2 contingency tables, 0.5 was added to the cell values to enable calculation of the likelihood ratios for the variables.[33] Extreme likelihood ratio upper confidence limits were truncated at 999.

Sensitivity analyses of 29 (16%) retrospective and eight (10%) prospective deceased prosthetic rehabilitation participants who could not be interviewed were performed for 4, 6, 8 and 12 months after discharge to identify the presence or absence of clinical prediction rules variables using date of death as the termination date for prosthetic use.

Results

Table 2 summarises the consecutive participants' eligibility for the study. The final response rates were 94% (n = 135) for the retrospective cohort and 97% (n = 66) for the prospective cohort. The retrospective cohort were interviewed at median = 1.9 years (IQR 1.4 to 2.5) and prospective at median 1.3 years (IQR 1.1 to 1.4) after discharge. Table 3 outlines the geographical distribution of participants, as measured by Accessibility Remoteness Index of Australia.[34]

Clinical prediction rules development interviews with the retrospective cohort were performed by telephone (n = 123), telehealth (n = 2) and in person (n = 10). Twelve interviews were performed with carer assistance due to language interpretation, hearing or intellectual disability. Clinical prediction rules validation interviews with the prospective cohort were performed by telephone (n = 47) and in person (n = 19). Carers assisted with two interviews where participants had a hearing or intellectual disability. Table 3 shows the retrospective and prospective cohort characteristics.

Clinical prediction rules development

From November 2009 until August 2011, 135 participants were interviewed; 94 (70%) were prosthetic users and 41 (30%) were non-users. At 4, 6, 8 and 12 months after discharge from rehabilitation 15 (11%), 15 (11%), 20 (15%) and 25 (19%) of participants, respectively, were non-users. As the number of prosthetic non-users and variables were identical for 4 and 6 months, these data were analysed as one time frame.

Of the 40 potential variables investigated for the univariate analysis (Box 1), a total of 16 variables were identified as being significant ($p < 0.10$) for prosthetic non-use at the 4-, 6- and 8-month timeframes, and 15 variables were significant at 12 months after discharge (Table 4, which is available in the eAddenda).

The predictor variables significant (95% CI) for prosthetic non-use after being entered into the backwards-stepwise logistic regression model are reported below. Full details, including associated accuracy statistics, are presented in Table 5.

Clinical prediction rules: 4 months

At 4 (and 6) months, the five variables that were predictive of prosthetic non-use included: amputation level above transtibial level, mobility aid use, dependence walking outdoors on concrete, very high number of comorbidities, and not having a diagnosis of type II diabetes.

Clinical prediction rules: 8 months

At 8 months, the three variables that were predictive of prosthetic non-use included: amputation level above transtibial level, mobility aid use, and dependence walking outdoors on concrete.

Clinical prediction rules: 12 months

At 12 months, the three variables that were predictive of prosthetic non-use included: amputation level above transtibial level, mobility aid use, and delay to prosthesis. The multifactorial causes of delay to prosthesis included: wound complications (n = 8), comorbidities (n = 3), orthopaedic injuries (n = 2) and deconditioning (n = 1).

Clinical prediction rules validation

From March 2011 until December 2012, 66 participants were interviewed, of whom 55 remained prosthetic users. There were eight non-users at 4 and 6 months after discharge from rehabilitation, which increased to ten at 8 months and eleven at 12 months. Similar to the retrospective cohort, prosthetic non-users and variables were identical for the 4-month and 6-month timeframes in the prospective cohort.

Survival curves (Figure 2) demonstrated a high level of concordance between the retrospective and prospective cohorts. From discharge there was rapid progression to prosthetic non-use, followed by linear decline after 1 month.

Associated accuracy statistics for having a combination of prosthetic non-use predictors (95% CI) for the clinical prediction rules time frames in the prospective cohort are reported below. Full details, including associated accuracy statistics, are presented in Table 6.

Four months

If four out of five predictors were present (LR+ = 43.9, 95% CI 2.73 to 999+), the probability of non-use increased from 12 to 86% ($p < 0.001$).

Eight months

If all three predictors were present (LR+ = 33.9, 95% CI 2.1 to 999+), the probability of non-use increased from 15 to 86% ($p < 0.001$).

Twelve months

If two out of three predictors were present (LR+ = 2.8, 95% CI 0.9 to 6.6), the probability of non-use increased from 17 to 36% ($p < 0.031$). Three cases of delay to prosthesis included: wound (2) and orthopaedic (1) complications.

Figures 3–5 (available in the eAddenda) illustrate the percentages of true to false positives for the clinical prediction rules time frames. This shows the clinical utility of using the clinical prediction rules for any one individual and the risk of appropriate classification.

Table 2
Summary of the consecutive retrospective and prospective cohorts.

Characteristic	Retrospective cohort	Prospective cohort
Time frame identified from Amputee Physiotherapy Service database	June 2006 to June 2009	July 2009 to July 2011
Consecutive tertiary rehabilitation patients identified from Amputee Physiotherapy Service database, n	208	99
K-level 0 participants[a], n (%)	32 (15)	11 (11)
K-level 1 to 4 participants[b], n (%)	176 (85)	88 (89)
K-level 0 deceased, n (%)	15 (47)	4 (36)
K-level 1 to 4 deceased, n (%)	29 (16)	8 (9)
Eligible participants, n	143	68
Ineligible participants, n		
excluded, minor lower limb amputation	1	2
excluded, still participating in rehabilitation	3	10
did not consent	3	0
Participants contacted, n	138	66
Unable to be contacted as they had moved interstate or overseas, n	5	2
Response rate, n (%)	135 (94)	66 (97)
Time to outpatient discharge (*d*)[c], median (IQR)	174 (103 to 314)	138 (88 to 201)

[a] Not prosthetic rehabilitation candidates.
[b] Prosthetic users at discharge.
[c] Participants participated in approximately two to three physiotherapy prosthetic gait retraining sessions per week as outpatients.

Table 3
Demographic and amputation details of prosthetic users and non-users in the retrospective and prospective cohorts.

Demographic and amputation details	Retrospective cohort		Prospective cohort	
	Users (n = 94)	Non-users (n = 41)	Users (n = 55)	Non-users (n = 11)
Gender, male, n (%)	74 (79)	29 (71)	50 (91)	8 (73)
Age at amputation, mean (SD)	55.1 (15.8)	58.3 (13.3)	55.3 (15.7)	49.5 (19.9)
Indigenous status, Aboriginal, n (%)	12 (13)	9 (22)	6 (11)	2 (18)
Accommodation after discharge from inpatient rehabilitation, n (%)				
home	91 (97)	37 (90)	55 (100)	11 (100)
residential care (hostel or nursing home)	3 (3)	4 (10)	0 (0)	0 (0)
metropolitan	56 (60)	28 (68)	34 (62)	9 (82)
country	38 (40)	13 (32)	21 (38)	2 (18)
Social support, lives with others, n (%)	77 (82)	31 (76)	42 (76)	10 (91)
Accessibility Remoteness Index of Australia[a]				
major cities of Australia (0 to 1.84)	66 (71)[a]	34 (83)	40 (73)	9 (82)
inner regional Australia (> 1.84 to 3.51)	8 (9)	0 (0)	7 (13)	0 (0)
outer regional Australia (> 3.51 to 5.80)	5 (5)	2 (5)	5 (9)	1 (9)
remote Australia (> 5.80 to 9.08)	0 (0)	2 (5)	2 (4)	0 (0)
very remote Australia (> 9.08 to 12)	14 (15)	3 (7)	1 (2)	1 (9)
Charlson Comorbidity Index, median (IQR)	2 (1 to 4)	5 (2 to 5)	2 (0 to 4)	3 (0.5 to 5)
Combined Age Charlson Comorbidity Index, median (IQR)	4 (1 to 5)	7 (3 to 7)	4 (1 to 6)	6 (1 to 7)
Comorbidities, n (%)				
diabetes type I	7 (8)	3 (7)	1 (2)	1 (9)
diabetes type II	35 (37)	19 (46)	21 (38)	6 (55)
peripheral arterial disease	44 (47)	25 (61)	30 (55)	7 (64)
cardiac condition	33 (35)	26 (63)	12 (22)	4 (36)
renal failure	13 (14)	10 (24)	5 (9)	4 (36)
stroke/transient ischaemic attack	8 (9)	5 (12)	4 (7)	0 (0)
arthritis	36 (38)	16 (39)	12 (22)	5 (45)
remaining lower limb pathology	78 (83)	36 (88)	36 (65)	11 (100)
Mental health issues, n (%)	24 (26)	8 (20)	8 (15)	5 (45)
Mild cognitive impairment, n (%)	3 (3)	4 (10)	2 (4)	1 (9)
Intellectual disability, n (%)	1 (1)	0 (0)	1 (2)	0 (0)
Substance abuse, n (%)				
drugs	7 (7)	4 (10)	2 (4)	3 (27)
alcohol	10 (11)	5 (12)	7 (13)	2 (18)
current smoker	20 (21)	14 (34)	13 (24)	4 (36)
Amputation cause, n (%)				
circulatory	18 (19)	15 (37)	16 (29)	3 (27)
infection	42 (45)	17 (41)	22 (40)	6 (55)
trauma	29 (31)	9 (22)	14 (25)	2 (18)
cancer	5 (5)	0 (0)	3 (5)	0 (0)
Amputation level, n (%)				
transtibial	78 (83)	25 (61)	50 (91)	10 (91)
knee disarticulation	4 (4)	2 (5)	1 (2)	0 (0)
transfemoral	20 (21)	28 (68)	9 (16)	5 (45)
major bilateral lower limb amputation	8 (9)	14 (34)	5 (9)	4 (36)
minor amputation of remaining limb	15 (16)	3 (7)	2 (4)	1 (9)
upper limb amputation/s	8 (9)	0 (0)	9 (16)	3 (27)

[a] n = 93. One person was excluded from this retrospective analysis because he moved overseas after discharge. All other retrospective analyses used n = 94.

There were no significant associations between having a number of clinical prediction rules variables for the time frames and cessation of prosthetic use due to death, based on 29 deceased participants from the retrospective cohort ($p = 0.164$) and eight deceased participants from the prospective cohort ($p = 0.170$).

Discussion

Few studies have examined factors at the time of discharge in order to determine prosthetic use into the future. This is the first study to propose and validate clinical prediction rules for timelines

Table 5
Associated accuracy statistics with 95% CI for having a combination of predictor variables at 4 (and 6), 8 and 12 months for the retrospective cohort.

Predictors present for clinical prediction rules time frames (n)	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	Probability of prosthetic non-use (%)	*p*-value
4 (and 6) months						
1	0.97 (0.74 to 1.00)	0.16 (0.13 to 0.16)	1.20 (0.85 to 1.19)	0.20 (0.0 to 2.04)	13	0.183
2	0.97 (0.72 to 1.00)	0.52 (0.48 to 0.52)	2.00 (1.40 to 2.09)	0.06 (0.0 to 0.57)	21	< 0.001
3	0.80 (0.53 to 0.95)	0.75 (0.72 to 0.77)	3.20 (1.87 to 4.08)	0.27 (0.07 to 0.65)	29	< 0.001
4	0.27 (0.10 to 0.33)	0.99 (0.97 to 1.00)	32.00 (3.61 to 748)	0.74 (0.67 to 0.92)	80	< 0.001
5	0.03 (0.00 to 0.06)	0.99 (0.99 to 1.00)	7.80 (0.00 to 999+)	0.97 (0.94 to 1.01)	0	0.223
8 months						
1	0.98 (0.78 to 1.00)	0.43 (0.39 to 0.43)	1.70 (1.29 to 1.76)	0.06 (0.00 to 0.55)	23	0.001
2	0.90 (0.69 to 0.98)	0.74 (0.70 to 0.75)	3.50 (2.31 to 3.98)	0.14 (0.02 to 0.44)	38	< 0.001
3	0.15 (0.04 to 0.26)	0.97 (0.96 to 0.99)	5.80 (0.96 to 34.30)	0.87 (0.75 to 1.00)	50	0.013
12 months						
1	0.96 (0.79 to 0.99)	0.42 (0.38 to 0.43)	1.70 (1.28 to 1.74)	0.10 (0.01 to 0.55)	27	< 0.001
2	0.72 (0.53 to 0.86)	0.76 (0.72 to 0.80)	3.05 (1.88 to 4.25)	0.37 (0.17 to 0.66)	41	< 0.001
3	0.24 (0.12 to 0.28)	0.99 (0.96 to 1.00)	26.40 (3.40 to 580.00)	0.77 (0.72 to 0.91)	86	< 0.001

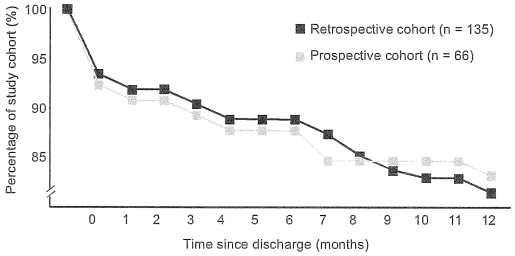

Figure 2. A survival curve for the proportion of individuals using prostheses for every month in the year following hospital discharge. Note: The retrospective and prospective cohorts show similar patterns and rates of prosthetic non-use.

of 4, 8 and 12 months post-discharge that use statistical optimisation modelling to select a parsimonious set of variables from the rehabilitation model of care, which predict increased likelihood of prosthetic non-use. Previous research has examined univariate associations with poor outcomes.[5] In the present study, a much wider range of perioperative and demographic factors were examined and confirmed that a large number of factors are significantly associated with prosthetic non-use. These were grouped into intrinsic, amputation and functional domains. The major point of difference from surgical studies[12,21,35] was that causative factors for amputation were not associated with non-use.

The key point of this research, however, was that multivariate predictive models were used to determine a predictive model of outcome at four time points. Three clinical prediction rules were derived and validated, as the results for the 4-month and 6-month outcomes were identical. These results validate that a subgroup of early prosthetic non-users exist and can be targeted. The high level of concordance between retrospective and prospective prosthetic non-use survival curves demonstrates that there was no substantial change in clinical practice (contamination) during the validation study. These findings call for development of a model of care that optimises outcome for these individuals. Rehabilitation may focus on optimising transfers, wheelchair mobility, physical fitness and mental wellbeing rather than prosthetic gait.

The present study found that having a very high number of comorbidities was significantly predictive of prosthetic non-use at 4 months, but not at later time periods. This was an interesting finding, as depending on how effectively comorbidities are managed they may become worse with age.[32] However, this finding suggests that if prosthetic use can be sustained for the first 4 months post-discharge in the presence of this disease burden, then such systemic conditions may not be highly related to non-use at a later time. The Charlson Comorbidity Index for both cohorts indicates that non-users were at greater risk of mortality from comorbid disease than users.[32]

Validated predictors for prosthetic non-use common to all three clinical prediction rules were amputation level above transtibial and mobility aid use. High amputation level has been associated in the literature with poor prosthetic outcome.[11,36] From a functional perspective, the transtibial prosthesis can be used to facilitate transfers, while the transfemoral prosthesis is only of functional assistance when an individual is standing or walking. This may result in some activities being performed with greater efficiency from a wheelchair or using assistive equipment (eg, individuals with transfemoral amputation may self-propel a commode rather than walking to the shower).

Mobility aid use at discharge is more common in individuals who premorbidly used aids, are frail, deconditioned, have remaining limb pathology (eg, claudication, osteoarthritis), and high or multiple limb amputation.[37,38] Mobility aids reduce functionality of gait by limiting capacity to carry objects, however, use may be necessary to prevent falls.[37,38] As mobility aid use is a predictor of non-use, future research may investigate interventional strategies (eg, mobility aid type, back pack use, prosthetic componentry) that potentially improve functionality of gait.

At 4 months and 8 months after discharge, dependence walking outdoors on concrete was a significant predictor of prosthetic non-use. Validation of this predictor with early prosthetic non-use is important, as many locomotor activities require the ability to walk outdoors on concrete (eg, shopping). Poor prosthetic outcome has been associated with indoors-only ambulation.[11,24]

Similar to the literature,[5] the present study validated a critical time frame in which gait retraining needs to occur, because at 12 months, a delay of >160 days was predictive of non-use. Wound complications were the commonest delay in both cohorts. Delays to walking generally result in prolonged wheelchair sitting and reduced physical activity. Rehabilitation programs may not provide the exercise intensity to overcome deconditioning or prevent complications (eg, joint contracture, muscle weakness) that limit walking capacity. Furthermore, individuals with severe comorbidities and frailty may adversely or not respond to exercise intervention.

Although the proportion of non-users of prostheses is relatively small, these people are difficult to identify; therefore, these clinical prediction rules will assist clinical decisions during rehabilitation and primary healthcare planning following discharge. The validated clinical prediction rules for 4 and 8 months had positive likelihood ratios of 43.9 and 33.9, respectively. These values are consistent with the interpretation that positive likelihood ratios of >5 are clinically significant.[28,39,40] In contrast, the 12-month clinical prediction rules were statistically significant for non-use ($p = 0.031$) but did not possess the predictive magnitude of the other clinical prediction rules. To improve the

Table 6
Associated accuracy statistics with 95% confidence intervals for having a combination of predictor variables at 4 (and 6), 8 and 12 months for the prospective cohort.

Predictors present for CPR time frames (n)	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	Probability of prosthetic non-use (%)	Accuracy (%)	Balanced accuracy (%)	p
4 (and 6) months								
1	0.94 (0.61 to 1.0)	0.14 (0.09 to 0.15)	1.09 (0.67 to 1.17)	0.43 (0 to 4.40)	14	24	54	0.519
2	0.93 (0.53 to 1.0)	0.66 (0.61 to 0.67)	2.8 (1.36 to 3.03)	0.10 (0 to 0.77)	26	69	80	0.002
3	0.50 (0.19 to 0.81)	0.86 (0.82 to 0.90)	3.6 (1.02 to 8.5)	0.58 (0.21 to 0.99)	33	82	68	0.013
4	0.38 (0.12 to 0.44)	0.99 (0.96 to 1.0)	43.9 (2.73 to 999+)	0.63 (0.56 to 0.92)	86	92	68	< 0.001
5	0.06 (0 to 0.12)	0.99 (0.98 to 1.0)	6.9 (0 to 999+)	0.95 (0.88 to 1.0)	50	87	52	0.259
8 months								
1	0.90 (0.57 to 0.99)	0.50 (0.44 to 0.52)	1.8 (1.0 to 2.06)	0.20 (0.01 to 0.98)	24	56	70	0.019
2	0.70 (0.38 to 0.91)	0.82 (0.76 to 0.86)	3.9 (1.6 to 6.5)	0.37 (0.10 to 0.81)	41	80	76	0.001
3	0.30 (0.09 to 0.35)	0.99 (0.96 to 1.0)	33.9 (2.1 to 999+)	0.71 (0.65 to 0.95)	86	89	65	< 0.001
12 months								
1	0.91 (0.60 to 0.99)	0.51 (0.45 to 0.53)	1.85 (1.08 to 2.1)	0.18 (0.009 to 0.9)	27	58	71	0.011
2	0.46 (0.19 to 0.72)	0.84 (0.78 to 0.89)	2.8 (0.9 to 6.6)	0.65 (0.31 to 1.03)	36	77	65	0.031
3	0.09 (0.005 to 0.14)	0.99 (0.97 to 1.0)	10.1 (0.19 to 999+)	0.92 (0.86 to 1.02)	67	84	54	0.095

clinical utility of the 12-month clinical prediction rules, future research may incorporate a follow-up assessment at 6-months post-discharge.

Amputation rate has been reported as being 38 times greater in Aboriginals who have diabetes.[41] In the present study, indigenous status, geographical isolation from health services and having diabetes were not predictive of prosthetic non-use. Environmental conditions in Aboriginal communities, where the terrain is rough, sociocultural factors and service model strategies such as telehealth may have contributed to sustained prosthetic use.

The present research had some potential limitations. The prosthetic-use interview relied on participant recall. Missing data is a potential issue for retrospective research; however, a strength of the present study was that it had minimal missing data. Mortality rate was high within the review period for the retrospective (16%) and prospective (10%) cohorts; however, the sensitivity analyses demonstrated that the deceased sub-groups did not bias clinical prediction rules development or validation. Although further validation could be undertaken at other rehabilitation centres, the use of the prospective cohort in the present study validates the use of these clinical prediction rules by health professionals.

In conclusion, this is the first study to integrate rehabilitation variables into a parsimonious set of predictors that are significant for prosthetic non-use at 4, 8 and 12 months after discharge, and validate these clinical prediction rules. The research has validated that a sub-group of early prosthetic non-users exists, and highlights a need to separate causative factors for amputation that impact on surgical outcome, from those related to prosthetic non-use. These validated clinical prediction rules may guide clinical reasoning and rehabilitation service development.

What is already known on this topic: Long-term functional use of a prosthesis following discharge from hospital is important for quality of life for lower limb amputees.
What this study adds: Clinical prediction rules can provide valid data to help identify people who are at risk of discontinuing use of their prosthesis in the year following discharge from hospital after lower limb amputation. Different predictors contribute to these clinical prediction rules, depending on the time frame considered (4, 8 or 12 months). Amputation above the transtibial level and use of a mobility aid were predictors that were common to the clinical prediction rules for all three time frames.

eAddenda: Figures 3, 4 and 5, Tables 1 and 4, and Appendices 1 and 2 can be found online at doi:10.1016/j.jphys.2014.09.003

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References

1. van der Linde H, Hofstad CJ, Van Limbeek J, Postema K, Geertzen JH. Use of the Delphi Technique for developing national clinical guidelines for prescription of lower-limb prostheses. *J Rehabil Res Dev.* 2005;42:693–704.
2. Broomhead P, Dawes D, Hale C, Lambert A, Quinlivan D, Shepherd R. *Evidence based clinical guidelines for the physiotherapy management of adults with lower limb prostheses*. London: Chartered Society of Physiotherapy; 2003.
3. Department of Health WA. In: Network AC, ed. In: *Amputee Services and Rehabilitation Model of Care*. Perth, Western Australian: Department of Health; 2008.
4. Campbell WB, Ridler BM. Predicting the use of prostheses by vascular amputees. *Eur J Vasc Endovasc.* 1996;12:342–345.
5. Sansam K, Neumann V, O'Connor R, Bhakta B. Predicting walking ability following lower limb amputation: a systematic review of the literature. *J Rehabil Med.* 2009;41:593–603.
6. Adams EFK, Alligood E. A systematic review of clinical predictors of outcomes in adults with recent major lower limb amputation - Final report. *VA Technology Assessment Program.* 2005;1–23.
7. Cumming J, Barr S, Howe T. Prosthetic rehabilitation for older dysvascular people following a unilateral transfemoral amputation. *Cochrane Database Syst Rev.* 2006;4:CD005260.
8. Jones L, Hall M, Schuld W. Ability or disability? A study of the functional outcome of 65 consecutive lower limb amputees treated at the Royal South Sydney Hospital in 1988–1989 *Disabil Rehabil.* 1993;15:184–188.
9. Lim TS, Finlayson A, Thorpe JM, Sieunarine K, Mwipatay BP, Brady A, et al. Outcomes of a contemporary amputation series. *ANZ J Surg.* 2006;76:300–305.
10. Basu NN, Fassiadis N, McIrvine A. Mobility one year after unilateral lower limb amputation: a modern, UK institutional report. *Interact Cardiovasc Thorac Surg.* 2008;7:1024–1026.
11. Taylor SM, Kalbaugh CA, Blackhurst DW, Hamontree SE, Cull DL, Messich HS, et al. Preoperative clinical factors predict postoperative functional outcomes after major lower limb amputation: an analysis of 553 consecutive patients. *J Vasc Surg.* 2005; 42:227–234.
12. Davies B, Datta D. Mobility outcome following unilateral lower limb amputation. *Prosthet Orthot Int.* 2003;27:186–190.
13. Fortington LV, Geertzen JH, van Netten JJ, Postema K, Rommers GM, Dijkstra PU. Short and long term mortality rates after a lower limb amputation. *Eur J Vasc Endovasc.* 2013;46:124–131.
14. Jones WS, Patel MR, Dai D, Vemulapalli S, Subherwal S, Stafford J, et al. High mortality risks after major lower extremity amputation in Medicare patients with peripheral artery disease. *Am Heart J.* 2013;165:809–815.
15. Pohjolainen T, Alaranta H, Kärkäinen M. Prosthetic use and functional and social outcome following major lower limb amputation. *Prosthet Orthot Int.* 1990;14: 75–79.
16. Kulkarni J, Pande S, Morris J. Survival rates in dysvascular lower limb amputees. *Int J Surg.* 2006;4:217–221.
17. Schoppen T, Boonstra A, Groothoff JW, de Vries J, Goeken LN, Eisma WH. Physical, mental, and social predictors of functional outcome in unilateral lower-limb amputees. *Arch Phys Med Rehabil.* 2003;84:803–811.
18. O'Neill BF, Evans JJ. Memory and executive function predict mobility rehabilitation outcome after lower-limb amputation. *Disabil Rehabil.* 2009;31:1083–1091.
19. Waters RL, Perry J, Antonelli D, Hislop H. Energy cost of walking of amputees: the influence of level of amputation. *J Bone Joint Surg Am.* 1976;58:42–46.
20. Bhangu S, Devlin M, Pauley T. Outcomes of individuals with transfemoral and contralateral transtibial amputation due to dysvascular etiologies. *Prosthet Orthot Int.* 2009;33:33–40.
21. Dillingham TR, Pezzin LE, MacKenzie EJ, Burgess AR. Use and satisfaction with prosthetic devices among persons with trauma-related amputations: a long–term outcome study. *Am J Phys Med Rehabil.* 2001;80:563–571.
22. Goktepe AS, Cakir B, Yilmaz B, Yazicioglu K. Energy expenditure of walking with prostheses: comparison of three amputation levels. *Prosthet Orthot Int.* 2010;34:31–36.
23. Penn-Barwell JG. Outcomes in lower limb amputation following trauma: a systematic review and meta-analysis. *Injury.* 2011;42:1474–1479.
24. Gailey RS, Roach KE, Applegate EB, Cho B, Cunniffe B, Licht 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;83:613–627.
25. Condie ME, McFadyen AK, Treweek S, Whitehead L. The trans-femoral fitting predictor: a functional measure to predict prosthetic fitting in transfemoral amputees – validity and reliability. *Arch Phys Med Rehabil.* 2011;92:1293–1297.
26. Raya MA, Gailey RS, Fiebert IM, Roach KE. Impairment variables predicting activity limitation in individuals with lower limb amputation. *Prosthet Orthot Int.* 2010;34:73–84.
27. Cleland JA, Childs JD, Fritz JM, Whitman JM, Eberhart SL. Development of a clinical prediction rule for guiding treatment of a subgroup of patients with neck pain: use of thoracic spine manipulation, exercise, and patient education. *Phys Ther.* 2007;87:9–23.
28. Childs JD, Cleland JA. Development and application of clinical prediction rules to improve decision making in physical therapist practice. *Phys Ther.* 2006;86:122–131.
29. Cleland JA, Mintken PE, Carpenter K, Fritz JM, Glynn P, Whitman J, Childs JD. Examination of a clinical prediction rule to identify patients with neck pain likely to benefit from thoracic spine thrust manipulation and a general cervical range of motion exercise: multi-center randomized clinical trial. *Phys Ther.* 2010;90: 1239–1250.
30. Laupacis A, Sekar N, Stiell IG. Clinical prediction rules. A review and suggested modifications of methodological standards. *JAMA.* 1997;277:488–494.
31. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40:373–383.
32. Brodersen KH, Ong CS, Stephan KE, Buhmann JM. The balanced accuracy and its posterior distribution. Paper presented at 20th International Conference on Pattern Recognition 2010. https://ieeexplore.ieee.org/xpl/mostRecentIssue.jsp?punumber = 5595335 (Accessed 3 Jul 2014).
33. Everitt BS. *The analysis of contingency tables.* Vol 45. CRC Press; 1992.
34. Trewin D. Australian Standard Geographical Classification (ASGC) 2005. 2005; 1216.0:1 to 240.
35. Dillingham TR, Pezzin LE, Shore AD. Reamputation, mortality, and health care costs among persons with dysvascular lower-limb amputations. *Arch Phys Med Rehabil.* 2005;86:480–486.
36. Nehler MR, Coll JR, Hiatt WR, Regensteiner JG, Schnickel GT, Klenke WA, et al. Functional outcome in a contemporary series of major lower extremity amputations. *J Vasc Surg.* 2003;38:7–14.

37. Gauthier-Gagnon C, Grisé MC, Potvin D. Enabling factors related to prosthetic use by people with transtibial and transfemoral amputation. *Arch Phys Med Rehabil.* 1999;80:706–713.
38. Franchignoni F, Orlandini D, Ferriero G, Moscato TA. Reliability, validity, and responsiveness of the locomotor capabilities index in adults with lower-limb amputation undergoing prosthetic training. *Arch Phys Med Rehabil.* 2004;85:743–748.
39. Lesher JD, Sutlive TG, Miller GA, Chine NJ, Garber MB, Wainner RS. Development of a clinical prediction rule for classifying patients with patellofemoral pain syndrome who respond to patellar taping. *J Orthop Sports Phys Ther.* 2006;36:854–866.
40. Jaeschke R, Guyatt G, Sackett DL. Users' guides to the medical literature. III. How to use an article about a diagnostic test. A. Are the results of the study valid? Evidence-Based Medicine Working Group *JAMA.* 1994;271:389–391.
41. Norman PE, Schoen DE, Gurr JM, Kolybaba ML. High rates of amputation among Indigenous people in Western Australia. *Med J Aust.* 2010;192:421.

CPR Manuscript Appendices

Appendix 1. Standard Outpatient Prosthetic Rehabilitation

K-level 1 to 4 participants underwent prosthetic rehabilitation as an outpatient service at the dedicated state amputee rehabilitation service, Royal Perth Hospital. Participants were progressed through a standardised gait retraining program, which included: strengthening; balance; stretching and cardiovascular exercises; learning to don, doff the prosthesis and monitor prosthetic fit; sit to stand; weight shift and walking drills in the parallel bars; transfers using the prosthesis; walking indoors and outdoors on a range of terrains and environmental conditions; stair climbing; and progression of mobility aids. Mobility aids included: single point walking sticks, elbow crutches, wheeled or non-wheeled Zimmer frames and four-wheeled walking frames. They were issued to individuals assessed as requiring a mobility aid at discharge. If a participant was unable to don their prosthesis or achieve locomotor milestones, their carer was taught how to assist. Running, sports and work-specific locomotor skills were taught to those who identified these as goals. Participants were discharged from physiotherapy when they achieved their individualised rehabilitation goals.

Participants received standardised prosthetic care from the onsite Royal Perth Hospital prosthetists during their physiotherapy gait-retraining sessions. This included prosthetic adjustment and new sockets, as required. Once gait retraining was completed and residual limb volume had stabilised, participants were referred by the multidisciplinary rehabilitation team for a definitive prosthesis.

Appendix 2. Instructions on how to use the clinical prediction rules for prosthetic non-use.

To use the clinical prediction rules for prosthetic non-use these scoring guidelines apply:

1. Amputation level – individuals with amputation level above transtibial (ie, knee disarticulation and above) score 1. Individuals with bilateral amputation where one side is **above** transtibial level (ie, knee disarticulation and above) score 1. Individuals with a transtibial level of amputation or bilateral transtibial amputations score 0.

2. Very high number of medical comorbidities – individuals with a total of 19 or more comorbidities score 1. This represents approximately the 95th percentile* of the prospective cohort. All medical conditions are counted including musculoskeletal pathologies (eg, back pain, adhesive capsulitis, etc) and mental health issues (eg, depression, anxiety, etc). Individuals with less than 19 comorbidities score 0.

3. Not having a diagnosis of type II diabetes – individuals score 1 if they **do not have** a diagnosis of type II diabetes. Individuals score 0 if they do have a diagnosis of type II diabetes; this includes those with type II diabetes that is diet controlled, medication or insulin controlled.

4. Delay to prosthesis – individuals with a delay to prosthetic fitting of 160 days or greater score 1. This represents approximately the 95th percentile* of the prospective cohort. Individuals with less than 160 days to prosthetic fitting score 0. Number of days to prosthetic fitting is calculated by counting the number of days from initial major lower limb amputation surgery to prosthetic fitting.

5. Mobility aid use at discharge – individuals who require a walking aid, including walking stick, crutches or walking frames, to walk indoors or outdoors during locomotor activities score 1. Those who do not use any form of mobility aid score 0.

6. Dependence walking outdoors on concrete at discharge – individuals who are unable or require physical assistance or another person standing by for assistance to walk outdoors on concrete or paved ground score 1. Those who are independent and able to walk outdoors on concrete or paved ground including those who require a mobility aid score 0.

Individuals score 1 or 0 based on the presence or absence of predictor variables for the time frames of 4, 8 and 12 months. The total number of predictor variables is summed for each of the time frames. The positive likelihood ratios from Table 6 allow health professionals to identify the level of risk that an individual has for prosthetic non-use based on having a number of predictor variables (eg, 1, 2, 3 or more) for the time frames.

For generalisation into other healthcare systems it was noted that the number of comorbidities and length of delay to prosthetic gait might be population or institutional sensitive. Therefore, other institutes may wish to identify comorbidities and delay in prosthetic gait retraining by taking the hospital context and flagging individuals who fall in the top 5 to 10 percentiles for each of these categories.

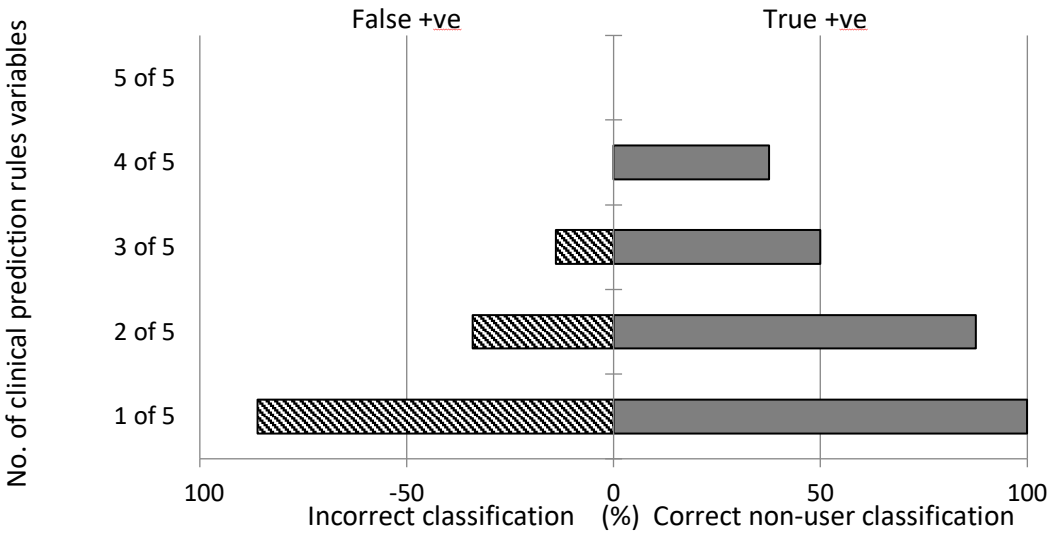

Figure 3. Prospective clinical utility figure showing the percentage of users classified as non-users (False +ve) and non-users correctly identified (True +ve) for each risk variable identified for the 4 and 6 months clinical prediction rules. Note: three of five variables present identified 50% of non-users with a false prediction of 14%. Four of five variables detected 38% of all non-users.

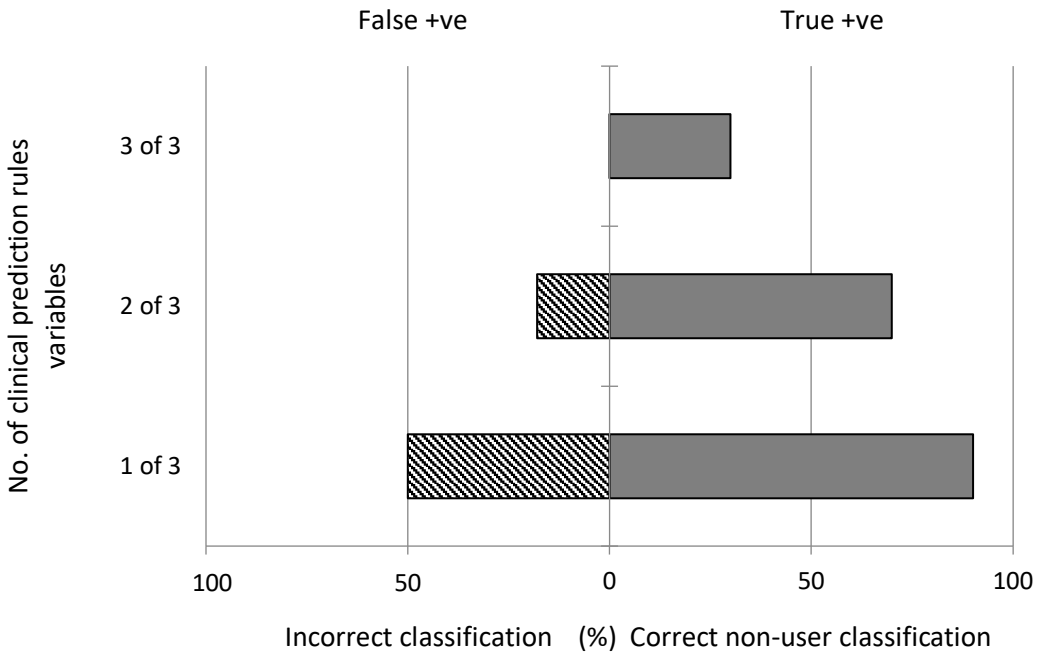

Figure 4. Prospective clinical utility figure showing the percentage of users classified as non-users (False +ve) and non-users correctly identified (True +ve) for each risk variable identified for the 8 months clinical prediction rules. Note: two of three variables present identified 70% of non-users with a false prediction of 18%. Three of three variables detected 30% of all non-users.

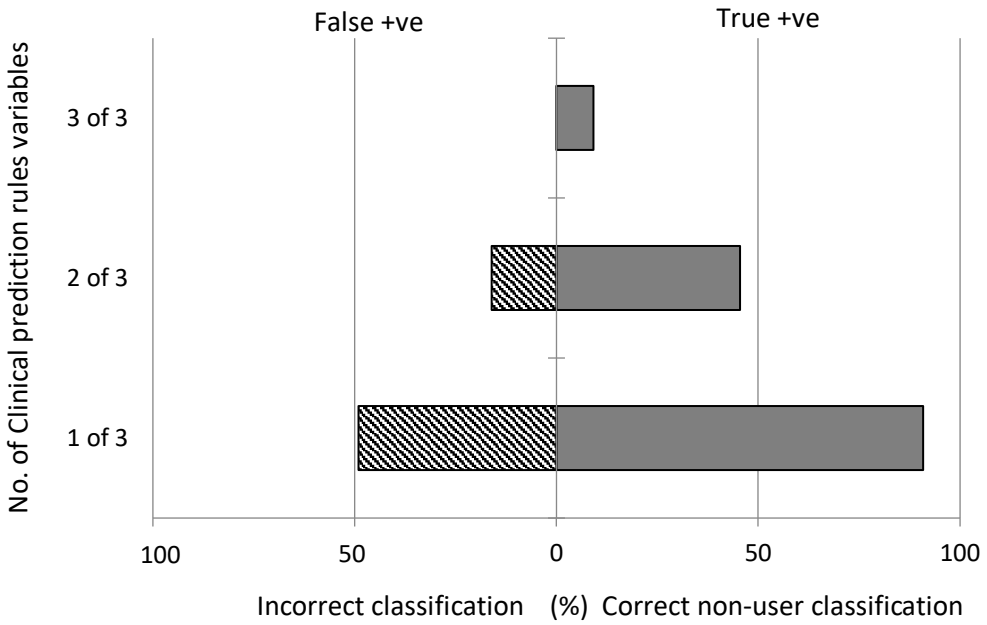

Figure 5. Prospective clinical utility figure showing the percentage of users classified as non-users (False +ve) and non-users correctly identified (True +ve) for each risk variable identified for the 12 months clinical prediction rules. Note: one of three variables present identified 91% of non-users with a false prediction of 49%. Two of three variables detected 45% of all non-users and falsely identified 16% of users.

Table 1. Dichotomous classifications of potential predictor variables used in CPR development.

Variables investigated	Dichotomous classification for CPR development
Gender	male or female
Indigenous status	Aboriginal or not Aboriginal
Amputation cause	atraumatic or traumatic
Age at amputation	<58 years or ≥58 years
Amputation level	transtibial or above transtibial
Major bilateral amputation	yes or no
Time from initial amputation to 2nd lower limb amputation	< 343 days or ≥ 343 days
Place of residence	metropolitan or country
Discharge destination	home or residential care
Time from amputation to prosthetic casting	< 156 days or ≥ 156 days
Time from amputation casting to fitting	< 6 days or ≥ 6 days
Time from amputation to prosthetic fitting	< 160 days or ≥ 160 days
Time from amputation to definitive prosthesis	< 301 days or ≥ 301 days
Wheelchair mobility in all environments	independent or dependent
Wheelchair type	manual or power
Transfer	independent or dependent
Transfer type	pivot or slideboard
Hopping	independent or dependent
Floor transfer	independent or dependent
At discharge:	
Mobility aid use	yes or no
Donning, doffing and monitoring prosthetic fit	independent or dependent
Prosthetic gait	independent or dependent
Indoors gait	independent or dependent
Outdoors gait on concrete	independent or dependent
Stairs	independent or dependent
Slopes	independent or dependent
Grass	independent or dependent
Gravel and uneven terrain	independent or dependent
High level balance activities	independent or dependent
Running	independent or dependent
Number of comorbidities	<19 comorbidities or ≥19 comorbidities
Diabetes	yes or no
Type I diabetes	yes or no
Type II diabetes	yes or no
Peripheral arterial disease	yes or no
Cardiac condition/s	yes or no
Renal failure	yes or no
Cerebrovascular accident and transient ischaemic attack	yes or no
Arthritis	yes or no
Remaining lower limb pathology	yes or no

Table 4. Significant univariate predictor variables (p < 0.100) for prosthetic non-use for 4 (and 6), 8 and 12 months.

Timeframe	Variable	Sensitivity	Specificity	LR+	LR–	*p*-value
4 (and 6) months	Age ≥ 58 yr	0.67	0.60	1.67	0.56	0.049
	Amputation level above transtibial	0.67	0.66	1.95	0.51	0.014
	Delay to prosthesis[b]	0.33	0.90	3.30	0.74	0.011
	Mobility aid use at discharge	0.97	0.53	2.07	0.06	< 0.001[a]
	Dependent at discharge with:					
	donning, doffing and monitoring	0.27	0.91	2.91	0.81	0.042
	prosthetic gait	0.20	0.94	3.43	0.85	0.048
	walking indoors	0.20	0.94	3.43	0.85	0.048
	walking outdoors on concrete	0.33	0.89	3.08	0.75	0.016
	walking up and down stairs	0.47	0.84	2.95	0.63	0.004
	walking up and down slopes	0.40	0.83	2.40	0.72	0.031
	walking on grass	0.40	0.84	2.53	0.71	0.023
	walking on gravel and uneven terrain	0.47	0.82	2.55	0.65	0.012
	Inability to perform high-level balance activities at discharge	0.97	0.18	1.18	0.18	0.133[a]
	High number of co-morbidities ≥ 19	0.27	0.91	2.91	0.81	0.042
	Not having diabetes	0.73	0.50	1.47	0.53	0.088
	Not having type II diabetes	0.80	0.43	1.39	0.47	0.094
8 months	Amputation level above transtibial	0.70	0.68	2.18	0.44	0.001
	Delay to prosthesis[b]	0.33	0.92	4.19	0.72	0.001
	Inability to hop	0.50	0.70	1.64	0.72	0.087
	Mobility aid use at discharge	0.98	0.56	2.20	0.04	< 0.001[a]
	Dependent at discharge with:					
	donning, doffing and monitoring	0.30	0.92	3.83	0.76	0.004
	prosthetic gait	0.20	0.95	3.83	0.84	0.020
	walking indoors	0.20	0.95	3.83	0.84	0.020
	walking outdoors on concrete	0.35	0.90	3.66	0.72	0.002
	walking up and down stairs	0.50	0.86	3.59	0.58	< 0.001
	walking up and down slopes	0.45	0.85	3.04	0.65	0.002
	walking on grass	0.45	0.86	3.23	0.64	0.001
	walking on gravel and uneven terrain	0.55	0.84	3.51	0.53	< 0.001
	Inability to perform high-level balance activities at discharge	0.98	0.19	1.21	0.13	0.061[a]
	Inability to run at discharge	0.98	0.15	1.14	0.16	0.125[a]
	Having a cardiac condition/s	0.65	0.60	1.63	0.58	0.037
	Not having arthritis	0.80	0.42	1.37	0.48	0.065
12 months	Amputation level above transtibial	0.64	0.68	2.01	0.53	0.003
	Delay to prosthesis[b]	0.32	0.92	3.88	0.74	0.001
	Inability to hop	0.48	0.70	1.60	0.74	0.085
	Mobility aid use at discharge	0.96	0.57	2.25	0.07	< 0.001
	Dependent at discharge with:					
	donning, doffing and monitoring	0.24	0.92	2.93	0.83	0.023
	prosthetic gait	0.16	0.95	2.93	0.89	0.069
	walking indoors	0.16	0.95	2.93	0.89	0.069
	walking outdoors on concrete	0.36	0.92	4.40	0.70	0.0002
	walking up and down stairs	0.48	0.87	3.77	0.60	< 0.001
	walking up and down slopes	0.44	0.86	3.23	0.65	0.001
	walking on grass	0.44	0.87	3.46	0.64	0.0003
	walking on gravel and uneven terrain	0.52	0.85	3.58	0.56	< 0.001
	Inability to perform high-level balance activities at discharge	0.98	0.20	1.22	0.09	0.027[a]
	Inability to run at discharge	0.98	0.16	1.16	0.13	0.067[a]
	Having a cardiac condition/s	0.68	0.62	1.78	0.52	0.007

[a] 0.5 was added to cells in the 2 x 2 contingency table where there was a zero count. [b] n = 134.
LR+ = positive likelihood ratio, LR- = negative likelihood ratio.

Appendix 4.2: Summary of prosthetic and physiotherapy intervention.

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Prosthetic rehabilitation was performed by K-level 1 to 4 participants as an outpatient service at the dedicated state amputee rehabilitation service, Royal Perth Hospital (RPH). Participants were progressed through a standardised gait retraining program which included: strengthening, balance, stretching and cardiovascular exercises, learning to don, doff and monitor prosthetic fit, weight shift and walking drills in the parallel bars, walking indoors and outdoors on a range of terrains and environmental conditions, stair climbing and progression of mobility aids. Mobility aids including: single point walking sticks, elbow crutches, wheeled or non-wheeled Zimmer frames and 4 wheeled walking frames were issued to individuals assessed as requiring a mobility aid at discharge. If a participant was unable to don their prosthesis or achieve locomotor milestones their carer was taught how to assist. Running, sports and work specific locomotor skills were taught to those patients who identified these as goals. Participants were discharged from physiotherapy when they achieved their individualised rehabilitation goals.

Participants received standardised prosthetic care from the onsite RPH prosthetists during their physiotherapy gait retraining sessions. This included prosthetic adjustment and new sockets as required. Once gait retraining was completed and residual limb volume had stabilised participants were referred by the multidisciplinary team for a definitive prosthesis.

Appendix 4.3 Summary of stepwise logistic regression data

Logistic regression information

A backward logistic regression was used to be inclusive of variables. In such cases the model has to be significantly improved to remove a variable. (As opposed to a forward model that requires the next variable to be included must significantly improve the model).

IBM SPSS Statistics 21.0 was used for the backward logistic regression.

The predictive outcomes for the 4 and 6 months were the same therefore the regression was run for both time periods.

Table. 4.4:. For the 4/6 months outcome there were 11 steps. The last 4 steps were:

Step	*Variable*	*Model Log Likelihood*	*Change in Log Likelihood*	*Significance*
Step 8	*Age 58 or greater	-32.357	4.294	.038
	Above transtibial amputation	-32.140	3.860	.049
	Mobility aid at discharge	-31.651	2.881	.090
	Dependence outdoors concrete	-37.492	14.56	.000
	Dependence on stairs	-32.089	3.756	.053
	Dependence on gravel & uneven terrain	-32.065	4.705	.030
	Comorbidities 19 or greater	-31.880	4.335	.037
	Not having type 2 diabetes	-30.210	.995	.319
Step 9	Above transtibial amputation	-31.566	3.707	.054
	Mobility aid at discharge	-37.487	15.54	.000
	Dependence outdoors concrete	-31.961	4.496	.034
	*Dependence on stairs	-31.672	6.143	.013
	Dependence on gravel & uneven terrain	-31.135	5.069	.024
	Comorbidities 19 or greater	-30.159	3.116	.078
	Not having type 2 diabetes	-29.713	2.225	.136
step 10	Above transtibial amputation	-29.812	2.422	.120
	Mobility aid at discharge	-36.238	15.27	.000
	Dependence outdoors concrete	-30.885	4.569	.033
	*Dependence on gravel & uneven terrain	-31.427	6.493	.011
	Comorbidities 19 or greater	-30.470	4.578	.032
	Not having type 2 diabetes	-29.686	3.010	.083
Step 11	**Above transtibial amputation**	**-29.446**	**2.530**	**.112**
	Mobility aid at discharge	**-29.311**	**2.259**	**.133**
	Dependence outdoors concrete	**-34.666**	**12.97**	**.000**
	Comorbidities 19 or greater	**-30.474**	**4.586**	**.032**
	Not having type 2 diabetes	**-28.601**	**.839**	**.360**

*Red variables are the step variable change.

Table 4.5:. For the 8 months there was a change, the regression took 13 steps.
The last 4 steps were:

Step	*Variable*	*Model Log Likelihood*	*Change Log Likelihood*	*Significance*
Step 10	Above transtibial amputation	-39.399	3.464	.063
	Delay to prosthesis 156 or greater	-46.940	18.54	.000
	Mobility aid at discharge	-40.491	5.647	.017
	Dependence outdoors concrete	-37.668	2.472	.116
	*Cardiac Conditions	-37.960	3.056	.080
	Arthritis	-45.720	18.57	.000
Step 11	Above transtibial amputation	-38.885	4.907	.027
	*Delay to prosthesis 156 or greater	-36.938	2.820	.093
	Mobility aid at discharge	-36.460	1.864	.172
	Dependence outdoors concrete	-44.284	17.51	.000
	Arthritis	-36.432	1.808	.179
Step 12	Above transtibial amputation	-37.809	4.562	.033
	Mobility aid at discharge	-36.759	4.009	.045
	Dependence outdoors concrete	-35.528	1.546	.214
	*Arthritis	-35.774	2.038	.153
Step 13	**Above transtibial amputation**	**-41.846**	**14.18**	**.000**
	Mobility aid at discharge	**-35.721**	**1.933**	**.164**
	Dependence outdoors concrete	**-37.070**	**4.631**	**.031**

*Red variables are the step variable change.

Table 4.6:. For the 12 months there was a change in the outcomes compared to 8 months. The regressions identified 12 steps. The last 4 steps were:

Step	*Variable*	*Model Log Likelihood*	*Change Log Likelihood*	*Significance*
Step 9	Above transtibial amputation	-53.126	17.846	.000
	Delay to prosthesis 156 or greater	-46.957	5.507	.019
	Mobility aid at discharge	-46.362	4.318	.038
	Dependence outdoors concrete	-44.203	1.751	.186
	*Dependence on slopes	-50.674	14.692	.000
	Cardiac Conditions	-45.073	3.490	.062
Step 10	Above transtibial amputation	-45.914	5.173	.023
	Delay to prosthesis 156 or greater	-43.328	1.123	.289
	Mobility aid at discharge	-43.739	1.945	.163
	Dependence outdoors concrete	-48.506	11.479	.001
	*Cardiac Conditions	-44.513	3.493	.062
Step 11	Above transtibial amputation	-45.410	5.286	.022
	Delay to prosthesis 156 or greater	-42.851	1.687	.194
	Mobility aid at discharge	-42.767	1.519	.218
	*Dependence outdoors concrete	-43.704	3.392	.065
Step 12	**Above transtibial amputation**	**-48.201**	**12.388**	**.000**
	Delay to prosthesis 156 or greater	**-43.996**	**3.978**	**.046**
	Mobility aid at discharge	**-45.209**	**6.403**	**.011**

*Red variables are the step variable change.

Appendix 5.1: Instructions on using the clinical prediction rules.

Appendix 5.1: Instructions on using the clinical prediction rules.

To use the clinical prediction rules for prosthetic non-use these scoring guidelines apply:

1. Amputation level – Individuals with amputation level above transtibial (i.e. knee disarticulation and above) score 1. Individuals with bilateral amputation where one side is **above** transtibial level (i.e. knee disarticulation and above) score 1. Individuals with a transtibial level of amputation or bilateral transtibial amputations score 0.

2. Very high number of medical comorbidities – Individuals with a total of 19 or more comorbidities score 1. This represents approximately 95th percentile of the prospective cohort. All medical conditions are counted including musculoskeletal pathologies (e.g. back pain, adhesive capsulitis etc.) and mental health issues (e.g. depression, anxiety etc.). Individuals with less than 19 comorbidities score 0.

3. Not having a diagnosis of Type 2 diabetes – Individuals score 1 if they **do not have** a diagnosis of Type 2 diabetes. Individuals score 0 if they do have a diagnosis of Type 2 diabetes; this includes those with Type 2 diabetes that is diet controlled, medication or insulin controlled.

4. Delay to prosthesis – Individuals with a delay to prosthetic casting of 160 days or greater score 1. This represents approximately 95th percentile of the prospective cohort. Individuals with less than 160 days to prosthetic casting score 0. Number of days to prosthetic casting is calculated by counting the number of days from initial major lower limb amputation surgery to prosthetic casting.

5. Mobility aid use at discharge – Individuals who require a walking aid including walking stick, crutches, or walking frames to walk indoors or outdoors during locomotor activities score 1. Those who do not use any form of mobility aid score 0.

6. Dependence walking outdoors on concrete at discharge – Individuals who are unable or require physical assistance or another person standing by to walk outdoors on concrete or paved ground score 1. Those who are independent and able to walk outdoors on concrete or paved ground including those who require a mobility aid score 0.

Individuals score 1 or 0 based on the presence or absence of predictor variables for the time frames of 4, 8, and 12 months. The total number of predictor variables are summed for each of the time frames. The positive likelihood ratios from Table 5.2 allow health professionals to identify the level of risk that an individual has for prosthetic non-use based on having a number of predictor variables (e.g. 1, 2, 3 or more) for the time frames.

Appendix 7.1A: Table 7.5A Correlation matrix (r_s) of locomotor tests.

Table 7.5A: Correlation matrix (r_s) for performance measures

	r_s			
	10MWT	TUGT	6MWT	FSST
10MWT (n)	1.0 189	-.84* 183	.79* 188	-.77* 184
TUGT (n)		1.0 188	-.85* 187	.85* 182
6MWT (n)			1.0 198	-.86* 189
FSST (n)				1.0 190

*p < .0001 (two tailed)

Appendix 7.1B Table 7.1B: The locomotor capabilities index 5 (LCI5).

Table7.1B: The locomotor capabilities index 5 (LCI5) by Franchignoni, Orlandini et al. (2004) has a 5 point ordinal scale.

THE LOCOMOTOR CAPABILITIES INDEX 5 (LCI5)

For interview subjects are asked, *"Whether or not you wear your prosthesis, at the present time, would you say that you are "able" to do the following activities with your prosthesis on?"*

ITEM	SCALE				
1. Get up from a chair	0	1	2	3	4
2. Walk in the house	0	1	2	3	4
3. Walk outside on even ground	0	1	2	3	4
4. Go up the stairs <u>with</u> a handrail	0	1	2	3	4
5. Go down the stairs <u>with</u> a handrail	0	1	2	3	4
6. Step up a sidewalk curb	0	1	2	3	4
7. Step down a sidewalk curb	0	1	2	3	4
Basic LCI5 score ____/28					
1. Pick up an object from the floor (when you are standing up in your prosthesis)	0	1	2	3	4
2. Get up from the floor (e.g. if you fell)	0	1	2	3	4
3. Walk outside on uneven ground (e.g. grass, gravel, slope)	0	1	2	3	4
4. Walk outside in inclement weather (e.g. snow, rain, ice)	0	1	2	3	4
5. Go up a few steps (stairs) <u>without</u> a handrail	0	1	2	3	4
6. Do down a few steps (stairs) <u>without</u> a handrail	0	1	2	3	4
7. Walk while carrying an object	0	1	2	3	4
Advanced LCI5 score ____/28					
Total LCI5 score ____/56					

Ordinal scale score definitions:
0 = No
1 = Yes with help
2 = Yes with supervision
3 = Yes, alone, with ambulation aids
4 = Yes, alone, without ambulation aids

Franchignoni, Orlandini et al. (2004)

Appendix 7.2B: Activity and participation questionnaire

Royal Perth Hospital Amputee Prosthetic Use Questionnaire

**Please note this questionnaire is a data cuing device for an experienced telephone interviewer.*

Date: ……..…… **Subject Code:** ……. **Verbal Consent:** ☐Yes ☐ No

Amputation Surgery Date/s: …….. **Hospital for Surgery:** ……

Accommodation: ☐Home ☐Hostel ☐Nursing Home ☐Remote Community ☐ Other

Do you live: ☐ Alone ☐ with husband / wife / partner ☐ with others? ……

Driving: ☐Yes ☐ No ……

Work: ☐Yes ☐ No Occupation:……

Age: …… **Gender:** ☐ Male ☐Female **Post Code:** ……

Amputation Cause: ☐ Circulatory ☐ Infective ☐ Trauma ☐ Other ……

Amputation Level/s:

(L) Lower Limb: ☐ Symes ☐ TTA ☐ KD ☐ TFA ☐ HD ☐ HP ☐ Other:

(R) Lower Limb: ☐ Symes ☐ TTA ☐ KD ☐ TFA ☐ HD ☐ HP ☐ Other:

Bilateral: ☐ Yes ☐ No

Upper Limb: ☐ Yes ☐ No *If yes, list:* ……

Diabetes: ☐ Yes ☐ No ☐ Type 1 ☐ Type 2 ☐ Insulin ☐ Medication ☐ Diet Controlled

Peripheral Arterial Disease: ☐ Yes ☐ No

Renal Failure: ☐ Yes ☐ No ☐ Haemodialysis ☐ Peritoneal dialysis Days: ……

General Health?: ……

When did you last attend an Amputee Clinic? Date: …… ☐RPH-SPC ☐SCGH ☐FHHS

1. **Do you ever have falls?** ☐ Yes ☐ No

   When? ……
   Describe / cause ……..
   Injuries ……...
   No. of falls since amputation (fall frequency) …….

2. **Could you get up off the floor independently after the fall (i.e. floor transfer)?**
   ☐Yes ☐No

3. **Are you using your prosthesis?**

   ☐Yes ☐No

   If yes what days of the week do you use your prosthesis?

   ☐Mon ☐Tues ☐Wed ☐Thurs ☐Fri ☐Sat ☐ Sun

4. **What type of prosthesis are you using?** ☐ Interim prosthesis ☐ Definitive prosthesis

5. **Who made your definitive prosthesis?**

   ☐TLC ☐FOS ☐ SWOPS ☐ Other ……

6. **If you are <u>not</u> using your prosthesis, why not?** ……

7. **How long after discharge from physiotherapy at RPH-SPC did you stop wearing your prosthesis?** *(*Cue with weeks, months & years)*

   ……

8. **Do you have pain in your good "remaining" leg?**
   ☐Yes ☐No

   If yes, describe Pain Type:

   ☐Claudication ☐ Orthopaedic ☐ Other ……

9. **Do you have any other problems with your good leg?***(Cue: ulcers, numbness, pins & needles, muscles not working)*

   ☐Yes ☐ No *If yes, describe:* ……

10. **Are you able to hop?**
    ☐Yes ☐ No

    If yes, what aid do you use?

    ☐No aids ☐EC ☐ AC ☐ WZF ☐ ZF ☐Other:……

11. **How do you transfer?**

    ☐Pivot ☐Slide Board ☐ Bottom Shuffle ☐Fwds-Bwds Shuffle ☐ Other
    (If prosthetic non-user go to question 18)*

12. **Do you use your prosthesis to transfer?**
    ☐Yes ☐No

13. **Can you put on your prosthesis by yourself?**
    ☐Yes ☐ No

14. **How many times each day do you <u>*transfer*</u> *(sit to stand)* using your prosthesis?**
    *(*Cue: wheelchair, car, toilet etc)*

    ……..

15. **For how long each day do you perform activities in *standing* using your prosthesis?** *(*Cue: Minutes, hours)*

……..

16. **For how long each day do you *wear* your prosthesis?**

…….

17. **For how long each day do you *walk* in your prosthesis?**

……..

18. **Do you use a walking aid to walk with your prosthesis?**
☐Yes ☐ No

If yes list type:

☐EC ☐WZF ☐ZF ☐ 4WF ☐walking stick ☐Other ……

☐Indoors aid: ……. ☐Outdoors aid: ……..

19. **How far can you walk in your prosthesis before resting?** *(*Cue: no. of blocks, metres, Km)*

……..

20. **Do you use a wheelchair?**
☐Yes ☐No Type: ☐ MWC ☐ EWC ☐ Scooter ☐Other……

21. **Do you use a wheelchair while also wearing your prosthesis?** ☐Yes ☐No

22. **Stump problems?** ☐Yes ☐No

☐**Skin** ……..

☐**Circulation** ……..

☐**Swelling** ……...

☐**Pain** ☐**PLP** ☐**Stump** ☐**Other**
……..

☐**Other** ……

Appendix 7.3B Table 7.3B: Cohort characteristics for prosthetic users and non-users.

Table 7.3B: Cohort characteristics for prosthetic users and non-users.

Demographic and Amputation Details	Users (n = 149)	Non-users (n = 52)	z or t value	p value
Gender, Male, n (%)	124 (83)	37 (71)	1.88	.06
Age at interview, mean (SD)	58.0 (15.6)	59.4 (15.6)	.745	.457
Indigenous status, Aboriginal, n (%)	18 (12)	11 (21)	-1.6	.11
Accommodation after discharge from inpatient rehabilitation, n (%)				
Home (not residential care)	146 (98)	48 (92)	1.92	.06
Metropolitan (not country)	90 (60)	37 (71)	-1.38	.17
Social Support, Lives with others, n (%)	119 (80)	41 (79)	0.16	0.87
Accessibility Remoteness Index of Australia (ARIA)†				
Major Cities of Australia (0 to 1.84)	106 (72)	43 (83)	-1.64	.101
Inner Regional Australia (>1.84 to 3.51)	15 (10)	0(0)	2.38	.017*
Outer Regional Australia (>3.51 to 5.80)	10 (7)	3 (6)	0.24	.81
Remote Australia (> 5.80 to 9.08)	2 (1)	2 (4)	-1.11	.267
Very Remote Australia (> 9.08 to 12)	15 (10)	4 (8)	0.50	.617
Charlson Comorbidity Index (CCI), median (IQR)	2 (0 to 4)	3 (1 to 5)	2.04	.04*
Combined Age CCI, median (IQR)	4 (1 to 5)	4 (3 to 7)	1.96	.05
Comorbidities, n (%)				
Diabetes Type I	8 (5)	4 (8)	-0.61	.542
Type II	59 (40)	25 (48)	-1.07	.285
Peripheral Arterial Disease	74 (50)	32 (62)	-1.48	.139
Cardiac Condition	45 (30)	30 (58)	-3.53	.0004*
Renal Failure	18 (12)	14 (27)	-2.52	.018*
Cerebrovascular accident / Transient Ischemic Attack	12 (8)	5 (10)	-0.35	.726
Arthritis	48 (32)	21 (40)	-1.07	.285
Remaining Lower Limb Pathology	114 (77)	47 (90)	-2.16	.031*
Mental health issues, n (%)	32 (21)	13 (25)	-0.525	.603
Mild cognitive impairment, n (%)	5 (3)	5 (10)	-1.78	.0735
Intellectual disability, n (%)	2 (1)	0 (0)	0.84	.401
Substance abuse, n (%)				
Drugs	9 (6)	7 (13)	-1.70	.089
Alcohol	17 (11)	7 (13)	-0.393	.697
Current smoker	33(22)	18 (35)	-1.78	.075
Amputation Cause, n (%)				
Circulatory	34 (23)	18 (35)	-1.67	.095
Infection	64 (43)	23 (44)	-0.16	.873
Trauma	43 (29)	11 (21)	1.08	.280
Cancer	8 (5)	0 (0)	1.70	.087
Amputation Level, n (%)				
Transtibial	128 (86)	35 (67)	2.95	.003*
Knee disarticulation	5 (3)	2 (4)	-0.17	.865
Transfemoral	29 (19)	33 (63)	-5.92	<.0001*
Major Bilateral Lower Limb Amputation	13 (9)	18 (35)	-4.45	<.0001*
Minor Amputation of Remaining Limb	17 (11)	4 (8)	0.75	.453
Upper Limb Amputation/s	17 (11)	3 (6)	1.17	.242

† One user excluded from the retrospective ARIA analysis as he resided overseas after discharge (n = 148). Please note that all other descriptive data analyses for prosthetic users (n = 149).
** p < .05*

Appendix 7.4B Table 7.4B: Frequency of mobility activities without a prosthesis performed by a cohort with lower limb amputation (n = 201) after discharge from rehabilitation.

Table 7.4B: Frequency of mobility activities without a prosthesis performed by a cohort with lower limb amputation (n = 201) after discharge from rehabilitation.

Functional Activity	n (%)
Wheelchair use	143 (71)
Wheelchair type	
Manual wheelchair	112 (78)
Power wheelchair	13 (9)
Motorised scooter	1 (1)
Both manual wheelchair and motorised scooter	17 (12)
Transfer type	
Pivot	128 (64)
Slide board	6 (3)
Lift or bottom shuffle transfer	21 (10)
Hoist	5 (3)
Hopping with or without a mobility aid	4 (2)
Do not transfer only use prosthesis and sit to stand	37 (18)
Floor Transfer	165 (82)
Hopping (in participants with unilateral lower limb amputation (n = 150))	91 (61)
Type of mobility aid used for hopping	33 (36)
No mobility aid used	33 (36)
Elbow crutches	3 (3)
Axillary crutches	12 (13)
Wheeled Zimmer frame	3 (3)
Zimmer frame	4 (4)
Rails	2 (2)
Holding onto car	1 (1)
Other	

Appendix 7.5B Table 7.6B: Mobility aid use reported by participants who were prosthetic users (n = 149).

Table 7.6B: Mobility aid use reported by participants who were prosthetic users (n = 149).

Details of mobility aid use and type of aid	% (n)
Participants who did not use a mobility aid	50 (74)
Participants who used a mobility aid	50 (75)
Type of mobility aid used indoors	
No aid	40 (30)
1 walking stick	21 (16)
2 walking sticks	3 (2)
1 elbow crutch	3 (2)
2 elbow crutches	11 (8)
Wheeled Zimmer frame	5 (4)
4 wheeled walking frame	16 (12)
Gutter frame	1 (1)
Type of mobility aid used outdoors	
No aid	3 (2)
1 walking stick	48 (36)
2 walking sticks	11 (8)
1 elbow crutch	4 (3)
2 elbow crutches	13 (10)
Wheeled Zimmer frame	4 (3)
4 wheeled walking frame	17 (13)
Gutter frame	0 (0)

Appendix 7.6B Table 7.7B: Self reported daily and weekly prosthetic use, daily and weekly number of sit to stands and maximal walking distance for prosthetic users.

Table 7.7B: Self reported daily and weekly prosthetic use, daily and weekly number of sit to stands and maximal walking distance for prosthetic users. Weekly usage was calculated by multiplying the number of week days the prosthesis is used by the number of hours it is used for each activity.

	Total users (n = 149)		Transtibial Amputation Group (n = 114)		Above Transtibial Amputation Group (n = 35)	
Self Reported Variables, median (IQR)	**Daily Use**	**Weekly Use**	**Daily Use**	**Weekly Use**	**Daily Use**	**Weekly Use**
Time standing, (hours)	2 (0.8 to 3.5)	14 (4.5 to 24.5)	2 (0.81 to 4)	14 (5.25 to 28)	2 (0.5 to 2.75)	14 (3.5 to 17.5)
Time walking, (hours)	2.5 (1.5 to 4.5)	17.5 (10.5 to 31.5)	3 (1.5 to 4.5)	21 (10.5 to 31.5)	2 (1.25 to 3)	14 (7 to 21)
Time worn, (hours)	14 (10.5 to 15.5)	98 (70 to 108)	14 (12 to 16)*	98 (84 to 112)†	10.5 (8 to 13)*	70 (45.8 to 91)†
Number of sit to stands	35 (25 to 55)	245 (161 to 385)	38 (25 to 59)	245 (175 to 411)	35 (25 to 55)	245 (140 to 385)
Maximal walking distance before resting, (m)		475 (138 to 2000)		400 (100 to 2000)		500 (200 to 1500)

* $p < .0001$
†$p < .001$
Note other categories were not significantly different ($z \leq 1.80$; $p \geq .07$) for reported weekly or daily usage by participants with transtibial or above transtibial amputation level.

Appendix 7.7B Table 7.9B: Age, comorbidity and gender characteristics of participants who do drive or work and those who do drive or work after amputation.

Table 7.9B: Age, comorbidity and gender characteristics of participants who do drive or work and those who do not drive or work after amputation.

Characteristic	Worker	Non-worker	Z score or t score	p value
Age, (years), mean (SD)	50.5 (14.5)	64.2 (13.8)	6.82	< .0001
Charlson Comorbidity Index (CCI) Score, median (IQR)	1 (0 to 2)	3 (2 to 5)	5.93	< .0001
Characteristic	Driver	Non-driver	Z score or t score	p value
Age (years), mean (SD)	56.0 (16.2)	61.0 (14.3)	2.22	.0274
Charlson Comorbidity Index (CCI) Score, median (IQR)	2 (0 to 3)	4 (2 to 5)	5.76	< .0001

Appendix 7.8B Table 7.11B: Complications of amputation, other pathologies and problems reported by a cohort with amputation.

Table 7.11B: Complications of amputation, other pathologies and problems reported by a cohort with amputation.

Self reported complications of amputation, other pathologies and problems	n (%)
Residual Limb (stump) issues	144 (72)
Type of issue*	
Wound or skin breakdown	82 (57)
Circulation	13 (9)
Oedema	38 (26)
Heterotrophic ossification	3 (2)
Pain	116 (81)
Phantom limb pain	97 (67)
Stump pain	35 (24)
Pain in Remaining Lower Limb	83 (49)
Type of lower limb Pain†	29 (33)
Claudication	66 (76)
Orthopaedic or musculoskeletal	2 (2)
Neuropathic	3 (3)
Other nociceptive pain	
Other lower limb pathology and symptoms reported by participants†	75 (44)
	26 (35)
Wounds	
Peripheral neuropathy	15 (20)
Motor	39 (52)
Sensory	15 (20)
Mixed	3 (4)
Charcot foot	11 (15)
Ankle or knee instability	1 (1)
Balance impairment	3 (4)
Cellulitis	10 (13)
Oedema	4 (5)
Cramps	6 (8)
Poor circulation	5 (7)
Other	

*Participants were able to report more than 1 residual limb issue therefore scores do not tally to 100%.
† Participants were able to report more than 1 remaining limb pain, pathology or symptom therefore scores do not tally to 100% and those with major bilateral lower limb amputation (n = 31) were excluded

Appendix 7.9B Table 7.12B: Self reported falls data for the total cohort with lower limb amputation, prosthetic users and non-users.

Table 7.12B: Self reported falls data for the total cohort with lower limb amputation, prosthetic users and non-users.

Falls category	Prosthetic Non-users (n = 52)	Prosthetic Users (n = 149)	Total (n = 201)
Frequency of falls since lower limb amputation, median (IQR)	2 (2 to 5)	2 (1 to 3)	2 (1 to 4)
Number of individuals who reported having a fall/s since amputation surgery, n (%)	37 (71)	102 (68)	139 (69)
Fall Mechanism, n (%):			
Transferring	17 (46)	21 (21)	38 (27)
Hopping	3 (8)	14 (14)	17 (12)
Walking with prosthesis	11 (30)	61 (60)	72 (52)
Recreational activities, exercise & sport	2 (5)	8 (8)	10 (7)
Phantom sensation	3 (8)	3 (3)	6 (4)
Wheelchair activities	11 (30)	9 (9)	20 (14)
Fell out or off bed	5 (14)	2 (2)	7 (5)
Medical cause (e.g. hypotension, hypoglycemia)	3 (8)	3 (3)	6 (4)
Equipment failure	0 (0)	1 (1)	1 (1)
Injury from fall, n (%):			
No injury	16 (31)	59 (58)	75 (54)
Minor injury	11 (21)	28 (27)	39 (28)
Major injury requiring medical treatment	10 (19)	15 (15)	25 (18)
Individuals who could independently perform a floor transfer after fall, n (%):	26 (70)	90 (88)	116 (83)

Appendix 8.1: Charlson Comorbidity Index Manuscript

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Appraisal | Clinimetrics

Charlson Comorbidities Index

Summary

Description: The Charlson Comorbidity Index (CCI) was developed and validated as a measure of 1-year mortality risk and burden of disease.[1–4] To account for age being an independent predictor of mortality, a Combined Age-CCI (CA-CCI) score can be generated.[1–3] The CCI has been extensively used in clinical research to address the confounding influence of comorbidities, predict outcomes, standardise comorbidities abstracted from medical records or administrative databases and for self report of comorbidities.[1,3,5–9] In clinical practice, the CCI reduces comorbidities into a single numeric score that may assist health professionals with stratifying patients into subgroups based on disease severity, developing targeted models of care and resource allocation.[3,8]

The CCI consists of 17 comorbidities, with two subcategories for diabetes and liver disease.[1–3] Comorbidities are weighted from 1 to 6 for mortality risk and disease severity, and then summed to form the total CCI score.[1–3] The CA-CCI is generated by adding 1 point to the CCI score for each decade of age over 40 years.[1–3] The CCI and CA-CCI require minimal training and are freely available for researchers and health professionals, with guidelines reported in Charlson et al.[1] To enable rapid electronic calculation of the CCI and CA-CCI, a Microsoft excel spreadsheet has been developed.[3] The CCI has been modified, with adaptations to comorbidities, administration and scoring.[3–7,9] The Self Reported-CCI (SR-CCI) can be self-administered or performed as a 10-minute interview.[6,7] The SR-CCI uses the same scoring algorithm as the CCI, except presence of liver disease is scored as 2 points.[6,7]

Psychometric properties: The CCI is reliable and valid for diverse clinical cohorts (eg, cancer, amputation and arthritis) in a variety of healthcare settings.[3,4,8,9] Charlson Comorbidity Index scores $\geq$ 5 have been associated with a 1-year mortality of 85%, while 10-year survival for a CA-CCI of 5 was 34%.[1] Charlson Comorbidity Index scores $>$ 8 have not been well studied.[1,3,10] Due to advances in disease management, the CCI was updated using International Classification of Diseases 10 codes and validated in six nations, including Australia.[4] The updated CCI and original CCI demonstrated similar levels of discrimination for in-hospital mortality with C statistics of 0.727 to 0.878 and 0.723 to 0.882, respectively.[4]

The CCI has moderate to good inter-rater reliability of 0.74 to 0.945 in older cohorts with cancer.[3,9] The CCI and SR-CCI have high test re-test reliability with intraclass correlation coefficients of 0.92 ($p < 0.0001$) and 0.91 ($p < 0.0001$), respectively.[7] A moderate level of agreement was identified between the SR-CCI and CCI, with most items having Kappa statistics (K) ranging from 0.433 to 0.541 ($p < 0.0001$), while diabetes had a high level of agreement ($K = 0.764$; $p < 0.0001$).[6] Spearman correlations up to 0.63 have been reported between the SR-CCI and CCI.[6,7]

The CCI has content validity, as the diseases and severity weights were statistically derived from relative risks of a proportional regression model to predict mortality.[1,9–11] One weakness that has been reported for the CCI is omission of diseases (eg, anaemia, mental illness), which are present in other indices.[3,11,12] However, the updated CCI retained 12 comorbidities, and prediction of mortality remained high. Increased number of comorbidities in indices (ie, 30 in the Elixhauser Comorbidity Measure versus 17 in the CCI) also potentially reduces utility.[4,11]

Traditional construct validity using the known groups method is rarely tested in comorbidity indices.[10,11] Poorer utilisation of cancer screening in patients with high CCI scores is an example of construct validity for the CCI.[10,11] There is no gold standard measure for comorbidity, so criterion validity (which encompasses concurrent and predictive validity) has been demonstrated for the CCI through comparison to other comorbidity indices and prediction of outcomes.[1,5,8–11] The CCI has moderate to good correlation (> 0.4) with other comorbidity indices and predictive validity for criterion such as mortality, readmission, disability and length of stay.[3,7,9,11]

Commentary

Comorbidity, which impacts on contemporary clinical practice and research, is a major consideration in health systems reform and funding models.[8] However, there is a lack of consensus on the most effective method for measuring comorbidity.[3,8–12] To ensure implementation of a comorbidity index that is sensitive, it is important to determine if the outcome of interest is mortality or function.[9,12] The CCI has utility due to low cost, ease of administration and interpretation in efficient timeframes.[3,7–9] The CCI is feasible in various healthcare settings, including those with limited access to medical records (eg, primary care, outreach).[9] The CCI can be incorporated into electronic medical record and data collection systems.[3] The SR-CCI has the potential to be biased by the client's medical knowledge, recall or literacy.[6,7,9] Depending on primary diagnosis and comorbidities being investigated, the CCI score may differ between studies (eg, in a client with leukaemia, COPD and myocardial infarction, the CCI score can be 2 or 3).[3] To enable standardised comparison of healthcare outcomes between different cohorts and centres, further research on measurement of comorbidity is warranted.

Provenance: Invited. Not peer reviewed.

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References

1. Charlson ME, et al. *J Chron Dis.* 1987;40:373–383.
2. Charlson ME, et al. *J Clin Epidemiol.* 1994;47:1245–1251.
3. Hall WH, et al. *BMC Cancer.* 2004;4:1471–2407.
4. Quan H, et al. *Am J Epidemiol.* 2011;173:676–682.
5. Amusat N, et al. *J Physiother.* 2014;60:217–223.
6. Ng X, et al. *Rheumatol Int.* 2015;35:2005–2011.
7. Katz JN, et al. *Med Care.* 1996;34:73–84.
8. Roffman CE, et al. *J Physiother.* 2014;60:224–231.
9. de Groot V, et al. *J Clin Epidemiol.* 2003;56:221–229.
10. Hall SF. *J Clin Epidemiol.* 2006;59:849–855.
11. Moltó A, et al. *Clin Exp Rheumatol.* 2014;32:S131–S134.
12. Groll DL, et al. *J Clin Epidemiol.* 2005;58:595–602.

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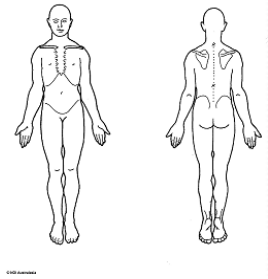
Appendix 8.2: Amputee Assessment Form

AMPUTEE REHABILITATION ASSESSMENT FORM 2009

SUBJECTIVE:	**Initial Assessment Date:**							**Case Manager:**				
Microalert Card:	No	Yes		White		Orange		Blue	Pre-operative Consultation:		No	Yes
Address:												
Telephone:	Home		Mobile					Next of Kin Details:				
Home Environment: Stairs: Other discharge issues (*eg Bathroom, Slopes, Aboriginal Community*):												
SHx:												
Care Packages:	No	Yes	Details:									
Hobbies, Interests, Occupation:												
HPC:												
Date of Amputation:												
Aetiology:		Circulatory		Infection		Trauma		Neoplasm		Other:		
Side & Level/s of Amputation:												
Revision Surgery:	No	Yes	Date & Details:									
Other Surgical Procedures:	Date & Details:											
ICU Admission	No	Yes	Date & Details:									
Post-operative Complications	No	Yes	Date & Details *(eg wound infection, MI, bladder, pressure area*):									
Acute Facility:		Admission Date:				Discharge Date:						
SPC Inpatient Rehabilitation	No	Yes	Admission Date/s:			Discharge Date/s:						
WellTel:	No	Yes	Admission Date/s:			Discharge Date/s:						
SPC Outpatient	No	Details:		Yes	Start Date:		Discharge Date:					
Amputee Study Information & Consent		Mobility Chart		Education Booklet		Exercise Card		Wheelchair		Shoes & gym clothes		
Goal Setting Meeting Date:		CMP		Discharge Summary		Volunteer Transport						

PMH:										
Peripheral Arterial Disease:	No	Yes	Hypertension:	No	Yes	Hypercholesteraemia:	No	Yes		
Remaining Limb Pathology:	No	Yes	Vascular Surgery *(eg angiogram, angioplasty, FPBG, stents)*:							
			Claudication Pain:							
			Ulcers:							
			Other:							
Diabetes	Type 1	Type 2	Diabetic Complications:							
				Retinopathy						
				Peripheral Neuropathy						
				Nephropathy						
				Cardiovascular						
				CVA						
				Other						
Renal Failure:	No	Yes	Details:							
				Haemodialysis:						
				Peritoneal Dialysis:						
				Renal Transplant:						
Cardiovascular Disease:	Details:									
Acquired Brain Injury:	No	Yes		Traumatic Brain Injury						
				CVA						
Other Neurology:										
Respiratory Disease:		COPD		Interstitial Lung Disease		Other:				
	Non-Smoker:		Ex-smoker, quit:			Smoker:				
Eyesight:	Hearing:		Cognition:							
Arthritis:		Osteoarthritis:		Rheumatoid Arthritis:		Gout	Other:			



Musculoskeletal Injuries & / or Multiple Trauma:

Weight Bearing Precautions:

Mobility Pre-operatively:	Distance:	Aids:	Limiting Factors:

The Locomotor Capabilities Index 5

Initial Assessment Mobility 6 months Pre-amputation **Date Assessed:** _____

For face-to-face interview: subjects to be asked "Whether or not you wear your prosthesis, at the present time, would you say that you are "able" to do the following activities WITH YOUR PROSTHESIS ON?"

ITEM			***SCALE***		
1. Get up from a chair	0	1	2	3	4
2. Walk in the house	0	1	2	3	4
3. Walk outside on even ground	0	1	2	3	4
4. Go up the stairs with a handrail	0	1	2	3	4
5. Go down the stairs with a handrail	0	1	2	3	4
6. Step up a sidewalk curb	0	1	2	3	4
7. Step down a sidewalk curb	0	1	2	3	4
Basic activities score ___/28					
1. Pick up an object from the floor (when you are standing up in your prosthesis)	0	1	2	3	4
2. Get up from the floor (e.g. if you fell)	0	1	2	3	4
3. Walk outside on uneven ground (e.g. grass, gravel, slope)	0	1	2	3	4
4. Walk outside in inclement weather (e.g. snow, rain, ice)	0	1	2	3	4
5. Go up a few steps (stairs) without a handrail	0	1	2	3	4
6. Do down a few steps (stairs) without a handrail	0	1	2	3	4
7. Walk while carrying an object	0	1	2	3	4
Advanced activities score ___/28					
TOTAL SCORE ___/56					

0 = No

1 = Yes with help

2 = Yes with supervision

3 = Yes, alone, with ambulation aids

4 = Yes, alone, without ambulation aids

Franchignoni, et al (2004)

The Locomotor Capabilities Index 5

3 months post-operatively & Discharge **Date Assessed:**

_____

For face-to-face interview: subjects to be asked "Whether or not you wear your prosthesis, at the present time, would you say that you are "able" to do the following activities WITH YOUR PROSTHESIS ON?"

ITEM			***SCALE***		
1. Get up from a chair	0	1	2	3	4
2. Walk in the house	0	1	2	3	4
3. Walk outside on even ground	0	1	2	3	4
4. Go up the stairs <u>with</u> a handrail	0	1	2	3	4
5. Go down the stairs <u>with</u> a handrail	0	1	2	3	4
6. Step up a sidewalk curb	0	1	2	3	4
7. Step down a sidewalk curb	0	1	2	3	4
Basic activities score ___/28					
1. Pick up an object from the floor (when you are standing up in your prosthesis)	0	1	2	3	4
2. Get up from the floor (e.g. if you fell)	0	1	2	3	4
3. Walk outside on uneven ground (e.g. grass, gravel, slope)	0	1	2	3	4
4. Walk outside in inclement weather (e.g. snow, rain, ice)	0	1	2	3	4
5. Go up a few steps (stairs) <u>without</u> a handrail	0	1	2	3	4
6. Do down a few steps (stairs) <u>without</u> a handrail	0	1	2	3	4
7. Walk while carrying an object	0	1	2	3	4
Advanced activities score ___/28					
TOTAL SCORE ___/56					

0 = No

1 = Yes with help

2 = Yes with supervision

3 = Yes, alone, with ambulation aids

4 = Yes, alone, without ambulation aids

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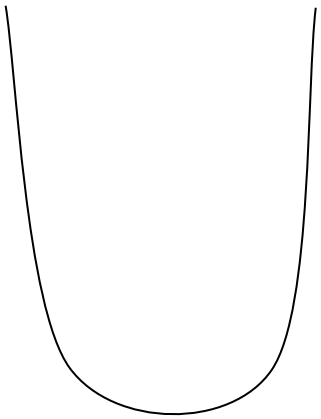
OBJECTIVE ASSESSMENT: **Pre-Prosthetic**

	Stump Description (*eg scab, slough, SSG, circulation*): Sutures / Staples Removal Date/s: Sensation: Scar Tissue:

Oedema Description			Date Commenced
Management		Bandage	
		Shrinker	
		RRD	
		Compression Pump	
		Massage	
		Other	

Phantom Limb Sensation:	No	Yes	Description:

Pain Description & Pain Score 0-10:	Phantom Limb Pain	Neuropathic	Stump	Other:

Pain Management:	Date Commenced
Medications	
Massage & Desensitisation Techniques	
Mirror Box	
Recognise CD	
TENS	
Other:	

Remaining Limb Details *(eg toe amputation, ulcers, claudication pain, Charcot foot, altered sensation ABI's)*:

Lower Limb ROM Date:	Left	Right		Left	Right	Other Joint ROM:
Thomas Test / Modified Thomas Test			Knee Extension			
Prone Hip Extension:			Knee Flexion			
Hip Flexion			Ankle Dorsiflexion			
Hip abduction			Ankle Plantarflexion			
Hip adduction			Ankle Inversion			
Hip Internal / External Rotation			Ankle Eversion			

Muscle Strength Date:	Left	Right	**Functional Strength & Endurance Date:**		
Hip extensors:				Achieved Task	No. of Repetitions
Hip Flexors:			Single Limb Calf Raise:		
Hip abductors:			Squat:		
Hip adductors:			Hop:		
Knee extensors:			Tricep Paddles:		
Knee flexors:			Upper Limb Strength:	Abdominal Strength:	
Plantar flexors:					
Dorsiflexors:					
Ankle Invertors / Evertors:					
Toe DF /PF's:					

Bed Mobility:	**Transfer:**
Bridging:	Pivot
Rolling:	Slide Board
Supine to Sitting:	Bottom Shuffle *(eg Forwards-Backwards, Sideways)*
Bottom walking:	Other:

Wheelchair Manipulation:				Indoors:	Outdoors:	Slopes:
	MWC		EWC			

Sitting Balance & Posture:

Single Limb Balance & Posture:	Timed Standing Balance (TFA & KD):

Hopping	No	Yes	Date Out of Parallel Bars:	Aid used:	Stairs:

Floor Transfer & mobility:

Kneeling / Knee walking:

Other:

OBJECTIVE: **Post-prosthetic & Outcome Measures**

Casting Date:	Fitting Date:	Prosthesis type:
Donning, doffing, monitoring fit:		

In The Parallel Bars:	**Date:**	**Date:**	**Date:**	**Date:**
Weight + Prosthesis				
Weight Through Prosthesis (3s)				
% Weight Borne				
NPRS (0-10/10)				

Observational Gait Analysis:	
Date First Out of the Parallel Bars: Aid Used:	Date Prosthesis First Taken Home:

AMPUTEE OUTCOME MEASURES					
10MWT:	**Date:**	**Date:**	**Date:**	**Date:**	**Date:**
Aid Used					
Mean Time (s)					
No. of Steps					
Velocity (ms^{-1})					
TUGT:	**Date:**	**Date:**	**Date:**	**Date:**	**Date:**
Aid Used					
Total Time (s)					
E/C's on/off Time					
Carrying Cup					
6MWT:	**Date:**	**Date:**	**Date:**	**Date:**	**Date:**
Aid Used					
Distance (m)					
Time & No. of Rests					
RPE					
4SST:	**Date:**	**Date:**	**Date:**	**Date:**	**Date:**
Aid Used					
Time (s)					

Walking Environment Progress:	High Level Balance:
Indoors:	Stepping onto Prosthetic Limb:
Stairs:	Balance on Prosthetic Limb:
Outdoors:	Jumping:
Grass:	Hopping:
Slopes:	Dual Task:
Gravel:	Running Drills:
Floor Transfer with Prosthesis:	Running:

Team Meeting & Discharge Planning:

Date:	Information:	Discharge Planning:
		Discharge Date: Discharge Destination: Care Management Plan: Physiotherapy Follow-up: Physiotherapy Days: Telehealth: Clinic Appointment: Volunteer Transport: Other (eg hydrotherapy referral):

Appendix 8.3: Data Retrieval Tool

Data Retrieval Tool for Amputee Patient Notes

Category	Data											
Subject Code:	DOB:			Age at Amputation:			Date of Death:					
Gender:		Male		Female	Indigenous Status:	1	A not TSI	2	TSI not A	3	A & TSI	4	Not TSI or A
Home Location:	Post Code:		Metropolitan suburb									
			Rural									
			Remote Community									
			Interstate									
			Overseas									
Pre-operative Education:	No	Yes	Details:									
MicroAlert Card	No	Yes	Details:									
Amputation Date/s:											ASA Score	
Amputation Side:	Left								Right			
Amputation Level:	TTA		TFA		Other:							
Revision Surgery of Amputation Level:	No	Yes	Revision Dates & Details:									
Surgical Procedures:	No	Yes	Dates & Details:									
Bilateral Amputee:	No	Yes	Details, Date of Contralateral Limb Amputation:									
Upper Limb Amputation:	No	Yes	Details:									
Amputation Cause:		Circulatory										
		Infective										
		Trauma										
		Neoplasm										
		Other:										
Acute Hospital:	RPH-WSC		SCGH		FHHS		Other:					
Acute Inpatient Episode:	Admission Date:				Discharge Date:							
					LOS:							
Inpatient SPC Rehabilitation Episode:	No	Yes	Admission Date:		Discharge Date:							
					LOS:							
WellTel Episode:	No	Yes	Admission Date:		Discharge Date:							
			Number of admissions:		LOS:							

Stump Wound	No	Yes	Stump Wound Infection	
	No	Yes	Stump Circulation (eg poor blood supply, haemorrhage)	
	No	Yes	Delayed Healing (> 21 Days)	Time to healing:
	No	Yes	Stump Trauma (eg haematoma from fall or bump)	
	No	Yes	Split Skin Graft	
Residual Limb Characteristics:	Wound (eg sutures, staples, eschar, slough, hypergranualtion)			
	Length (eg short, normal, long)			
	Shape (eg normal, dog ear, bulbous)			
	No	Yes	Special Surgical Techniques (eg bony fusion Tibia To Fibula)	
	No	Yes	Stump complications (eg blisters, ulcers, fragile skin, scar tissue, heterotrophic ossification)	
Sutures	Removal Date:			
ICU Admission	No	Yes	Dates & Details:	
Post-operative Complications	No	Yes	Wound Infection	
	No	Yes	Circulatory (eg ischaemic stump, DVT, PE, haemorrhage, CVA)	
	No	Yes	Cardiac (eg MI, heart failure etc)	
	No	Yes	Respiratory Complications (eg pneumonia, Respiratory Failure)	
	No	Yes	Organ Failure (eg Renal failure, other)	
	No	Yes	Sepsis	
	No	Yes	Bladder complications	
	No	Yes	Hypoglycemia	
	No	Yes	Other (eg pressure sore)	

Traumatic Amputee	No	Yes	Injury List:
Comorbidities / PMH:	No	Yes	List:
Smoking	No	Yes ___/day	Ex-smoker quit _____
Alcohol Excess	No	Yes	Details:
Drug Abuse	No	Yes	Details:
Hypercholesterolaemia	No	Yes	
Hypertension	No	Yes	
Obesity	No	Yes	
Peripheral Arterial Disease	No	Yes	
Cardiovascular Disease	No	Yes	
Lung Disease	No	Yes	COPD
	No	Yes	Interstitial Lung Disease
	No	Yes	Home Oxygen
	No	Yes	Other
AAA	No	Yes	Details:

Diabetes		No	Yes	Type 1	Type 2	
Diabetic Complications	Microvascular	No	Yes	Peripheral Neuropathy:	Lower Limbs	Upper Limbs
		No	Yes	Charcot Foot:		
		No	Yes	Retinopathy:		
		No	Yes	Nephropathy:		
	Macrovascular	No	Yes	Peripheral Vascular Disease:		
		No	Yes	Cardiovascular Disease:		
		No	Yes	CVA:		
		No	Yes	Bladder:		
		No	Yes	Other:		
Renal Failure		No		Yes		
		No	Yes	Peritoneal Dialysis		
		No	Yes	Haemodialysis		
		No	Yes	Renal Transplant		
Acquired Brain Injury		No	Yes	CVA		
		No	Yes	Traumatic Brain Injury		
Cognitively Impaired		No	Yes	MMSE / Other:		
Cancer		No	Yes	Details:		
Remaining Limb Pathology		No	Yes	Toe, forefoot or other amputation		
		No	Yes	Pressure sores, Ulcers		
		No	Yes	Claudication pain		
		No	Yes	Vascular Surgery – bypass graft, angioplastly, stent, other		
		No	Yes	Neuropathic foot / Peripheral neuropathy Details:		
		No	Yes	Charcot foot		
		No	Yes	Orthopaedic Surgery (eg TKR, THR)		
		No	Yes	Orthopaedic Injuries Weight bearing precautions / other		

	No	Yes	Contracture (eg hip, knee, ankle joint)	
	No	Yes	Other:	
Ankle Brachial Indexes	No	Yes	Left Lower Limb	Right Lower Limb
Musculoskelatal Injuries	No	Yes	Upper Limb Injuries with weight bearing precautions	
	No	Yes	Shoulder Pain	
	No	Yes	Back Pain	
	No	Yes	Hip Pain	
	No	Yes	Knee Pain	
	No	Yes	Arthritis (eg OA, RA, gout)	
	No	Yes	Other	
Vision	No	Yes	Normal	
	Deficit Details:			
Hearing	No	Yes	Normal	
	Deficit Details:			
Pre-operative mobility	Distance Walked			
	No	Yes	Walking Aid	
	No	Yes	Limiting Factors	
Falls	No	Yes	Pre-operative	
	No	Yes	Post-operative	
	No	Yes	Post-prosthetic fitting	
LCI	Results			
Wheelchair mobility at inpatient discharge	No	Yes	Independent all environments *If assistance, details:*	
Transfer at inpatient discharge	No	Yes	Pivot	
	No	Yes	Slide board	
	No	Yes	Bottom shuffle (forwards, sideways, backwards)	
Hop	No	Yes	Independent, Aid Used:	
	No	Yes	Stairs	

Floor transfer & mobility	No	Yes	Bed to floor	
	No	Yes	Wheelchair to floor	
	No	Yes	Floor mobility (eg Bottom walking, crawling, knee walking)	
	No	Yes	Other (eg step to floor)	
Interim Prosthesis	No	Yes	Details:	
	No	Yes	Casting Date:	Time to Casting:
	No	Yes	Fitting Date:	Time to Fitting:
Donning / Doffing / monitoring fit of prosthesis	No	Yes	Independent	
	If No, state assistance level			
10MWT	Results			
TUGT	Results			
6MWT	Results			
FSST	Results			
Prosthetic Gait at Discharge from SPC:	No	Yes	Independent	
	If No, state assistance level			
	Aids used			
	No	Yes	Independent indoors	
	No	Yes	Independent outdoors on concrete	
	No	Yes	Independent up and down stairs	
	No	Yes	Independent on slopes	

	No	Yes	Independent on grass			
	No	Yes	Independent on gravel, uneven terrain			
	No	Yes	Independent at high level balance activities (eg single prosthetic limb balance, hopping, jumping, dual tasks & walking)			
	No	Yes	Running			
	No	Yes	Other			
Social Support at discharge	No	Yes	Lives alone			
	No	Yes	Spouse or partner			
	No	Yes	Other (eg carer, son, daughter, sister, brother, mother, father)			
Destination Discharged To:	No	Yes	Home			
	No	Yes	Hostel			
	No	Yes	Nursing Home			
	No	Yes	Hospital Transfer, Details:			
	No	Yes	Other			
Outpatient Physiotherapy	No	Yes	SPC Outpatients	Number of sessions		
	No	Yes	WellTel			
	No	Yes	Referral to country outpatient physiotherapy			
	No	Yes	Referral to other outpatient physiotherapy			
Telehealth	No	Yes	Dates			
Definitive Prosthesis Prescription Date:	Last SPC Amputee Clinic Date:					
Definitive Manufacturer	FOS		TLC	SWOPS	Other	
Clinic attendance at SCGH or FHHS	No	Yes	Details			

Appendix 8.4 Table 8.3: Summary of comorbidities and procedures for a cohort with lower limb amputation (n = 201) at hospital admission.

Table 8.3: Summary of comorbidities and procedures for a cohort with lower limb amputation (n = 201) at hospital admission.

Comorbidity or procedure	n (%)
Diabetes	93 (46.3)
Type 1	12 (6)
Type 2	81 (40.3)
Macrovascular complications of diabetes	
Stroke / TIA	17 (8.5)
Peripheral Arterial Disease	67 (33.3)
Ischaemic Heart Disease	40 (19.9)
Microvascular complications of diabetes	
Peripheral neuropathy	62 (30.8)
Retinopathy	32 (15.9)
Nephropathy	38 (18.9)
Renal failure	32 (15.9)
Autonomic neuropathy	1 (0.5)
Charcot arthropathy	8 (4.0)
Cardiovascular disease	
IHD	62 (30.8)
Heart failure	16 (8)
Cardiomyopathy	4 (2.0)
Arrhythmias	13 (6.5)
Angina	7 (3.5)
Peripheral arterial disease	105 (52.2)
Abdominal Aortic Aneurysm	2 (1.0)
Hypertension	103 (51.2)
Hypercholesterolaemia	81 (40.3)
Cerebrovascular disease / CAD	7 (3.5)
DVT	10 (5.0)
PE	5 (2.5)
Surgical Procedures	
Cardiac surgery	
CABG	21 (10.4)
Coronary angioplasty or stents	9 (4.5)
Permanent Pacemaker	2 (1.0)
Mitral or Aortic valve replacement	4 (2.0)
Lower limb Revascularisation surgery	
Bypass graft surgery	26 (12.9)
Angioplasty	9 (4.5)
Stents	9 (4.5)
Endarterectomy	4 (2.0)
Thrombectomy	1 (0.5)
Abdominal Aortic Aneurysm repair	4 (2.0)
Carotid endarterectomy	7 (3.5)
Previous amputation surgery to lower or upper limbs	
Toe amputation	19 (9.5)
Transmetatarsal or Transtarsal amputation	5 (2.5)
Transtibial amputation	6 (3.0)
Knee disarticulation	1 (0.5)
Transfemoral amputation	0 (0)
Upper limb amputations	3 (1.5)

Comorbidity or procedure	n (%)
Respiratory Disease	
COPD	12 (6.0)
Asthma	18 (9.0)
Bronchiectasis	3 (1.5)
Asbestosis & Interstitial lung disease	5 (2.5)
OSA	6 (3.0)
Pneumonia	6 (3.0)
ARDS	1 (0.5)
Aspergillous	1 (0.5)
Sarcoidosis	1 (0.5)
Rheumatologic Disease	
OA	48 (24)
RA	11 (5.5)
SLE	2 (1.0)
Gout	22 (10.9)
Septic arthritis	3 (1.5)
Musculoskeletal Pathology	
Back pathology	45 (22.4)
Neck Pathology	6 (3.0)
Hip pathology	16 (8.0)
Knee pathology	51 (25.4)
Ankle pathology	3 (1.5)
Shoulder pathology	51 (25.4)
Elbow pathology	8 (4.0)
Wrist pathology	9 (4.5)
Hand or Finger	14 (7.0)
Upper limb fractures	10 (5.0)
Lower limb fractures	19 (9.4)
Lower limb deformity	7 (3.5)
Osteoporosis	9 (4.5)
Orthopaedic procedures	
Total hip replacement	8 (4.0)
Total knee replacement	15 (7.5)
Total ankle replacement	5 (2.5)
Ankle fusion	4 (2.0)
Total shoulder replacement	1 (0.5)
ACL reconstruction	4 (2.0)
Spinal fusion	6 (3.0)
Falls	6 (3.0)
Neurological Disease	
Stroke	12 (6)
TIA	5 (2.5)
Traumatic Brain Injury	3 (1.5)
Brain tumour	1 (0.5)
Epilepsy	6 (3.0)
Polio	1 (0.5)
Dementia or mild cognitive impairment	11 (5.5)
Intellectual disability	2 (1.0)
Renal failure	32 (15.9)
Renal impairment	38 (18.9)
Renal transplant	5 (2.5)

Comorbidity or procedure	n (%)
Skin disorders	
Toe, foot and leg ulcers	67 (33.3)
Burns to feet	3 (1.5)
Cellulitis of lower limbs	12 (6.0)
Cancer	18 (9.0)
Mental Illness	
Depression	27 (13.4)
Anxiety or panic disorders	7 (3.5)
Schizophrenia	1 (0.5)
Attempted suicide or self harm	2 (1.0)
Substance Abuse (current or past use)	16 (8.0)
ETOH (current or past use)	24 (11.9)
Smoking	51 (25.4)
Ex-smoker	61 (30.3)
Visual impairment	22 (10.9)
Cataract	20 (10.0)
Hearing impairment	17 (8.5)
Gastrointestinal disease	
Bowel cancer	8 (4.0)
Hernia	5 (2.5)
Peptic ulcer disease	5 (2.5)
Liver failure	0 (0)
Hepatitis	4 (2.0)
Alcoholic liver disease	2 (1.0)
GORD	16 (8.0)
Colonic polyps	4 (2.0)
Procedures	
Hernia repair	4 (2.0)
Bowel surgery	8 (4.0)
Appendicectomy	10 (5.0)
Cholecystectomy	7 (3.5)
Obesity and or body mass index > 30	41 (20.4)
Sepsis	3 (1.5)
Hypothyroidism	8 (4.0)
AIDS	0 (0)
Pain disorders	
Complex regional Pain Syndrome	3 (1.5)
Chronic headaches	3 (1.5)
Neuropathic leg pain	3 (1.5)

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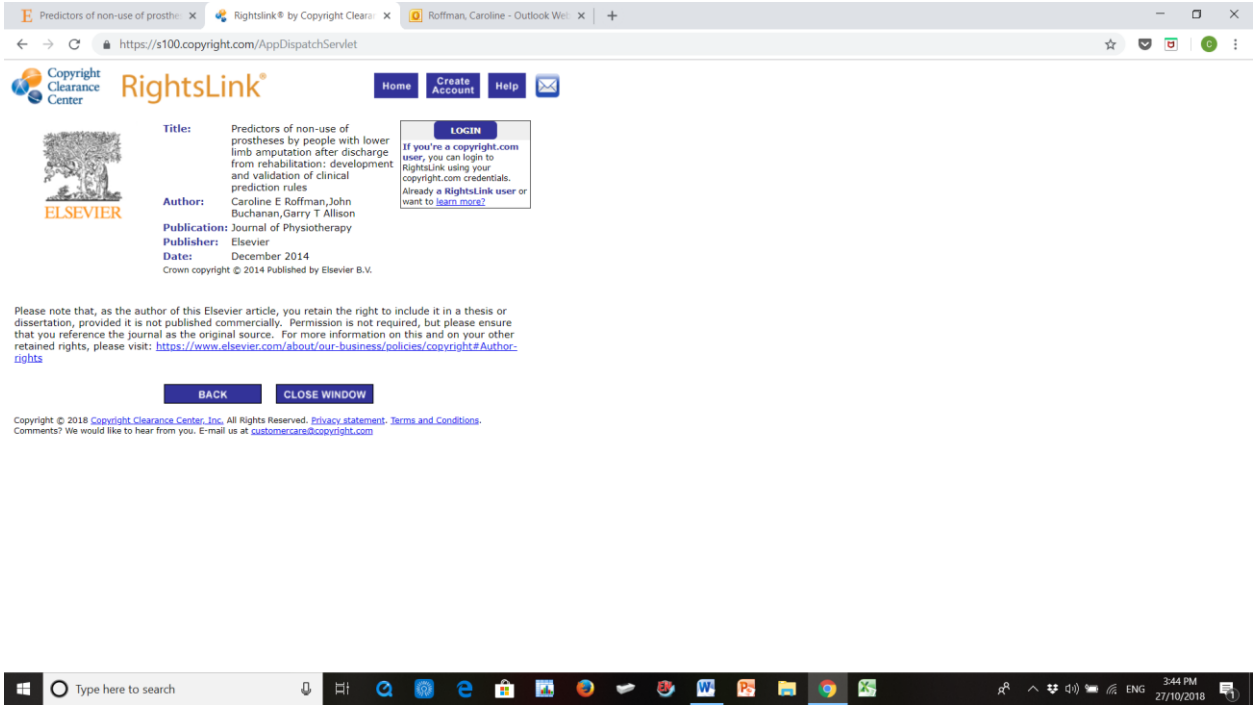
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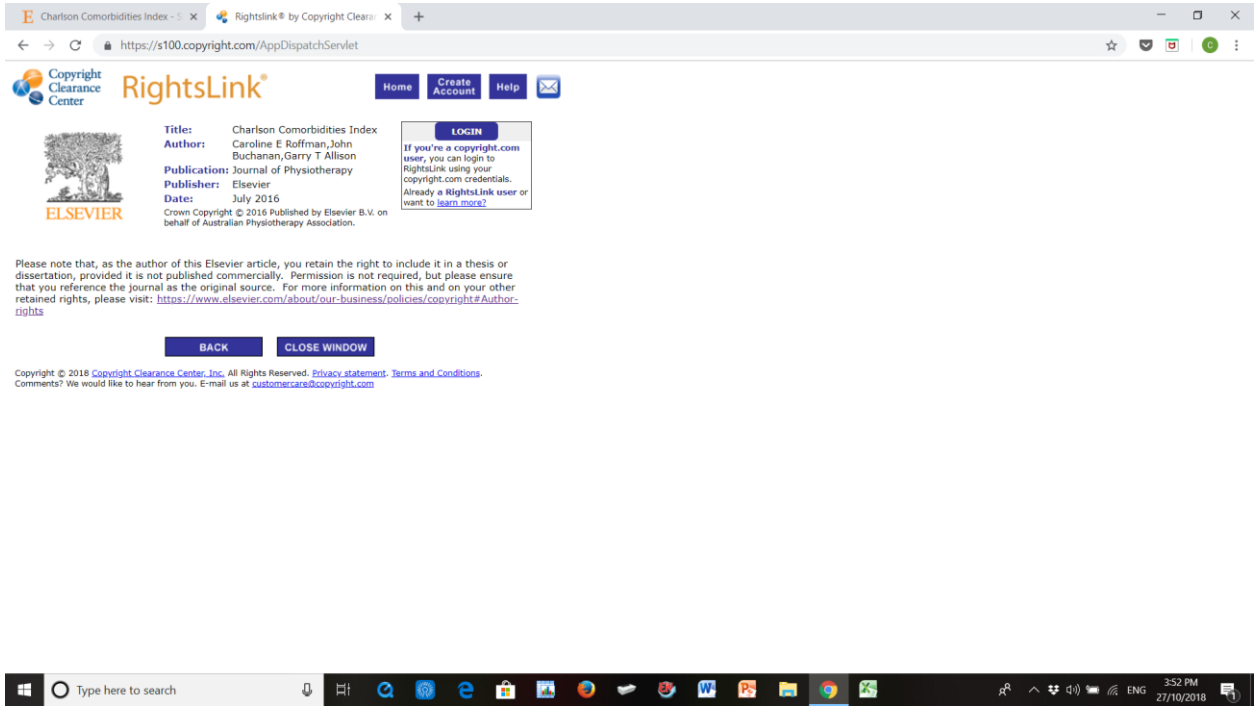
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