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Davie-Smith, Fiona (2017) *Factors influencing quality of life after lower extremity amputation for peripheral arterial occlusive disease.* PhD thesis.

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Factors Influencing Quality of Life after Lower Extremity Amputation for Peripheral Arterial Occlusive Disease

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Submitted in fulfilment of the requirements of the Degree of Philosophy

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March 2017

Abstract

Background

Recent literature suggests that 84% of lower extremity amputations (LEAs) are due to peripheral arterial occlusive disease (PAOD), and half of those will have diabetes. Only 40% will go on to rehabilitate with a prosthetic limb and the remainder will be wheelchair dependent. Until now, the majority of research has focused on the short-term clinical outcomes in this population e.g. prosthetic fitting, morbidity and mortality rates. There is a dearth of research into the long-term impact of a LEA on the individual's quality of life (QoL), especially in those with PAOD with or without diabetes.

Aim

This thesis aims to determine which factors influence QoL after an LEA due to PAOD in the presence or absence of diabetes.

Methods

A prospective review of medical case notes and other relevant documentation was conducted on all patients who underwent a major lower extremity amputation for PAOD in NHS Greater Glasgow and Clyde in Scotland, between 1st March 2014 and 28th February 2015. Patients who consented to follow-up completed the EQ-5D-5L QoL measure, Reintegration into Normal Living (RNLI) and the Prosthetic Limb Users Survey of Mobility (PLUS-M), 6 and 12 months after LEA. Semi-structured interviews were conducted on 15 participants who completed follow up questionnaires to explore their views and experiences of living with a LEA and to understand which factors influence their QoL.

Results

There were 171 participants with a LEA in one year and their mean age was 66.2 years, 75% were males and 53% had diabetes. Over two thirds of the cohort lived in the two most deprived areas in Glasgow. From the follow up questionnaires (n=101) participation, measured by the RNLI had the greatest influence on QoL six and twelve months after LEA. Limb fitting positively influenced QoL, however, level of mobility was poor for all levels of LEA and there was a positive association between mobility (PLUS-M) and QoL. Mortality was seven times greater in those who were not limb fitted. Face-to-face interviews identified five broad themes that influenced QoL: the prosthesis; experience of

pain; social support/isolation; sense of self/identity and interactions with others with an amputation.

Conclusion

Quality of Life was influenced by several factors, primarily participation, which was improved if limb-fitted. Those of male gender, younger age and diagnosed with diabetes were more likely to have a prosthesis fitted. While having a prosthesis did not determine QoL per se, those with greater levels of mobility were more likely to be able to participate, feel less isolated and require less social support which afforded them greater levels of QoL. Conversely, those who were wheelchair dependent or had poorer levels of prosthetic mobility reported lower levels of QoL; which was associated with dependence on social support, feelings of isolation and changes in the way they felt about themselves.

(Word count- 55,377)

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Acknowledgements

There have been many people who have made it possible for me to complete this piece of work and I wish to thank them for all their help, support and encouragement over the past few years. To my supervisors, Professor Lorna Paul, Dr Brian Kennon and Professor Sally Wyke, thank you for your time, expertise and constant support and advice which has been indispensable. Particular thanks to Lorna, without you I would have never have undertaken this work and have progressed in my career; you have kept me on the right path and have always been there day and night, for which I am truly grateful.

This PhD study would not have been possible without the participants who have generously given their time. I have learned so much from them and have completely changed my view of what is important in life after amputation. In addition, they have been a constant source of inspiration and have always been encouraging and engaged in the project and for that I am very appreciative.

Thanks go to the physiotherapy team at the Vascular Unit, Linsay and Ann, and the physiotherapy and prosthetic team at the limb fitting centre, particularly Joanne and Elena, all of whom were vital in ensuring that I was able to recruit. There have also been many steering group meetings and I thank all the clinicians who gave their time and advice.

People tell you that the PhD experience is a lonely one and I am fortunate to never have found this to be the case. This is due to my dear colleagues and friends at the University of Glasgow without whom I would definitely not be sitting writing this. The writers retreats and gin tasting nights have been invaluable and special thanks go to: Dr Elaine Coulter -we will always have Thailand; Dr Clare McFeely- we will always have the Bank Street Café; Kath Sharp- we will always have early mornings at the library and late nights with sherry; and Kath….you're next!

Finally to Malcolm, always the voice of reason, whom I dedicate this thesis to and am very much looking forward to spending time with.

Declaration

I declare that, except where explicit reference is made to the contribution of others, this thesis is the result of my own work and has not been submitted for any other degree at the University of Glasgow or any other institution.

Fiona Davie-Smith

List of Publications

Papers

Davie-Smith, F., Coulter, E., Kennon, B., Wyke, S. and Paul, L., 2017. Factors influencing quality of life following lower limb amputation for peripheral arterial occlusive disease: A systematic review of the literature. *Prosthetics and Orthotics International*. doi: 10.1177/0309364617690394.

Conference Proceedings

Oral

Davie-Smith F, Paul L, Stuart W, Kennon B, Young R. 2016. Quality of life and mobility following Lower Extremity Amputation in different Socioeconomic groups. Vascular Societies Annual Scientific Meeting. (Awarded Richard Wood Prize)

Davie-Smith F. 2016. Which Factors Influence Quality of Life After Lower Extremity Amputation. Foot in Diabetes UK Conference and Exhibition.

Davie-Smith F. 2016. Functional & Rehabilitation Outcomes Following Major Lower Limb Amputation. Podiatry Symposium "Bring Legs to Life".

Davie-Smith F. 2016. Good Quality of Life: A Patients Perspective. Scottish Physiotherapy Amputee Research Group Conference.

Davie-Smith F, Kennon B, Wyke S, Stuart W, Paul L. 2016. Quality of Life, Social Integration and Mobility Six Months after Amputation: A comparison between those with and without Diabetes. Diabetes UK Professional Conference. (Shortlisted for AHP Award)

Davie-Smith F. 2016. Quality of Life of the Glasgow Amputee Population. All Party Parliamentary Group on Vascular Disease.

Davie-Smith F. 2015. The Glasgow Amputee Population: pre, peri and post- amputation. British Association of Chartered Physiotherapists in Amputee Rehabilitation Conference (Awarded Louise White Prize)

Davie-Smith F. 2015. A Systematic Review of Quality of Life (QOL) of Amputees. World Confederation of Chartered Physiotherapists Congress.

Poster

Davie-Smith F, Kennon B, Wyke S, Stuart W, Paul L. 2016. Quality of Life of the Glasgow Amputee Population. NHS Scotland Event.

Davie-Smith F, Kennon B, Wyke , Stuart W, Paul L. 2015. To compare demographic and clinical characteristics of those with and without diabetes that undergo a lower extremity amputation in Glasgow, UK. World Confederation of Chartered Physiotherapists Congress.

List of Abbreviations

The following abbreviations were used in this thesis:

ADL	Activities of Daily Living
DM	Diabetes Mellitus
eGFR	Glomerular Filtration Rate
EWA	Early Walking Aid
FCI	Functional Comorbidities Index
HbA1c	Glycated Haemoglobin
LCI-5	Locomotor Capabilities Index-5
LEA	Lower Extremity Amputation
NHS GG&C	NHS Greater Glasgow & Clyde
PAOD	Peripheral Arterial Occlusive Disease
PLUS-M	Prosthetic Limb User Survey of Mobility
PPAM Aid	Pneumatic Post Amputation Mobility Aid
QoL	Quality of Life
RNLI	Reintegration to Normal Living Index
TFA	Trans-femoral amputation
TKA	Through knee amputation
TMA	Trans-metatarsal amputation
TTA	Trans-tibial amputation
SIMD	Scottish Index of Multiple Deprivation
SPARG	Scottish Physiotherapy Amputee Research Group
WHO	World Health Organisation

Chapter 1
Introduction

Lower Extremity Amputations (LEA) are performed for various reasons e.g. tumour, trauma, congenital abnormalities, orthopaedic complications or due to Peripheral Arterial Occlusive Disease (PAOD). Global incidence of major LEA ranges from 3.6 to 68.4 per 100,000 of the total population, and in the UK, incidence is 3.9 to 7.2 per 100,000 of the population (Moxey *et al.* 2011).

A lower extremity amputation is a permanent disabling surgery; when performed because of PAOD it is often lifesaving and pain relieving, and is undertaken to improve the overall health of an individual. However, this comes at the cost to the individual in terms of affecting their ability to function on a daily basis. Lower extremity amputations also have wider implications, as they are associated with increased levels of anxiety and depression, altered body image and social discomfort, all of which are a psychological burden for the patient and their family (Horgan and MacLachlan 2004).

The most common cause of LEA is Peripheral Arterial Occlusive Disease (PAOD) (Scott 2012). Approximately 85% of LEAs that are undertaken globally are due to PAOD, and approximately 50% of those will have diabetes (Tentolouris *et al.* 2004, Moxey *et al.* 2011). Peripheral Arterial Occlusive Disease reduces the blood supply to the lower limbs and is prevalent in 12-14% of the population (Norgren *et al.* 2007, Al-Qaisi *et al.* 2009). Diabetes is also associated with poor peripheral arterial supply to the lower limbs (Davis *et al.* 2004, Chen *et al.* 2011). LEA occurs in those with diabetes most commonly due to diabetic foot disease, where accidental trauma of the lower limb leads to ulceration or ischaemia due to a compromised vasculature system. Currently there are approximately 2.6 million people with diabetes in the UK and this disease is becoming more prevalent (Diabetes 2015).

Lower extremity amputations represent a significant financial burden on the health service, with costs for in-patient care estimated to range from £20,000 to £50,000 per person (Ollendorf *et al.* 1998). Additionally, there is a significant longer term economic impact as rehabilitation and social care are required (Ebskov 2006). The annual NHS cost of LEAs

(not including rehabilitation or social care) is estimated to be £50-£75 million, or 0.5% of the NHS budget (Moxey *et al.* 2010).

Fifty to sixty percent of those who have LEAs due to PAOD with or without diabetes have a life expectancy of two years post amputation; which in many cases is a poorer long term prognosis than lung cancer patients (Davis *et al.* 2004). Five years post LEA, mortality rates range from 52% to 80% (Thorud *et al.* 2016). Proximal LEAs at the trans-femoral level and increasing age are associated with increased mortality (Thorud *et al.* 2016). Furthermore, a LEA in the presence of diabetes increases the risk of mortality by 55% compared to those who have a LEA for PAOD alone (Inderbitzi *et al.* 2003, Schofield *et al.* 2006, Heikkinen *et al.* 2007).

Life after a LEA is inextricably altered as only 40% will go on to rehabilitate with a prosthetic limb and the remainder will be wheelchair dependent. This will fundamentally impact upon a person's ability to function indoors and outdoors and subsequently affect their Quality of Life (QoL). Until now, the majority of research has focused on the short term clinical outcomes in this population and have considered prosthetic fitting, morbidity and mortality rates. There is a dearth of research into the long-term impact of a LEA on the individual's QoL, especially in those with PAOD with or without diabetes. This thesis aims to provide new knowledge as to how an LEA affects a person's quality of life up to 12 months after amputation.

1.1 Investigations central to this thesis

This thesis will present three related studies, involving those with a LEA due to PAOD in the presence or absence of diabetes. The research project was undertaken in collaboration with the University of Glasgow, NHS Greater Glasgow & Clyde and Diabetes UK. The funding for the research was provided through a Diabetes UK Sir George Alberti Fellowship.

1.2 Aims of the investigations

The overall aim of the research presented here was to identify and examine the factors that influence a person's QoL after a LEA.

1.3 Research questions
Primary research question:

1a) Is QoL affected by an LEA?

1b) Which factors influence QoL after an LEA?

Secondary research questions:

2. What are the characteristics of the population who have a LEA?

3. What is the mortality rate following LEA and what factors are associated with mortality?

4. Does diabetes influence outcomes after LEA?

5. What are the rates of limb fitting and level of mobility achieved following LEA; and what factors are associated with this?

6. What are the views and experiences of people who had a LEA and which factors do they report as influencing their QoL?

To answer these questions, three studies were undertaken:

1) Systematic literature review
A systematic literature review, examined the factors influencing QoL following LEA for Peripheral Arterial Occlusive Disease (RQ1b).

2) Longitudinal cohort study
The findings from the systematic review guided the main study: a longitudinal cohort study of prospectively collected data on all those who underwent a LEA in one year due to PAOD in Greater Glasgow & Clyde (RQ2-5).

2b) Follow up questionnaires
In addition, those in the cohort who gave consent were followed up 6 and 12 months after a LEA to assess their participation, QoL and mobility if they had been fitted with a prosthesis (RQ 1a and 1b).

3) Face to face interviews

The final study involved in-depth interviews of a sub-group of this cohort and provided the opportunity to explore in more detail and depth the factors which influence QoL following a LEA (RQ 6).

1.4 Thesis guidance

The thesis commences with an explanation of the background to LEA including the pathophysiology of PAOD and diabetes; limb salvaging surgery; risk factors for LEA; level of LEA; patient pathway from LEA to discharge; limb fitting decision; prosthetics, mortality and socio economic influences (Chapter 2). The systematic literature review (Chapter 3) focuses on QoL after LEA due to PAOD. Chapters 4 and 5 describe the methods of the cohort study and the results respectively. Chapters 6 and 7 describe the methods employed for the face-to-face interviews and the subsequent findings. Finally, conclusions are drawn in Chapter 8 and the key findings and recommendations are discussed.

Chapter 2

Background to the literature

This chapter will describe the causes of lower extremity amputation (LEA), risk factors for LEA and implications from having this life altering surgery.

2.1 Lower extremity amputation

A lower extremity amputation (LEA) is performed as a consequence of disease or damage to the limb that has rendered it no longer viable; or because it is a threat to the morbidity and mortality of the person. A meta-analysis found that, globally, the prevalence of LEAs ranged from 3.6 to 68.4 per 100,000 of the population and in England, between 2003 and 2008, 5.1 per 100,000 of the population underwent a major LEA, figures which remained unchanged in the 5 years of the study (Moxey *et al.* 2010).

Lower extremity amputations are categorised as minor or major. A minor LEA is defined as an amputation through, or distal, to the ankle joint (Svensson *et al.* 2011). The removal of toes, forefoot (trans-metatarsal) or any excision of tissue below the ankle are commonly performed and allow a functional level of mobility post operatively (Uzzaman *et al.* 2011). A major LEA is defined as removal of the limb from the level of the ankle joint or above, i.e. trans-tibial amputation (TTA), through knee amputation (TKA), trans-femoral amputation (TFA), hip disarticulation (HD) and hemi-pelvectomy (HP) levels (Figure 2.1).
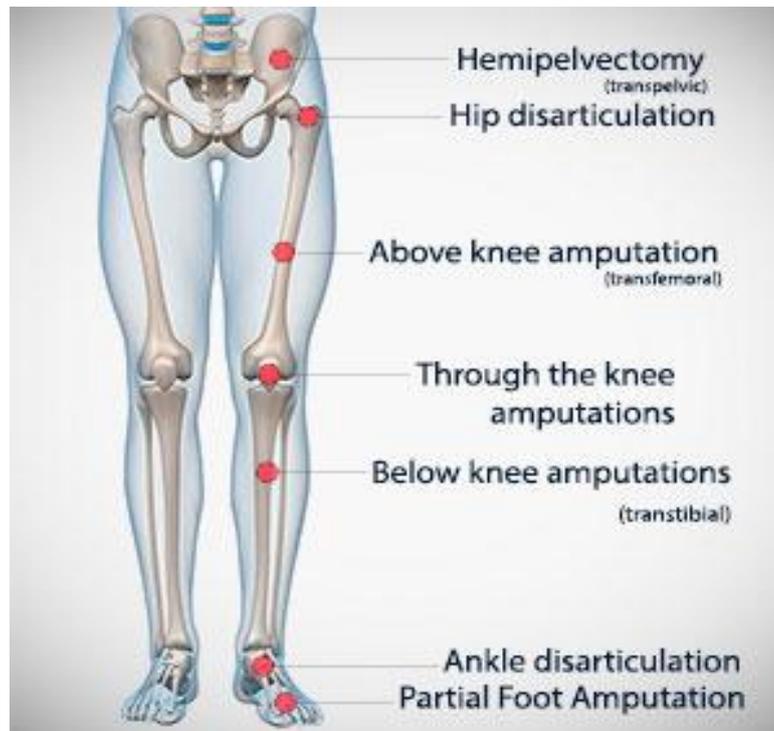
Figure 2.1 Lower extremity amputation levels.
Accessed 10.12.16 from http://www.cpousa.com/prosthetics/lower-extremity/.

The level of a major lower extremity amputation is often predetermined by the location of the injury or disease process. A major LEA will be performed due to trauma, tumour, congenital limb abnormalities, and orthopaedic complications but most commonly due to peripheral arterial occlusive disease (PAOD). The population who undergo a LEA due to PAOD will be the focus in this thesis.

Approximately 85% of LEAs in Scotland are due to PAOD (Scott 2012). The National Vascular Society of Great Britain and Ireland states the two most common levels of major LEA for PAOD patients are at the trans-tibial and trans-femoral levels. A recent audit of the National Vascular Registry of Great Britain and Ireland recorded 5318 major LEAs were performed between 1st January 2014 until 31st December 2015 due to PAOD; 60% were trans-tibial amputations (TTA) and 40% trans-femoral amputations (TFA) (Waton *et al.* 2015). However, as the registry relies on individual centres reporting, it is estimated that these figures only account for 55% of those actually performed, therefore the actual numbers of LEAs may be much greater.

The National Vascular Registry also reported that over half of those who have a LEA also have diabetes. Diabetes is the leading cause of LEAs across the globe (Carmona *et al.*

2005, Papazafiropoulou *et al.* 2009). Internationally, there are more people with diabetes than without diabetes undergoing a LEA, and those with diabetes have a 30 times greater risk of having a LEA compared to those without diabetes (Moxey *et al.* 2011). Approximately 2.9 million people in the UK have diabetes and with rising prevalence, so the number of people requiring LEAs is likely to increase (Diabetes UK: State of the nation 2012 report. http://www.diabetes.org.uk/Documents/Reports/State-of-the-Nation-2012.pdf).

The distribution of LEAs by aetiology is reported annually by the Scottish Physiotherapy Amputee Research Group (SPARG) (Table 2.1). This group conducts an annual national audit that reports on all major LEAs performed in Scotland and follows the progress of the person from LEA through to the end of their physiotherapy rehabilitation. This audit is mandatorily reported and quality checked with a 99% completion rate. The numbers of major LEAs in Scotland has remained relatively constant from 2009 to 2014, at 700 to 800 per annum. Rates of major LEAs in the rest of the UK are reportedly 6000 per annum and as stated above the majority of these are due to PAOD with over half also having a diagnosis of diabetes (Mayor 2014).

Table 2.1 Aetiology of lower extremity amputations in Scotland over a six-year period.

	2009	2010	2011	2012	2013	2014
Aetiology	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)
PAOD	44.6% (325)	43.2% (316)	46.2% (318)	43.7% (307)	42.6% (342)	39.3% (319)
PAOD + DM	39.0% (284)	45.4% (332)	39.0% (269)	42.0% (295)	43.7% (351)	46.6% (378)
Trauma	2.2% (16)	1.5% (11)	1.6% (11)	2.7% (19)	1.6% (13)	2.1% (17)
Tumour	2.5% (18)	1.2% (9)	1.7% (12)	1.4% (10)	1.6% (13)	2.0% (16)
Congenital	1.5% (11)	0.3% (2)	0.6% (4)	0.4% (3)	0.2% (2)	5.5% (5)
Orthopaedic	4.5% (33)	3.8% (28)	5.8% (40)	3.7% (26)	4.9% (39)	5.5% (45)
Blood-borne infection	0.3% (2)	0.7% (5)	0.4% (3)	0.9% (6)	1.0% (8)	0.9% (7)
Drug abuse	1.6% (12)	0.7% (5)	1.5% (10)	1.7% (12)	1.6% (13)	1.7% (14)
Renal Failure	0.1% (5)	0.7% (5)	0.7% (5)	0.1% (7)	0.5% (4)	0.1% (1)
Other	2.2% (16)	1.9% (14)	2.2% (15)	2.0% (14)	2.1% (17)	1.2% (10)
Not recorded	1.0% (7)	0.5% (4)	0.1% (1)	0.4% (3)	0.1% (1)	0% (0)
Total	100% (729)	100% (731)	100% (688)	100% (702)	100% (803)	100% (812)

Abbreviations: PAOD=Peripheral Arterial Occlusive Disease, DM=Diabetes Mellitus

The SPARG audit consistently reports that in Scotland approximately 86% of LEAs are due to PAOD with or without diabetes. The same report also states that 47% of all LEAs due to PAOD will also have diabetes. In comparison, Moxey et al (2010) reported that 39% of those who underwent a LEA due to PAOD also had diabetes (Moxey *et al.* 2010). This is slightly lower than the numbers reported by SPARG, however the figures by

Moxey et al (2010) relate to data gathered a number of years ago between 2003 and 2008 and rates of diabetes have since risen (DiabetesUK_Facts_Stats_Oct16.pdf).

Diabetes accounts for over half of the LEAs performed, type I diabetes is responsible for 10% with type II accounting for the remaining 40%. Even allowing for the significant improvement in the management of diabetes related foot problems a proportion of people with diabetes will proceed to LEA. The increase in prevalence of type II diabetes is likely to lead to more LEAs. The rise in type II diabetes is global, and within the UK alone has risen from 1.4 in 10^6 in 1996 to 2.9 in 10^6 in 2014, with an expected prevalence of 5 in 10^6 in the year 2025 (accessed 26/01/2017 http://www.ncepod.org.uk/2014lla.html).

Diabetes increases the risk of neuropathy and peripheral arterial occlusive disease; both risk factors for foot ulceration and LEA. In up to 85% of persons with diabetes who undergo a LEA there is a pre-existing foot ulcer, often as a result of accidental trauma to the lower limb. In persons with diabetes this is further compounded by poor peripheral arterial supply resulting in relatively high rates of LEA (Davis *et al.* 2004, Chen *et al.* 2011). The rate of LEA is often as much as 7 times higher in persons with diabetes compared to those without (Ikonen *et al.* 2010) with between 5.6 to 600 per 10^5 people with diabetes receiving a major LEA each year.

2.2 Mortality

A lower extremity amputation due to PAOD with or without diabetes is associated with a high mortality rate, with approximately 40-50% not surviving beyond two years (Jones et al 2013). This prognosis is poorer than lung cancer patients (Davis *et al.* 2004). Increasing age, history of heart failure, renal failure, cancer, and chronic obstructive pulmonary disease are all independent predictors of mortality after LEA (Sawalha *et al.* 2016). A LEA due to PAOD is thought to be an indicator of the aggressive atherosclerotic disease process, and as such, many of those with a LEA due to PAOD will have high levels of co-morbid diseases e.g. cardiac, cerebrovascular and renal. The pathophysiology of PAOD, the main cause of LEA, will be explained along with the association between PAOD and diabetes and the combined effect on risk of LEA.

2.3 Peripheral arterial occlusive disease

As already stated, PAOD is the most common cause of LEA. This is defined as a significant narrowing of the arteries distal to the arch of the aorta (Cassar *et al.* 2009). It is a slow and progressive condition that is due to lipid rich materials accumulating at points of haemodynamic stress in the lower limbs e.g. vessel bifurcations and branches (Peach *et al.* 2012). This narrowing is commonly an atherosclerotic manifestation that causes stenosis and occlusion of non-cerebral and non-coronary arteries (Peach *et al.* 2012).

Often known as the 'poor relation' to heart disease and stroke, with little public awareness of the condition, PAOD is an important marker for overall cardiovascular health (Peach *et al.* 2012). PAOD is prevalent in 3-10% of the population, rising to 10-20% in those over 70 years (Norgren *et al.* 2007). It affects approximately 27 million people in Europe and North America alone (Peach *et al.* 2012) and approximately half of those will be symptomatic and suffer from intermittent claudication (IC). Intermittent Claudication is a common symptom of PAOD and is defined as "aching or cramping pain, accompanied by tightness or fatigue in the leg muscles or buttocks" (da Cunha-Filho *et al.* 2007). For some, this pain arises only during strenuous activity; for others, it starts after walking a few metres. The key factor is that the pain stops within a few minutes of resting. Intermittent Claudication affects 4.5% of the population aged 55 to 74 increasing in incidence with age. It is a marker for systemic atherosclerotic disease and has a 20-30% five-year mortality and a 50% ten-year mortality (Peach *et al.* 2012). However for every one patient with IC symptoms there are three others who have PAOD and are asymptomatic (Norgren *et al.* 2007).

For many, the diagnosis of PAOD is from a subjective history, including IC symptoms, pedal pulse examination and an ankle brachial pulse index (ABPI). The ABPI is a non-invasive test which is calculated by dividing the ankle systolic blood pressure by the brachial systolic pressure, as a fall in blood pressure in an artery at the ankle relative to the central blood pressure would suggest a stenosis in the arterial conduits somewhere in between the aorta and the ankle (Al-Qaisi *et al.* 2009). A normal ABPI ranges from 0.91 to 1.3 (Pei 2016). A diagnosis of mild PAOD ranges from 0.7 to 0.9 and moderate from 0.41–0.69. Those with ratios of less than or equal to 0.4 have severe disease and may present with critical ischaemia. Peripheral Arterial Occlusive Disease (PAOD) is graded by the Fontaine classification system which rates the severity of the lower limb ischaemia into

four stages (Becker 1984) (Table 2.2). The system is based on clinical symptoms, and is commonly used in clinical research rather than patient care (Hardman *et al.* 2014).

Table 2.2 The Fontaine classification.

Stage I	Clinically symptom free
Stage II	Mild claudication induced by exercise
	A. Mild claudication at a distance >200m
	B. Moderate to severe claudication at a distance <200m
Stage III	Ischaemic symptoms at rest, pain mostly in the feet
Stage IV	Trophic Ulcers
	A. Limited gangrene
	B. Extensive gangrene

(Gulati *et al.* 2017)

Sixty five per cent of those with PAOD have evidence of one other vascular disease, demonstrating the multi-morbidity of these patients (Norgren *et al.* 2007) (Figure 2.2). Patients with PAOD have a five-fold increased risk of Myocardial infarction (MI) and 2-3 fold increased risk of stroke (Norgren *et al.* 2007). Three quarters of deaths in those with PAOD are attributable to MI and stroke (Cassar *et al.* 2009).

Figure 2.2 Overlap between coronary artery disease, peripheral arterial occlusive disease and cerebral artery disease.

Most patients with PAOD are managed medically with drugs and lifestyle changes rather than revascularization or bypass surgery. In severe cases, a major LEA may be required, however less than 3% of those with IC symptoms from PAOD will require a LEA within 5 years of diagnosis, and half of those will have a diagnosis of diabetes. The most severe form of PAOD is known as critical limb ischaemia (CLI) and can lead to limb loss or death if not treated promptly. Limb salvage surgery, aims to revascularise the lower limb with a bypass or through radiological guided angioplasty and insertion of a stent. Both options are often performed for CLI as an attempt to save the limb and avoid a major LEA. This can be performed endovascularly with angioplasty or openly with arterial bypass surgery (Goodney *et al.* 2009). One study found that revascularisation can delay a patient requiring a major LEA by up to 5 months (Faglia *et al.* 2009). However, the same authors reported that those who progressed to a LEA after revascularization were more likely to be younger, with longer duration of diabetes, compared to those who did not require a LEA (Faglia *et al.* 2006). Norgren et al (2007) suggests that the decision to persevere with limb salvaging procedures or minor amputations should be weighed against the ability to amputate at a functional level that aids independence (Norgren *et al.* 2007). Attempts to save the limb can be a long process with many surgeries, which for some will always result in a TFA, alternatively a TTA may be performed instead of any limb salvaging surgery to avoid this process and allow the patient to regain their mobility in a shorter period.

The prevalence of PAOD is similar in males and females (Kannel *et al.* 1970, Aronow and Ahn 1994, Criqui *et al.* 1997). However, more males have LEAs due to PAOD than

females (Carmona *et al.* 2005, Lim *et al.* 2006, Heikkinen *et al.* 2007, Izumi *et al.* 2009, Jeffcoate and Margolis 2012) which may be due to higher smoking rates in males compared to females, a significant risk factor for PAOD. Another theory is the hormonal protection females are given from oestrogen until the menopause which can shield against atherosclerotic build up (Jonasson *et al.* 2008). The protection up to the menopausal years may contribute to the observation that females are generally older than men when they have an LEA. However, when diabetes is also present the gender difference is negligible regardless of age.

2.4 Peripheral arterial occlusive disease and diabetes

Diabetes creates an abnormal metabolic state that increases the risk of all atherosclerotic disease including peripheral arterial occlusive disease (Beckman *et al.* 2002) The arterial system; specifically, the vascular smooth muscle, platelet function and endothelial cells are fundamentally altered by complications of diabetes; such as hyperglycaemia, insulin resistance and hypercholesterolemia (Beckman *et al.* 2002). Longer duration and poorer control of diabetes, is associated with an increase in the severity of PAOD (Beckman *et al.* 2002). Thus, intermittent claudication, is twice as prevalent in those with diabetes, compared to those without diabetes (Norgren *et al.* 2007). Studies in those with diabetes have shown with every 1% increase in HbA1c, there is a 26% increased risk of PAOD (Selvin and Erlinger 2004).

In addition to PAOD causing ischaemia, the diabetic foot is also at high risk of infection and neuropathy (Edmonds 2006). The consequence of the neuropathic joint is the risk of ulcers created from significant disruption of the bony architecture (Rogers *et al.* 2011). This may occur from a combination of the reduced sensation of the foot and a lack of awareness of pain from ill-fitting footwear or injury. This leads to skin breakdown and ulcer formation and, with these unfavourable conditions and the presence of PAOD, poor healing (Prompers *et al.* 2008), which predisposes the patient to a high risk of amputation (Layden *et al.* 2012). Patients with diabetes and PAOD are also known to have more severe disease distal to the popliteal artery compared to those with PAOD alone (Jude *et al.* 2001) and this may influence the level of any resulting LEA.

A diagnosis of PAOD increases the prevalence of multi-morbid disease, especially in those over 65 years old (Meves *et al.* 2010), depicted in Figure 2.2. Additionally, there are

known links between multi-morbidities, poor health and socio-economic deprivation, which in turn impacts on rates of both minor and major LEAs due to PAOD (Ferguson *et al.* 2010). People who live in the most deprived areas undergo more LEAs than those in more affluent areas (Ferguson *et al.* 2010). Within Glasgow, where the data for this thesis was collected, there are more people with multi-morbid disease living in deprived areas than live in more affluent areas (Bailey *et al.* 2003). Within Greater Glasgow & Clyde, almost half of the population reside in the most deprived areas. In contrast, less than 4% of the population live in the most affluent areas in Glasgow (Walsh 2008).

2.5 Level of lower extremity amputation

The most common levels of LEA for PAOD are trans-tibial (TTA) and trans-femoral (TFA). The importance of maintaining the knee joint cannot be underestimated, as the likelihood of being able to mobilise with a TT prosthetic, where the knee is retained, is far greater than a TF prosthesis due to the increased energy expenditure required (Waters *et al.* 1976). Age also has an influence over level of amputation with older adults having more proximal trans-femoral amputations compared to those who are younger which reduces the chance of prosthetic fitting and function. This variation in age at time of LEA is also seen in those who have diabetes, those with diabetes who have an LEA due to PAOD are generally younger compared to those without diabetes who require an LEA (Davie-Smith *et al.* 2015). The same authors also found there were more distal LEAs in those with diabetes, and reported a TTA:TFA ratio of 2.33:1 in those with diabetes compared to 0.93:1 in those without diabetes (Davie-Smith *et al.* 2015). The level of LEA and presence of co-morbidities have a direct impact on life expectancy; with a mortality rate within the rehabilitation period of 22% in those with a more proximal LEA compared to 12% in those with a distal LEA.

As well as having a fundamental impact on a patients function and quality of life, a LEA has a significant socioeconomic impact due to the after-care and the social support required in assisting the patient in the long term (Ebskov 2006). The level of dependency or mobility that a patient will have after LEA will be determined during the immediate post-operative period as they participate in rehabilitation (Broomhead *et al.* 2003).

2.6 Patient journey

A lower extremity amputation due to PAOD and/or diabetes is normally an elective procedure as often attempts have been made to save their limb and when these have failed the patient is informed that the LEA is inevitable. However, for those with critical limb ischaemia due to PAOD, the LEA will often be an emergency surgery as the ischaemic limb threatens immediate morbidity and mortality. In some cases of infected diabetic foot ulcers the risk of spreading sepsis requires an emergency LEA. The 30-day survival is poorer for those who have an emergency LEA compared to those undergoing elective surgery (14.3% versus 7.8%) (Aulivola *et al.* 2004). Irrespective of emergency or elective surgery, a similar patient pathway is followed post-operatively in most centres (Figure 2.3).

The patient may be in the ward environment for 25-35 days depending on local protocols and the majority of patients will attend rehabilitation during that period for wheelchair mobility and transfer practice. There will also be an assessment period for prosthetic rehabilitation and, if appropriate, the use of an early walking aid to mobilise in the gym setting. The assessment for prosthetic fitting will depend on previous mobility, morbidity, cognition, residual limb and contra-lateral limb condition, and compliance with rehabilitation. The specialist physiotherapist, in conjunction with the multi-disciplinary team usually completes the assessment.

Once the patient is medically fit to go home, their house is assessed and any adaptations made to facilitate the discharge process. At this time, the patient will usually be wheelchair dependent as the limb fitting process does not start until 3-4 weeks' post-operatively at the earliest and it takes approximately a further 3- 4 weeks to receive a definitive prosthesis (Condie *et al.* 1996).
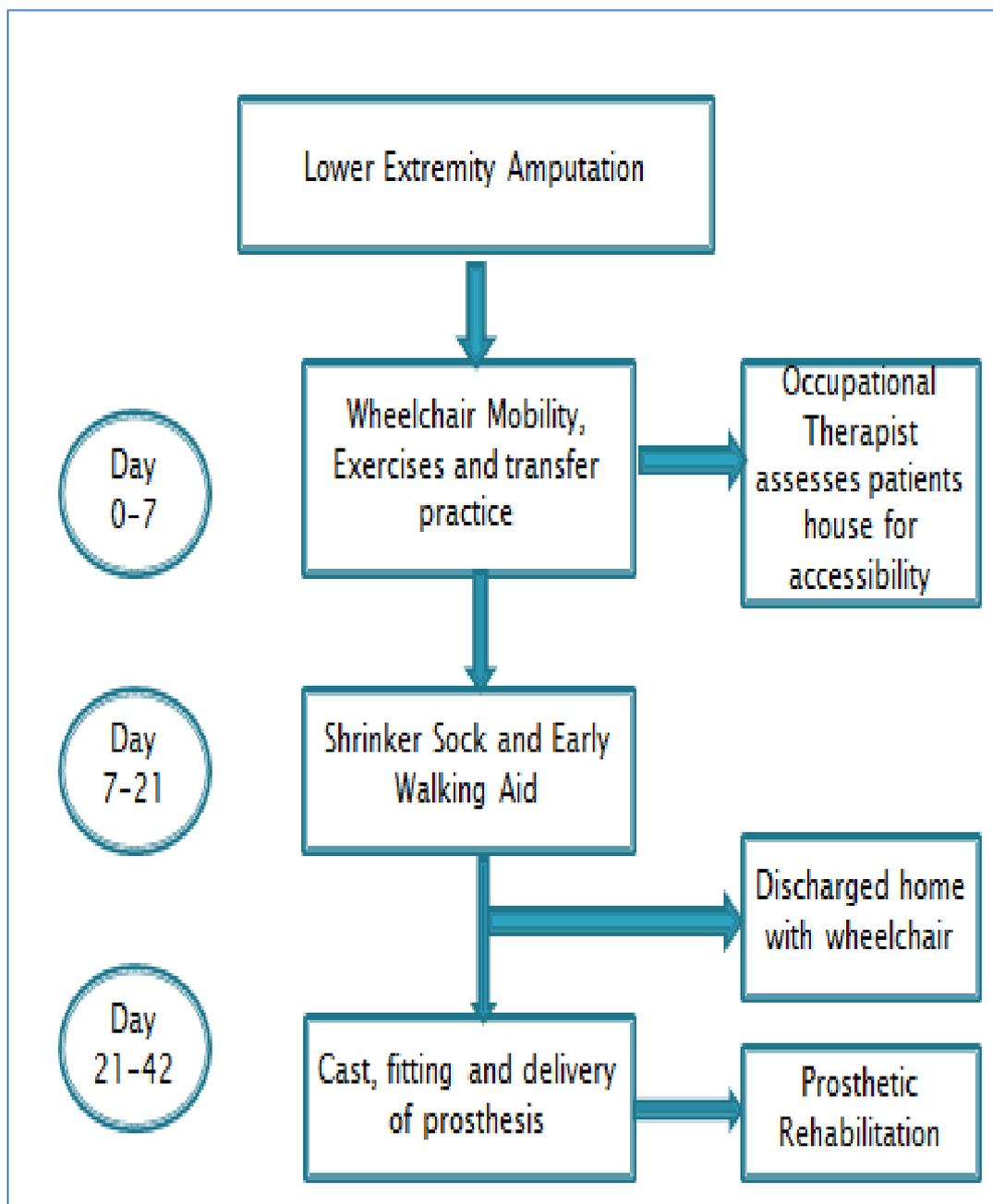
Figure 2.3 Patient pathway following lower extremity amputation.

2.7 Prosthetic fitting

For those who receive a prosthesis, the preparation for prosthetic fitting starts immediately after LEA for both TTA and TFA levels. Stump oedema is reduced to prepare the stump (residuum) for prosthetic casting. Shrinker sock therapy provides compression that gradually shapes and shrinks both the trans-femoral and trans-tbial stump in size (Figure 2.4).

Trans-Femoral Shrinker	Trans-Tibial Shrinker

Figure 2.4 Shrinker sock therapy.
Accessed 27.01.2017 https://www.pelsupply.com/products/productline/3/25

Approximately a week after LEA surgery, the patient is able to also start using an early waking aid. Early walking aids are used for patients with TTA and TFA levels of LEA and were pioneered over 40 years ago (Russek 1969, Kihn *et al.* 1972, Pollack Jr and Kerstein 1984). The most common early walking aid is the Pneumatic Post Amputation Mobility Aid (PPAM Aid) (Figure 2.5) which allows for early mobilisation following LEA and aids cardiovascular fitness to improve the psychological wellbeing of the patient. The PPAM Aid also compresses the stump which increases circulation, reduces oedema and promotes wound healing, all of which are essential to allow early prosthetic fitting (Smith *et al.* 2003, Sanders and Fatone 2011). Chen et al (2008) found that early gait training improved patient satisfaction and daily usage of their prosthetic limb (Chen *et al.* 2008). The use of shrinker socks and early walking aids is similar in patients with a TTA or TFA. Current clinical guidelines recommend use of the PPAM aid commences from 6 days post–amputation surgery following satisfactory wound assessment (Dawson I 2008, Bouch *et al.* 2012).

Figure 2.5 Pneumatic Post Amputation Mobility Aid.
Accessed 04/11/2016 http://www.bbc.co.uk/news/blogs-ouch-28225622

The TTA and TFA prosthesis both depend upon a good socket and suspension system as this is the interface between the residual limb and the prosthetic device (Colombo *et al.* 2011). However, there are different types of socket and suspensions for different levels of LEA. Patients who receive a trans-tibial amputation (TTA) are expected to have a better functional outcome compared to those with a trans-femoral amputation (TFA) as the knee joint is maintained which leads to a more normal gait pattern, better balance, and lower energy cost of walking (Highsmith *et al.* 2010).

The TTA prosthesis uses the most common form of the Patellar Tendon Bearing (PTB) design known as the patella tendon supracondylar (PTS) socket. Pressure tolerant areas such as the patella tendon are loaded and sensitive areas such as distal end of tibia are relieved (Figure 2.6). The PTS socket is still favoured today in clinical practice because it is less expensive to provide and the normal variation in stump volume during the rehabilitation programme can be managed relatively easily using stump socks. Furthermore, the need for a separate suspension system is lowered as the medial and lateral femoral condyles allow the socket to be suspended without a suspension sleeve or pin and lock mechanism (Pirouzi *et al.* 2014).

Figure 2.6 Trans-tibial prosthesis.
Accessed 21/12/2016 http://cpo.biz/transtibial-prosthesis/

Figure 2.7 Pin and lock mechanism for trans-tibial amputation suspension.
Accessed 21/12/2016 *http://www.ottobockus.com/prosthetics/info-for-new-amputees/prosthetics-101/keeping-your-leg-on-(suspension)*

The TFA prosthesis has two different designs of socket available; the quadrilateral socket and the ischial containment socket (Gholizadeh *et al.* 2014) (Figure 2.8). Current NHS practice for those with a TFA due to PAOD is to use a quadrilateral socket design where weight bearing is mainly through the ischial tuberosity (Figure 2.9). This design is favoured because of cost and ease of manufacture. Although the quadrilateral socket is extensively used, gait deviations are more pronounced due to the inability to control hip abduction, which results in a wide base of support causing higher energy requirements for

walking. Patients also complain that quadrilateral sockets are uncomfortable to sit down in due to the ledge for the ischial tuberosity.
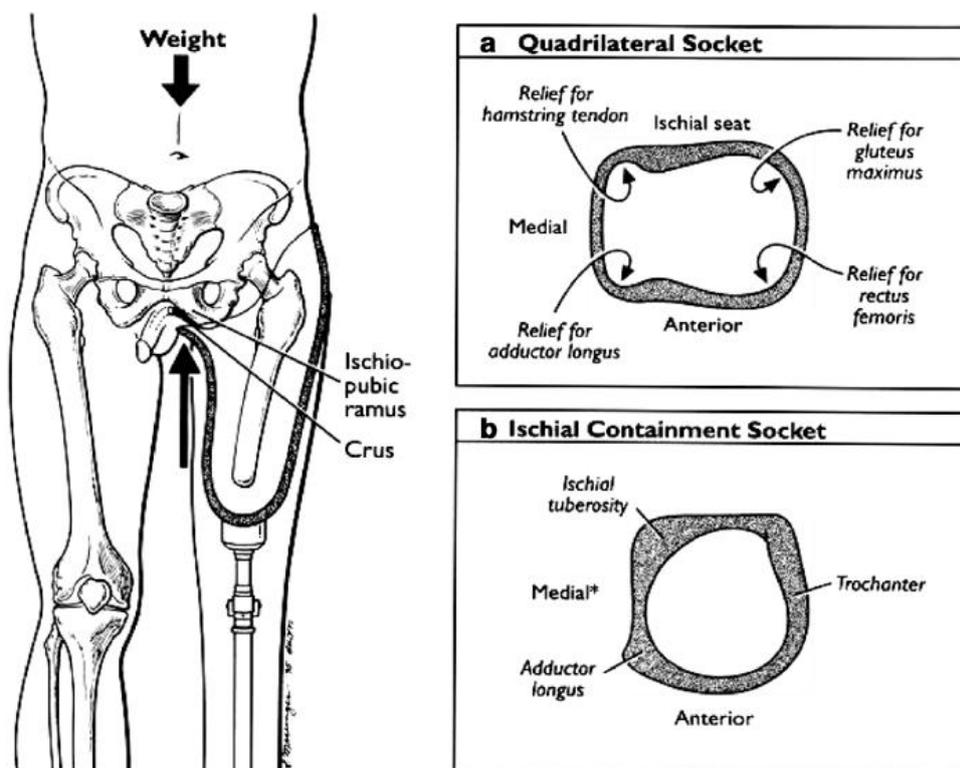
Figure 2.8 Trans-femoral amputation socket designs.
Accessed 21/12/2016 http://www.nature.com/ijir/journal/v15/n4/fig_tab/3901015f1.html)

Figure 2.9 Trans-femoral amputation prosthesis with quadrilateral socket.
Accessed 21/12/2016 http://www.medicus.ca/en/products/orthotics-prosthetics/prosthetics

In order to maintain the connection between the quadrilateral socket and the residual limb during gait, the suspension method typically used is a Total Elastic Suspension (TES) belt. The TES belt is similar to a corset as it is applied tightly around the waist and connects to the socket (Figure 2.10). The TES belt has been shown to be cumbersome, bulky and restrictive and encourages heat retention (Kapp 1999). It requires good cognitive function, a strong upper body and an ability to stand on one limb, to apply the TES belt; all of which may be compromised in this population (Cole 2003). For those who have an ischial containment socket, the suspension system can be a silicone liner, which is attached through suction or a pin, and lock mechanism which connects the prosthesis to the residual limb. This gives a more secure method of suspension than a TES belt and allows for greater hip control. However, a silicone liner cannot be used with a quadrilateral socket, as it tends to tear easily.

Figure 2.10 Total elastic suspension.
Accessed 21/12/2016 http://www.ortho-europe.com/product/5845/

Once the prosthesis is prescribed, manufactured and fitted, the patient undertakes approximately 12 weeks of gait rehabilitation with the physiotherapist in order to become as independently mobile as possible.

2.8 Prosthetic gait rehabilitation

Prosthetic rehabilitation begins with donning and doffing (putting on and taking off) of the prosthesis in order to ensure the patient can establish a good and comfortable fit. Immediate gait training commences within the parallel bars for support until the patient has the balance, technique and confidence to progress out with the bars onto a walking aid. Gait re-education then progresses to different environments, surfaces and terrains to ensure the patient can manage to walk around and perform activities of daily living as independently and safely as possible with or without walking aids. Once the patient and physiotherapist have met the agreed goals from the start of physiotherapy the patient is discharged with prosthetic reviews as required. Although this is an overview of rehabilitation, different NHS trusts may vary in the delivery of prosthetic gait rehabilitation; however, all will have the same focus on function and ambulation with a prosthesis.

The presence of other co-morbidities and the progression of the PAOD may affect the person's quality of life. As quality of life after a LEA is central to this thesis the following chapter is a systematic literature review, which explores the factors that influence quality of life after a lower extremity amputation due to PAOD.

Chapter 3

Factors influencing quality of life following lower extremity amputation for peripheral arterial occlusive disease: A systematic review of the literature

This systematic review, conducted in December 2015 was written and submitted to the International Journal of Prosthetics and Orthotics in June 2016 and accepted for publication in December 2016 (Davie-Smith *et al.* 2017). In order to ensure that the literature search was current, the search strategy was rerun in January 2017, two studies were found; however, neither was included. The first was a systematic review of people who had their LEA due to trauma (Christensen *et al.* 2016) and the other examined cognitive function as opposed to QoL in a population with mixed aetiology (Morgan *et al.* 2016).

3.1 Introduction

Quality of life (QoL) is defined as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (WHOQOL 1997). In studies examining QoL for those with a LEA there are no validated quality of life outcome measures; therefore, generic quality of life outcome measures are used. The International Classification of Functioning and Disability Framework (ICFDF) focuses on the function/disability of the person rather than the contextual factors such as the environment (Hemmingsson and Jonsson 2005). Within the ICFDF, disability is seen as a result of the interplay between impairment, activities of daily living and participation in wider valued activities (WHO 2001).

A person who has a LEA due to Peripheral Arterial Occlusive Disease (PAOD), has a poorer quality of life compared to someone who has a LEA for other reasons such as trauma or tumour (Pernot *et al.* 2000). To maximise rehabilitation outcomes an understanding of the factors that influence a person's quality of life following a LEA due to PAOD, is essential for healthcare professionals. A previous literature review assessed

quality of life in those with a LEA for all aetiologies, including trauma, tumour, orthopaedic complications and PAOD (Sinha and Van Den Heuvel 2011). The majority of the 26 articles included had amputee populations of mixed aetiologies such as trauma or tumour (n=16), did not distinguish between upper and lower limb amputations (n=2) and compared major lower limb amputations to other surgeries (n=2) (Sinha and Van Den Heuvel 2011). To date, no systematic review has been undertaken that examines the factors that influence quality of life in those with LEA for PAOD. The aims of this systematic review were to report the quality of life of those with a LEA due to PAOD, and to identify the factors that influence quality of life after a major LEA due to PAOD.

3.2 Methods

3.2.1 Search Strategy

A systematic literature review was undertaken in December 2015 using EBSCO and OVID which searched MEDLINE, CINAHL, Pubmed and PsychINFO databases. Web of Science and Cochrane databases were searched separately and all literature published from database inception to the end of 2015 were included. The search strategy included specific keywords and combined Medical Search History (MeSH) headings which were exploded for greater depth and the following terms were used: foot or feet, "lower limb", knee, leg, amput*, "above knee", "below knee", "lower extremity stumps", "limb absence", "limb loss", "limb removal", "quality of life", quality of life, "Peripheral Vascular Disease", "peripheral arterial occlusive disease", "diabetes mellitus", "diabetes", "DM", "type II diabetes", "Activities of daily living", "Physical and Rehabilitation medicine", "Rehabilitation Centres", Rehabilitation, "Mobility Limitation", "Phantom Limb", "Phantom Pain". The use of Boolean terms "AND" and "OR" enhanced the search. Citations of relevant articles were also reviewed for possible inclusion.

3.2.2 Inclusion and exclusion criteria

Articles were included if the entire amputee study population had an LEA due to PAOD; participants were 18 years old or over; the full text article was published in English; had a sample of more than 10 participants; reported the results of one or more quality of life outcome measures and was empirical research. Articles were excluded if they were; case-

studies, reviews, editorial opinions, testimonies, biography/interviews, books, progress reports, conference abstracts or posters, discussion papers, guidelines, discussed other people's quality of life, e.g. a carer's or family member's rather than a patient's quality of life, and did not use an objective outcome measure which meant all qualitative studies were excluded. Also excluded were articles that were a development or validation of an outcome measure to assess quality of life, if the populations studied were of mixed aetiology or if participants underwent an amputation for reasons other than PAOD.

The literature search produced 333 articles; 201 from OVID, 122 from EBSCO, 4 from Web of science, 1 from Cochrane and 5 from reference lists. Two systematic reviews were identified, one was not relevant (Cumming *et al.* 2015) and the other provided back referencing of cited articles that could be included (Sinha and Van Den Heuvel 2011). Fifty-four duplicate articles were removed. The titles of 279 articles were screened initially by one reviewer (FDS) which resulted in 209 being excluded. Then, two reviewers (FDS & EC) examined the abstracts of the remaining 70 articles and excluded a further 58 articles. This resulted in 12 full text articles for review and assessment (Figure 3.1).

3.2.3 Quality assessment

The included articles were scored using a quality assessment tool with 19 criteria, adapted from a previous systematic review (Sinha and Van Den Heuvel 2011). In order to bring the quality assessment in line with the STROBE guidelines (Poorolajal *et al.* 2011) one further criterion was added; evidence of limitations, creating a 20 criteria tool (Table 3.1). This additional criteria assessed whether the authors had accounted for potential bias and discussed any limitations of their research. The maximum quality assessment score was 38 points, this was based on three sub-categories (i) the source population, (11%), (ii) study population characteristics, (42%) and (iii) methodological characteristics (47%) (Sinha and Van Den Heuvel 2011).
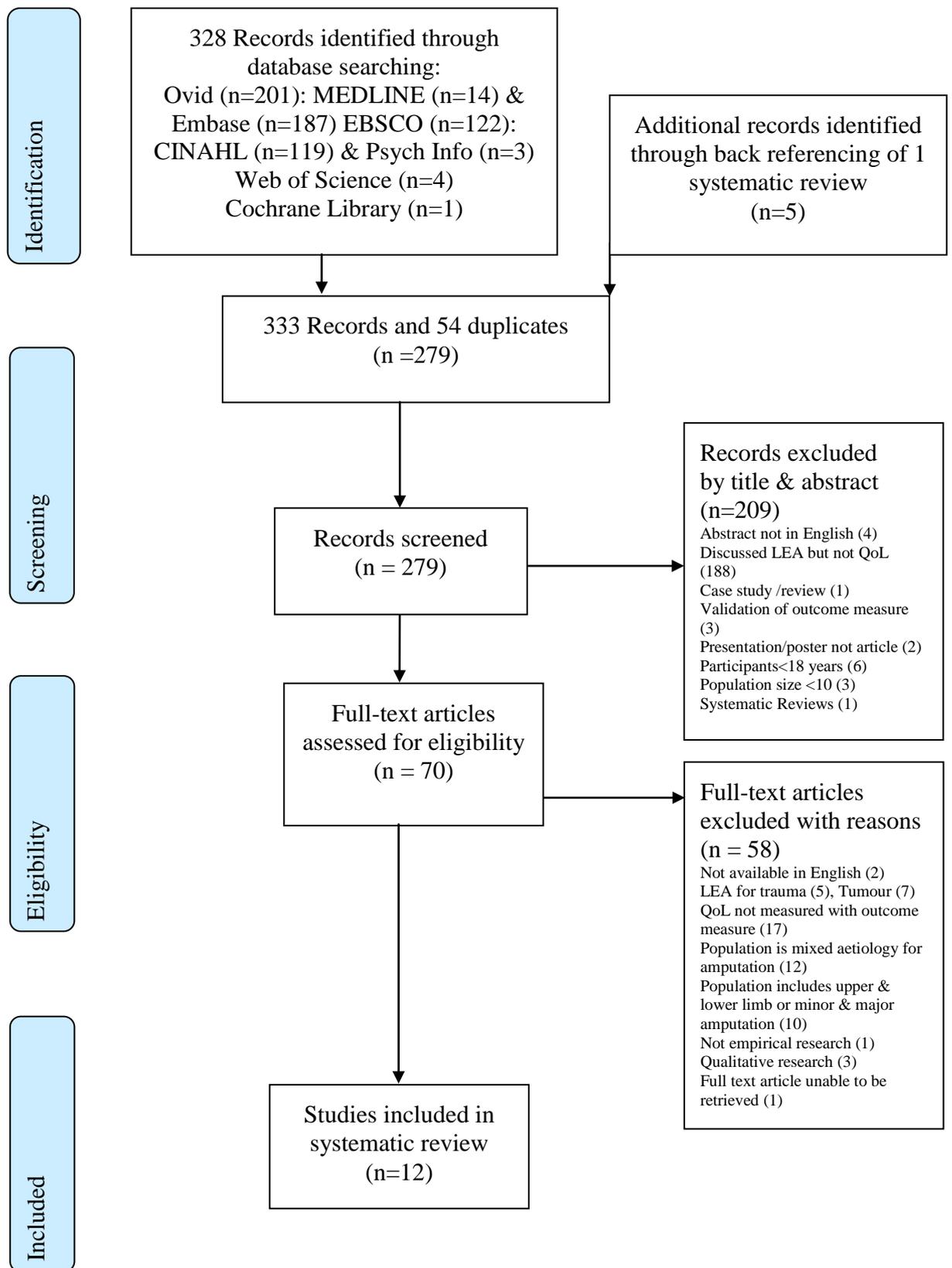
Figure 3.1 Study attrition diagram.
Abbreviations: QoL=Quality of Life

Table 3.1 Quality Assessment Criteria and scores used to rate the articles

Category	Criteria	Scores
(1) Source Population		
A	Description of source population	Not available (0) Ambiguous (1) Available (2)
B	Description of inclusion/ and or exclusion criteria	
(2) Study population characteristics		
C	Age	Not available (0) Partially available (1) Available (2)
D	Gender	
E	Education	
F	Employment Status	
G	Marital Status	
H	Comorbidity	
I	Economic Status	
J	Data presentation of relevant O/M	
(3) Methodological characteristics		
K	Representative population	Not clear (0) Partially (1) Yes (2)
L	Study design/study type	Not clear (0) Cross sectional design (1) Retrospective / mixed design (2) Prospective design (3)
M	Population selection	Non randomised (0) Randomised / NA (1)
N	Instruments used	Non validated (0) Partially validated (1) Validated (2)
O	Statistical methods for O/M	Non appropriate (0) Partially appropriate (1) Appropriate (2)
P	Control for confounding variables	Not considered (0) Partially considered (1) Fully considered (2)
Q	Response Rate vs. Drop outs	<60%/not mentioned (0) 60-80% (1) >80% (2)/NA (2)
R	Characteristics of drop outs	Not reported (0) Reported (1)/NA (1)
S	Relevant O/M	Not well defined (0) Well defined (1)
T	Limitations	Not considered (0) Partially considered (1) Fully considered (2)

Abbreviations: O/M =Outcome Measures

*Quality assessment tool adapted with STROBE tool from Sinha et al (Poorolajal *et al.* 2011, Sinha and Van Den Heuvel 2011)

A preliminary assessment was conducted where all three reviewers read one article independently and scored it, then met to discuss the scoring and agreement was achieved. Each article was then independently scored by two of three assessors, and when agreement could not be met, the third assessor was consulted to ensure consensus was reached. Following this, the remainder of the articles were scored with two assessors.

3.3 Results

The twelve studies that were eligible for inclusion are presented in Table 3.1. This highlights each study's aims, population, QoL outcome measure and findings; studies were grouped by methodological design (Table 3.2).

Table 3.2 Evidence table summarising the twelve included papers.

Author, Year, Design & Quality Assessment Score	Aim of Study	Sample population	Time Point(s)	QoL Outcome Measures(s)	Main findings
Buijck et al (2012) QA=47%	To determine what affects QoL in the home environment following LEA after a period of in-patient rehabilitation in the elderly population.	n=27 people: Mean ge 75 years Major LEA's 8TFA, 4 TKA & 15 TTA. All elderly and discharged from in-patient care to home.	3 months after in-patient discharge	Research & Development Corporation Measure of Quality Of Life (RAND-36)	21 people were fitted with a prosthesis;8 were fitted for cosmetic purposes and were immobile, 11 achieved limited mobility with a walking aid and 2 were mobile without walking aids. Mean QoL score ranged from 22-87, and low QoL (on physical function) was correlated positively to poor functional ambulation score. High QoL scores were associated with low scores for depression and neuropsychiatric symptoms. Pain was not associated with any factors
Fortington et al (2013) QA=71%	To describe changes in HRQoL from amputation to 18 months post-amp in lower limb amputees and compare this to a normal population.	Mean age 67.8 years (±13) n=82 LEA, 30 TFA/TKA & 52 TTA.	At LEA & 6 & 18 months post LEA	Research & Development Corporation Measure of Quality Of Life (RAND-36 Dutch version)	TK & TF level of amputations were linked to a significantly lower level of physical function than TTA. The ability to walk was related to improved social function & higher QOL Most change in QoL occurred in first 6 months post LEA Age was a significant factor in HRQOL in physical function Lower QoL in LEAs was reported in all domains compared to population norms. All able to walk 500m pre LEA (n=82) At 6 months, (n=46), 21 were able to mobilise 500m, 9 had improved and 16 were not mobile Between 6 and 18 months (n=35) 17maintained their mobility and 11 improved, 7 were not mobile
Norvell et al (2011) QA=92%	Examine factors associated with mobility	n=87 Mean age 62 years at time of LEA and	At LEA & 12 months post LEA	Satisfaction With Life Scale (SWLS)	Decline in mobility in all groups over time from pre- LEA, however this was greatest in TFA's If mobility success was achieved then participants were more

	success during first year following 1st major unilateral LEA +/- DM.	(TMA=27, 52=TTA,8-TFA) n=75 at follow-up (TMA=26, TTA=42,TFA=7)			likely to have improved satisfaction with life Although 50% of the group reported low to moderate levels of mobility this was associated with mobility satisfaction. Mobility measured with LCI-5 change score from pre LEA to 12 months post LEA. All reported a decline in mobility at 12 months post LEA.
Mac Neill et al (2008) QA=68%	To examine long term outcome; prosthetics and QoL, after bilateral trans-tibial amputation.	n=82 at baseline Mean age 68.5 years and n=34 followed up at 3.7 years post amputation	~3.7 years post LEA	Houghton SF-12 Qualitative measures of ADL	85% of those who survived at 3.7 years were wearing their prosthesis daily, (69% were able to mobilise for 15 minutes outdoors once a week) with higher SF-12 scores in the mental health aspect than the physical aspect. Those living alone reported better mental health and were more independent than those who lived with others.
Abdelgadir et al (2009) QA=68%	To compare two groups of people with differing durations of diabetes, one group had lower extremity amputations (LEA).	n=60 major LEAs (44 TTA & 16 TFA) Mean age 57.4 years (±10.5) compared to 60 people without LEAs, all of whom had DM.	~5.3 Years since LEA	Medical Outcome Study questionnaire (MOS) Sense Of Coherence scale (SOC)	Reduced mobility in LEAs was highly correlated to the role physical aspect of the QoL scores Increased duration of diabetes, worsening symptoms and undergoing an LEA were associated with poor QoL Longer time since LEA was associated with lower QoL compared to more recent LEA QoL was greatest in those with improved family satisfaction and better sleep No prosthetic wearing time or mobility distance was recorded.
Cox et al (2011) QA=58%	To determine QoL and functional independence of those with a LEA who have diabetes.	n= 87 (64 TTA & 23 TFA) Mean age 62 years (±9.9), all with diabetes	From 1-3 years since LEA	World Health Organisation Quality of Life Scale (WHO-QOL-BREF)	Those with a TTA recorded improved QoL and functional independence compared to those with a TFA Females had a higher QoL in all 4 domains Positive correlation was found between functional independence and QoL in all participants No prosthetic wearing time or mobility distance was recorded.

Deans et al (2008) QA=63%	Investigate the link between physical activity and associated QoL	n=25 Mean age 66 years of a possible 75 unilateral LEAs (22 TTA & 3 TFA) who were fitted with a prosthesis.	Discharged from out-patient prosthetics for > 2 years from LEA	Trinity Amputee and Prosthetic Experience Scale (TAPES) World Health Organisation Quality of Life Scale (WHO-QOL BREF)	Correlation between functional score on the TAPES and the physical function aspect of the QoL measure. Correlation between social aspects of both scales suggesting that people with LEAs place more emphasis on their social status and interactions than on physical fitness No prosthetic wearing time or mobility distance was recorded.
Harness et al (2001) QA=60%	To assess prosthesis related QoL	60 unilateral TTA Mean age 65.9 years (±1.4)	Minimum of 6 months prosthetic use (median 24 months)	Prosthetic Evaluation Questionnaire (PEQ)	Social burden correlated positively with the ability to mobilise with prosthesis Satisfaction correlated with less pain and the ability to mobilise Weak association between pain and residual limb health and ability to mobilise with a prosthesis No prosthetic wearing time or mobility distance was recorded.
Pell et al (1993) QA=63%	To assess the effect of LEA on QoL and compare this to population norms	n=130 Median age 73 years (86 TTA & 44 TFA)	Median of 38 months since time of LEA	Nottingham Health Profile (NHP)	Those with a LEA have a lower QoL than population norms. QoL is directly linked to mobility 87% wore their prosthesis and 42% were mobile with their prosthesis Isolation is more pronounced in those with a LEA despite social situation even when compared to controls who lived alone
Remes et al (2010) QA=79%	To assess QoL of amputees with PAD	59 unilateral amputees (13 TTA, 28 TFA, 18 Bilateral) Mean age 75.2years (±10.7)	2 years after LEA	Research & Development Corporation Measure of Quality Of Life (RAND-36) Six Item Brief Social Support Questionnaire (SSQ6) Geriatric Depression Scale (GDS)	Home dwelling amputees had good QoL compared to those in institutions and those who could not walk Mini mental score lower in those with LEA More co-morbidities in those with LEA Reduced mobility was an independent factor in poor QoL 25 were prosthetic wearers and 4 had no issues mobilising 100 m, 21 reported limited mobility with prosthesis Similar health satisfaction & social support between controls & LEAs More depression in those who were in care homes or could

				15D Health Related Quality Of Life (15D HRQOL) Satisfaction With Life Scale (SWLS)	not mobilise Although those with a LEA had reduced physical function they had larger social support structure than those without an LEA
Tennvall et al (2000) QA=68%	Compare Health Related QoL in people with DM who attended foot clinic	n=26 major LEAs (level not stated). Mean Age 67 years A total of 310 people were surveyed, the remainder had foot ulcers or minor amputations Response Rate of 70%	1-3 years post LEA	Euroqol Quality of Life Questionnaire (EQ-5D-5L Swedish version)	People who had major LEA had lower QoL compared to those with current foot ulcer or minor LEA People who had minor LEA had higher QoL than those with no LEA and a current foot ulcer No prosthetic wearing time or mobility distance was recorded.
Thompson et al (1995) QA=37%	To compare distal bypass surgery with major LEA in terms of QoL	n=24 LEA Median Age 69 years compared to n=48 bypass	Retrospective but no date given	A self-assessment QoL including Hospital Anxiety & Depression Scale (HADS) 9 point scale of social function 4 point mobility scale	Bypass group had lower levels of depression, impairment and greater mobility than LEA group in terms of QoL QoL was lower overall for those with a LEA indifferent of whether bypass had failed or not. No prosthetic wearing time or mobility distance was recorded.

Abbreviations: QA=Quality Assessment, LEA=Lower Extremity Amputation, TTA=Trans-tibial Amputation, TKA=Through Knee Amputation, TFA=Trans-femoral Amputation, SF=Short Form, QoL=Quality of Life, ADL=Activities of Daily Living

3.3.1 Scoring of quality assessment

Quality Assessment scores ranged from 36% to 92%. Reviewers reached agreement of all final scores. The majority of the included articles were of good quality, with ten of the twelve articles scoring more than 50%. Analysed by subcategories, ten of the twelve articles achieved the maximum score for source population, however only four articles achieved a score over 50% for study population characteristics. The methodological characteristics subcategory had higher quality scores; with the majority (11 of 12) scoring over 60% (Table 3.3).

Table 3. 3 Quality assessment scores of the twelve included papers.

	Source Population				Study Population Characteristics										Methodological Characteristics												Quality Scores	
	A	B	Total	%	C	D	E	F	G	H	I	J	Total	%	K	L	M	N	O	P	Q	R	S	T	Total	%	Overall Total	%
Abdelgadir (2009)	2	2	4	10	2	2	1	0	0	0	0	2	7	18	2	1	1	2	2	1	2	1	1	2	15	40	26	68
Buijck (2012)	2	0	2	5	1	2	0	0	0	0	0	2	5	13	2	3	1	2	2	0	0	0	1	0	11	29	18	47
Cox (2011)	2	2	4	10	2	2	0	0	0	0	0	2	6	16	1	1	1	2	2	0	2	1	1	1	12	32	22	58
Deans (2008)	2	2	4	10	1	2	2	0	2	0	0	2	9	24	2	1	1	2	2	0	0	0	1	2	11	29	24	63
Fortington (2013)	2	2	4	10	2	2	0	0	0	0	0	2	6	16	2	3	1	2	2	2	1	1	1	2	17	45	27	71
Harness (2001)	2	2	4	10	2	2	0	0	0	1	0	2	7	18	2	1	1	2	2	0	2	1	1	0	12	32	23	60
Neill (2008)	2	2	4	10	2	2	0	0	0	2	0	2	8	21	2	2	1	1	2	1	2	0	1	2	14	37	26	68
Norvell (2011)	2	2	4	10	2	2	2	2	2	2	2	2	16	42	1	3	1	1	2	2	2	0	1	2	15	40	35	92
Pell (1993)	2	2	4	10	1	2	0	0	1	0	0	2	6	16	2	1	1	2	2	2	2	1	1	0	14	37	24	63
Remes (2010)	2	1	3	8	2	2	2	0	2	2	0	2	12	31	2	1	1	2	2	1	2	1	1	2	15	40	30	79
Tennvall (2000)	2	2	4	10	2	2	0	0	0	1	0	2	7	18	2	1	1	2	2	2	1	1	1	2	15	40	26	68
Thompson (1995)	2	2	4	10	1	0	0	0	0	0	0	1	2	5	1	1	1	1	2	0	1	1	0	0	8	21	14	36

3.3.2 Sample populations

Sample sizes ranged from n=24 (Thompson *et al.* 1995) to n=130 (JP Pell *et al.* 1993). Sampling techniques included purposive (JP Pell *et al.* 1993, Thompson *et al.* 1995, Tennvall and Apelqvist 2000, Deans *et al.* 2008, Abdelgadir *et al.* 2009, Remes *et al.* 2010, Cox *et al.* 2011, Norvell *et al.* 2011, Fortington *et al.* 2013a), convenience (Neill *et al.* 2008, Buijck *et al.* 2012) and random sampling (Harness and Pinzur 2001). Comparison groups included age and gender matched controls (JP Pell *et al.* 1993, Abdelgadir *et al.* 2009, Remes *et al.* 2010); those with limb salvaging surgery (Thompson *et al.* 1995); and those with foot ulcers (Tennvall and Apelqvist 2000).

3.3.3 Study designs

Study designs were cross sectional (n=8) (JP Pell *et al.* 1993, Thompson *et al.* 1995, Tennvall and Apelqvist 2000, Harness and Pinzur 2001, Deans *et al.* 2008, Abdelgadir *et al.* 2009, Remes *et al.* 2010, Cox *et al.* 2011); prospective (n=3) (Norvell *et al.* 2011, Buijck *et al.* 2012, Fortington *et al.* 2013a) and mixed methods (n=1) (Neill *et al.* 2008). The time points chosen to assess quality of life ranged from 3 months after in-patient discharge (Buijck *et al.* 2012) to 5.3 years after LEA (Abdelgadir *et al.* 2009). The length of time between outcome measurements in prospective longitudinal studies also varied from date of LEA, 6 and 18 months post LEA (Fortington *et al.* 2013a) to 6 weeks and 12 months post LEA (Norvell *et al.* 2011).

3.3.4 Outcome measures

A variety of generic quality of life outcome measures was used across the studies: the Research & Development Corporation measure of quality of life (RAND-36) (n=3) (Remes *et al.* 2010, Buijck *et al.* 2012, Fortington *et al.* 2013a); the World Health Organisation quality of life scale (WHOQOLBREF) (n=2) (Deans *et al.* 2008, Cox *et al.* 2011) (n=2); the 12 item short form survey (SF12)(n=1) (Neill *et al.* 2008) and the Euro Quality of life (EQ-5D) (n=1) (Tennvall and Apelqvist 2000). Although none of these measures have been validated for use with the LEA population, Sinha et al (2014) reported high internal consistency for the Short Form-36 in the LEA population (Sinha *et al.* 2014b) The same authors found a significant correlation between the Trinity Amputation and Prosthetic Experience Scale (TAPES) and the Physical and Mental component summaries

of the Short Form 36 (SF-36) QoL measure in the LEA population (Sinha *et al.* 2014b). The Prosthetic Evaluation Questionnaire (PEQ) (n=1) (Harness and Pinzur 2001) is specific to those who have a prosthesis after LEA. Other scales such as the Satisfaction With Life Scale (SWLS) (n=2), (Norvell *et al.* 2011); Sense of coherence scale (n=1) (Abdelgadir *et al.* 2009); Nottingham health profile (n=1) (JP Pell *et al.* 1993); and a 9-point scale of social function (n=1) (Thompson *et al.* 1995) were also used.

Ten studies used a single measure to assess quality of life (JP Pell *et al.* 1993, Tennvall and Apelqvist 2000, Harness and Pinzur 2001, Deans *et al.* 2008, Neill *et al.* 2008, Abdelgadir *et al.* 2009, Cox *et al.* 2011, Norvell *et al.* 2011, Buijck *et al.* 2012, Fortington *et al.* 2013a). One study used three measures(Mac Neill *et al.* 2008) and another used four measures (Remes *et al.* 2010). Seven studies measured quality of life alongside other factors such as physical function, depression, social support, prosthetic use and change in walking (Thompson *et al.* 1995, Deans *et al.* 2008, Neill *et al.* 2008, Remes *et al.* 2010, Cox *et al.* 2011, Norvell *et al.* 2011, Buijck *et al.* 2012).

3.3.5 Walking ability and use of prosthesis

Walking with a prosthesis was the most notable factor that influenced QoL, and was reported by all twelve studies. The other factors that were identified that influenced QoL were gender, age, diabetes and family support (Table 3.2).

When comparing quality of life of people after LEA to age and gender matched controls, after controlling for social isolation and emotional distress, the ability to walk was still found to significantly influence quality of life (JP Pell *et al.* 1993, Abdelgadir *et al.* 2009). Norvell et al (2011) found that those with poor to moderate mobility as per the LCI-5 score reported greater quality of life compared to those who were unable to walk (Norvell *et al.* 2011). In addition, Deans and colleagues (2008) suggested that the association between quality of life and walking was due to the positive influence of walking with a prosthesis on social interaction, rather than improving physical fitness (Deans *et al.* 2008).

Two cross-sectional studies compared those with a LEA to people with active foot ulcers (Tennvall and Apelqvist 2000) and bypass graft (limb salvaging surgery) (Thompson *et al.* 1995). Both studies concluded that the quality of life of those with a LEA was significantly poorer than those with active foot disease or surgery. Those who underwent a LEA had

higher levels of depression and were less mobile than those who underwent a bypass graft (Thompson *et al.* 1995). Mobility was self-reported on a four point scale and those with a LEA were significantly less mobile than those with revascularisation; however no information about prosthetic use or distances covered was given. Although the results are as expected, this article was a retrospective study with a relatively small number of those with LEA (n=26) compared to those with a bypass graft (n=86) and the study's quality assessment score was low (Table 3.2).

3.3.6 Level of lower extremity amputation

Two studies of prospective design examined the effect of level of LEA on QoL (Norvell *et al.* 2011, Fortington *et al.* 2013a), both achieving high quality assessment scores (Table 3.3). Those with a TTA reported better quality of life, compared to those with a TFA (Fortington *et al.* 2013a). This was due to improved walking ability and thus greater social function in those who had a TTA. A decline in quality of life and walking was observed over 12 months after LEA in all participants with LEA regardless of level (Fortington *et al.* 2013a), however, this decline in quality of life was greatest in those with a TFA (Norvell *et al.* 2011). In one study of people with unilateral TTA a strong association was found between quality of life and the ability to walk (n=60) (Harness and Pinzur 2001), however the sample all received prosthetic rehabilitation and were therefore more likely to be mobile.

3.3.7 Age, co-morbidities and gender

There was a strong association between being over 65 years of age at the time of LEA and reduced ability to walk, which ultimately had a detrimental effect on quality of life (Norvell *et al.* 2011, Fortington *et al.* 2013a). With increasing age there was a higher incidence of co-morbid disease (Fortington *et al.* 2013a) which may have affected quality of life directly or indirectly through the influence of the co-morbid conditions on walking ability.

The presence of diabetes was associated with a lower quality of life following LEA. Furthermore, the longer the duration of diabetes and its associated secondary complications, the poorer the quality of life (Abdelgadir *et al.* 2009). Other co-morbidities

such as hypertension, alcohol dependence, anxiety and depression are reported to negatively influence quality of life (Norvell *et al.* 2011). Two studies found that gender influences quality of life with women having higher quality of life following LEA (Abdelgadir *et al.* 2009, Cox *et al.* 2011) especially in those under 60 years old.

3.3.8 Social situation

Living at home and being able to walk, was positively associated with quality of life (Remes *et al.* 2010). Poor QoL and depressive symptoms were more prevalent in those living in a care home or in those who were wheelchair-bound within their home environment (Remes *et al.* 2010). Neill et al (2008) found that those who had bilateral TTA's and lived alone scored higher on the mental health aspect of quality of life and higher on the activities of daily living on the Frenchay Activities Index, than those who lived with family (Neill *et al.* 2008). The authors also suggested that poorer quality of life was attributed to social isolation, 24% of people were housebound, however social isolation was reported to be present even if participants did not live alone (JP Pell *et al.* 1993).

3.4 Discussion

The aims of this systematic review were to identify the factors that influence quality of life after LEA for PAOD. Although this review found there was general agreement that those with a LEA have poorer quality of life compared to their healthy peers; walking ability was the central influencing factor. This determined the ability to live independently and participate in social activities, which also affected quality of life. The findings showed that, the ability to walk with a prosthesis had the strongest influence on quality of life. Many factors affect the ability to walk with a prosthesis, such as level of LEA, co-morbid diseases, psychological motivation, living situation and social function.

Our review concurs with some of the findings of Sinha et al (2011) who also found that limited walking ability negatively influences quality of life in those with a LEA (Sinha and Van Den Heuvel 2011). In addition, the current review found that the ability to participate socially, perform activities of daily living and live independently influences the quality of life of a person with a LEA due to PAOD. The age range of the populations studied in this

review was from 56 to 75 years old. Of all the studies included in this review, only one study reported that quality of life declined with increasing age; specifically, over 65 years old.

This review is novel as it focuses solely on those who have a LEA due to PAOD as opposed to previous reviews, which have examined heterogeneous groups of those with amputations. LEAs due to PAOD are the most common and have the greatest impact on health resources.

Factors such as advancing age and co-morbidities, notably diabetes, negatively influence the probability of successfully walking with a prosthesis and therefore quality of life (Abdelgadir *et al.* 2009, Norvell *et al.* 2011, Fortington *et al.* 2013a). The majority of those with a LEA due to PAOD are over 65 years old and approximately half will have diabetes. The presence of arterial disease in other organs adds to the co-morbid burden of this patient group and compromises their ability to walk with a prosthesis. All of this reduces their life expectancy. One solution to improving the QoL of non-prosthetic users may be extending rehabilitation and integration with prosthetic users to allow for improvements in morale and social integration (JP Pell *et al.* 1993). Quality of life was greater in those with a TTA compared to a TFA. Those with distal amputations e.g. TTA, are more likely to have successful prosthetic management, less likely to need walking aids and more likely to engage in meaningful vocational and social activities (Sansam *et al.* 2009). Hagberg et al (2006) concluded that those with a TFA had poorer quality of life, than those with a TTA, as they required a higher level of energy expenditure to walk, due to the loss of the knee joint (Hagberg 2006). In addition, it is possible that lower mood and higher psychological burden may reduce the inclination to participate in rehabilitation which lowers the successful use of a prosthesis.

Two studies in this review examined the gender differences in QoL (Abdelgadir *et al.* 2009, Cox *et al.* 2011). Improved quality of life was reported in females, compared to males, and was attributed to their higher levels of physical function. These findings conflict with previous literature, in which males were found to have greater quality of life (Sinha and Van Den Heuvel 2011). However, the review by Sinha et al (2011) included those with LEAs for non-vascular causes. Therefore, it is possible that quality of life following a LEA may be greater in females when it is due to PAOD and improved in males

when the LEA is due to trauma or tumour. Further research is warranted to examine these gender differences.

There were conflicting results regarding family support and its impact on quality of life. Those who live alone may be more capable, both cognitively and physically, and therefore have a better QoL (Mac Neill *et al.* 2008). Mac Neill et al (2008) also suggested a cause and effect relationship between quality of life and living alone (Mac Neill *et al.* 2008). More specifically, those who lived alone were more able to perform activities of daily living independently; a third engaging in social outings on a weekly basis. Consequently, they had better mental health as they felt less burdensome and relied less on others. Conversely, two studies suggested that living with family was associated with better quality of life in comparison to those who lived alone (Pell *et al.* 1993, Abdelgadir *et al.* 2009). Although these studies focussed on living with family, the rating of good quality of life may be replicated in a supportive environment such as residential or assisted living complex.

There are no validated QoL outcome measures available for the LEA population, accommodating both wheelchair and prosthetic mobility. The TAPES was used in one study, however this only assesses the function of prosthetic users (Deans *et al.* 2008). The Prosthetic Evaluation Questionnaire (PEQ), which has a sub-section that measures quality of life, is the only outcome measure that has been validated for use in those with a LEA. Despite this, it is only relevant for those who receive a prosthesis and was only used in one study included within this review (Harness and Pinzur 2001). Developing and validating a quality of life outcome measure for this population is imperative to allow for more rigorous future longitudinal studies, systematic reviews and meta-analyses.

This review has demonstrated that being able to walk with a prosthesis is the main factor affecting quality of life after a LEA for PAOD. A number of factors such as age, level of amputation, and the presence of co-morbidities also affect quality of life in those with PAOD, but are not modifiable. It is therefore important that rehabilitation focus on modifiable factors, particularly with regards walking. Furthermore LEAs due to non-vascular aetiologies have benefitted from advances in prosthetic technologies and access to rehabilitation (Datta *et al.* 2005, Chin *et al.* 2006). The improved technology may benefit amputees in terms of prosthetic comfort, pain relief and energy conservation improving walking ability.

3.4.1 Study limitations

This review was limited to studies published in English. It was also limited by the heterogeneity of the study designs included. Due to the variety of outcome measures used it was not possible to conduct a meta-analysis. Studies using qualitative methodologies were excluded from the review however they may have added context to the factors that influence QoL.

3.4.2 Conclusions

This review is novel in its focus on those with a LEA due to PAOD and has identified the factors that influence quality of life in this population. Walking is the main factor that influences quality of life following LEA, therefore rehabilitation should focus on gait re-education with a prosthesis. In order to improve quality of life there is an identified gap in the literature and the need for more prospective longitudinal studies with a standardised outcome measure, which can examine the possible change in quality of life over time.

Recognising the need for longitudinal cohort studies with standardised outcome measures, both for QoL and mobility; the following chapter describe the methods of a prospective longitudinal cohort study, which examines a population with a LEA due to PAOD.

Chapter 4
Methods of Cohort Study

4.1 Introduction and rationale

There have been many studies examining the morbidity and mortality of those with a major lower extremity amputation (LEA) due to peripheral arterial occlusive disease (PAOD). However, there have been no prospective studies to date that have examined and followed a cohort of people with a LEA during in-patient, out-patient phases and with long term follow up. Nor have any studies determined quality of life, participation and mobility one year after LEA.

To address the gaps in the literature identified in Chapter 3, this cohort study was designed to describe the population who undergo major LEAs due to PAOD, and to follow them up at 6 monthly intervals. This research study will report on 6 and 12 month follow up, however the study is continuing to follow all those until 100% attrition is reached. This allows for a detailed picture of disease burden and impact on the patient from the hospital setting fat time of initial LEA.

Following the main aim, objectives and overview of the study design, a description of the methods employed in this cohort study are presented.

4.1.1 Objectives

The cohort study aimed to ascertain the factors that influenced QoL after a LEA. In order to do this, the population of people who have a major LEA were described in relation to socio-demographic characteristics, level of LEA, mortality, prosthetic status, co-morbid disease and socio-economic deprivation. In addition, clinical outcomes were examined at time of LEA and then again at 6 and 12 months post, LEA and the patient reported outcomes of quality of life, participation and mobility at 6 and 12 months post LEA.

The cohort study aimed to address the following research questions:

Primary research questions:

1a) Is QoL affected by an LEA?

1b) Which factors influence QoL after an LEA?

Secondary research questions:

2. What are the characteristics of the population who have a LEA, and how do they change over one year?

3. What is the mortality rate following LEA and what factors are associated with mortality?

4. Does diabetes influence outcomes after LEA?

5. What are the rates of limb fitting and level of mobility achieved following LEA; and what are the associated factors?

4.2 Methods

4.2.1 Study design

A prospective cohort study of all people who had a major LEA between 1st March 2014 until 28th February 2015 in Greater Glasgow and Clyde was undertaken. Participants' medical and rehabilitation notes were reviewed at time of LEA, to discharge from outpatient rehabilitation and six and twelve months after their LEA. A subgroup of this cohort, who gave informed consent, also completed follow up questionnaires at 6 and 12 months after LEA.

4.2.2 Setting

All of the participants were recruited from NHS Greater Glasgow & Clyde (NHS GG&C) which is the largest health board in the UK. Over a quarter (27%) of LEAs in Scotland are

performed within NHS GG&C. At the time of the study six hospitals performed major amputations within NHS GG&C; Western Infirmary, Gartnavel General Hospital, Royal Alexandria Hospital, Glasgow Royal Infirmary, Southern General Hospital and Inverclyde Royal Hospital (Figure 4.1). The Western Infirmary housed the Centralised Vascular Unit, where the majority of LEA's were carried out whilst the other five hospitals undertook fewer LEAs within their orthopaedic or surgical wards. After data collection was complete, many of these hospitals were amalgamated to the Queen Elizabeth University Hospital on the site of the Southern General Hospital.
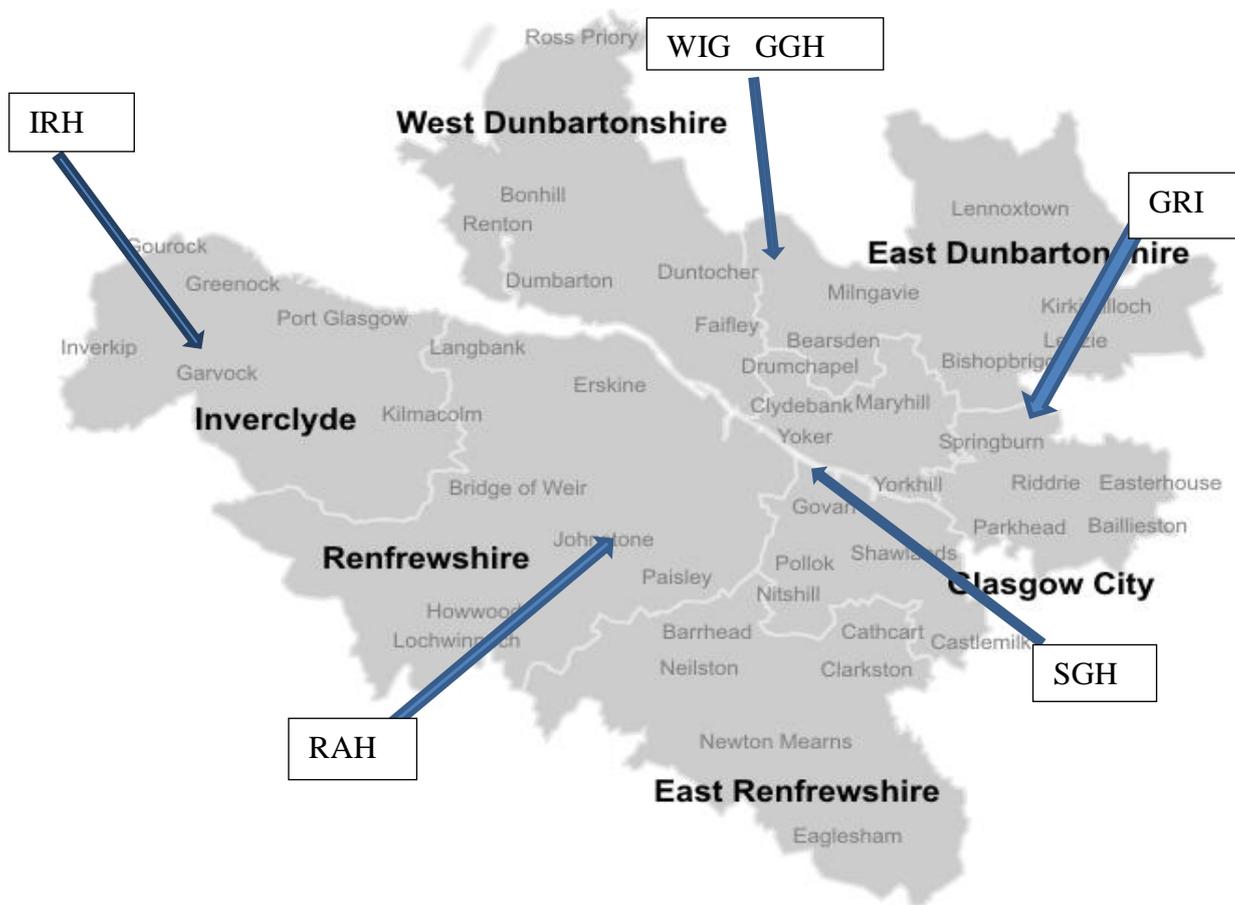
Figure 4.1 Geographical location of acute hospitals in NHS Greater Glasgow and Clyde.

Abbreviations: GGH=Gartnavel General Hospital, WIG=Western Infirmary Glasgow, IRH=Inverclyde Royal Hospital, RAH=Royal Alexander Hospital, GRI=Glasgow Royal Infirmary, SGH=Southern General Hospital

The Centralised Vascular Unit in the Western Infirmary was visited twice weekly in order to enrol all people who had undergone a LEA. The lead physiotherapists of the orthopaedic

or surgical wards in the remaining five hospital sites were contacted weekly to ascertain whether there were any new patients who might be eligible for the study. If there were, then these sites were visited immediately to access the medical case notes of potentially eligible participants. After initial enrolment into the cohort study, the Principal Investigator (PI) continued to visit the hospital sites to ensure data collection from time of surgery throughout to discharge from in-patient and out-patient services was complete. There were subsequent visits to the Centralised Vascular Unit, as the cohorts' data at 6 and 12 months after the initial LEA could be accessed from one central server.

4.2.3 Participants

All participants enrolled into the cohort study were 18 years old and over, and had a major LEA above the ankle performed within NHS GG&C. Participants were excluded if their LEA was due to trauma, congenital abnormality, tumour or orthopaedic complications, or had a trans-pelvectomy or hip disarticulation LEA. All enrolled participants underwent a medical case note review of routinely collected data. This took place at time of LEA, discharge from in-patient setting and then if applicable on discharge from out-patient rehabilitation, and then at 6 and 12 months after LEA. To add to this data, a subgroup of the cohort consented to complete participant reported outcomes of quality of life (QoL), participation and mobility, six and twelve months after their LEA. The flow of participants through the study is explained in Fig 4.2.

Once enrolled into the cohort study, the Principal Investigator (PI) spoke to the treating physiotherapist and examined the medical case notes to ascertain the participants' eligibility to consent to the follow up questionnaires aspect of the study. When applicable, a participant information sheet (PIS) (Appendix I) was given to the potential participant and when the PI was at the hospital site the patient was given the opportunity to ask further questions regarding the study and the PIS. The PI then took informed written consent (Appendix II) from the participant and this was recorded on the participant identification log (Appendix III). Three consent forms were signed by the participant and the PI; one for the PI's study site file, one for the participant and one that was included in the participant's medical case notes. The participant's GP was also notified by letter (Appendix IV) that their patient was involved in the study.

The entire cohort was eligible for inclusion to participate in the questionnaire follow up aspect of the study. Those who were unable to read or speak English and those who were deemed by medical staff as not having capacity under the terms of "The adult with incapacity (Scotland) act" (2000) were excluded. If pre-operative sepsis was present and participants were not deemed to be cognitively capable of taking part at point of initial recruitment into the study then they were reviewed within 2 weeks of their LEA, whilst still an in-patient, to assess if their cognition had improved and recruitment was possible.

4.2.4 Ethical approval

Ethical approval was obtained from the West of Scotland NHS Research Ethics Committee (14/WS/0016) on the 8th January 2014. Research and Development approval was gained from NHS Greater Glasgow & Clyde in January 2014. Participants had the right to withdraw from the study at any point for any reason. If a participant withdrew, then their completed follow up questionnaires were analysed until that point. Data from those who died were collected until that point and included in the analysis. Participants who did not return their completed questionnaires were sent an additional/reminder letter and if no response was gained from this contact then their data were recorded as missing. Over time there was a natural attrition, due to mortality. Characteristics of those who consented to follow up and did not respond were also noted, and compared to those who responded.

For each participant, their unique participant identification number, their hospital identifier (CHI number) and the hospital where the amputation was performed were logged on the participant identification log (Appendix III). This was held in paper format and stored within a locked cupboard in a locked file at the Centralised Vascular Unit in the Western Infirmary. The unique participant identification number and the corresponding case note information collected for the study was held on an encrypted USB for purposes of analysis, within the Nursing & Healthcare school of the University of Glasgow, in a locked drawer in a locked room. Responses to the follow up questionnaires were inputted to an excel spreadsheet and kept in electronic format on an encrypted USB stick. The Data Protection Act 1998 was adhered to at all times. To enable evaluations and/or audits from regulatory authorities, the investigator agreed to keep records, including the identity of all participating subjects (sufficient information to link records), all original signed informed consent forms, serious adverse event forms, source documents, and detailed records of

treatment disposition in accordance with ICH GCP, local regulations, or as specified in the Clinical Study Agreement.

Electronic anonymised data was thenstored in a locked filing cabinet in a locked room within the University of Glasgow for long term storage.
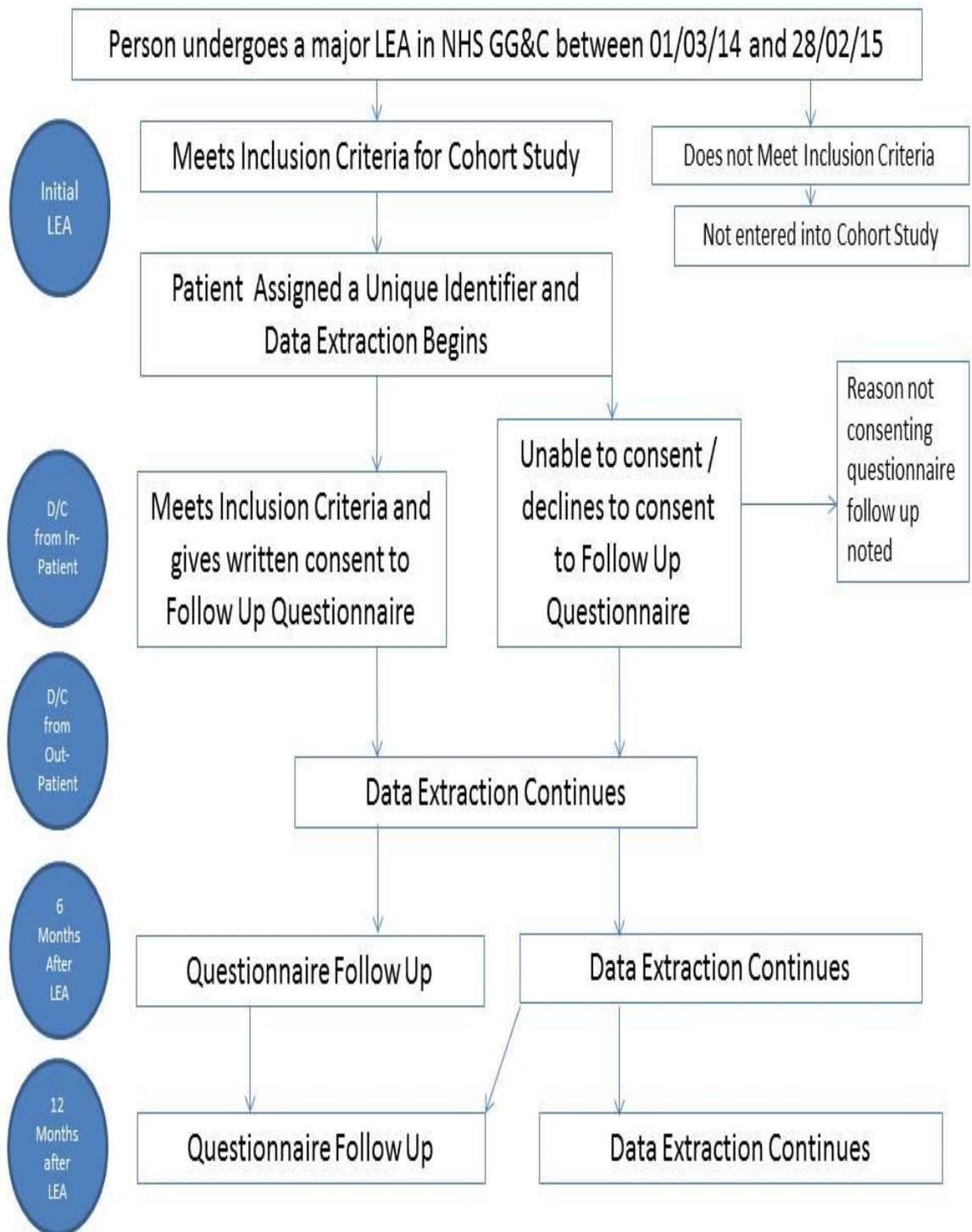
Figure 4.2 Participant Journey through Cohort Study

Abbreviations: LEA=Lower Extremity Amputation; NHS GG&C= NHS Greater Glasgow and Clyde

4.2.5 Data sources

Routinely collected data required on each variable were extracted from a variety of sources. The initial visit required the PI to review the medical case notes both hard copy and electronic. Hard copies were located in the ward, the electronic version was accessed through the Track Care database which also hosts the Clinical Portal system which links information in all hospitals and GP practices in NHS GG&C. Accessing both systems and the paper medical case notes allowed all variables in Tables 4.1 and 4.2 to be collected. Information on sociodemographic descriptors was accessed from the in-patient admitting case notes also held in the ward. Other variables (Table 4.3) were extracted from information collected by the treating physiotherapist when they assessed the patient before or immediately after LEA. The variables in Table 4.4 on housing, accessibility and social situation were all extracted from the occupational therapists' environmental visit report which was undertaken within 2 weeks of the LEA surgery. Data on the contralateral foot were accessed from the physiotherapy notes as the contralateral foot was reviewed daily during treatment sessions. Immediately prior to discharge, all of the variables in Table 4.5 were recorded from the physiotherapy and occupational therapy notes. Data extraction of variables relating to the participants' diabetes (Table 4.6) was done through the electronic clinical portal system and any issues affecting rehabilitation from the physiotherapy notes.

All data pertaining to prosthetic fitting, discharge from out-patient physiotherapy and final mobility (the LCI-5) was accessed on site, from the limb fitting register (ReTis), at the West of Scotland Mobility and Rehabilitation Centre (West MARC). This was an additional electronic resource shared between prosthetists and physiotherapists. If the patient was not a successful prosthetic user, the reason for not completing rehabilitation was also extracted from here. This information was then verified by accessing the Scottish Physiotherapy Amputee Research Group (SPARG) data base which holds all data on each patient with an LEA in Scotland. If the participant did not go directly home from hospital and was transferred to another unit then the date, destination and reason for transfer was extracted from the electronic clinical portal system.

4.2.6 Variables

Data extraction in the cohort study included a large number of variables; the initial data was extracted immediately after the participants LEA (Table 4.1, 4.2, 4.3).

Sociodemographic and any limb salvaging surgery pre LEA and reason for LEA were recorded. Variables collected at initial entry into the study were assigned a code to assist with categorisation and analysis (Table 4.1). Reason for LEA was gathered from the admitting case note and verified in the operation notes within the electronic medical case notes; the options were ischaemia, infection or both ischaemia and infection, or other. Whether the participant had limb salvaging surgery within a year or more than a year of this LEA was recorded and the most recent limb salvaging surgery procedure was categorised further as there may have been multiple procedures in the months and years leading up to the LEA.

The participants' postcodes at time of LEA were converted to a socioeconomic descriptor using the Scottish Index of Multiple Deprivation (SIMD) tool. The SIMD consists of seven domains, each with the most up to date information on current income; employment; health; education skills and training; geographic access to services; housing and crime. The SIMD uses the 6505 geographical data zones within Scotland to categorise a person's index of deprivation into a quintile, where SIMD 1 is the poorest area and SIMD 5 the most affluent area; this ranking allows for comparison of postcode areas along the scale of 1- 5 (http://doc.ukdataservice.ac.uk/doc/6870/mrdoc/pdf/6870technical_report_2006.pdf).

Table 4.1 Variables collected immediately after lower extremity amputation.

Variable	Coding
Age at time of LEA	Date of LEA – DOB
Gender	Male/Female
Ethnicity	Caucasian/Asian/Black
Level of LEA	TTA/TFA/TKA
Side of LEA	Left/Right
Date of LEA	dd/mm/yy
Previous LEA	Yes/No (If yes then level, side and date)
Grade of Surgeon	Consultant/Registrar
Surgery Type	Elective/Emergency
Reason for LEA	Ischaemia/Infection/Ischaemia & Infection
Postcode	Converted to SIMD Quintile

Abbreviations: LEA=Level of Amputation, TTA=Trans-tibial, TFA=Trans-femoral, TKA=Through Knee, DOB=Date of Birth, SIMD=Scottish Index of Multiple Deprivation

Whether a participant had their limbs imaged prior to LEA e.g. MRA or CTA was documented. If limb salvaging surgery was undertaken, then this was categorised by time (more than 12 months or less than 12 months from LEA) and whether it was invasive revascularisation or not (Table 4.2). A participant's renal function was ascertained from the glomerular filtration rate (eGFR) blood test result.

Table 4.2 Pre lower extremity amputation variables.

Variable	Option
Imaged < 12 months before LEA (MRA/CTA)	Yes/No
Limb Salvaging Surgery > 12 months before LEA	Yes/No
Limb Salvaging Surgery<12months before LEA	Yes/No
Limb Salvaging Surgery <12 months pre LEA	Surgical procedure/ Radiological procedure/ Combination of surgical/radiological procedure

Abbreviations: MRA=Magnetic Resonance Imaging, LEA=Lower Extremity Amputation, eGFR=Glomerular Filtration Rate

Socio-demographic variables were extracted from the physiotherapy and occupational therapy notes. In addition, the participant's cognitive ability was assessed by the occupational therapist (OT) and a thorough cognitive examination was conducted by the OT if indicated. Smoking and alcohol status, were categorised at time of LEA. Employment, educational level, falls history, driving status and whether they had any commitments as a carer or received a package of care (home help), were asked by the occupational therapist and extracted from their OT assessment (Table 4.3).

Co-morbidities of each participant were inputted into the Functional Co-Morbidities Index (FCI) which is a tool to categorise a person's function as high or low (Groll *et al.* 2005). In the context of the cohort study the FCI assessed a participant's pre-morbid status prospectively as it was completed at time of LEA (Appendix V). There are 18 conditions that are scored, including respiratory and cardiac problems, anxiety and depression. The score given is 0 if the participant is not diagnosed with the condition and 1 if the condition has been diagnosed. A condition must be documented in the medical notes to be a diagnosed condition. This tool gives a maximum score of 18 which means all co-morbidities are diagnosed. The validity of this tool was analysed in a study by (Groll *et al.* 2005) who showed that the FCI correctly categorised participants into low, moderate and high physical function in over 77% of cases. In the cohort study the FCI was routinely collected by the treating physiotherapist and recorded in the medical notes, the researcher

completed this tool independently with a thorough medical and case note review to ensure rigour.

Table 4.3 Socio-demographic variables.

Variable	Coding
Highest level of Education achieved	School/Further Education
Employment 6 months pre LEA	Retired/ Employed/ Unemployed/ Long term sick
Smoking Status at time of admission	Non-smoker/ current smoker/ ex-smoker
Alcohol consumption at time of admission	No alcohol intake/ Average intake/ Excess Intake/ history of previous excess intake
Falls Within 6 months of LEA	None/ 1 Fall/>1 Fall
Cognition Within 6 months of LEA	Not Ax & Intact/ Ax & Intact/ Impaired & not Ax/ Impaired & Ax
Package of care at time of admission	Yes/No
FCI Score On admission for LEA	Score from 0-18

Abbreviations: LEA=Lower Extremity Amputation, Ax=Assessed, FCI=Functional co-morbidities index

Thereafter data were extracted from the relevant clinical records as the participant progressed through their rehabilitation as an in-patient. Each participant had an occupational therapy environmental visit (EV) assessment completed within a week of amputation. Type of housing, social situation and accessibility was recorded in their EV report which was in their therapy notes. The condition of the contralateral foot was assessed thoroughly by the physiotherapist soon after amputation along with any treatment or referral, this information was found in the therapy notes. If there was evidence of a Charcot joint being the primary reason for amputation or occurring on their contralateral limb this was also recorded. Participants self-reported community ambulation, driving status, regular exercise and level of mobility (Locomotor Capabilities Index, LCI-5) six months prior to LEA was also recorded from the physiotherapy assessment (Table 4.4).

The LCI-5 consists of a subjective list of 14 task related questions, asked of the participant by the treating physiotherapist at the start of in-patient rehabilitation and gathers data on how the participant perceives their own mobility 6 months before amputation. The scores range from 0 (unable to do the task) to 4 (independently able to do the task with no walking aid)(Franchignoni *et al.* 2004). The LCI-5 has two subsections, basic activities such as sit to stand and walking indoors and advanced activities such as walking outdoors, getting up from the floor and carrying objects.

The basic and advanced sections have a maximum score of 28 giving an overall total of 56 which equates to the overall mobility of a person. The higher the score of the LCI, the greater the mobility of the participant. Recent research found that the advanced mobility section was the most sensitive to change following LEA (Norvell *et al* 2011). The LCI-5 is only relevant to prosthetic limb users as only they have their scores recorded post limb fitting. Franchignoni et al (2004) found that construct validity of the LCI-5 was high and was accurate when summing up the global mobility of participants during their prosthetic training (Franchignoni *et al.* 2004) (Appendix VI).

The questionnaire part of the cohort study required the PI to review the electronic medical case notes of those participants to ensure that the following were checked before questionnaires were sent to the participant's home: they had survived to 6 months; were not in hospital; their address was correct and to ascertain if they had been discharged from rehabilitation with a prosthesis. Once this information was verified, the follow up questionnaires were posted to the participants. All of the participants received a quality of life and a participation questionnaire, and those who had a prosthesis also received a Prosthetic Limb User Survey of Mobility (PLUS-M) questionnaire.

Table 4.4 Data extracted from occupational therapy and physiotherapy records.

Variable	Coding
Type of Housing	Owner occupier/ Private Rent/ Social Housing/ Sheltered Housing/ Nursing Home/ Homeless
Access to House	Housebound/ Single room living/ Full access internal & external/ External access only & limited internal access
Social Situation	Lives alone/ Lives with partner/ Lives with family
CL Foot Issues	Yes /No Ischaemia/ Ischaemia & Ulcer/ Non-ischaemic & Ulcer/ Charcot/ Issues with minor amputation
CL Foot Treatment	Yes/ No Conservative Management/ Orthotics/Surgery
LCI-5 Score	Basic Score max 28 Advanced Score max 28

Abbreviations: LEA=Lower Extremity Amputation, LCI-5= Locomotor Capability Index, CL=Contralateral

If the participant fell and injured themselves causing a delay in their rehabilitation then this was recorded from the physiotherapist records along with the healing status of their stump (residuum). If applicable, any inter-current illness that the participant had during their in-participant stay which reduced or delayed rehabilitation was recorded from the physiotherapy and medical notes (Table 4.5).

Table 4.5 Issues prior to discharge from in-patient care.

Variable	Coding
Falls Whilst In-Participant	If rehabilitation was delayed as a consequence
Stump Issues	Infection/ Ischaemia/ Delayed Healing/ Contracture/ Ischaemia & Contracture
Revision Surgery	If yes then date (dd/mm/yy) Revised to same level Revised to higher level
Referral to Prosthetic Centre	Yes/No
Discharge date & Location	Own Home Other accommodation (SIMD) Transfer to different hospital
Community OT Referral	Yes/No

Abbreviations: OT=Occupational Therapist, SIMD=Scottish Index of Multiple Deprivation

Additional variables for those diagnosed with diabetes were extracted; type of diabetes, treatment, glycated haemoglobin (HbA1c) and issues affecting rehabilitation (Table 4.6). Type of diabetes was categorised by Type I or II along with the current diabetes therapy; insulin, oral medication or a combination of both or if the participant was diet controlled with no prescribed medication. The most recent HbA1c was recorded from the electronic medical record system Clinical Portal. This denotes a participant's average plasma glucose concentration for the previous three months. Control was defined as follows: good <58mmol/mol, moderate 58-75mmol/mol moderate or poor >75mmol/mol. If there was a prescription for a sulphonylurea this was noted. If the participant had not been able to attend in-participant rehabilitation or became unwell during a rehabilitation session due to diabetes, the number of times this occurred and whether it was for hypoglycaemia or hyperglycaemia, was recorded from the physiotherapy notes.

Table 4.6 Diabetes information.

Variable	Coding
Type of Diabetes	Type I or Type II
Current Treatment	Insulin/ OHA/ Insulin & OHA/ Diet
Prescribed Sulphonylurea	Yes/No
HbA1c	Level recorded prior to LEA
Rehab affected by DM	Yes/No

Abbreviations: DM=Diabetes Mellitus, OHA=Oral Hypoglycaemic Agent, HbA1c=Glycated Haemoglobin, LEA=Lower Extremity Amputation

For participants referred for prosthetic assessment; data were extracted from electronic records at the Southern General Hospital in the specialist prosthetic centre, West MARC. Date of prosthetic fitting was defined as the date that the participant started gait rehabilitation with their prosthesis. The length of out-patient physiotherapy was defined as time taken from commencement of gait rehabilitation with their prosthesis until date discharged from regular out-patient physiotherapy. Throughout this period data were extracted where applicable on; inter-current illness, hospital readmissions, stump and contralateral foot issues, change in LEA level, change in housing situation, diabetes related issues, mobility as recorded by the locomotor capabilities index (LCI-5) and mortality.

Data extraction continued at 6 and 12 months after the initial LEA. The variables in Table 4.7 were recorded to determine if there had been any changes to level of LEA, mortality and housing (Table 4.7).

Table 4.7 Six and twelve month review.

Variable	Coding
Readmission	Date of readmissions occurring between in-participant discharge and 6 months after LEA
Reason for Readmission	Vascular or other
If further LEA surgery - change in level of LEA	New level of LEA and date of surgery
Prosthetic Fitting	Yes/No If No, reason for not fitting with prosthesis
Postcode	Converted to SIMD
Diabetes Medication	Medications compared to initial review
Morbidity	FCI Score
Mortality	Date and cause of death

Abbreviations: LEA=Lower Extremity Amputation, SIMD= Scottish Index of Multiple Deprivation, FCI= Functional co-morbidities index

Quality of Life (EQ-5D-5L)

Quality of Life questionnaires were only completed by those who consented to follow up and were not part of the routinely collected data. Quality of Life was measured with the EQ-5D-5L (Appendix VII). This outcome measure was selected as it is low on participant demand and is applicable to the population of amputees, irrespective of mobility status. The EQ-5D-5L describes and values health in five domains: mobility; self-care; usual activities; pain/discomfort and anxiety/depression (Herdman *et al.* 2011). Each question has five response options; no issues, slight issues, moderate issues, severe to extreme issues relating to that specific domain. The measure includes a health descriptor where the participant scores their health that day on a visual analogue scale of 0 to100.

The EQ-5D-5L scores the participant's health at that time with a score of 1 to 5 for each of the five health domains e.g. 11111 is a participant with no issues in mobility, self-care, usual activities, pain or anxiety/depression. Alternatively, a health domain of 32551 would indicate moderate issues with mobility (3), mild issues with self-care (2) and extreme issues with usual activities (5) and extreme issues with pain (5) and no issues with

anxiety/depression (1). The health domain is then inputted into a cross-tab calculator and is converted to a health index score which ranges from one (best health possible) to zero (no health or dead). Additionally, there is the possibility of a negative score up to minus one, which would indicate that the participant's QoL is worse than death.

Reintegration to Normal Living Index (RNLI)

The measure of participation was the Reintegration to Normal Living Index questionnaire (Wood-Dauphinee *et al.* 1988) (Appendix VIII). This is a self-reported measure of a person's global function; in this case after LEA. The RNLI is applicable to those who may or may not be mobile after their LEA and has high validity, both construct and convergent when used alongside a HRQOL measure (Wood-Dauphinee *et al.* 1988). The RNLI has eleven statements such as *"I move around my community as I feel necessary"* and *"I assume a role in my family which meets my needs and those of other family members"*; each statement is rated from 0, unable to do, through to 10, completely able to do. The RNLI assesses quantitatively, the degree to which individuals who have experienced traumatic or incapacitating illness achieve reintegration into normal social activities with a maximum score of 110, which is converted to an adjusted percentage score. A score of 100% describes complete reintegration and the minimum score of zero describes no reintegration.

Prosthetic Limb User Survey of Mobility (PLUS-M)

Participants who received a prosthetic limb after their LEA were also asked to complete the Prosthetic Limb User Survey of Mobility (PLUS-M) (Appendix IX). This is a self-report instrument for measuring walking ability with a prosthetic limb after an LEA (Hafner *et al.* 2015). There are twelve statements and the participant is asked to rate how able they were to complete the tasks within the statements. Statements include *"are you able to step up and down curbs"* and *"are you able to keep up with others when walking"*; other statements ask about walking both indoors and outdoors and enquire about the participants balance when walking on uneven surfaces or those on an incline. These tasks are scored on a five point Likert scale ranging from unable to do (1) to completely able to

do (5). This score is then converted to a PLUS-M t-score, which ranges from 21.8 - no mobility, to 71.4 which is independently mobile.

The PLUS M, EQ-5D-5L and the RNLI questionnaires were posted to the participants six and twelve months after their LEA with a covering letter reminding them of the study and an explanation of how to complete the questionnaires along with contact details of the researcher and a stamped addressed envelope to return them (Appendix X). If the participant had not returned the questionnaires within three weeks, then a reminder letter was posted to them.

4.2.6 Objectivity

The Principal Investigator was an NHS employee who had over 10 years' clinical experience in the field of amputee rehabilitation and was familiar with the hospital sites, electronic records systems and other therapy notes and databases. As they were not the participant's treating physiotherapist, they were able to collect and collate the data ethically.

4.2.7 Study size

There were 180 and 198 people who underwent a LEA in NHS GG&C in the years 2011 and 2012 respectively. These numbers were used as an indicator of the potential size of the cohort that could be recruited in the 12-month study period between 1st March 2014 and 28th February 2015.

4.3 Data management and statistical methods

Each participant in the cohort study was given a unique numerical identifier, and all variables were coded on input into a Microsoft Excel spreadsheet then transferred to SPSS (Windows v.22) for analysis. This allowed for the cohort data to be managed., firstly to undertake descriptive statistics, then associations and regression analysis. The statistical methods employed for each of the research questions are detailed below. All tests were at

the 5%, *p <0.05* level of significance. All statistical analysis was conducted in consultation with a bio-statistician at the Robertson Biostatistics Centre, University of Glasgow.

Primary research questions:

1a) Is QoL affected by an LEA?

Analysis of QoL health index scores and comparison to the Euroqol scores for the population without an LEA

1b) Which factors influence QoL after an LEA?

Responses to the follow up questionnaires were analysed by SIMD quintile, diabetes status, level of LEA and limb fitting. Correlation analysis was used to describe the strength and direction of the association between the continuous variables (e.g. QoL Health Index, RNLI and PLUS-M scores). For parametric correlations, Pearson's correlation was used and for non-parametric, Spearman was used, r values were interpreted as: small (r=.10-.29); medium (r=.30-.49) or large (r=.50-1.0) (Griffith 2007). Multiple regression analysis was conducted to ascertain, which variables had the most influence on QoL at 6 and 12 months following LEA

2. What are the characteristics of the population who have a LEA, and how do they change over one year?

Descriptive statistical analyses were performed for all variables in the cohort study at initial LEA and then at 6 and 12 months after LEA.

Analysis of Variance (ANOVA) were undertaken to compare; those with and without diabetes: glycaemic control and level of LEA; reason for LEA; age at time of LEA and SIMD; level of LEA and other variables such as mortality; limb salvaging surgery, falls history; FCI.

Independent sample T-tests examined level of LEA in relation to prosthetic fitting and diabetes. Post hoc analyses were conducted to ascertain differences between groups within variables such as level of LEA.

3. What is the mortality rate following LEA and what factors are associated with mortality?

Descriptive statistical analysis and logistic regression analysis was performed to assess the impact of age, diabetes, gender and limb-fitting on mortality, one year after LEA. Comparisons were also made between those who had consented to follow up questionnaires and those who did not consent

4. Does diabetes influence outcomes after LEA?

All analysis in RQ 1, 2, 3 and 5 were conducted to compare those with and without diabetes in relation to variables such as level of LEA, limb-fitting, mortality, QoL, participation and mobility.

5. What are the rates of limb fitting and level of mobility achieved following LEA; and what are the associated factors?

Descriptive analysis of limb-fitting over the one year period in reference to the changing levels of LEA of the cohort were performed. Analysis of mobility measures LCI-5 and PLUS-M were conducted in reference to variables such as age, gender, level of LEA, SIMD, FCI and pre LEA surgery.

Chapter 5

Results of Cohort Study

5.1 Participant journey

There were 183 people who had a lower extremity amputation (LEA) in the study period from 1st March 2014 to 28th February 2015. Twelve people were not eligible for enrolment into the cohort study as their LEAs were not due to PAOD and/or diabetes (Appendix XI).

One hundred and seventy-one people met the inclusion and exclusion criteria and their participant journey through the study is shown in Figure 5.1. Data were extracted for all 171 participants during in-patient stay, discharge from the hospital setting, discharge from out-patient rehabilitation, and finally at 6 and 12 months after LEA.

In addition to data extraction, for those who provided informed consent, follow up questionnaires were completed at 6 and 12 months after LEA. A third (n=56) of the cohort were unable to provide written, informed consent to participate in the questionnaire follow up due to reasons such as cerebrovascular accidents (CVA), cerebral atrophy through alcohol excess or short term memory loss (Table 5.1). Fourteen of the remaining 115 participants declined to consent to receive follow up questionnaires therefore a total of 101 participants gave written consent to complete follow up questionnaires.

Table 5.1 Reasons unable to consent to questionnaire follow up.

Reason	Cohort (n=56)
Adult with incapacity	12.5% (n=7)
Not cognitively able	44.6% (n=25)
Medically unwell	19.7% (n=11)
Transferred out with NHS GG&C	14.3% (n=8)
Unable to speak English	8.9% (n=5)

Abbreviations: NHS GG&C= NHS Greater Glasgow & Clyde
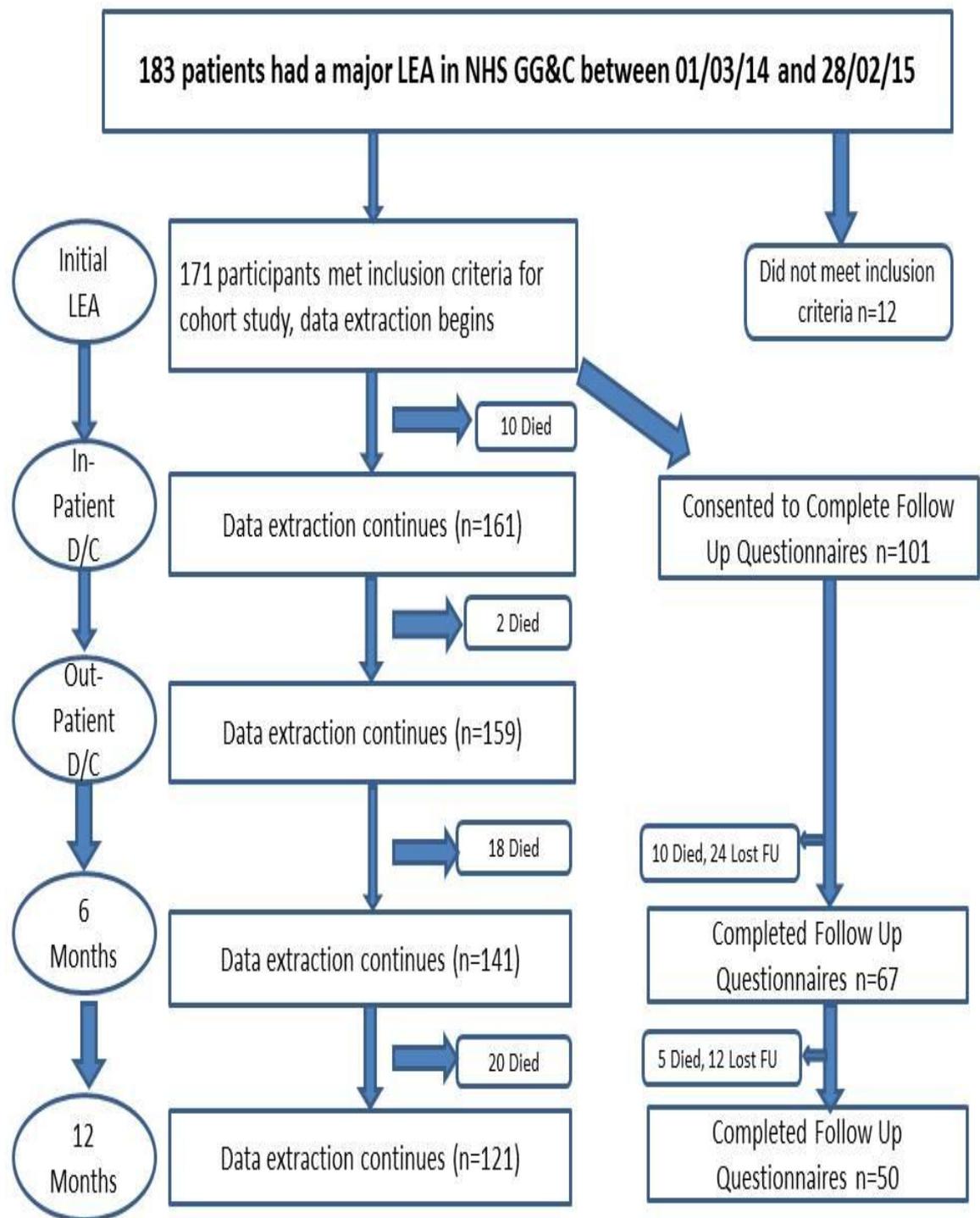
Figure 5.1 Participant journey through cohort study.

Abbreviations: LEA=Lower Extremity Amputation, D/C=Discharged, NHS GG&C= NHS Greater Glasgow & Clyde, FU=Follow Up

5.2. Description of participants in cohort

The participants will be described firstly by sociodemographic variables and then at pre, peri and post amputation phases, with key associations between variables examined statistically at each stage.

5.2.1. Demographic and social characteristics

The cohort is described in Table 5.2. The mean age of the cohort was 66.2 years (SD 11.4), and there were more males than females (74.9% and 25.1% respectively). The majority of the participants lived in the poorest areas in NHS GG&C, SIMD 1 (43.9%) and SIMD 2 (23.4%). Most were not educated beyond school level (91.8%) and 70% were retired.

Fifty-three percent of the cohort were living with diabetes (n=91) prior to their LEA; 17 had type I and 74 had type II diabetes. The five participants of Asian ethnicity all had diabetes.

There were 29 (17%) who came into the study with an existing LEA. Twenty-seven of this group went on to have their contralateral limb amputated, thus having bilateral LEAs. The remaining 2 participants had a more proximal amputation on the same side i.e. had their original trans-tibial amputation (TTA) re-amputated to trans-femoral (TFA) level.

More participants underwent a TTA (60.2%) than a TFA (39.8%). One participant underwent bilateral TTA in the same operation, and this was included in those with a unilateral TTA. There were significantly more participants with a TTA who had diabetes (n=70), compared to those without diabetes (n=33) ($p<0.001$) when a Chi Square test was performed.

A large proportion of the cohort lived in social housing (52.0%) and 22.8% had a package of care prior to admission. Social situations varied, 3.5% of participants (n=6) were carers for others at time of admission and 14% (n=24) had children, who were still dependent, living at home with them. At time of LEA, just under half 48.5% (n=83) reported being able to walk around their community in the previous 6 months and only 16% (n=28) were driving a car. Very few (4%, n=7) were actively exercising prior to LEA.

When comparing the variables in Table 5.2 between those with and those without DM, only prevalence of smoking and excess alcohol consumption were significantly different; both were higher in those without diabetes compared to those with diabetes (both *p<0.001*).

Table 5.2 Socio-demographic descriptors of cohort.

Variable	Cohort (n=171)
Age mean (St Dev)	66.2 years (±11.4)
Gender	
Males	74.9% (n=128)
Females	25.1% (n=43)
Ethnicity	
Caucasian	97.1% (n=166)
Asian	2.9% (n=5)
Social deprivation	
SIMD 1 (most deprived)	43.9% (n=75)
SIMD 2	23.4% (n=40)
SIMD 3	16.4% (n=28)
SIMD 4	5.3% (n=9)
SIMD 5 (least deprived)	11.1% (n=19)
Highest Level of Education Achieved	
School	91.8% (n=157)
Further Education	8.2% (n=14)
Employment	
Retired	69.6% (n=119)
Working	6.4% (n=11)
Unemployed	14.1% (n=24)
Long term sick	9.9% (n=17)
Diabetes Diagnosis	
Diabetes	53.2% (n=91)
No Diabetes	46.8% (n=80)
Smoking Status	
Non-Smoker	25.7% (n=44)
Ex-Smoker	26.3% (n=45)
Current Smoker	48.0% (n=82)
Alcohol Intake	
No Alcohol Intake	46.2% (n=79)
Average Alcohol Intake	25.7% (n=44)
Excess Alcohol Intake	15.2% (n=26)

Previous Excess Alcohol Intake	12.9% (n=22)
Level of amputation	
TTA	59.6% (n=102)
TFA	39.8% (n=68)
Bilateral TTA	0.6% (n=1)
Housing	
House Owner/ Occupier	38.0% (n=65)
Private Rent	2.9% (n=5)
Social Housing	52.0% (n=89)
Sheltered House	5.3% (n=9)
Nursing Home	0.6% (n=1)
Homeless	1.2% (n=2)
Wheelchair Access within the house	
Full Access	20.5% (n=35)
Housebound	26.3% (n=45)
Single Room Living	50.9% (n=87)
Single room living & external access	2.3% (n=4)
Living Situation	
Lived Alone	37.4% (n=64)
Lived with Partner	43.9% (n=75)
Lived with Family	10.5% (n=18)
Lived with Family & Partner	7.6% (n=13)
Lived in a Nursing Home	0.6% (n=1)

Abbreviations: SIMD=Scottish Index of Multiple Deprivation, TTA=Trans-tibial amputation, TFA= Trans-femoral amputation

5.2.2. Pre-operative variables

Prior to LEA, 85.4% of the cohort had their limbs radiologically imaged to ascertain whether any limb salvaging surgery could be performed (Table 5.3). Chi square tests found no association between having invasive revascularisation and diabetes status pre LEA (*p=0.541*) (Table 5.3).

Table 5.3 Imaging and limb salvaging surgery pre lower extremity amputation.

Variable	Cohort (n=171)
Imaged Pre LEA	85.4% (n=146)
Not Imaged Pre LEA	14.6% (n=25)
Limb Salvage Surgery more than12 months pre LEA	
Yes	21.6% (n=37)
No	78.4% (n=134)
Limb Salvage Surgery in the 12 month period before LEA	
Yes	56.1% (n=96)
No	43.9% (n=75)
Invasive Revascularisation	
Yes	65.5% (n=112)
No	34.5% (n=59)

Abbreviation: LEA=Lower Extremity Amputation

5.2.3. Contralateral foot

The contra-lateral foot was assessed at time of LEA and this was categorised into "no issues" or "issues". No issues were defined as good circulation, nail condition and skin integrity. Issues were defined as poor capillary refill, skin breakdown or ulcers or painful to touch. Of those with a unilateral LEA, 39.9% had contralateral foot issues (57/143) with ischaemia being the most common reason (18.1%). Conservative management of the contralateral foot (20.5%) was more likely than active treatment such as bypass (1.8%) or angioplasty (2.9%). Some patients did not have a contra-lateral foot (16.4%) or had previous minor amputations of their contralateral foot (2.3%) (Table 5.4).

Table 5.4 Contralateral Foot.

Contralateral Foot	Cohort (n=171)
Contralateral Foot Condition	
No issues	50.3% (n=86)
Issues	31.0% (n=53)
Major Amputation	16.4% (n=28)
Minor Amputation	2.3% (n=4)
Contralateral Foot Issues	
N/A (no issues or previous LEA)	70.2% (n=120)
Ischaemia	18.1% (n=31)
Ischaemia & Ulcer	7.6% (n=13)
Non ischaemic ulcer	2.3% (n=4)
Charcot	1.2% (n=2)
Minor amputation	0.6% (n=1)
Contralateral Foot Treatment	
N/A (no issues or amputation)	70.2% (n=120)
Angioplasty	2.9% (n=5)
Lower Limb Bypass Surgery	1.8% (n=3)
Conservative Management	20.5% (n=35)
Orthotic Device	1.2% (n=2)
Major Amputation	2.9% (n=5)
Minor amputation & Lower Limb Bypass	0.6% (n=1)

Abbreviation: NA=Not Applicable

5.2.4. Cognition, falls and co-morbidity

Three quarters of the participants (77.2%) were deemed to have no cognitive impairment by the medical or therapy staff. A fifth of the cohort (21.1%) reported having fallen more than once in the 6 months prior to their LEA; however, a larger proportion of the cohort (67.8%) reported no falls in that time period. Chi square tests found no significant differences between those with and without diabetes in terms of falls history (*p=0.910)* or cognition (*p=0.060*).

The median score of the Functional Co-morbidity Index (FCI) was 5.0, this was higher in those with diabetes as this condition added to the overall score. Despite this, an independent sample T-test, found no statistically significant difference between those with and without diabetes ($p=0.838$).

There were a small number of participants who were on renal replacement therapy (n=8, 4.6%) and four (2.4%) participants had received renal transplants. Renal function was assessed from the Glomerular Filtration rate (eGFR) of the participants prior to LEA, and 20.5% had an eGFR <60mmol/l at time of LEA, which is below normal function (Table 5.5). Those without diabetes had better renal function compared to those with diabetes ($p<0.001$) (Appendix XII).

Table 5.5 Cognition, falls history and functional co-morbidity index.

Variable	Cohort (n=171)
Cognition*	
Not impaired & not formally assessed	74.3% (n=127)
Not impaired and assessed	2.9% (n=5)
Impaired and not formally assessed	12.9% (n=22)
Impaired and formally assessed	9.9% (n=17)
Falls in the 6 Months Pre LEA	
No Falls	67.8% (n=116)
1 Fall	11.1% (n=19)
More than 1 Fall	21.1% (n=36)
Functional co-morbidity	
FCI (mean score)	5.1 (SD 2.3)
Renal Issues	
Renal Replacement Therapy	4.6% (n=8)
Renal Transplant	2.4% (n=4)

Abbreviations: LEA=Lower Extremity Amputation, FCI=Functional Co-morbidity Index
*Formal Assessment of cognition with completion of Addenbroke's Cognitive Examination

5.2.5. Diabetes

Ninety-one participants (53.2%) in the cohort had diabetes; of which 18.7% (n=17) had type I and 81.3% (n=74) had type II diabetes. Participants with diabetes have their HbA1c levels measured quarterly and the most recent reading prior to their LEA was recorded (mean 73.6mmol/l (±21.5)). An ANOVA found no difference between the recorded HbA1c and level of LEA ($p=0.453$).

Almost two thirds of those with type II diabetes (64.9%, n=48) were being treated with insulin (Appendix XIII). Over a quarter (28%) of those with type II diabetes were prescribed a sulphonylurea. Two participants, although classed as having diabetes, had pancreatic transplants and controlled their diabetes with diet. There were statistically more people with diabetes taking cholesterol lowering therapy in the form of statins (n= 80) compared to those without diabetes (n=54) ($p=0.0023$) when a Chi Squared test was performed.

5.2.6. Statistical comparison between pre-operative variables and participant characteristics

There was a statistically significant difference in age at time of LEA when SIMD quintiles were compared, (ANOVA ($F_{(4,166)} =6.29$, $p <0.001$)) (Figure 5.2). Post Hoc comparisons using the Tukey HSD test indicated that, on average, those in SIMD 1, 3 and 4 were significantly younger than those in SIMD 5 (Table 5.6). There was no statistically significant difference between the ages of those in SIMD 2 compared to all other quintiles. However, those living in the least deprived areas were, on average, 13 years older at time of LEA than those living in the most deprived areas.
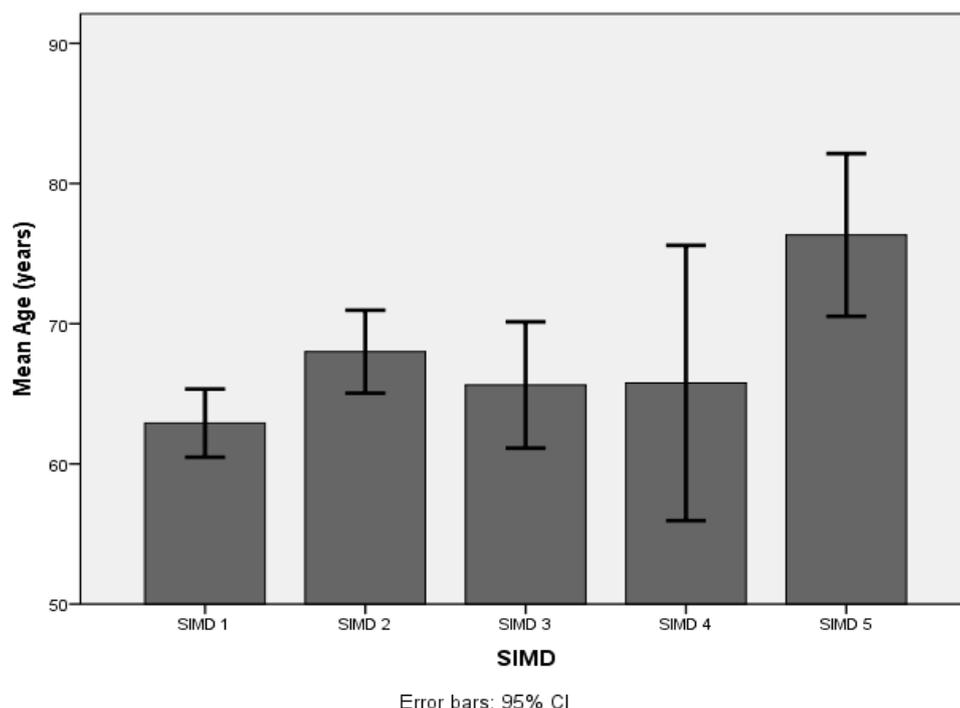
Figure 5.2 Age and Scottish index of multiple deprivation.

Abbreviations: SIMD=Scottish Index of Multiple Deprivation

Table 5.6 Post hoc analysis of age and the Scottish index of multiple deprivation at time of lower extremity amputation.

	Mean Age (years)	SIMD 1	SIMD 2	SIMD 3	SIMD 4	SIMD 5
SIMD 1	62.9 (±10.6)	-	0.114	0.782	0.943	<0.001*
SIMD 2	68.0 (±12.8)	0.943	0.980	1.000	-	0.113
SIMD 3	65.6 (±9.3)	0.114	-	0.898	0.980	0.047*
SIMD 4	65.8 (±11.6)	0.782	0.898	-	1.000	0.009*
SIMD 5	76.3 (±12.0)	<0.001*	0.047*	0.009*	0.113	-

Abbreviations: SIMD=Scottish Index of Multiple Deprivation
* Tukey HSD test and overall significance of 95% as opposed to independent tests

Of those who had limb salvaging surgery in the 12 months prior to their LEA, more went onto have TTAs compared to TFAs, and this difference was significant ($\chi2$ (2, n=171)=8.3, *p=0.016*) (Table 5.7).

Table 5.7 Limb salvaging surgery and level of initial lower extremity amputation.

Level	TTA	TFA
Limb Salvaging Surgery (n=96)	64.7% (n=66)	44.1% (n=30)
No Limb Salvaging Surgery (n=75)	36.3% (n=37)	55.9% (n=38)

 Abbreviations: TTA=Trans-tibial amputation, TFA= Trans-femoral amputation

When comparing falls history and co-morbidities in the participants, there was a significant association between FCI score and falls history, ANOVA (F (2,171) =5.7, *p <0.004*). Post Hoc comparisons using the Tukey HSD test indicated that the mean FCI score was significantly higher in those who had fallen more than once compared to not having any falls in the 6 months prior to their LEA (*p=0.009*) (Table 5.8).

Table 5.8 Functional co-morbidity index score and falls history.

Falls History	Mean FCI Score
All	5.1 (±2.3)
No Falls	4.7 (±2.2)
1 Fall	5.8 (±2.2)
More than 1 Fall	5.9 (±2.3)

Abbreviations: FCI=Functional Co-morbidities Index
Mean ± standard deviation

5.3 Peri-operative variables

The main reason for having a LEA was ischaemia (52.0%) (Table 5.9). However, more people with diabetes had their LEA due to a combination of ischaemia and infection (n=44) compared to those without diabetes (n=11) and this was statistically significant ($\chi2(2,n=171)=39.3$, *p<0.001*).

Surgery was predominantly scheduled as an elective procedure (91.8%); however, a small percentage of participants (8.2%) had their LEA as an emergency procedure. More LEAs were undertaken by Surgical Registrars (56.1%) compared to Consultant Surgeons (43.9%) (Table 5.9). There were more revision surgeries required in those undertaken by registrars compared to consultants and this difference was statistically significant ($\chi2$ (2,n=171)=7 1, *p<0.029*).

Table 5.9 Surgery variables: reason for lower extremity amputation, type of surgery and surgeon grade

Variable	Cohort (n=171)
Ischaemia	52.0% (n=89)
Infection	15.8% (n=27)
Ischaemia and infection	32.2% (n=55)
Elective Surgery	91.8% (n=157)
Emergency Surgery	8.2% (n=14)
Consultant Surgeon	43.9% (n=75)
Surgical Registrar	56.1% (n=96)

5.4. Post-operative variables

Fourteen participants fell while an in-patient and 11 of those damaged their stump. In relation to wound healing, 26.3% (n=45) were noted to have issues with wound healing and 14% (n=25) went on to have revision surgery; to the same level (n=7) or to a more

proximal level (n=18). Additionally, there was deterioration of the contra-lateral foot in 5 people resulting in them having a LEA of their contralateral limb (Table 5.10).

Table 5.10 Stump issues after lower extremity amputation.

Stump Issues	Cohort (n=171)
None	73.7% (n=126)
Infection	1.8% (n=3)
Ischaemia	8.2% (n=14)
Both infection and ischaemia	2.9% (n=5)
Delayed healing	12.3% (n=21)
Flexion contracture	0.6% (n=1)
Ischaemia and contracture	0.6% (n=1)
Revision surgery	
No surgery	85.4% (n=146)
Revised to same level	4.1% (n=7)
Revised to higher level	10.5% (n=18)
Contralateral limb amputation	2.9% (n=5)

Re-amputations and contralateral limb amputations during in-patient stay meant the overall pattern of LEA levels changed. At in-patient discharge, there were more participants with a TTA (43.9%, n=75) and fewer with a TFA (36.8%, n=63). The remaining participants (19.3%, n=33) had bilateral LEAs.

After undergoing a LEA 62.6% (n=107) of the cohort were discharged home, 21.6% (n=37) were transferred to other hospitals for further rehabilitation and 8.2% (n=14) died whilst in the acute ward. The remaining 13 were; rehoused (n=8), discharged to a nursing home (n=4) or to live with other family members (n=1). The mean length of in-patient stay

was 48 days (±48.6) for the whole cohort and for those who were discharged directly home the mean length of stay was 31.9 days (±17.3).

The majority of the participants had a referral to community occupational therapy (COT) for adaptations to be made to their homes (82.5%, n=141). However, data was not available on the completion of these adaptations.

5.4.1. Prosthetic fitting

Almost half of the cohort (n=85, 49.7%) achieved prosthetic fitting, of which more had a TTA (n=52, 61.2%). Those who achieved prosthetic fitting were on average around four years younger than those who did not (mean 64.2years; ±10.3 and mean 68.1 years, ± 12.1 respectively). Eight people who had undergone revision surgery, whilst an in-patient after their LEA had prosthetic fitting. No one with bilateral TFAs were referred for prosthetic fitting (Table 5.11).

Table 5. 11 Prosthetic fitting by level of lower extremity amputation.

Level of LEA	Cohort (n=85)
TTA	61.2% (n=52)
TFA	24.7% (n=21)
Bilateral TTA	10.6% (n=9)
Bilateral TFA	0% (n=0)
TTA and TFA	3.5% (n=3)

Abbreviations: TTA=Trans-tibial amputation, TFA=Trans-femoral amputation

The mean time to receive a prosthesis after LEA was 93.9 days (±56.5). Those with a unilateral TTA received their prosthesis almost four weeks earlier than those with a unilateral TFA. Those with diabetes received their prosthesis almost a month earlier (83.0

days ±49.6) than those without diabetes (109.6 days ±62.6), and an independent sample t-test found this difference was statistically significant (*p=0.040*) (Table 5.12).

Table 5.12 Mean number of days to receive prosthesis.

Level of LEA	Mean days to Receive Prosthesis (SD)
All Levels	93.9 (±56.5)
TTA	84.1 (±52.6)
TFA	122.9 (±60.7)
Bilateral TTA	71.3 (±42.1)
TTA and TFA	129.3 (±66.1)

Abbreviations: L/F=Limb Fitted, TTA=Trans-tibial amputation, TFA=Trans-femoral amputation, ±= Standard Deviation

Length of out-patient rehabilitation was derived from the length of time between in-patient discharge to outpatient discharge. This calculation found that participants, who attended the limb-fitting centre, on average two times per week, received 6 months of prosthetic rehabilitation (Table 5.13).

Table 5.13 Length of time of out-patient rehabilitation.

Level of LEA	Length of time of Rehabilitation
All (n=85)	185.8 ±129.4
TTA (n=52)	158.5 ±110.9
TFA (n=21)	221.1 ±141.8
Bilateral TTA (n=9)	186.7 ±133.4
TTA and TFA (n=3)	396.7 ±128.6

Abbreviations: TTA=Trans-tibial amputation, TFA=Trans-femoral amputation
Mean number of days ± Standard Deviation

There was a statistically significant difference between length of time attending out-patient rehabilitation when levels of LEA were compared (*p=0.006*). Those with a TFA received an extra 9 weeks of out-patient rehabilitation than those with a TTA (*p=0.207*). Post Hoc comparisons using the Tukey HSD test indicated that the mean length of time attending out-patient rehabilitation was statistically greater for those with bilateral LEAs (TTA and TFA) compared to those with a unilateral TTA (Table 5.14).

Table 5.14 Post hoc analysis of length of time attending out-patient physiotherapy and level of lower extremity amputation.

Level of LEA	TTA	TFA	Bilateral TTA	TTA and TFA
TTA	-	0.207	0.921	0.008*
TFA	0.207	-	0.983	0.100
Bilateral TTA	0.921	0.893	-	0.056
TTA and TFA	0.008*	0.100	0.056	-

Abbreviations: TTA=Trans-tibial amputation, TFA=Trans-femoral amputation
*p value <0.05 is significant

5.4.2. Prosthetic mobility at out-patient discharge

The Locomotor Capability Index (LCI-5) change score (pre LEA mobility score minus post LEA mobility score) describes the change in mobility after LEA for those who received a prosthesis. A high score suggests a decline in mobility and a negative score an improvement in mobility. Those with unilateral LEAs had scores closer to zero (suggesting maintenance of their mobility), than those with bilateral LEAs, whose mobility deteriorated after LEA (Table 5.15). Those with a TTA achieved a similar level of mobility after their LEA as they had reported pre surgery (LCI-5 change score 0.7). The impact of level of LEA on LCI-5 change score was not found to be statistically significant when a one way between groups ANOVA was conducted (F $(3, 81) = 1.6$, $p=0.185$).

Table 5.15 Mean locomotor capability index change scores by level of lower extremity amputation.

Level of LEA	Cohort (n=85)
TTA (n=52)	0.7 (±19.0)
TFA (n=21)	5.8 (±20.1)
Bilateral TTA (n=9)	12.7 (±23.7)
TTA & TFA (n=3)	18.3 (±7.2)

Abbreviations: LEA=Lower Extremity Amputation, TTA=Trans-tibial amputation, TFA=Trans-femoral amputation

5.4.3. Participants not fitted with a prosthesis

Overall, those who were not fitted with a prosthesis were significantly older than those who were limb fitted ($p=0.026$) (Table 5.16). There was also a statistically significant difference in the mean age when all of those not fitted were compared by level of LEA ($p=0.033$). When the ages of those with a TFA were compared, those who were limb-fitted were approximately 2 years older than those who did not limb fit. Due to the small number of bilateral LEAs post hoc analysis was conducted with those with all bilateral amputations as one group (regardless of level) (n=15). The only significant finding was that those with a unilateral TTA who were not limb fitted were older than those who were ($p=0.017$).

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Reasons for not receiving a prosthetic limb included immobility pre-amputation (12.3%, n=21); bilateral proximal amputations (14%, n=24); cognitive impairment (1.8%, n=3); contralateral foot problems (5.8%, n=5), declined or failed to attend (4.1%, n=7) or hip fracture (1.2%, n=1). When considering those who received a prosthesis there was no correlation between the length of time attending out-patient physiotherapy and the LCI-5 change score (r=0.098, n=85, *p=0.377*).

Table 5.16 Mean age people of limb fitted and non limb fitted by level of lower extremity amputation.

Mean Age (years)	Limb Fitted (n=85)	Non Limb Fitted (n=86)
All Levels	64.2 (±10.3)	68.1 (±12.1)
TTA	63.7 (±10.8)	74.3 (±11.9)
TFA	67.5 (±10.1)	65.6 (±12.5)
Bilateral TTA	61.8 (±8.3)	59.3 (±13.7)
Bilateral TFA	N/A	66.9 (±8.2)
TTA and TFA	58.7 (±7.3)	69.4 (±6.9)

Abbreviations: L/F=Limb Fitted, TTA=Trans-tibial amputation, TFA=Trans-femoral amputation, ± Standard Deviation, N/A=not applicable

5.5. Analysis of variables over time

Data extraction took place at five time points in the participant journey (Figure 5.1). The time points at initial entry to the study and in-patient and out-patient discharge have been reported in Sections 5.2-5.4. The six and twelve month time points, saw data extraction focus on mortality, level of LEA, FCI, readmission to hospital and re-housing.

5.5.1. Mortality

Overall mortality increased from 5.8% (n=10) at 30 days post LEA, to 17.5% (n=30) 6 months post LEA to 29.2% (n= 50) 12 months after LEA. Those who died were compared by level of LEA, results showed participants with a TFA had higher rates of mortality at all three time periods compared to those with a TTA (Table 5.17). The level of LEA at discharge from hospital was not significantly associated with mortality at 6 months (*p=0.307*).

Up to 12 months following LEA, the mean age at time of death was 68.9 years (±11.2). Those who died within 30 days of their LEA were approximately 3.4 years older than those who survived beyond this time period. There was no association between age at time of death and level of LEA (*p=0.362*). Mortality was not significantly different when comparing SIMD quintiles (*p=0.263*). Percentages are in relation to each level of LEA.

Table 5.17 Mortality in the first year following lower extremity amputation by level of amputation.

Level of LEA	30 days	6 months	12 months
Total Mortality	5.8% (n=10)	17.5% (n=30)	29.2% (n=50)
TTA	4% (n=3)	12.5% (n=8)	25.0% (n=14)
TFA	7.9% (n=5)	26.7% (n=16)	48.9% (n=23)
Bilateral TTA	0%	0%	31.3% (n=5)
Bilateral TFA	10% (n=2)	28.6% (n=6)	36.4% (n=8)

Abbreviations: TTA= Trans-tibial amputation, TFA=Trans-femoral amputation. (n=171).

Logistic regression was performed to assess associations between age, diabetes, gender and limb-fitting on mortality 12 months after LEA. The full model containing all variables was statistically significant X^2, (4, n=50)=30.9, *p<0.001*. Not having a prosthetic limb i.e. not limb fitting was most strongly associated with mortality (B=1.965, *p<0.001*); those who

were not fitted with a prosthetic limb were 7 times more likely to die, after adjustment for age, gender and diabetic status (OR: 7.137) (Table 5.18).

Table 5.18 Logistic regression for mortality.

Independent variable	Odds Ratio	Significance (p)	Confidence Interval
Increasing Age	0.985	0.340	0.954 to 1.016
Male Gender	2.194	0.079	0.914 to 5.265
Not Limb-Fitted	7.137	<0.001*	3.146 to 16.192
Diabetes	0.723	0.388	0.347 to 1.509

*Statistically significant p<0.05

5.5.2. Level of lower extremity amputation

During the 6 months after LEA, 8.1% of the cohort had further amputation surgery, this included both contralateral limb LEAs, re-amputations of their stump to a higher, more proximal level and revisions of their stump with no change to level. The majority of this surgery took place during the initial in-patient stay (Table 5.10), 4.3% (n=6) had their contralateral limb amputated within 6 months and a further 5% (n=6) between 6 and 12 months following LEA (Table 5.19). These re-amputations and contralateral limb amputations increased the proportion of participants living with bilateral LEAs (19.3% at baseline, 24.8% at 6 months and 31.4% at 12 months). Of those that underwent further amputations, one did not survive beyond 6 months and two did not survive beyond twelve months.

Table 5.19 Further amputation surgery over one year.

	Time Period	
	IP D/C to 6 Months (n=161) – (n=141)	6 Months to 12 Months (n=141) – (n=121)
Further LEA surgery	8.1% (n=13)	4.3% (n=6)
Amputation to higher level	4.4% (n=7)	0% (n=0)
LEA of Contralateral Limb	3.7% (n=6)	4.3% (n=6)
Died	n=1	n=2

Abbreviations: LEA=Lower Extremity Amputation, IP=In-Patient, D/C=Discharge
NB.There were no participants with further surgery who remained at the same level of LEA and the change in level of LEA is specific to that time period

5.5.3. Functional co-morbidities index

The FCI was reviewed at baseline and again at 6 and 12 months after LEA. Mean scores at these time points were similar (Table at 5.20). There was no significant change in FCI from baseline to 6 months after LEA (t=-1.641, df170, *p=0.103*), however there was an increase in FCI between 6 and 12 months after LEA (t=-2.018, df 170,*p=0.045*), and between baseline and 12 months after LEA (t=-2.571, df 170, *p=0.011*).

Table 5.20 Functional co-morbidity index over time.

Functional co-morbidity index	Whole Cohort
Baseline (n=171)	5.053 ± 2.25
6 Months (n=150)	5.076± 2.29
12 Months (n=132)	5.099± 2.30

NB. Three decimal places due to small variation in mean FCI scores
Mean ± standard deviation

5.5.4. Readmission and rehousing

From date of in-patient discharge to 6 months after LEA, 34.9% (n=53) of participants were readmitted to hospital. Reasons for re-admission ranged from elective procedures such as cataract surgery to emergency surgery for rupture of abdominal aortic aneurysm. There was no significant difference between prosthetic users (n=23) or non-users (n=30) and the number of readmissions ($p=0.070$) nor between SIMD quintiles and number of readmissions ($p=0.677$).

From 6 to 12 months after LEA, 32.6% (n= 46) were readmitted and again no significant difference was found between SIMD quintiles ($p=0.522$). Over the twelve months following LEA 61.5% (n=99) of participants were readmitted to hospital.

In one year following LEA, 35 participants were rehoused; 8 at in-patient discharge, 18 within the first 6 months and a further nine within the first year of LEA. Rehousing was predominantly in people who lived within the lowest socio-economic area (SIMD 1) where almost three quarters were rehoused (74.1%).

5.6. Follow up

Overall 59.1% (n=101) of the cohort provided written consent to follow up, 32.7% (n=56) were unable to consent and 8.2% (n=14) declined to consent. There were no significant differences between those who did and did not agree to questionnaire follow up in terms of gender ($p=0.677$), age ($p=0.146$), diabetes ($p=0.673$), level of LEA ($p=0.082$) or SIMD

(*p=0.468*) suggesting that those who gave consent to the follow up questionnaires were representative of the cohort (Table 5.20).

Table 5.21 General descriptors of whole cohort and those who did and did not consent to questionnaire follow up.

	Full Cohort (n=171)	Unable to Consent (n=56)	Declined to consent (n=14)	Consented (n=101)
Males	74.9% (n=128)	67.9% (n=38)	78.6% (n=11)	78.2% (n=79)
Age (years)	66.2 (±11.4)	67.7 (±11.7)	67.1 (±9.8)	65.2 (±11.4)
DM	53.2% (n=91)	51.8% (n=29)	50% (n=7)	54.5% (n=55)
Level of LEA on entry into cohort study				
TTA	59.6% (n=102)	50% (n=28)	42.9% (n=6)	67.3% (n=68)
TFA	39.8% (n=68)	50% (n=28)	57.1% (n=8)	31.7% (n=32)
Bilateral TTA	0.6% (n=1)	0% (n=0)	0% (n=0)	1.0% (n=1)

Abbreviations: DM=Diabetes, LEA=Lower Extremity Amputation, TTA=Trans-tibial amputation, TFA=Trans=femoral amputation

Six months after LEA the response rate for completion of questionnaire follow up was 66.3% (n=67). One third (33.7%, n=34) who initially consented to follow up did not respond, 10 were in hospital and unable to complete them, 8% had since died (n=14) and the remaining 10 were uncontactable. The response rate reduced to 49.5% (n=50) 12 months after LEA as two participants had died, 6 were in hospital and the remaining 9 were uncontactable, thus 50 people completed 12 month questionnaire follow up.

5.6.1. Quality of life

The 67 participants who completed the quality of life (EQ-5D-5L) questionnaires 6 months post LEA, scored their quality of life in each of five domains, the maximum score of 5 equated to having extreme problems in that domain. Participants reported that the domains of mobility (mean score 3.4 ± 1.4) and returning to usual activities (mean score 3.1 ± 1.3) were the most problematic. The three remaining domains were all scored lower; self-care (mean score 2.2 ± 1.1), anxiety/depression (mean score 2.6 ± 1.0) and pain and discomfort (mean score 2.0 ± 1.1) respectively (Figure 5.5). All scores were higher than EQ-5D-5L scores for the age matched general population (mobility 1.9, self-care 1.0, usual activities 1.5, anxiety/depression 1.7, pain/discomfort 1.2) suggesting poorer quality of life in those with LEA (Herdman *et al.* 2011).

The mean health index quality of life score, calculated from the responses given for each domain in the EQ-5D-5L, ranges from -1 to +1. The mean score 6 months after LEA was 0.37 (± 0.37) for those who completed the questionnaires (n=67). This reduced, 12 months after LEA to 0.33 (± 0.39) (n=50). As the questionnaires specifically asked about quality of life, participation and mobility, the responses were compared by socio-economic status (SIMD), diabetes and level of LEA. The FCI score of the participants was also recorded to provide a fuller description.

When health index scores were categorised by SIMD quintile, six months after LEA those in the lowest socio-economic group (SIMD 1) had the lowest mean score (0.26 ± 0.39) compared to all other areas (SIMD 2-5). This pattern was similar at 12 months after LEA, with those in SIMD 1 reporting a QoL score of 0.14 (± 0.40) (Figure 5.3 and Table 5.22). However, there were no statistically significant differences in QoL Health Index scores between SIMD quintiles when analysed by a one way ANOVA , 6 months ($F_{(4,62)} = 1.7$, *p=0.161*)) and 12 months after LEA ($F_{(4,43)} = 2.4$, *p=0.065*).
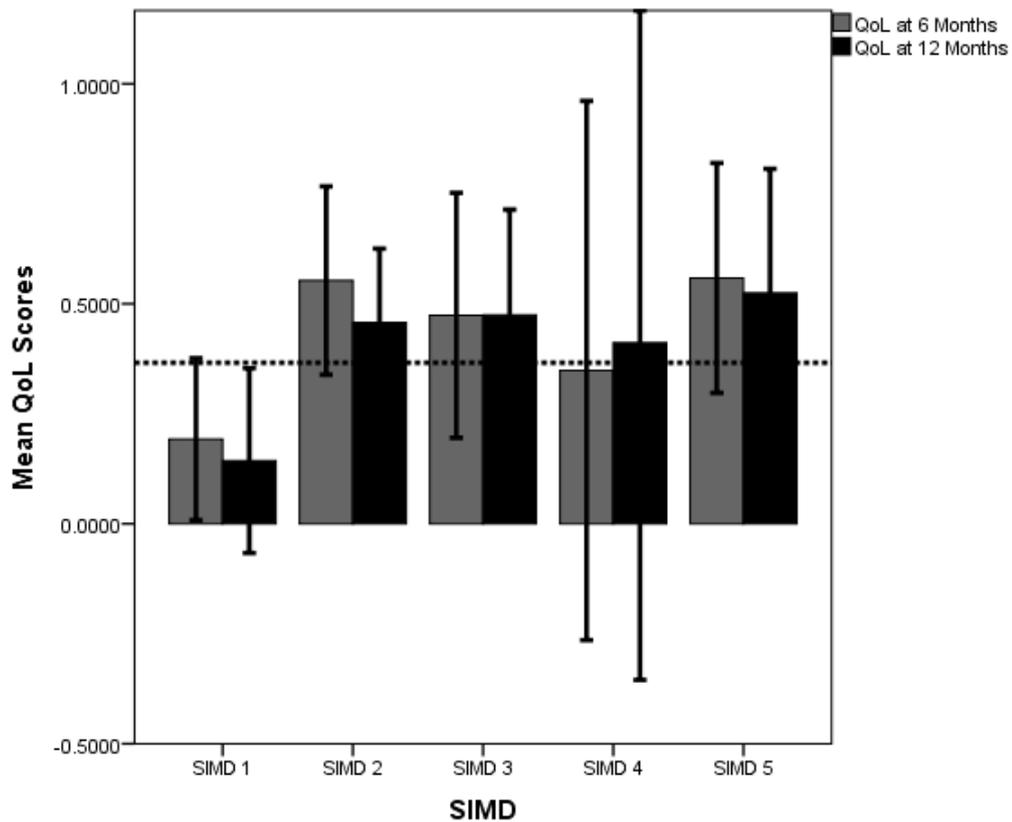
Figure 5.3 Health index scores at 6 and 12 months by Scottish index of multiple deprivation.

Abbreviations: SIMD=Scottish index of Multiple Deprivation, QoL=Quality of Life

A paired sample t-test was conducted to determine if there was a difference in mean health index scores 6 and 12 months after LEA. The number of participants had reduced at 12 months, due to mortality or admission to hospital, so the scores of only 50 participants who completed questionnaires at both time points were analysed (n=50). There was no statistically significant difference between mean health index scores 6 months (M=0.39 ±0.37) and 12 months after LEA (M=0.36 ±0.38), t (47)=0.826, *p=0.413).*

Table 5.22 Quality of life health index scores at 6 and 12 months after lower extremity amputation by Scottish index of multiple deprivation.

SIMD Quintile	Mean QoL Health Index Score (EQ-5D-5L) (+1 to -1)	
	6 Months	12 Months
SIMD 1	0.26 (±0.39)	0.14 (±0.40)
SIMD 2	0.51 (±0.29)	0.46 (±0.22)
SIMD 3	0.41 (±0.37)	0.47 (±0.34)
SIMD 4	0.35 (±0.39)	0.41 (±0.48)
SIMD 5	0.54 (±0.30)	0.52 (±0.34)
All	0.37 (±0.37)	0.33 (±0.39)

Abbreviations: SIMD=Scottish Index of Multiple Deprivation, QoL=quality of life
NB. SIMD 1=Most deprived and SIMD 5=least deprived

There were more health index scores reported below zero for those in SIMD 1 (Figure 5.3) Health index scores were lower for those in SIMD 1 compared to the mean, with participants in SIMD 5 having similar scores at 6 and 12 months. Conversely, there was an improvement in the mean health index scores on average in those from SIMD 3 and 4, between 6 and 12 months (Table 5.22).

When the participants were categorised by SIMD quintile there was evidence of those in SIMD 1 reporting more difficulties in each domain compared to those in SIMD 5, however a between groups test found no statistical significance between SIMD quintiles (*p=0.094*) (Figure 5.4).
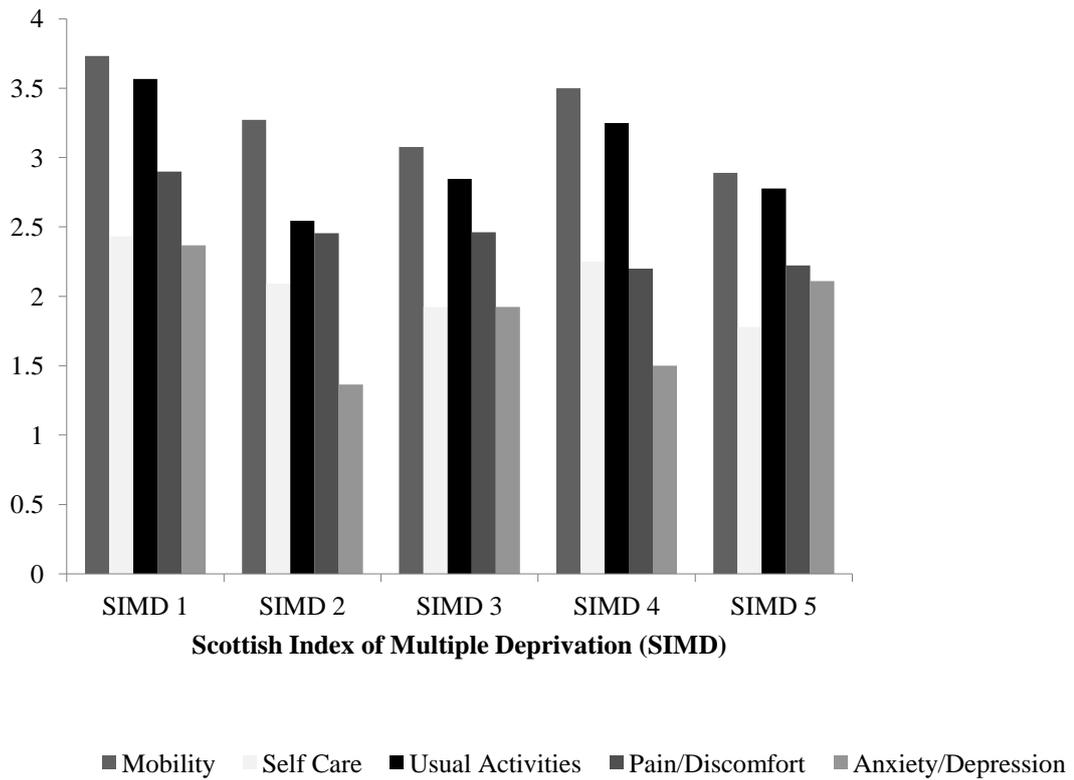
Figure 5.4 Mean score of QoL domains by Scottish index of multiple deprivation, 6 months after LEA.

Abbreviations: SIMD= Scottish Index of Multiple Deprivation

5.6.2. Quality of life and diabetes status

Higher levels of quality of life were reported by those with diabetes compared to those without diabetes, 6 months and 12 months after LEA. There is also an observed pattern of QoL reducing over time in both those with and without diabetes, however this difference was not statistically significant (*p=0.145 and p=0.1043 respectively*) (Table 5.23).

Table 5.23 Quality of life health index scores at 6 and 12 months after lower extremity amputation by diabetes.

Diagnosed with Diabetes	Mean QoL Health Index Score (EQ-5D-5L) (+1 to -1)	
	6 Months	12 Months
Diabetes	0.43 (±0.39)	0.41 (±0.40)
No Diabetes	0.30 (±0.33)	0.23 (±0.36)
All	0.37 (±0.37)	0.33 (±0.39)

Abbreviations: QoL=Quality of life

5.6.3. Quality of life and level of lower extremity amputation

The highest scores for QoL were reported by those with a unilateral TTA at 6 months (0.53) and 12 months (0.49). There was only one participant with a bilateral TFA who completed the questionnaire follow up, and they reported their QoL as - 0.04 at 6 months, which equates to them describing their QoL as "worse than death". However, 12 months after their LEA they reported an improvement in their QoL to 0.19 (Table 5.24).

Table 5.24 Quality of life by level of lower extremity amputation 6 and 12 months after lower extremity amputation

		Mean QoL Health Index Score (EQ-5D-5L) (+1 to -1)		
Level of LEA	n	6 Months	n	12 Months
TTA	34	0.53 (±0.34)	28	0.49.(±0.40)
TFA	22	0.19 (±0.36)	14	0.15 (±0.32)
Bilateral TTA	5	0.41 (±0.29)	4	0.11 (±0.30)
TTA and TFA	5	0.18 (±0.20)	3	-0.04
Bilateral TFA	1	-0.04	1	0.19 (±0.19)
All	67	0.37 (±0.37)	50	0.33 (±0.39)

Abbreviations: LEA=Lower Extremity Amputation, TTA=Trans-tibial amputation, TFA=Trans=femoral amputation

There were statistically significant differences between level of LEA and QoL Health Index scores 6 months following LEA (*p=0.004*) but not at 12 months (*p=0.030*). Post hoc analysis with Tukey HSD tests showed that at 6 months, the only statistically significant difference to be between those with a unilateral TTA and a unilateral TFA (*p=0.002*); such that those with TTA reported better QoL.

5.6.4. Quality of life and prosthetic fitting

After LEA, almost half of the cohort (n=85) received a prosthetic limb, and 64.7% of these participants completed the follow up questionnaires (n=55). Six months after LEA, those who did not have a prosthesis, but agreed to follow up, had a mean QoL score of -0.03 compared to those with a prosthesis 0.46, and this difference was significant when tested with an independent sample t-test (*p<0.001*). Twelve months after LEA, QoL was relatively unchanged and there was a slight improvement in the QoL of those not limb fitted, however the QoL remained significantly better for those who were limb fitted (*p<0.001*) (Figure 5.5, Table 5.25).

Table 5.25 Quality of life by limb-fitting status.

Limb Fitting	Mean QoL Health Index Score (EQ-5D-5L) (+1 to -1)	
	6 Months (n=67)	12 Months (n=50)
Limb Fitted	0.46 (±0.33)	0.42 (±0.35)
Not Limb Fitted	-0.03 (±0.25)	-0.11 (±0.26)

Abbreviations: QoL=Quality of Life

Those who received a prosthesis (n=55) reported higher levels of QoL 6 months after LEA and this declined slightly at 12 months. Those who did not receive a prosthesis reported their QoL as poor 6 months after LEA and many reported this as worse than death at 12 months after LEA as demonstrated by a score of less than zero (Figure 5.5, Table 5.25).
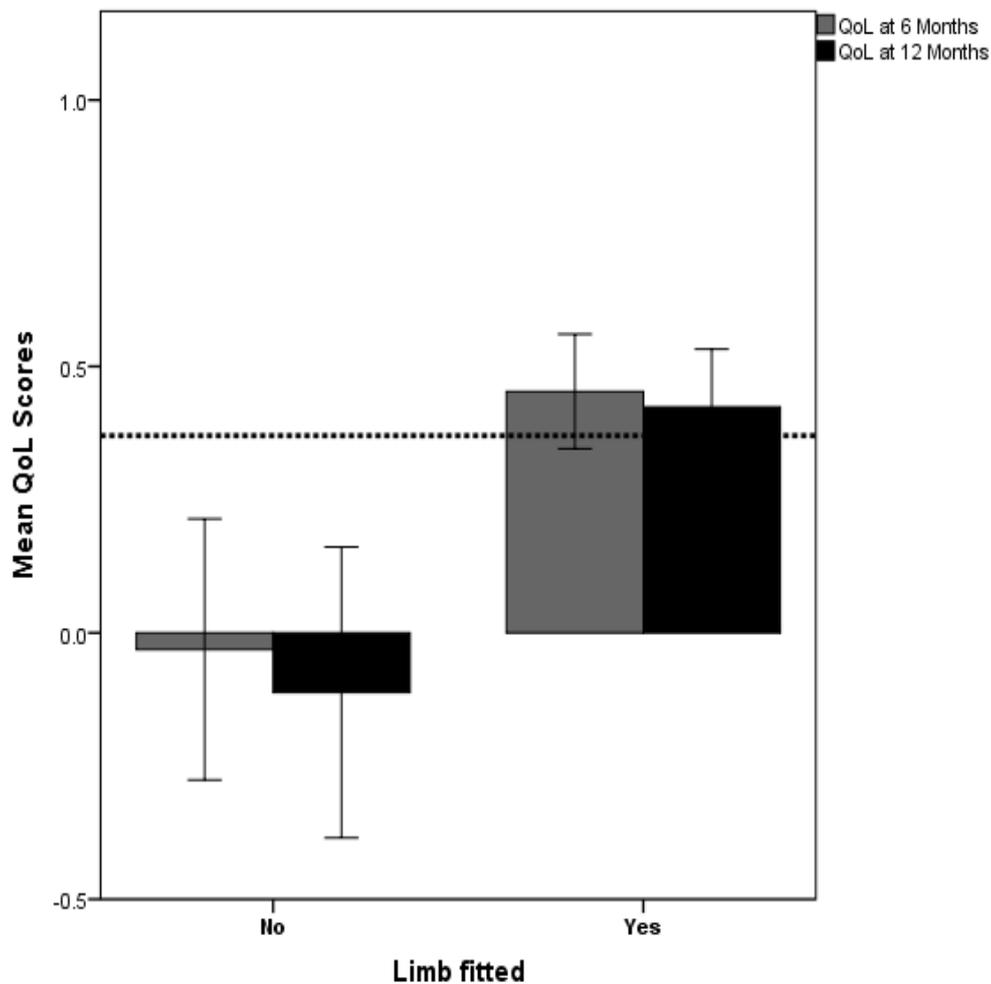
Figure 5.5 Mean quality of life at 6 and 12 months by limb fitting status.

Abbreviations: QoL= Quality of Life

5.7. Reintegration to normal living index 6 and 12 months following lower extremity amputation

The Reintegration to Normal Living Index (RNLI) questionnaire was completed by all consenting participants. RNLI scores range from 0-100, with a score of 100 representing fully reintegrated to their life and community after LEA. The mean RNLI score for the cohort was 55.7 (±23.3) 6 months after LEA, and 56.6 (±24.5) 12 months after LEA. A paired sample t-test found no significant difference between RNLI scores at 6 and 12 months *(p=0.731)*. The scores from the RNLI were examined by socio-economic status (SIMD), diabetes and level of LEA.

5.7.1. Reintegration to normal living index and socio-economic status

The mean RNLI scores from SIMD 1 to 5, ranged from 47.8 to 71.9, 6 months after LEA compared to 53.6 to 67.7, 12 months after LEA. When categorised by SIMD quintile, those in the most deprived area, SIMD 1, reported the lowest participation 6 and 12 months post LEA (47.8 and 53.6 respectively) (Table 5.26, Figure 5.6).

Table 5.26 Reintegration to normal living index scores at 6 and 12 months by Scottish index of multiple deprivation.

SIMD	RNLI Score (0-100)	
	6 Months	12 Months
SIMD 1	47.8 (±24.6)	49.0 (±24.9)
SIMD 2	61.8 (±21.6)	52.1 (±20.9)
SIMD 3	55.7 (±23.9)	58.4 (±27.6)
SIMD 4	62.5 (±16.8)	74.3 (± 10.8)
SIMD 5	71.9 (±11.0)	67.7 (±25.3)
All	55.7 (±23.3)	56.6 (±24.5)

Abbreviations: SIMD Scottish Index of Multiple Deprivation, RNLI Reintegration to Normal Living Index, ± Standard Deviation

Although mean RNLI scores were similar at 6 and 12 months after LEA, there were some improvements and deteriorations when considering the SIMD quintile (Table 5.26). There was an improvement in participation in those who lived in SIMD 1, 3 and 4, however there was a deterioration in those who lived in SIMD 2 and 5, with the greatest reduction in SIMD 2.
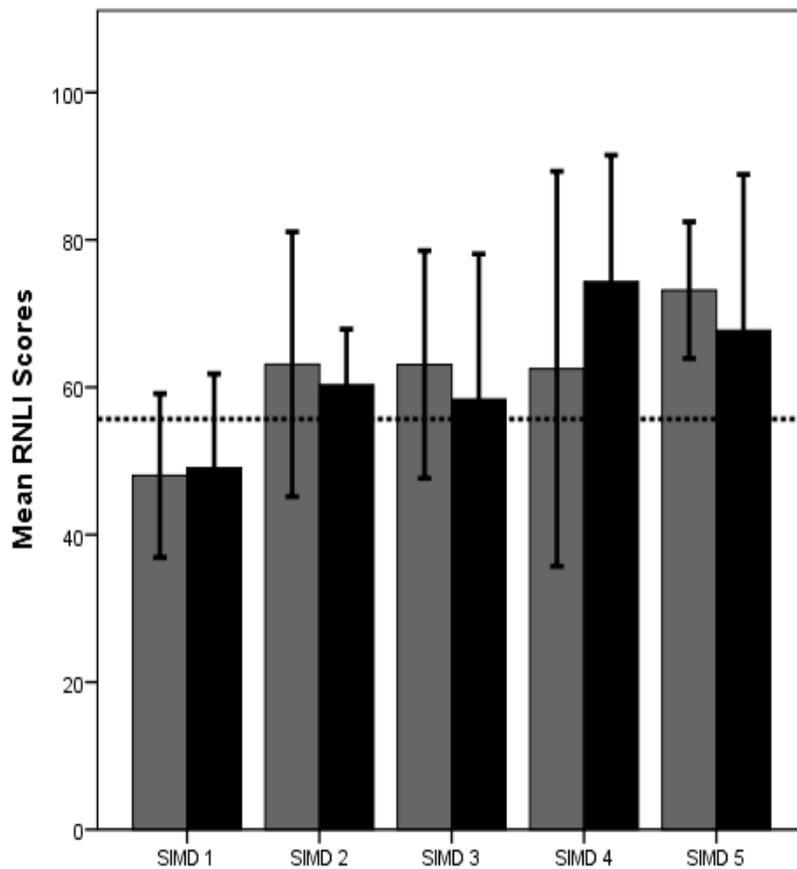
**Figure 5.6** Reintegration to normal living index scores at 6 and 12 months by Scottish index of multiple deprivation.

Abbreviations: SIMD Scottish Index of Multiple Deprivation, RNLI Reintegration to Normal Living Index

5.7.2. Reintegration to normal living index and diabetes

Those with diabetes had higher levels of participation than those without diabetes, 6 and 12 months after LEA. However, this difference was not statistically significant when a one-way ANOVA was performed at 6 months (*p=0.534*) and 12 months (*p=0.634*).

Participation scores of those with diabetes were compared at the two time points, there was an increase in levels of participation from 6 to 12 months after LEA (*p=0.001*). Those without diabetes reported slightly lower levels of participation at 12 months compared to 6 months but this difference was not significant (*p=0.068*) (Table 5.27).

Table 5.27 Reintegration to normal living index scores at 6 and 12 months after amputation by diabetes.

	RNLI Score (0-100)	
	6 Months	12 Months
Diabetes	57.4 (±24.7)	59.4 (±26.0)
No Diabetes	53.8 (±21.6)	53.0 (±22.5)
All	55.7 (±23.3)	56.6 (±24.5)

5.7.3. Reintegration to normal living index by level of lower extremity amputation

Overall there was a small rise in participant reported participation from 6 to 12 months after LEA (Table 5.28). There was a statistically significant difference in RNLI scores between levels of LEA 6 months after LEA (ANOVA (4, n=66) =2.603, *p=0.044)*. This was also the case, 12 months after LEA (4, n=49) =2.996, *p=0.028)*. Those with a unilateral TTA had the highest levels of participation (64.2±21.9) and those with bilateral TTA reported the lowest scores (42.7±20.0) 6 months after LEA. The same pattern was observed 12 months after LEA (Table 5.28).

Table 5.28 Reintegration to normal living index scores at 6 and 12 months by level of lower extremity amputation.

Level of LEA	RNLI Score (0-100)	
	6 Months	12 Months
TTA	64.3 (±21.9)	65.5 (±25.2)
TFA	47.6 (±24.3)	45.2 (±19.8)
Bilateral TTA	42.7 (±20.0)	33.2 (±13.8)
Bilateral TFA	*43.0	*43.0
TTA and TFA	49.3 (±14.9)	53.0 (±14.5)
All	55.7 (±23.3)	56.6 (±24.5)

Abbreviations: LEA=Lower Extremity Amputation, TTA=Trans-tibial amputation, TFA=Trans-femoral amputation
*One participant with bilateral TFA

5.7.4. Statistical analysis of reintegration to normal living index 6 months after lower extremity amputation

Reintegration to Normal Living Index (RNLI) had a moderate to high correlation with QoL and PLUS-M (0.634 and 0.555 respectively, $p <0.001$) at 6 month follow up (n=67). Similarly, 12 months after LEA (n=50) both QoL and PLUS-M had high correlations to RNLI (0.845 and 0.755 respectively, $p<0.001$). QoL and mobility (PLUS-M) explained 38.9% of the variance in RNLI. QoL had more influence on participation (Beta 0.546)($p<0.001$) compared to mobility (Beta 0.111, $p=0.684$) 6 months after LEA.

5.8. Prosthetic limb user survey of mobility 6 and 12 months after lower extremity amputation

The Prosthetic Limb User Survey of Mobility (PLUS-M) was completed at 6 months following LEA by those who had achieved prosthetic fitting (n=55), the minimum value was 21.8 which represented a wheelchair user and not using the prosthesis; and the maximum value achievable was 74.1, which translated to independent mobility, with no difficulty over long distances. Six months after LEA, the mean PLUS-M score of the cohort was 39.1 (±11.8), this level of mobility was generally maintained 12 months after

LEA (38.9 ±11.9). The scores from the PLUS-M were examined by socio-economic status (SIMD), diabetes and level of LEA.

5.8.1. Prosthetic limb user survey of mobility and socio-economic status

Those in SIMD 1 reported lower levels of mobility 6 and 12 months after LEA (37.4, 34.6 respectively) compared to the overall mean (39.1, 38.9 respectively) (Table 5.29 and Figure 5.7). The PLUS-M t-scores were not significantly different across the SIMD quintiles at 6 or 12 months after LEA (*p=0.628* and *p=0.164 respectively*), however mobility was reported as poor for all given that two questionnaires were only appropriate for those limb-fitted.

Table 5.29 Prosthetic limb user survey of mobility and Scottish index of multiple deprivation.

SIMD	PLUS-M t-Score (21.8-71.4)	
	6 Months (n=55)	12 Months (n=41)
SIMD 1	37.4 (±10.5) (n=23)	34.6 (±10.8) (n=14)
SIMD 2	42.5 (±8.1) (n=9)	39.7 (±11.3) (n=8)
SIMD 3	37.2 (±15.9) (n=12)	40.4 (±10.6) (n=9)
SIMD 4	47.1 (±0.9) (n=2)	55.2 (±4.5) (n=2)
SIMD 5	40.8. (±13.4) (n=9)	42.3 (±13.5) (n=8)
All	39.1 (±11.8)	39.4 (±11.7)

Abbreviations: SIMD=Scottish Index of Multiple Deprivation, PLUS-M=Prosthetic Limb User Survey of Mobility
SIMD variable treated as unordered categorical
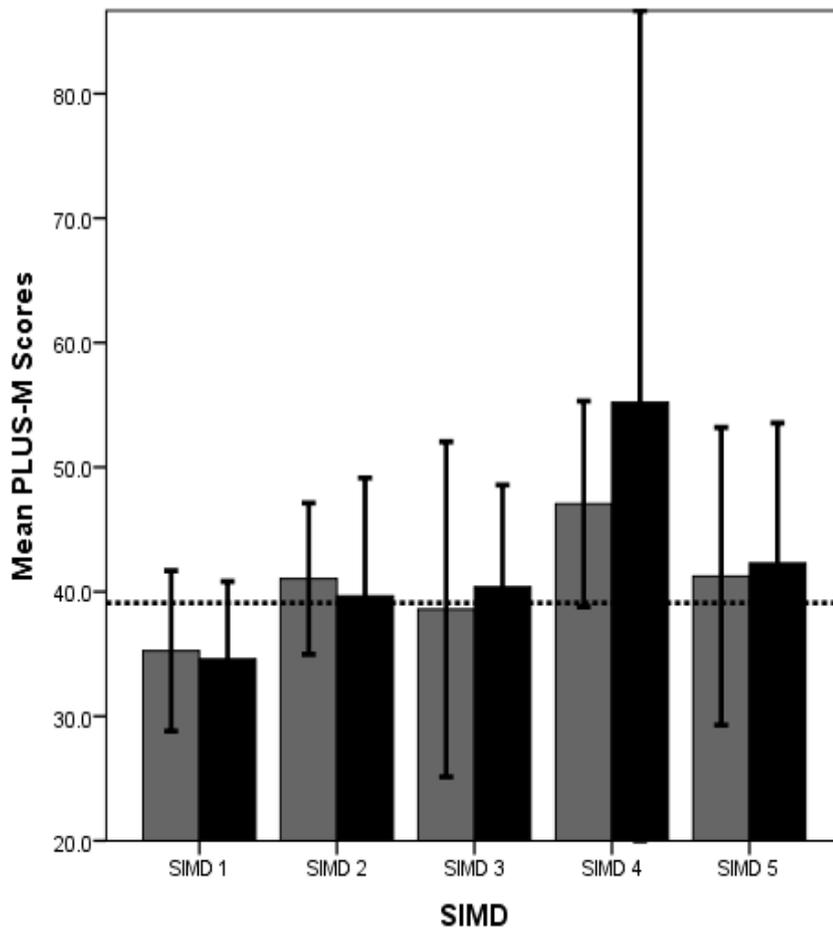
Figure 5.7 Prosthetic limb user survey of mobility scores at 6 and 12 Months by Scottish index of multiple deprivation.
Abbreviations: SIMD=Scottish Index of Multiple Deprivation, RNLI=Reintegration to Normal Living Index, PLUS-M=Prosthetic Limb User Survey of Mobility

5.8.2. Prosthetic limb user survey of mobility and level of lower extremity amputation

Analysis of PLUS-M scores by level of LEA showed that mobility was poorer in those with a TFA (mean 35.1 ± 13.1) compared to those with a TTA (mean 42.8 ±10.5), 6 months after LEA. Those with a bilateral LEA reported the poorest mobility at 6 months (mean score 30.0 ±8.5). The difference in mobility across the varying levels of LEA was statistically significant (*p=0.022*). Twelve months after LEA, those with a unilateral TTA reported the highest level of mobility (Table 5.30). However, post Hoc comparisons using the Tukey HSD test indicated that the difference was not statistically significant between groups, possibly due to the small numbers (Table 5.31).

Table 5.30 Prosthetic limb user survey of mobility scores and Level of lower extremity amputation.

Level of LEA	PLUS-M t-Score (21.8-71.4)	
	6 Months (n=55)	12 Months (n=41)
TTA	42.8 (±10.4) (n=31)	46.0 (±8.7) (n=25)
TFA	35.1 (±13.1) (n=14)	30.2 (±8.5) (n=10)
Bilateral TTA	35.2 (±9.2) (n=5)	25.6 (±6.6) (n=3)
TTA and TFA	25.9 (±7.1) (n=5)	28.5 (±6.5) (n=3)
Bilateral TFA	N/A(n=0)	N/A (n=0)
All	39.1 (±11.8)	39.4 (±11.7)

Abbreviations: PLUS-M=Prosthetic Limb User Survey of Mobility, TTA= Trans-Tibial Amputation, TFA=Trans=Femoral Amputation, N/A =Not applicable

At 6 months after LEA there were no significant differences between levels of mobility (PLUS-M) and level of LEA when post-hoc analysis was conducted (Table 5.31).

Table 5.31 Post hoc analysis of prosthetic limb user survey of mobility scores and level of lower extremity amputation.

Level of LEA	TTA	TFA	Bilateral TTA	TTA and TFA
TTA	-	0.127	0.485	0.067
TFA	0.127	-	1.000	0.560
Bilateral TTA	0.485	1.000	-	0.660
TTA and TFA	0.067	0.560	0.660	-

*TTA=Trans-Tibial Amputation, TFA=Trans=Femoral Amputation

Higher levels of mobility were reported in those with unilateral LEAs compared to bilateral LEAs at both time points. From 6 to 12 months after LEA, those with a unilateral TTA and those with a TTA and TFA (bilateral) demonstrated improvement in their mobility, all other groups demonstrated a decline in their mobility (Table 5.30 and Figure 5.8). There were no participants with bilateral TFA who had achieved prosthetic fitting.
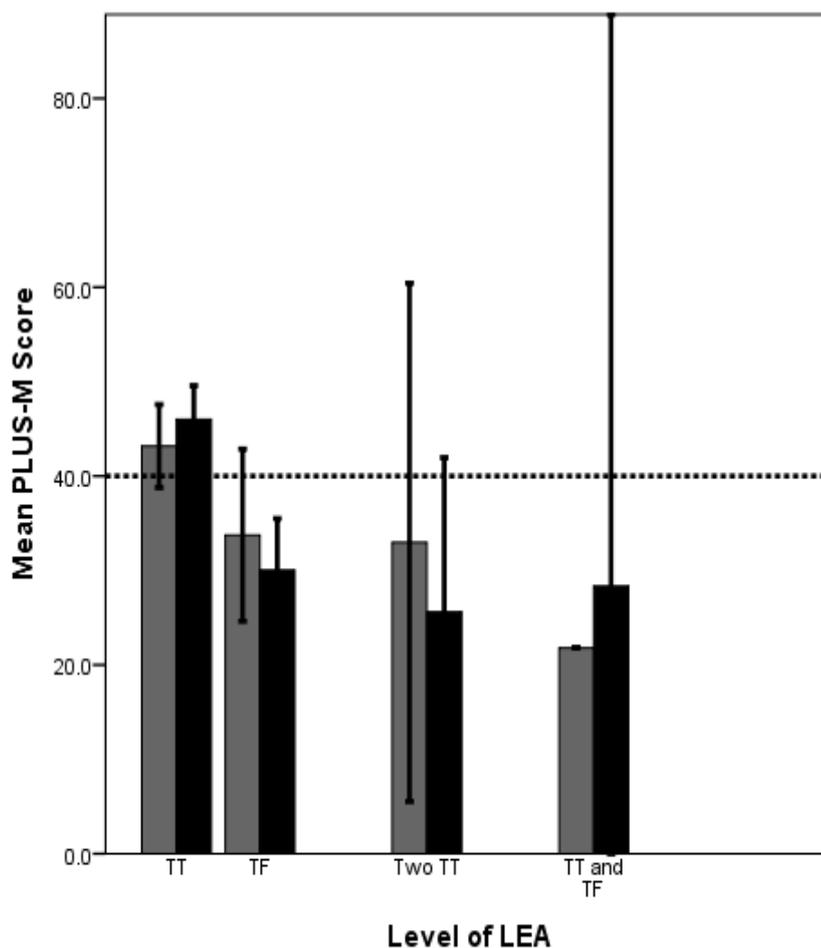
Figure 5.8 Prosthetic limb user survey of mobility scores, 6 and 12 Months after lower extremity amputation.

Abbreviations: LEA=Lower Extremity Amputation, TTA=Trans-Tibial Amputation, TFA=Trans=Femoral Amputation

5.8.3. Prosthetic limb user survey of mobility and diabetes

Those with a unilateral TTA and diabetes reported lower levels of mobility on the PLUS-M score at 6 months after LEA, 42.4 ($\pm$10.8), compared to those without diabetes, 44.1 ($\pm$10.0), however this difference was not statistically significant (*p=0.696*). When all levels

were analysed, at 6 and 12 months after LEA, those with diabetes were more mobile compared to those without diabetes, however this difference was not statistically significant 6 months (t(54)=1.321, *p=0.256*); or 12 months (t (41)=8.371, *(p=0.006)* after LEA.

Mobility scores of those with diabetes improved from 6 to 12 months after LEA however declined in those without diabetes. There was no significant difference between these groups at 6 months, independent sample t-test (*p=0.256*), however this difference was significant at 12 months, independent sample t-test (*p=0.006*) (Table 5.32).

Table 5.32 Prosthetic limb user survey of mobility scores by diabetes.

	PLUS-M t-score (21.8-71.4)	
	6 Months	12 Months
Diabetes	41.2 (±11.7)	43.2 (±11.0)
No Diabetes	35.2 (±13.1)	33.0 (±12.9)
All	39.1 (±11.8)	38.9 (±11.9)

Abbreviations: PLUS-M=prosthetic Limb User survey of mobility

5.9. Statistical analysis of quality of life 6 and 12 months after lower extremity amputation

Quality of life was the dependent variable of most interest in this study and the basis of the primary research question:

1b) Which factors influence QoL following LEA?

Statistical analysis was undertaken to ascertain which independent variables influenced QoL as measured by the health index of the EQ-5D-5L.

5.9.1. Statistical analysis of quality of life 6 months after lower extremity amputation

Multiple regression was conducted to ascertain, which variables from participation, limb fitting, gender, diabetes age, SIMD and level of LEA had the most influence on QoL 6 months following LEA. The PLUS-M scores were not included in this analysis as not all had received a prosthesis, therefore a separate analysis was performed for those who were limb-fitted (Section 5.9.2.). Multiple regression found that participation as measured by RNLI had the strongest influence on QoL (Beta 0.995, *p<0.001*). Male gender (Beta -0.600, *p=0.003*) also influenced QoL as did limb-fitting (Beta 0.390, *p<0.001*) this was statistically significant. Although the remaining variables strongly correlated with QoL, these were not statistically significant. This model accounted for 75.4% of the variance in QoL (Table 5.33).

Table 5.33 Multiple linear regressions with quality of life as a dependent variable 6 months after lower extremity amputation.

Independent	Correlation (r)	Beta Values	Significance (p)
Age	0.719	-0.98	0.754
Gender	0.613	0.238	0.003*
Diabetes	0.721	0.060	0.586
SIMD	0.695	0.097	0.440
Level of LEA	0.461	0.258	0.035
Limb-Fitted	0.775	0.390	<0.001*
RNLI	0.831	0.995	<0.001*

Abbreviations: SIMD=Scottish Index of Multiple Deprivation, LEA= Lower Extremity Amputation, RNLI=Reintegration to Normal Living Index

5.9.2. Statistical analysis of quality of life 6 months after lower extremity amputation for those with a prosthesis

Multiple regression was conducted on those who had received a prosthesis and had completed the PLUS-M mobility measure, to ascertain, which variables from mobility, participation, limb fitting, gender, diabetes age, SIMD and level of LEA had the most influence on QoL 6 months following LEA (n=54). Mobility had the strongest influence on QoL (Beta 1.164, $p<0.001$) in this group 6 months after LEA. High levels of participation, measured by the RNLI, and male gender, were also influential on QoL, both were statistically significant. All of the variables included explained 87.2% of the variance on QoL (Table 5.34)

Table 5.34 Multiple linear regressions with quality of life as a dependent variable 6 months after lower extremity amputation for those who were limb fitted.

Independent	Correlation (r)	Beta Value	Significance (p)
Age	0.832	-0.271	0.235
Gender	-0.776	-0.523	0.003*
Diabetes	0.809	-0.013	0.930
SIMD	0.744	0.078	0.439
Level of LEA	0.569	-0.042	0.617
RNLI	0.890	0.491	0.009*
PLUS-M	0.910	1.164	<0.001*

Abbreviations: RNLI=Reintegration to Normal Living Index, PLUS-M=Prosthetic Limb User Survey of Mobility

5.9.3. Statistical analysis of quality of life 12 months after lower extremity amputation

Multiple regression analysis was conducted using the data gathered 12 months following LEA, with the same model as previously used at 6 months post LEA, with QoL as the

dependent variable. However, the 6 month QoL health index score was added as an independent variable to examine if QoL 6 months after LEA had any influence on QoL 12 months after LEA. 85.7% of the variance was explained by these variables (Table 5.35). The QoL score at 6 months was strongly correlated to the 12-month score and this was statistically significant (*p=0.037*). RNLI had the strongest influence on the 12 month QoL scores and was also statistically significant (*p<0.001*) (Table 5.35). At 12 months, gender had no influence on QoL *(p=0.137).*

Table 5.35 Multiple linear regressions with quality of life as a dependent variable 12 months after lower extremity amputation.

Independent	Correlation (r)	Beta Values	Significance (p)
Age	0.687	-0.359	0.207
Gender	0.627	-0.292	0.137
Diabetes	0.706	0.151	0.416
SIMD	0.724	0.156	0.190
Level of LEA	0.378	-0.157	0.117
Limb Fitted	0.737	-0.127	0.634
QoL at 6 Months	0.842	0.242	0.037*
RNLI	0.861	1.208	<0.001*

Abbreviations: RNLI=Reintegration to Normal Living Index, QoL=quality of life

5.9.4. Statistical analysis of quality of life 12 months after lower extremity amputation for those with a prosthesis

Twelve months after LEA, fewer participants with a prosthesis completed the follow up questionnaires, hence provided mobility data (n=42). In a similar manner to the six-month data, analysis was conducted to ascertain which factors influenced QoL twelve months

after LEA. The model included the following variables: gender, diabetes, age, SIMD, level of LEA at 12 months, RNLI at 12 Months, PLUS-M at 12 months and the QoL score from the 6-month questionnaire. All of these variables accounted for 93.4% of the variance in QoL.

Mobility (PLUS-M), age, participation, presence of diabetes and previous QoL measure at 6 months, were all found to strongly influence QoL in those with a prosthesis, 12 month after LEA, and were also statistically significant (Table 5.36).The findings of this model differ from the model six months after LEA (Table 5.34), participation remains highly influential on QoL, with the addition of age, diabetes and mobility all contributing to QoL, Gender had no influence on QoL at 12 months which was in contrast to 6 months.

Table 5.36 Multiple linear regressions with quality of life as a dependent variable 12 months after lower extremity amputation for those who were limb fitted.

Independent	Correlation (r)	Beta Value	Significance (p)
Age	0.779	-0.823	<0.001*
Gender	0.782	0.079	0.599
Diabetes	0.787	-0.451	0.015*
SIMD	0.781	0.033	0.723
Level of LEA	0.447	0.023	0.776
QoL at 6 Months	0.867	0.278	0.003*
RNLI	0.913	0.492	0.016*
PLUS-M	0.905	1.275	<0.001*

*RNLI Reintegration to Normal Living Index, PLUS-M prosthetic Limb User survey of mobility

5.10. Research Findings

The key findings of this study will be summarised with reference to the research questions posed in Chapter 4 and will highlight other novel findings:

Primary research questions:

1a) *Is QoL affected by an LEA?*

QoL was lower for all those with a LEA (0.37 at 6 months, 0.33 at 12 months) compared to the age matched population norm.

1b) *Which factors influence QoL after an LEA*

Participation, measured by the Reintegration to Normal Living Index (RNLI) had the greatest influence on QoL, 6 and 12 months after LEA; when the whole cohort were analysed. Male gender and limb fitting also positively influenced QoL at 6 months.

Also, when the whole cohort were considered, at 12 months after LEA, only participation and QoL reported at 6 months were the influencing factors

Considering only those who were limb fitted, mobility, participation and male gender were the most influential factors on QoL 6 months after LEA

Considering only those who were limb fitted, mobility, participation, lower age, presence of diabetes and QoL at 6 months were all found to influence QoL 12 months after LEA.

QoL was lowest in those who lived in the poorest areas (SIMD1), however there were no statistically significant differences in QoL between SIMD quintiles at 6 or 12 months.

QoL was highest in those with a TTA who had a prosthesis; this same group also reported the highest level of mobility (PLUS-M), and this improved between 6 and 12 months after LEA.

QoL did not change significantly from 6 to 12 months after LEA and was lower for those in SIMD 1 compared to SIMD 5.

Secondary research questions:

2. *What are the characteristics of the population who have a LEA, and how do they change over one year?*

Participants in the cohort study were predominantly male (74.9%), retired (69.6%) and living in the poorest areas in Greater Glasgow and Clyde (67.3%, (SIMD 1 and 2).

On discharge home after LEA the majority (79.5%) were housebound and, of those, 64% were restricted to single room living.

There was an increase in the number of participants with bilateral LEAs over the twelve months, as more participants underwent re-amputations to more proximal levels or had an LEA of their contralateral limb.

3. *What is the mortality rate following LEA and what factors are associated with mortality?*

Thirty-day mortality was 5.8%, and this increased to 17.5% at 6 months and 29.2% at 12 months.

Those with a TFA had the highest mortality rate 30 days, 6 and 12 months following LEA compared to those with other levels of LEA.

Mortality was 7.14 times higher in those who did not receive a prosthesis after adjustment for age, diabetes and gender.

4. *Does diabetes influence outcomes after LEA?*

Approximately half of the cohort had diabetes (53.2%) and there were significantly more participants with diabetes (n=70) who had a TTA compared to those without diabetes (n=33) (*p<0.001*).

The presence of diabetes was found to positively influence QoL at 12 months in those who were limb-fitted, but this may be related to the level of amputation (more likely TTA) rather than diabetes per se.

There was an increased prevalence of smoking and alcohol consumption in those without diabetes and these were the only differences in socio-demographic variables between the two groups.

Those with diabetes reported better QoL and higher levels of participation and prosthetic mobility compared to those without diabetes however, these differences were not statistically significant.

5. *What are the rates of limb fitting and level of mobility achieved following LEA; and what are the associated factors?*

Almost half of the cohort (n=85, 49.7%) had a prosthesis fitted and the majority had a TTA (61.2%).

Participants with a prosthesis were approximately 4 years younger than those without a prosthesis;

Those with a TFA prosthesis received approximately 9 more weeks of rehabilitation.

At time of discharge from rehabilitation those with a TTA had achieved a similar level of mobility to their pre LEA level.

Mobility measured by the PLUS-M was poor for all with a prosthesis although those with a TTA prosthesis reported higher levels of mobility.

Other Key Findings

Those living in the most deprived area were, on average, 13 years younger at time of LEA than those living in the most affluent area.

More participants who had limb salvaging surgery in 12 months prior to their LEA had a TTA compared to a TFA.

Three quarters of the cohort had no diagnosed cognitive impairment at time of LEA.

39.9% of those with a unilateral LEA had contralateral foot issues and conservative management was the most common treatment.

Chapter 6

Methods for qualitative interview study

6.1 Introduction

This chapter describes the methods used to conduct the qualitative interviews to investigate the views and experiences of people who had a LEA and the factors they report as influencing their quality of life (QoL). As with the cohort study, in Chapter 4, the rationale, aims, research questions, study design and methods are presented. This chapter also describes the sampling and recruitment of participants, the development of the interview guide, approach to analysis and reflexivity, the broad themes and sub-themes and ethical considerations. Finally, the rationale for a mixed methods approach and the how qualitative and quantitative data were integrated is discussed.

6.2 Research design and rationale

The systematic literature review, presented in Chapter 3, suggested that quality of life (QoL) after lower extremity amputation (LEA) due to peripheral arterial occlusive disease (PAOD), with or without diabetes, was poorer than QoL in an age matched population. The review also found that QoL was higher in those who had a prosthesis especially those who used the prosthetic limb for functional and social tasks such as activities of daily living, returning to hobbies, employment and socialising.

The results of the cohort study, presented in Chapter 5, similarly found that those who received a prosthetic limb reported better QoL, six and twelve months after LEA than those without a prosthesis. The Reintegration to Normal Living Index measures the extent to which those who have experienced traumatic or incapacitating illness have reintegrated into normal social activities (e.g. recreation, movement in the community, and interaction in family or other relationships).

We know, from the preceding studies, that being fitted with a prosthesis after LEA is important to conduct functional tasks and enable a return to usual activities. Although the

prosthesis may enhance QoL, there are no studies that have examined the participants' views and experiences of living with a LEA due to PAOD. Furthermore, there have been no studies that have investigated what other factors may impact on their QoL.

The overall aim of the qualitative interview study was to investigate the views and experiences of people who had a LEA and examine the factors they felt influenced their QoL.

The interview study addressed three research questions:

1. What is the experience of living with a LEA, and how does this impact on QoL?

2. How does having a prosthesis influence QoL?

3. What would improve quality of life?

Semi-structured interviews were used to investigate the experience of living with a LEA and how this impacted on QoL from people's own perspectives. Interviewing was favoured over focus group discussions as it allowed the participant to discuss their own personal experience in a one to one setting rather than being influenced by responses from a group (Creswell 2009). Focus groups participants may find it difficult to express a view or an experience if no-one else appears to have experienced the same thing or to be expressing it in the discussion. Also a face to face interview was expected to be a more comfortable arena than a focus group to discuss sensitive topics, that may arise (Willig 2013).

The choice of semi-structured interviews over structured and in-depth interviews was chosen because the use of open ended questions allowed for a conversational dialogue which can feel more natural to both interviewee and interviewer (Britten 1995). Although the semi-structured interview was driven by the overarching research question on QoL, it allowed the participant to tell their own story but structured and guided by the answers to the open ended questions (Bryman 2015). The semi-structured interview also allowed for clarification of points in the use of prompts and flexibility in the order that questions were asked while ensuring all participants interviews covered the same topics (Mason 2002).

Taylor (2005) stated that interviews allow the researcher to explore participant's attitudes and perceptions of their lives (Taylor 2005). Hence the ability to determine what it was

about doing normal day to day or social activities and how this was so valuable in protecting quality of life could be examined in a naturalistic way (Polit and Beck 2004). Prompts were used in order to clarify why certain tasks were more difficult in a wheelchair or with the prosthesis, and to gain an understanding of the participant's priorities in relation to their QoL. Thus, in summary, face to face interviews allowed QoL to be investigated from participants' own perspectives (Corbin and Strauss 2014) which could not be achieved from the cohort study. Overall qualitative methods allowed a greater understanding of the complexities of life after LEA, of which little was known in the population of those with PAOD (Kumar and Phrommathed 2005). This would seem to be a valuable and useful enterprise in trying to understanding and improve care.

Conducting interviews in the home environment is said to allow for a more comfortable discussion than, say, in a setting such as a hospital or out-patient rehabilitation centre. The ability to build a rapport can be facilitated by discussing everyday topics such as the journey to get there, the garden, and family photos (Sivell *et al.* 2015). These discussion topics could also be useful if the participant is upset during the interview as it allows for distraction techniques to be brought in more naturally e.g. asking about the people in photographs on display or pets that may be in the room where the interview is taking place.

Interviewing in people's homes gave the additional benefit of observing the individual in their own environment and physical obstacles that the participant would encounter such as driveways, uneven pavements, steps and narrow doors to access their house were observed and recorded in the field notes. These field notes were then used to contextualise issues that were relevant to the thematic analysis. The home setting also was designed to allow participants to be more honest and open in their answers about their experiences than they might have been if they had to return to the rehabilitation setting where they might feel they had to be positive (Gerrish and Lacey 2010). Given the challenges with mobility many faced, the logistics of travelling to the rehabilitation centre would have been difficult.

6.3 Methods

6.3.1 Recruitment

Participants were recruited from the cohort study presented in Chapter 4, Table 4.2. All participants who had given written consent to complete the follow up questionnaires were

eligible for inclusion. All those who were medically unwell and currently an in-patient or had a new diagnosis of a cognitive or speech deficit that prevented them from taking part in an interview, since consenting, six months previously, were excluded from participating in the interviews.

6.3.2 Sampling

Samples in qualitative studies are not recruited to represent a wider population but to allow an understanding of an experience (Guba and Lincoln 1994). Therefore, purposive sampling allowed the inclusion of a wide variety of people with a common experience (Charmaz 2000); in this case a LEA. Maximum variation sampling is the most common type of purposive sampling (Sandelowski 1995). Its purpose is to select participants whose experience will answer the research question to the fullest. Coyne (1997) identifies that in maximum variation sampling, participants may vary by demographic characteristics such as age, sex, and occupation or according to political or ideological beliefs (Coyne 1997). Thus "information-rich" participants are recruited who vary demographically and experientially. In this way, a range of views and experiences of the phenomenon under investigation can be obtained (Ziebland and McPherson 2006).

Maximum variation sampling was employed to recruit participants for the face-to-face interviews. The EQ-5D-5L quality of life measure was the tool used to identify as wide a range of participants as possible. Participants who consented to follow up questionnaires in the cohort study completed this outcome measure at 6 months after LEA. The Health Index Score generated from the QoL measure (EQ-5D-5L), ranges from -1 to +1. Three categories ensured a range of QoL scores were included, these were: 0.51 to 1.0; from 0 to 0.49, and less than zero (Table 6.1). Ethical approval (Section 6.3.3) was given for up to 20 participants to be interviewed; twenty was chosen as a pragmatic number which could potentially be achieved within the time available for this mixed methods study (Bryman 2015) and this had been suggested in the original project proposal. However, there was agreement within the supervisory team that this sample size may reduce if data saturation were achieved. The term data saturation is widely accepted in qualitative research to guide sample sizes (Mason 2010) and is a term used to describe the end point of recruiting participants into the study, where no new information is gained and the participant's answers to the questions were being repeated.

Participants who returned their completed questionnaires were assigned a category as per Table 6.1. When potential participants in each QoL range were identified, they were contacted by telephone and invited to participate in a face-to-face interview. As it was not known what effect gender had on QoL, all attempts to keep the genders proportionately represented were made.

Table 6.1 Sampling framework for all eligible participants.

Health Index Score Range	Number of Participants	Gender	
(-1 to +1)	Total n=67	Male	Female
0.51-1.0	32	28	4
0.01-0.5	23	14	9
0 or less	12	7	5

Data saturation was achieved after 10 interviews, however, to ensure that data saturation had truly been reached, a further 5 interviews were conducted (Bowen 2008). At this point there was agreement with the supervisory team that there was no further development of understanding of the topic (Mason 2010). This was also defined as the point of informational redundancy (Guba and Lincoln 1994) and no new participants were required to be invited for interview. Recruitment of interviewees is summarised in Figure 6.1.
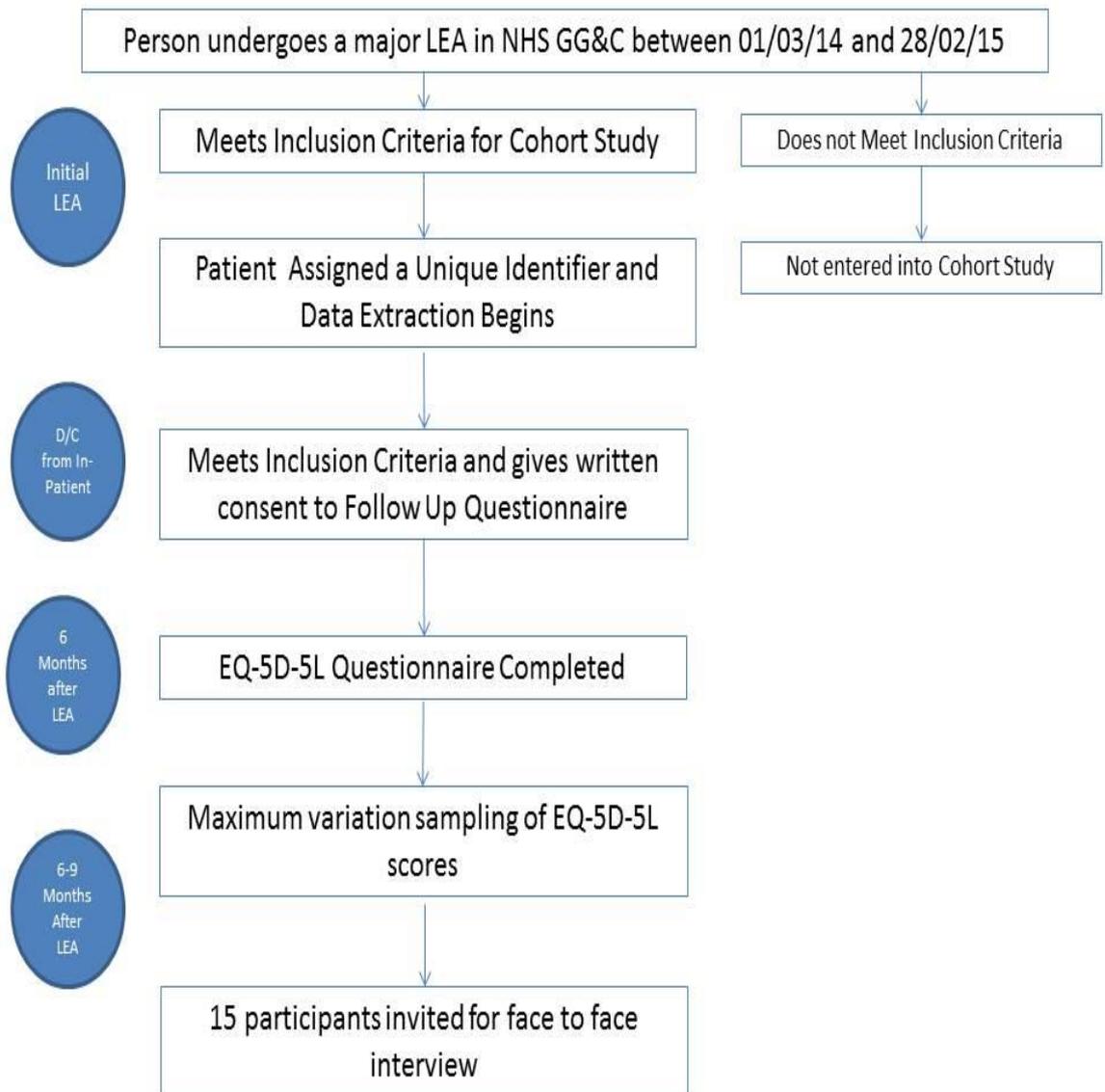
Figure 6.1 Participant recruitment and sampling for face-to-face interviews.

Abbreviations: LEA=Lower Extremity Amputation, EQ-5D-5L=Quality of Life Questionnaire, NHS GG&C= NHS Greater Glasgow & Clyde

Once verbal agreement was gained a Participant Information Sheet (PIS) (Appendix I) was posted to the participant and a mutually agreed date was arranged to visit the participant in their home. If this was not agreeable to the participant, then the interview location was moved to the gym in West MARC at the Southern General Hospital; one participant preferred this arrangement. Prior to the interview the project was explained, its purpose and confirmed that the findings would be anonymised. The participant had the opportunity to ask questions prior to giving written consent.

6.3.3 Lone working and ethics

The University of Glasgow Lone Working policy was adhered to; the supervisor was informed of the time and location of the interview along with the participant's name. The supervisor was contacted by phone immediately before and after the interview took place.

Ethical approval for the qualitative aspect of this study was obtained from the West of Scotland Research Ethics Committee (14/WS/0016) in October 2014. Research and Development approval was gained from NHS Greater Glasgow & Clyde (GN13DI563) in October 2014. Two ethics amendments were made following the pilot interviews; the first to include the written consent of partners participating in the interview. The second amendment to allow the researcher to contact the relevant GP if anything that the participant said during interview gave cause for concern. Both amendments were accepted as minor changes by the Research Ethics Committee in November 2014.

6.3.4 Development of the topic guide

To ensure the interview did not lose sight of the research question, an interview guide was devised (Willig 2013). Combining the structure of the interview guide with the open-endedness of the questions is said to help build a rapport with the participant. There are several types of questions that can be included in a topic guide, Kvale (1996) suggests nine types of interview questions which include opening, follow up, probe and indirect questions (Kvale 1996). However, Charmaz (2000) takes a simpler approach which was followed here were the question type was designed around the stage of the interview (Charmaz 2000).

An initial question was developed to commence a dialogue. The first question asked was; *"Can you tell me how your life has been since the amputation?"* This allowed the participant to tell the story of their amputation; as it was an impartial question from the researcher's perspective (Patton 2005) and allowed for exploration of the participant's experiences on the broader topic of quality of life after LEA.

Intermediate questions then focused on QoL and rehabilitation since LEA. These questions asked about participant's mobility in their home and outside, returning to their usual activities and asking how they felt about themselves since their LEA. They were developed to understand the issues around participation and prosthetic use that were raised in the follow up questionnaires.

The interview then finished with an open question that encouraged some reflection on what the participant felt they would advise another person in this situation to do *"Do you have a take home message for anyone going through this same experience?"*

It was essential to ensure that the questions were relevant to each participant e.g. ensuring only those who had a prosthetic limb were asked about the rehabilitation setting. Prior knowledge of each participant's reason for LEA, rehabilitation achievements and demographic details from the cohort study were noted before each interview to ensure correct questions were asked.

A small pilot study was undertaken to improve interview skills and to support the development of the topic guide. Three pilot interviews with participants who had a LEA six months previously were conducted. All three were initially enrolled into the cohort study however their LEAs were due to orthopaedic complications rather than PAOD, therefore their data was not included in the cohort study as it did not meet the inclusion criteria. As no details on participants' aetiology, rehabilitation achievements, QoL or and demographic details were available from prior data collection. The pilot participants were asked to complete the QoL measure EQ-5D-5L prior to interview (Figure 6.2).

1. Can you tell me how your life has been since the amputation?

2. Can you tell me how you have been managing since you got home from hospital?

3. Can you think of any problems since you have come home?

4. Do you remember any of the discussions about getting an artificial leg?

5. Do you remember being part of any of the discussions?

6. What were your expectations about walking or not after the amputation?

7. Can you tell me what has made you want to walk again?

8. How have you found using a wheelchair to get around?

9. How do you feel about being in a wheelchair?

10. How has losing your leg affected the way you feel about yourself?

11. Is there anything that you can suggest that could help with this?

12. What was the support like when you came home?

13. Have you felt your relationships have changed since losing your leg?

14. Can you think of anything that would make your life better at present?

15. Can you tell me about your health just now?

16. Can you think back to before your amputation, do you feel any differently now?

17. Do you have a take home message for anyone going through this same experience?

Figure 6.2 Pilot interview guide.

Following the three pilot interviews, transcription and initial analysis, amendments to the topic guide were made. The first of these was the opening question which was changed to "*Can you tell me about your life before the amputation and how it compares to now?*" This was felt to be a more appropriate question in terms of comparing how their life had changed from before their LEA to 6 months afterwards and gave the participant a chance to reflect on this change. It also allowed for more appropriate exploratory questions to be asked afterwards by the researcher.

The two closed questions that started with "Do you remember" were removed as they had yielded very short responses. The question *"How do you feel about being in a wheelchair?"* was removed as it did not produce any meaningful answers for discussion. Additional questions were added to the end of the topic guide to allow for more open discussion and these were ordered to allow for the interview to end on a more positive note. The question; *"If we could wave a magic wand, what would make life better?"* and; *"What makes for a good day?"* were added to explore if there had been a positive experience since their amputation. Prompts were also used rather than additional questions, which stimulated a more open conversation rather than a question and answer session.

During the pilot interviews, all three participants were keen to start talking prior to and after the interview was being recorded, consequently, vital information was being missed. Participants were asked to refrain from speaking in detail until the interview had begun, in order to capture all the interview data, and once the last question had been answered the participant was given a few more moments to add anything else before the interview finished and the recording was stopped (Figure 6.3). In the pilot phase, one participant requested that their partner be present for the interview, in order to accommodate them and allow for clarity during transcription, the partner was asked to speak after the participant.

1. Can you tell me about your life before the amputation and how it compares to now?

In what way has it changed?

2. Can you tell me how you have been managing since you got home from hospital?

What would make life easier for you?

3. What things have you had to adjust to since coming home in relation to moving around?

Can you tell me some more about how you have done this?

4. Do you remember being part of any discussions about getting or not getting an artificial leg?

Can you tell me about these?

5. What were your expectations about walking (or not) after your amputation?

6. How do you manage to get around the house?

7. Can you tell me what made you want to walk again?

Was there anything that you feel stopped you from walking again?

8. Has losing your leg affected how you think of yourself?

Can you say more about that?

Some people find it affects how they interact with other people. Have you found that?

Is there anything that you can suggest that could help you with this?

9. Was there any support when you came home?

Can you tell me about this?

10. Have your relationships changed since losing your leg?

Can you describe how?

11. Can you tell me what makes for a good day?

Can you tell me some more about this?

12. Can you tell me about your health just now?

Can you think of anything that would make this better?

13. Can you think back to before your amputation? Do you feel any different now?

14. If we could wave a magic wand, what would make life better?

15. Do you have a take home message for anyone going through this same experience?

Figure 6.3 Final interview guide.

During each interview active listening aiding responses without leading the participant (Bryman 2015). Although the interviews were recorded, it was possible to take some field notes while the participant was talking which allowed for appropriate prompts and related questions to be asked, without disturbing the flow of the interview (Edwards and Holland 2013).

Immediately after the interviews, and after leaving the participant, a reflective account of each experience was written. This included a description of the participant's home i.e. outside steps, driveway, uneven path; whether the participant was wearing their prosthetic leg; obstacles inside their home; and whether the participant was sitting in their living room or whether they had a commode and TV by their bedside. A field note was made if the participant had been emotional at any time during the interview, whether tearful, angry or jovial, and a reflection of how the partner (if present) had been toward the participant. The process of writing and reflecting upon the interviews was a useful experience when transcribing the interviews as the memory of the experience was more clearer. Writing the reflective account was also a useful tool in processing what had been discussed in the interview, realising the effect that the LEA had on the participant since their discharge from rehabilitation and to consider if there were contrasts from a clinician's perception of life after LEA compared to that of a researcher.

In order to successfully interview participants, several skills are thought to be required concurrently (Hoffmann 2007). Taylor (2005) suggests that although interview skills are improved with experience, the researcher could build upon their own interpersonal communication skills to conduct a successful interview (Taylor 2005). Emphasis was placed on active listening to identify areas for discussion to explore during the interview. The ability to remain reflexive during the interview is an acquired skill whereby the researcher is able to follow the participant's responses in line with the topic guide whilst giving direction with prompts or anticipating when to be silent, and observe changing mood, tone emotion or behaviour (Denzin 2001). As a physiotherapist well versed in communicating with patients, families and health professionals on a daily basis, these skills already existed, however their implementation in this new setting required practice. In order to do this a conscious effort was made to allow the participant to collect their thoughts after each question and response, not 'jumping in' too quickly with the next question and all the while preparing for the next question with a field note or use of the

topic guide. During the interview, it was possible to gauge the tone of the participant's response, and react with an appropriate non-verbal or altered tone to allow for further discussion.

After each interview, it was useful to talk to the primary supervisor about the interview and some aspects of the reflective account in order to discuss the emotional response and how to adjust from the role of a clinician to a researcher. During some of these conversations the general sadness felt from undertaking the interview was expressed e.g. about participants' home situation and/or the low mood. In two of the interviews, one participant and one participant's partner (separate interviews) were crying, and although they were informed that the interview could be stopped, they insisted on continuing. Afterwards they said that they had appreciated the ability to talk about their feelings so openly. There were frequent meetings with the supervisory team during this part of the study to present the initial analysis and this aided with the reflexivity.

Several participants talked about feeling low in mood at times however there was no action taken such as contacting their GP. After each interview a thank you card was sent to the participant with a contact phone number included if they wanted to get in touch. No-one took up this offer but three participants reported they appreciated the card.

6.3.5 Data processing and management

The digitally audio recorded interview data were transferred to a password protected secure server at the University of Glasgow. Verbatim transcribing was undertaken shortly after each interview (Bazeley and Jackson 2013). The first eight interviews were transcribed by before asking for an external company (UK Transcription Service), to complete the final seven; this was due to time constraints. All fifteen interviews were listened to whilst reading the transcripts to ensure moments such as pauses, crying, interruptions or gesturing to objects in the room which had been jotted down as field notes were noted in square brackets within the text. This process ensured transcription was accurate and complete, and also allowed for immersion within the data and aided when noting common themes or differences between interviews. This process of continuous comparison is recommended by Miles and Huberman (Miles and Huberman 1994).

Transcribed recordings of the interviews were also stored on the secure server. Maintaining confidentiality through the anonymity of the participant was essential to ensure data were not identifiable to any person involved. Once the interviews were transcribed the identifiable information was removed from the transcripts and only the participant number remained which allowed for analysis to be anonymised.

As there was a large volume of text produced from the fifteen interviews NVivo, the computer software package was used to manage the data. The transcribed texts were uploaded to the software package. Although NVivo is described as qualitative analysis software, it is more accurate to describe its use in this study as an organisational one, it allowed for codes to be applied to the text and for broad themes to be identified in the text, whilst organised in a coherent manner (Gibbs 2002).

6.3.6 Data coding and analysis

There are many ways to analyse qualitative data, however there is general agreement that the process should be started early on in data collection, should be continuous and repetitive (Bradley *et al.* 2007). With this in mind, as already reported, the interviews were transcribed within days of being conducted and were read and re-read (Pope *et al.* 2000). Initial analysis was conducted using a structured thematic approach, similar to the approach used in the "personal experience of health and illness (DIPex) interviews (Ziebland and McPherson 2006). The first four transcripts were read by the supervisory team and ideas for coding were developed. A coding frame was established and the transcripts were coded to these broad themes.

To ensure each participant's views and experiences were represented and included in the analysis the "One Sheet of Paper" (OSOP) method was implemented (Ziebland and McPherson 2006). The OSOP method encouraged the reading of each excerpt of the interviews and for notes to be taken down on one large sheet of paper along with the code, the relevant participant ID number and the exact line from the transcript that it related to (Fig 6.4). The OSOP method is a well-developed visual tool used in qualitative research. It allowed areas that the participants had discussed to be coded in order to highlight commonalities and differences in their perspectives. For example, when participants discussed the prosthesis some talked of the lack of technology, while others talked about the discomfort of wearing it and others spoke of how it was useful to use it to go outdoors.

All of these perspectives were able to be gathered in an organised manner and identification of any common participant characteristics were noted such as gender, level of LEA or SIMD, e.g. if all of those who spoke negatively of their prosthesis had a trans-femoral level of LEA rather than a trans-tibial LEA, this could be noted. All of this information was managed and analysed whilst keeping the main theme of quality of life central to the analysis.

Broad themes were identified within the transcripts, all of which were guided by the research questions and related to QoL. Coding with OSOP analysis was then conducted on the first four transcripts to the broad themes and to identify sub-themes. Each coded extract was read and re-read to identify subthemes within the 'broad' theme and coding was quality-checked by a second member of the supervisory team. These sub-themes were then applied to the remaining eleven transcripts and participant ID numbers were used for comparison of similar or contrasting views of a sub-theme.
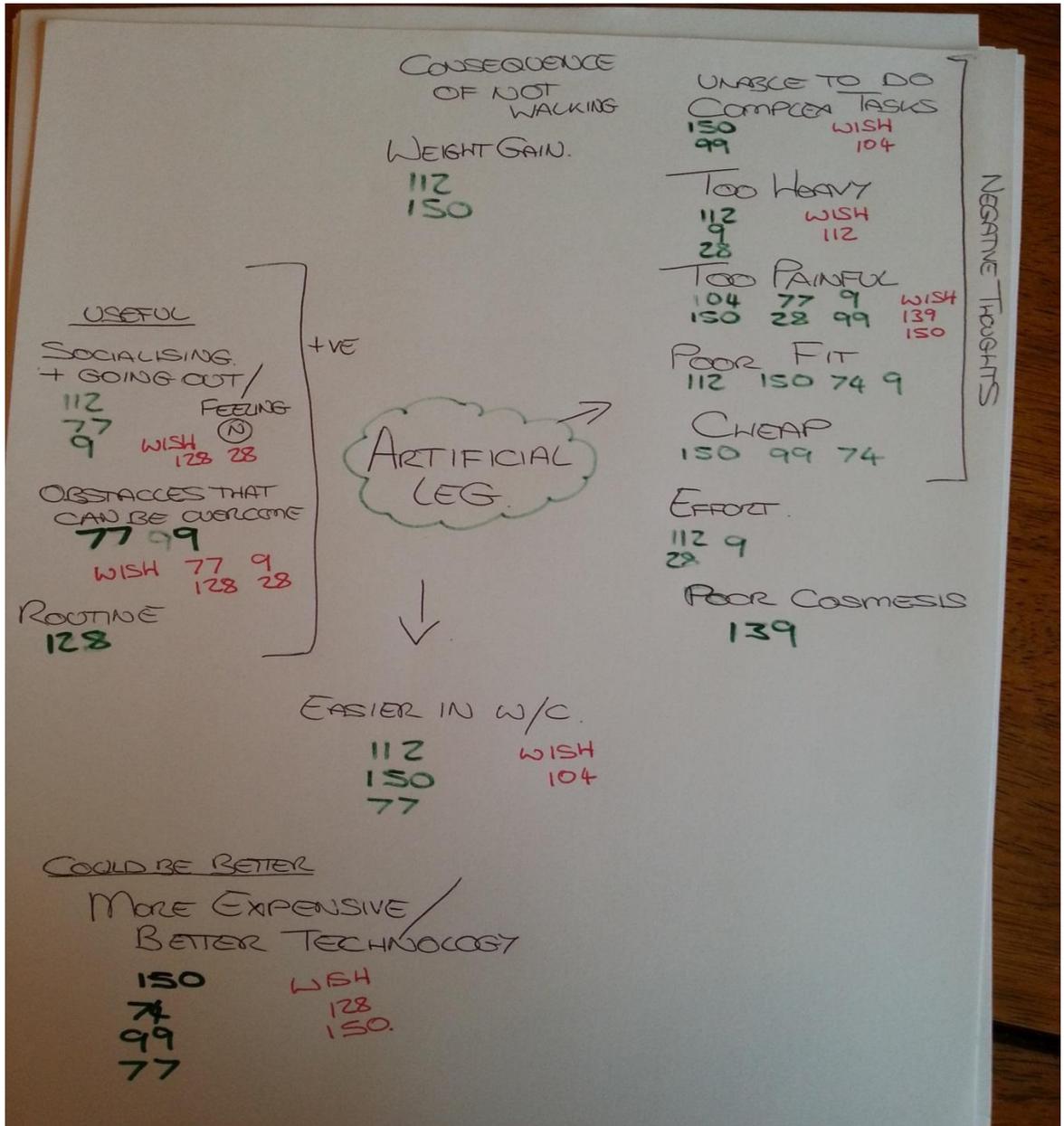
Figure 6.4 The one sheet of paper analysis.

6.4 Rationale for mixed methods

This technique known as mixed methods; is the process of collecting, analysing and mixing both quantitative and qualitative data to understand the research problem (Creswell 2014). Although the mixed methods approach can be difficult to implement, it is useful to amalgamate both research methodologies in order to provide additional insight to the findings (Simons and Lathlean 2010), however the timing and sequencing of amalgamation should be given due consideration and may be dependent on the experience of the researcher and their time limits (Creswell, 2014). Creswell states that there are three

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possible mixed methods designs: *convergent*; *exploratory* and *explanatory sequential* (Creswell 2009). The latter of these, explanatory sequential design is when the quantitative data is collected first and then the qualitative study is conducted with a specific purpose to help understand or explain certain aspects within the quantitatively collected data. This is also known as a quantitative study with qualitative research embedded in its design (Creswell and Clark 2007, Merriam and Tisdell 2015).

An explanatory sequential design was used in the current study where the cohort study was commenced and once participants 6 months follow up was completed, the face to face interviews were conducted (Figure 6.5) Both studies were then analysed separately and the results combined for interpretation (Sandelowski 1995, Creswell 2014). Although O'Caithan and colleagues suggest combining the data at the analytical stage, this approach is complex and requires a higher level of research experience (O'Cathain *et al.* 2010). Additionally, conducting and analysing both studies in sequence was thought to be more effective in answering the research questions whilst also time efficient for the researcher in the long term (Creswell and Clark 2007). Once the interview transcripts were analysed and the themes identified, these themes were then contrasted and compared with the results of the cohort study in Chapter 5.
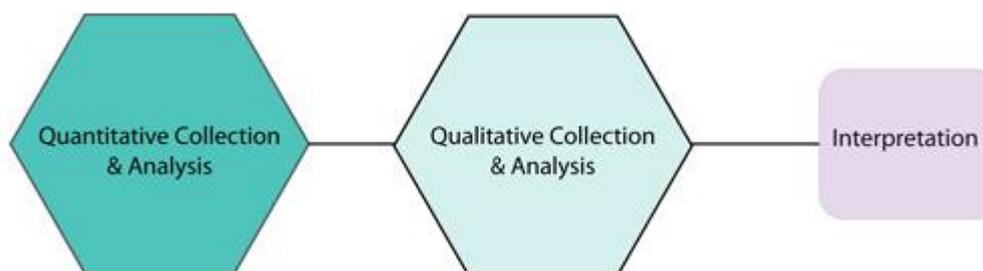
Figure 6.5 Explanatory sequential mixed methods design.

It is the interpretation of findings from both studies that enrich the final results and bridges the gap between the two i.e. the cohort results and the interview findings (Onwuegbuzie and Leech 2005, Johnson *et al.* 2007). This improves the evidence base (Polit and Beck 2004), in this case identifying the factors that influence QoL after a LEA. Combining and interpreting the results of studies, quantitative with qualitative, to address one question is sometimes called triangulation (Simons and Lathlean 2010). Bowling suggests that triangulation may have two possible outcomes: the same results were produced from both studies i.e. the cohort and the face to face interviews; or differences would be identified i.e.

(Bowling 2014). Farmer et al (2006) developed a protocol that expands on Bowling's definition of triangulation which could have the result of enhancing the validity and credibility of findings (Farmer *et al.* 2006). They define triangulation as identifying convergence, complementarity and dissonance between studies. Their triangulation protocol suggests four possible outcomes; agreement, partial agreement, silence and dissonance (Farmer *et al.* 2006).

In order to allow clear interpretation within the current mixed methods study, both studies were analysed separately. The triangulation protocol by Farmer et al (2006) was implemented to ensure that all of the key findings were discussed (Farmer *et al.* 2006).

The implementation of the triangulation protocol was a five step process (Figure 6.6). The relevant findings of the literature review, cohort study and face to face interviews were each related to the research questions. This allowed identification of key results and assisted in identifying where the results were in agreement or had partial agreement. It also allowed results that had only emerged from one study to be identified i.e. silence and if there were conflicting results then these were categorised as dissonance.

Sorting	Sort findings from each data source or method into similarly categorized segments that address the research question(s) of interest to determine areas of content overlap and divergence.
Convergence Coding	Identify the themes from each data source. Compare the findings to determine the degree of convergence of (a) essence of the meaning and prominence of the themes presented and (b) provincial coverage and specific examples provided in relation to each theme. Characterize the degree and type of convergence using the following typifications of concurrence (or nonconcurrence) within theme areas.
	Agreement (e.g., meaning and prominence are the same, provincial coverage and specific examples provided are the same). Partial Agreement There is agreement on one but not both components (e.g., the meaning or prominence of themes is the same, provincial coverage or specific examples provided are the same). Silence One set of results covers the theme or example, whereas the other set of results is silent on the theme or example. Dissonance There is disagreement between the sets of results on both elements of comparison (e.g., meaning and prominence are different; provincial coverage and specific examples provided are different).
Convergence Assessment	Review all compared segments to provide a global assessment of the level of convergence. Document when and where researchers have different perspectives on convergence or dissonance of findings.
Completeness Assessment	Compare the nature and scope of the unique topic areas for each data source or method to enhance the completeness of the united set of findings and identify key differences in scope and/or coverage.
Researcher Comparison	Compare the assessments of convergence or dissonance and completeness of the united set of findings among multiple researchers to (a) clarify interpretations of the findings and (b) determine degree of agreement among researchers on triangulated findings. made.
Feedback	Feedback of triangulated results to research team and/or stakeholders for review and clarification

Figure 6.6 Triangulation protocol.
(Farmer *et al.* 2006)

The key results from the cohort study and the five themes identified from the face to face interviews were examined, with the main findings of the literature review; whilst keeping the primary and secondary research questions at the forefront. Each of these four elements will be discussed at the beginning of Chapter 8 in relation to the two studies.

Chapter 7

Findings of Qualitative Interview Study

This chapter presents the findings from the qualitative interview study. First participant characteristics are described, then the thematic analysis.

7.1 Participants

As described in chapter 6, participants were selected for interview through maximum variation sampling from the results of the quality of life (QoL) questionnaire, which was completed 6 months after LEA. Fifteen eligible participants were identified and invited for a face-to-face interview. All fifteen consented; ten males and five females; and if their partner was present and wanted to participate they were allowed to do so and this happened in four cases.

Participants were aged between 54 to 81 years old. Three had bilateral lower extremity amputations (LEAs) and the remaining twelve had unilateral LEAs; six at trans-femoral (TFA) and six at trans-tibial (TTA) level (Table 7.1). The majority of the participants (n=9) lived in the two most deprived areas of NHS Greater Glasgow and Clyde (NHS GG&C) compared to three participants who lived in the most affluent areas. Twelve of the participants had a prosthetic limb however only eight were mobile with their limb at the time of interview i.e. 6 months after LEA.

Despite differences in socio-economic status, age, level of LEA and prosthetic use the thematic analysis revealed many shared experiences in relation to quality of life after LEA. This chapter will now present these findings

Table 7.1 Participant characteristics.

Participant	Gender	Age	Level of LEA	Diabetes	Health Index (-1 to +1) *	RNLI (0 to 100)*	PLUS-M (21 to 74)*	Limb Fitted	SIMD	Lives Alone
9	F	81	TFA	No	0.21	62	61	Yes	5	No
28	M	55	TTA + TFA	No	0.03	56	21.8	Yes	1	Yes
50	F	55	TTA	Yes	0.18	77	N/A	No	1	N/H
59	M	67	TFA	No	-0.08	38	21.8	Yes	1	Yes
74	F	65	TTA	Yes	0.68	73	47.1	Yes	5	No
77	M	56	TFA	No	-0.06	34	21.8	Yes	1	No
83	M	78	TTA	No	0.56	73	47.1	Yes	3	No
99	M	54	TTA	Yes	0.80	68	49.1	Yes	5	No
104	M	74	TFA	Yes	-0.44	37	N/A	No	1	No
112	M	54	TTA +TFA	Yes	0.21	42	21.8	Yes	3	Yes
119	M	54	TTA	Yes	0.67	81	41.5	Yes	1	No
128	M	65	TTA x2	Yes	0.23	38	33.2	Yes	3	No
139	F	56	TTA	Yes	0.21	51	36.4	Yes	1	No
141	F	69	TFA	Yes	0.05	46	N/A	No	2	Yes
150	M	62	TFA	No	0.07	39	32.2	Yes	1	No

Abbreviations: LEA= Lower Extremity Amputation, RNLI= Reintegration to Normal Living Index; PLUS-M= Prosthetic Limb User Survey of Mobility, SIMD= Scottish Index of Multiple Deprivation, TFA= Trans-Femoral Amputation, TTA= Trans-Tibial Amputation, N/A= Not Applicable; N/H= Nursing Home. *minimum and maximum ranges in brackets

7.1.1 Participant interviews

The interviews lasted between 30-75 minutes with all participants consenting to the interviews being digitally recorded.

At the beginning of the interview, participants were informed that their participation was voluntary and that the interview could be stopped at any time or if they became upset. Four of the participants' partners contributed to the interviews, in all cases the partners' felt it had been a good opportunity to talk about their role in the participant's journey after LEA. During the interviews, one participant and one participant's partner (separate interviews) were upset and they were informed that the interview could be stopped if they got upset but all wished to carry on. Although several other participants talked about feeling low in mood at times there was no other action taken such as contacting their GP. After the interview several of the participants said that the interview, although difficult at times, had given them an opportunity to discuss their feelings in a comfortable environment and were appreciative of this opportunity.

7.1.2 Overview of thematic analysis

The principal focus of this study was "quality of life" (QoL) and accounts suggested that five experiences were critical to the quality of life of participants after an LEA. These five experiences made up the five broad themes identified in Figure 7.1. Each theme along with the associated sub-themes, which reference how they influenced the participant's QoL. Illustrative quotes were used to substantiate analysis and individual participant numbers are provided in parenthesis. The following section (7.2) focuses on the central theme QoL, while the remaining broad themes, and their sub-themes, are discussed in the subsequent sections.
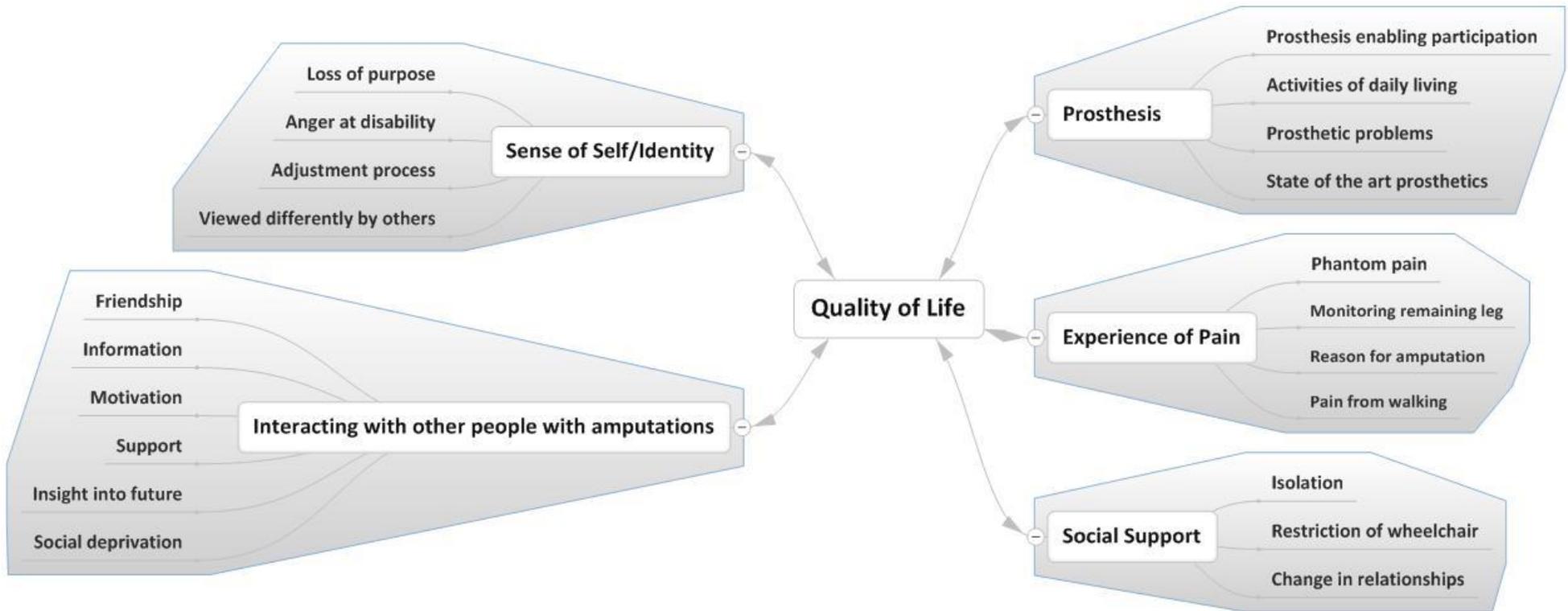
Figure 7. 1 Themes and sub-themes influencing quality of life.
Abbreviations: LEA= Lower Extremity Amputation.

The focus of this study was to understand the views and experiences of people who had a LEA and explore the factors they reported as influencing their QoL (RQ 6). The following section (7.2) focuses on the central theme QoL, while the remaining broad themes, and their sub-themes, are discussed in the subsequent sections.

7.2 Quality of life

Throughout the interviews participants spoke of their QoL in different ways. They talked about what was important to them and how the LEA had affected their lives. However, the clearest answer to what influenced QoL was brought out in the question, which was asked towards the end of the interview, "What makes for a good day?" This allowed participants to reflect more on how the LEA had affected their QoL as many compared their "good day" with one from prior to their LEA.

Participants talked about returning to the activities that they enjoyed before their LEA as making for a good day. This 56-year-old male who had received a trans-femoral prosthesis but rarely used it, reported his QoL as "worse than death". He was housebound and on his own most days while his family were at work, therefore his social life was dependent upon being taken out by friends and family at weekends or evenings. In response to the question of what makes a good day he said:

> *"Days when I get out and play snooker. I enjoy that because it gets me out for say four hours or so. I always go there with my son, my brother and his son. There are always four of us. We have a laugh, a couple of drinks and just have a game of snooker. It breaks it up, breaks the week up"* (Participant 77)

Another participant, a 54-year-old male, with a TTA, who was able to walk independently indoors and outdoors; talked about being out with his friends and family as making good day. He spoke about the importance of being able to go out and socialise in a similar way to before his LEA.

> *"I had a cracking day the other day, Saturday we went for lunch and then went to football and then we went back down to the pub and I get back here after being thrown in a taxi about half eight and then put to bed. Great day"* (Participant 99)

Although many reflected on good QoL as being able to do the same things as before their LEA, one participant said that "*every day was a good day*" because they knew that the LEA had saved their life. This 54-year-old male, with a trans-tibial prosthesis, who walked with one stick, scored his QoL as above average. He was appreciative of his independence and reflected on how important it was that he could choose where and when he went out.

> "*For a good day? Just being out and about, this is going to sound cheesy but to me every day makes for a good day, because what I went through, when you learn that you were within a couple of hours of dying and now I'm able to get up just like I've done and even get a bus into town and go wherever I want, get whatever I want, take my time, go over and see whoever I want*" (Participant 119)

Without this independence there were some participants who directly expressed that the LEA had such a detrimental effect on them that they had no QoL. This 55-year-old female, who had a TTA, did not receive a prosthesis was unable to live at home as her house was not wheelchair accessible; instead she lived in a nursing home and was completely dependent upon staff for all care. The participants' response to the question 'what makes for a good day?' was that she said did not feel she had had a good day since her LEA. When she talked about her daily routine, she said each day was repetitive and there was no indication of any enjoyment.

> "*I get up during the day into my wheelchair and I go down the stairs and there are activities on. I do the activities, then I go for my dinner, I come back up and then I go back to the activities again at 2:30. When that finishes at 4:00 I come up here (single room) and I put my nightie on and then I'm in my bed*" (Participant 50)

This was one example of the negative effect that a LEA could have on a person, causing them to be totally dependent upon others. Although on the face of it you might expect this woman to have a lot of support because she lived in the nursing home she felt isolated and spent a large amount of time alone and in bed in a single room. This theme of social support was a commonly expressed throughout the interviews.

7.3 Social support

The theme of social support relates, as participants spoke about it, to the importance of having a support network, whether this was family, friends, or more formal support e.g. home help. In many cases it was essential for the participant to have assistance with activities of daily living (ADL), self-care and going outdoors. Lack of social support seemed to have a detrimental effect on the participant, often causing low moods and feelings of isolation. However, for those whose family were able to look after and assist them, participants talked of how this caused a change in their relationship dynamics. The theme of social support was often discussed in more depth by those who were less mobile with their prosthesis or indeed wheelchair dependent (Figure 7.2).

Figure 7. 2 Social support.

7.3.1 Isolation

Feelings of isolation were evident throughout the interviews, this 54-year-old male with bilateral LEAs, who had two prosthetic limbs fitted, lived alone. He was rehoused to a disabled access flat as his house was not suitable for a wheelchair; he defined what isolation meant to him.

> *"Isolation is nobody coming up to visit you, no contact with your friends, even your family"* (Participant 112)

Others used the analogy of living in a prison to describe the social isolation felt after an LEA and the importance of social interactions to enhance QoL. A 54-year-old male, who also had bilateral LEAs and prosthetic limbs but found it too difficult to walk, was reliant on his wheelchair and was very aware of the importance of social interaction.

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"here (in own house) you feel quite isolated, especially living yourself, you feel shut away at times, you don't see any neighbours, you don't hear a noise, it's like being locked away like some kind of prisoner, I'm living myself and not really interacting with anybody which is no good at all, definitely not good" (Participant 28)

Similarly, a female who was wheelchair dependent, living on her own and had regular home help and a very supportive family talked about how the loneliness affected her mood.

"I do find myself occasionally feeling like going into a corner and having a good old cry, more so recently...I think it's just being on my own……. the girl (home help) went away just about 9 o'clock. There will be nobody coming back now until about half past 4. (In between that there's lunch people, which reminds me I must phone them to say, "Don't bring me lunch today) I don't know. Sometimes I feel a bit down. More so recently. I don't understand why. They're only in and out, but it's just that somebody coming in and have a wee blether for five minutes. It makes all the difference" (Participant 141)

The feelings of being low in mood were evident throughout the interviews and some, despite isolation, chose not to interact with others because of feeling differently about themselves. The same participant who described isolation as being a prisoner (Participant 28) was aware of how important social interaction was, and talked about the difficulty motivating himself to be sociable since his LEAs.

"I get good days, bad days, some days I feel like shutting myself away from the world, a wee bit depressed, try to look ahead and say, sometimes I think what's the point in all this, you know, not to the point of suicide don't get me wrong but some days aye you know…" (Participant 28)

There was also insight into how the physical difficulties experienced when going outside combined with a change in their identity contributed further to psychological isolation. The two men who described isolation previously (participants 112 and 28) were neighbours and both had been rehoused due to access issues in their previous homes. This was one of them

describing a conversation they had about their life since the LEAs, he was reflecting on the isolation that they both were feeling.

> *"when I spoke to my friend (who also has an amputation) along the road the other day he was saying he feels isolated and a burden on people and you do feel a burden on people, I mean I'm 54 and I don't want to be a burden on anybody, I think it's common to feel isolated because you're not the same as everybody else who has a pair of legs, you can't just jump out to the pub or the shops you have to wheel yourself down and you're just different, just very different, so isolation does come in as a big part of my life just now, being isolated in my house even though I've got a nice house, I mean I can get on and off the bus if I want but you just don't want to do that you just don't want people staring at you, you really don't want that at all…."* (Participant 112)

Using the wheelchair increased the isolation, as certain environments became inaccessible. Even if they had a prosthetic limb fitted there were often times when it was too difficult to walk and the wheelchair was the only means of mobility. Compounding these physical restrictions were the feelings that arose from being in a wheelchair, some were embarrassed and felt people treated them differently to people who could walk. As the interviews took place in the participants own homes; and physical obstacles that the participant would encounter outside and inside their home, such as driveways, uneven pavements, narrow doorways, and stairs were observed and recorded in the field notes.

7.3.2 Restriction of wheelchair

Due to the physical restrictions described by the participants, many were living in one room, which contained their bed, commode, TV and kettle. The remainder of their house was not accessible by wheelchair or, if using a prosthesis, accessing other rooms required more physical capability than they had. The limited access within their home and the outside environment, along with the physical restriction imposed upon them by the wheelchair and/or the prosthesis, led to feelings of isolation and altered dynamics within their relationships. Participant 104, a male with a trans-femoral amputation, who was not fitted with a prosthesis, talked about the layout of his home having to change because he was dependent upon the wheelchair and how the rest of his house became inaccessible.

"My house is halved in two. It's a great joke I know, but three bedrooms up the stairs. Now I've got an extra bedroom but it's in the living room" (Participant 104)

This same participant talked about the wheelchair as determining where he could go.

"Before, I could do things a normal person could do, which I can't do now, obviously. So take it from there. Walking, you name it, could go anywhere I wanted to go. Now I'm confined to a wheelchair, wherever a wheelchair can go I can go, but that's it" (Participant 104)

This participant who had a trans-femoral amputation, and had not been limb fitted, spoke of the considerations and her frustration of being in a seated position and totally dependent upon the wheelchair.

"...Being aware of the fact that, "Right think before you do anything. Are you strapped in?" It's tiny wee things. You buzzed the phone bit there (door entry system). I suddenly realised that's too high. I can't reach that. So I had to get a guy out to come and lower it. My heating controls, it's a wee electronic, I had to get that lowered. I've just suddenly realised, because I was saying to my son the other day, my wee spy thing because you keep saying don't open the door, I said, "You need to do another one lower down because I can't see through that." It's all these silly wee things." (Participant 141)

Although the majority of the participants had prosthetic limbs, all had been issued with a wheelchair after their LEA. Despite the possibility of being able to walk in the future, all had talked of their reliance on the wheelchair for longer distances or for ADLs. However, many did not view their use of the wheelchair positively and felt restricted by it. Participant 112, who had both legs amputated and had been fitted with prosthetic legs, still relied on his wheelchair for outdoor mobility. He talked about feeling self-conscious when he was in his wheelchair, and at times this was enough to stop him going out at all.

"...being in a wheelchair, you feel uncomfortable amongst other people, I went down the town last Sunday and people stare at you in the wheelchair, I mean they stare because you've got no legs and that's very off putting, it puts you off going out and it stops you going into town or socialising and that" (Participant 112)

Others had similar experiences of feeling excluded from usual interactions when out in a wheelchair. Participant 28 talked about the difference between sitting and standing in relation to being part of the community. This made him reluctant to socialise outside of his home.

> *"I don't mind people staring at my metal legs I don't give a toss but see when I'm in a wheelchair it's totally the opposite I don't feel like I am part of the community in the wheelchair, standing up I am the same height as you, I can eyeball you, it's just much more normal even with poles for legs but in a wheelchair you feel very awkward and people stare at you much more"* (Participant 28)

A female participant who had a unilateral trans-tibial amputation and had been successful with prosthetic fitting talked about how the physical position of sitting meant she felt restricted and unable to do daily tasks. She felt that the early experience of having to use the wheelchair until she could walk was the main cause of her low mood, however she did feel it also motivated her to improve her prosthetic use.

> *"I just absolutely detested the feeling of being down at that angle which sounds really silly but I just didn't like it at all. In some ways I think that helped me actually because I was quite determined that I would get out of the wheelchair as soon as possible. You can't really do much in your house. You can't carry things. Well you can put things in the wheelchair but I think that was probably my lowest time. I thought I wouldn't be able to do anything again"* (Participant 74)

The overarching sense, in all accounts, was that quality of life was lowered by being disabled by an environment inaccessible to a wheelchair, unable to access the outdoors and in some cases the indoor environment. This was exacerbated by the sense of being socially excluded by people outside the home because of being disabled. It was this dependence on the wheelchair and having to be in a seated position as opposed to standing that affected their QoL.

> *"It's non-quality of life, that's what it is because you're stuck (Pointing to wheelchair). There is nothing you can do, is there?"* (Participant 104)

The inaccessibility of the environment outdoors was expressed clearly by many participants. Prior to receiving her prosthesis this woman had become totally dependent upon her husband to help her with her wheelchair both inside and outside the house.

> *"The other thing was that I couldn't get out of the house because there was nothing at the back door. There was nothing that I could hold on to. There was no ramp. We actually bought a ramp but it was impossible. My husband had to lift the wheelchair and me more or less out of the door. For quite a few weeks, I think about six weeks at least I wasn't really going out. Or if I was going out I thought I was going to break my husband's back trying to get me out the door"* (Participant 74)

This dependence upon others led to many participants talking about a change in their relationships since their LEA, through increased reliance on family and friends.

7.3.3 Change in relationships

Returning home from hospital after the LEA and not being able to walk caused many participants to notice the change in their own capabilities and the need to ask others for help. Some accepted the assistance in the transitional period while others commented on how it motivated them in their rehabilitation to return to their independent selves. A 56-year-old female who was previously working and physically active on a daily basis, had a trans-tibial amputation. Her home was inaccessible in the wheelchair and she had a period of weeks before being able to start walking with a prosthesis. She felt the carer role that her husband and friends took on held her back from achieving independence and also changed the dynamic of her relationships.

> *"I think to begin with there were so many people here (in own home) that I didn't have to do anything , and that's probably been bad in my part because no matter what I went to do "sit down, I'll do it" and it wasnae helping me at all, since then I've got rid of all the people, mostly, my pal was in this morning but she was in for business rather than to do something for me, hubbys been back to his work, he was off his work for a long time looking after me, and if he wasnae here my pal was here so it was just constant and that definitely did hold me back"* (Participant 139)

Others appreciated that if they did not have a family or a person to help them they would be extremely restricted by being unable to walk, as they couldn't reach cabinets or carry out simple tasks. This female with a TTA was appreciative of the help her husband gave her.

> *"It's all the stupid wee things that are frustrating. Will you get that cup down for me? Will you do this? Will you do that?" (Laughter) I'm lucky I've somebody to do that, otherwise I would need everything at that level (indicates to sitting level)"* (Participant 74)

Rather than feeling the increased reliance on their partner altered the relationship for the worse, the same participant felt that they were closer since her LEA.

> *"I think my husband and I are probably closer. I think we are closer yes. Apart from that it is just the same, just very good, very, very good. My relationship with my daughters is the same. It was a very good relationship before and I would say it is probably even better now. Of course with my grandchildren that is the important bits of my life, and my mother in law who is very supportive because she says nice things to me every time I go. But no I think my relationships are probably stronger and closer"* (Participant 141)

However, this was not the case for all participants, as many resented being dependent on their partners, but said they used these feelings as motivation for progressing in rehabilitation.

> *"I went to the gym (in the limb fitting centre) for the first time and I was so amazed because I hadnae seen so many amputees, for by being in the hospital, but I hadnae seen so many amputees in a gym and each one was so far on from where I was at that point I was like Oh My God, am I ever going to be like that and I think when I came home I said to my husband, "you think I'm going to be disabled for the rest of my life? You think I'm going to need to depend on you?" And he said "well, yeah" and my pal said the same thing and I said "well get it out of your heads that is not going to happen, I'm going to walk and I'm going to do things that I've always*

done and I'm going to get back my life", so I think that was the start of it" (Participant 139)

Participants talked of changes to their family dynamics since their LEA e.g. partners becoming carers and family relationships changing since their LEA, with family taking on the role of carer and spending more time with the participant as a consequence.

The husband of this participant had become her full time carer and became upset when talking about the effect of his wife's disability on both their lives. Prior to the LEA they were very active and when asked what life was like from before the LEA to now, he added to the participant's response and his emotion was clear.

"To me there's a complete difference between having complete mobility and not having any mobility. It has affected our way of life completely. You can't say it's for the best. It's diabolical. ... It's terrible to have gone from the one extreme to the other extreme, in a way of life, as a result of this amputation." (Husband of Participant 9)

Although some family were able to take on the role of full time carers, Participant 50 who had lived on her own prior to her LEA did not have this option and was not able to return home. At 55 years old, this female who had a TTA was unable to receive a prosthesis due to co-morbidities had to go to a nursing home as her own house was inaccessible; it was this that she attributed to her deteriorating relationship with her son.

"My son doesn't like it in here. I've only seen him, I think, twice from when I came in and I'll be in a year in January. That hurts me so much. He was my first one. The girls will go to me; the blue eyed boy has not been up yet. That does hurt me" (Participant 50)

To offset the lack of social support that many felt, the importance of interacting with other people with amputations was discussed. Participants talked about the experience of meeting other people with LEAs as helping them out of their isolation and, through seeing how others were doing, were reassured that it was possible to return to a sense of normality. However, meeting other people with LEAs tended to occur in the limb-fitting

centre where they attended for out-patient physiotherapy, and only those who received a prosthesis experienced this opportunity.

7.4 Interacting with other people with amputations

Interacting with other people with a LEA could be both a negative or positive experience for many. Positives were the ability to interact with others with similar experiences, build friendships and share information. At times this was the motivation needed to progress in their prosthetic rehabilitation. Other participants felt the experience of meeting others with a LEA was negative as it made them realise that prosthetic use would be unattainable for them. The experience of seeing others whose disease had progressed was distressing and being exposed to the social deprivation was difficult for some. Nonetheless, all the interactions were felt to impact on the participant's view of their quality of life (Figure 7.3).
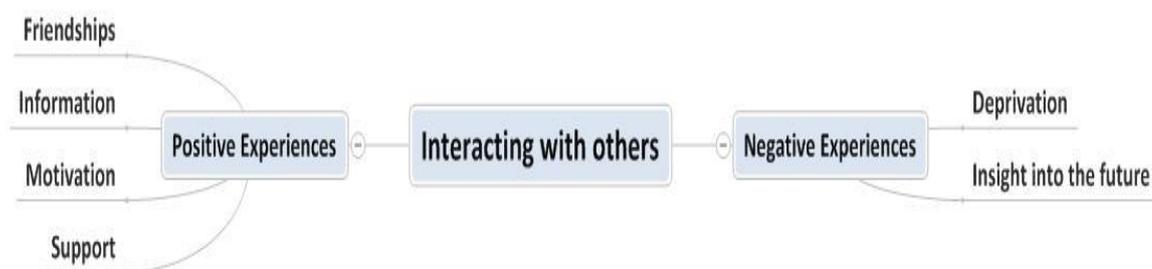
Figure 7. 3 Interacting with other people with amputations.

7.4.1 Positive experience

The benefit of meeting others with a LEA was clear from observations as well as from interviews. For example, field notes identified a stark difference in the demeanour of participant 128 (65-year-old male with bilateral LEAs) between seeing him in the limb-fitting centre, as the researcher had previously seen him, and then at home when interviewed. In the limb-fitting centre he was talkative and jovial, at home, interviewed with his wife, he was very low in mood. When asked about this difference in his demeanour he explained that only others with a LEA could understand what life was like.

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"Well when I'm in the gym there's a lot of people there, I know them all I don't know their names, you sit and talk away, yesterday we were sitting and talking away at the table the four of us, and we were talking about the hospitals and the wee female said I fell, the boy said I fell and all, then George said I fell too, and I said me too……, the four of us fell in the same hospital (laughs), it is so much better speaking to folk that have the same problems" (Participant 128)

Several participants talked about the supportive network they experienced by going to the limb-fitting centre, as they were able to talk to others in the same situation. For some, the interactions developed into friendships outside of the limb fitting centre. For example,.

"Well I've met new friends through the hospital, well that's one, two three four chaps that I am friendly with" (Participant 28)

While participants attended the limb fitting centre and spoke to each other there was an opportunity to share knowledge of their prosthetic limbs. Participants talked about the positive experience of gaining practical tips from other patients on managing tasks with the prosthesis. For example, this man who had received a trans-femoral prosthesis, talked about how he found out how to make dressing himself easier with the prosthetic limb.

"See I talked to different people with different legs and different amputees that had like buttons and whatever. There was some rotor. It was like a disc thing that goes in. They put it in your knee. One of the amputees was saying about it. He said that helped him a lot for bending the leg. He put it that way, that way (Pointing to his leg). He said, "You put your clothes on it. You go to bed at night and you put your clothes on it. When you are putting them on you just put your clothes on and your leg just fits." He said he got it done in ….(limb fitting centre). I was like that, "Well I want one of them." He said, "Well just say." I didn't say because I didn't know if they still did them or not" (Participant 77)

As well as practical tips, some experienced empathy from other patients and the ability to discuss issues and share experiences seemed to help with the adjustment process. This man felt that the ability to talk about shared experiences to people in the same situation was very important.

"you come here, you come to a place like ... (limb fitting centre) and you feel comfortable, why? Because we are all the same, we can talk about it, we can mingle with each other, we feel comfortable with each other and I think if you ask anybody, I think that's what everyone feels, they'll say "I feel much more comfortable here", we can talk about things, we can talk about our amputations, phantom pains and this and that but outside you can't talk to, I can't talk to anyone, I mean phantom pain they say what's a phantom pain? Things like that you feel a lot of people guys and women say that they feel comfortable here they can talk, there's no one here staring at you to, we're in the same boat basically" (Participant 112)

7.4.2 Negative experience

Although most of the interactions among people with LEAs were positive, there was an awareness that everyone had different goals and what some felt was good quality of life was in contrast to others. This was evident when those from different socio-economic backgrounds were talking to each other. One participant from the most affluent area reported the highest QoL score and said he felt distressed by seeing the social deprivation of others with a LEA.

"One of the people I did see over in... (limb fitting centre) was a wee guy, he had both legs amputated, one about four years……. He was quite happy to walk from his house to the pub, a couple of pints and then back at night. I thought, "God, is that going to be it?" I know people have different aspirations in life and I just thought I could have picked this guy up and cuddled him and taken him home. I think he split up with his wife and all that kind of thing. There are problems" (Participant 99)

Another negative experience was meeting and speaking to people who initially had a LEA of one limb and then over the course of rehabilitation underwent a further LEA of their remaining limb. Not only was this distressing to observe but increased the awareness of the disease process of peripheral arterial occlusive disease (PAOD). It also caused participants to think about this as a possibility in their future.

"Another one (another patient) he was going in for his second operation to get his other leg off. I hope it never comes to that, oh no I couldn't cope with that" (Participant 104).

This insight into the future was compounded when participants who became friends through the limb fitting centre found out that their friend had died. However, there was little insight as to the cause of their death being due to PAOD. This 67-year-old participant, who lived alone, talked about how he had made friends and then he heard that the person had died.

"It definitely makes it difficult because when you see them and they become friends with you and all of a sudden, that's it, away. As I say, I don't know what happened to Jimmy, I was going to phone him up. All I'd heard was that he'd passed away, but I don't really know what's happened……. he was a young man" (Participant 59).

The majority of interactions amongst participants occurred in the limb-fitting centre, and this prompted a lot of discussion about the artificial leg or prosthesis.

7.5 Prosthesis

From a physiotherapist perspective, being fitted with an artificial leg or a prosthesis is often a measure of successful rehabilitation after LEA. The prosthesis is seen as a device that can enable people with a LEA to participate fully in daily life. This concept of participation is embedded within the rehabilitation journey; and is central to the International Classification of Function, Disability and Health (Hemmingsson and Jonsson 2005). Many of the participants experienced barriers to using their prosthesis to walk following discharge from rehabilitation. Although, twelve of the fifteen participants had prosthetic limbs, eight reported being able to walk with them but only four, all of whom had a TTA, were wearing them during the interview.

Walking with the prosthesis enabled some of the participants to return to social activities and perform Activities of Daily Living (ADL); both of which were deemed as important to their QoL. However, prosthetic problems were discussed and some tasks were felt to be

more energy consuming when using the prosthesis. Within the limb fitting centre there were occasions where participants would observe ex-military personnel with LEAs who had been given prosthetics with state of the art technology. This created some discussion around improvements in technology being useful to those in the study, who would not normally have access to such specialist prosthetics (Figure 7.4).
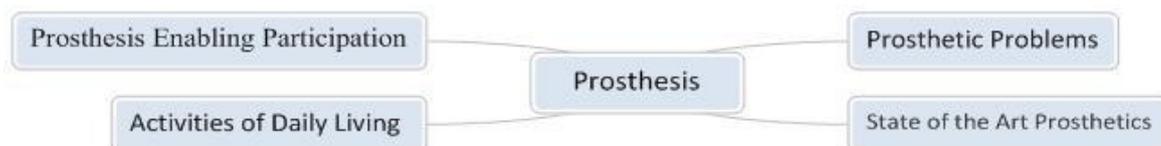
Figure 7. 4 Prosthesis.

7.5.1 Prosthesis enabling participation and activities of daily living

Participation varied from being able to complete ADLs, to being independent with personal care or to be outdoors and socialising. One of the participants who had bilateral trans-tibial amputations was wearing his prosthetics during the interview. Half way through the interview, this gentleman needed the toilet and was very proud to demonstrate that he was able to walk to the toilet independently with a walking frame.

> *"I just use my zimmer (walking frame) and I have my legs on from when I wake up in the morning until I go to bed, they're on all day"* (Participant 128)

This participant's wife felt that the prosthetics allowed him to do the things that he used to do and that prior to walking he felt embarrassed by being so dependent upon the family for self-care.

> *"He was crabbit, because he couldn't go to the toilet himself and had to use the commode so that was difficult, but once he got his leg he was up and down to the toilet himself and that's better than when he came home I think it was just embarrassing for him so I think that's why he wanted to keep walking so he could go to the toilet himself."* (Wife of Participant 128)

However, others felt that the inability to walk without a walking aid was a hindrance in being able to do ADLs. This man with a TFA spoke about the difficulties of using walking sticks.

> *"I can't do things about the house that I used to do and that frustrates me, even making the tea you've got to have your wheelchair if you've got your leg and the two sticks you can't pick the cup up"* (Participant 150)

Another participant, who was able to walk indoors and outdoors with her TTA prosthesis and one stick, chose to use her wheelchair in conjunction with the prosthesis for ADLs.

> *"Well as far as feeding the dogs and washing the dishes I can do that sitting down, the only thing that's a bother to me is the height of the units, you know I had to stand up for certain things but if I felt staggery then I just had to sit down, the chair was with me all the time"* (Participant 139)

Despite the difficulties with walking aids, there was an awareness of how the prosthesis enabled access to the outdoors that the wheelchair did not afford. The same man who struggled with ADLs and was not wearing his trans-femoral prosthesis during the interview appreciated its use in places where stairs would have been an issue if he had not been able to walk.

> *"Yes like that birthday we went to (gesturing to his wife) I don't take the wheelchair but then I got there and needed the toilet and the stairs were like that (gestures to being steep) I thought Oh no and they weren't broad either but I had to do it."* (Participant 150)

Similarly, this female who struggled with the prosthesis indoors was able to overcome obstacles like stairs by using her prosthesis. This allowed her to accompany her husband and enjoy their previous routine of going with him to the velodrome.

> *"It's just as well, because the lift has been broken at the velodrome for weeks now, so I have to walk down the steps. They've got a rail, and that's the best thing that can happen"* (Participant 9)

Contrary to the researcher's perception that a prosthetic limb allowed for successful rehabilitation, participants did not report the same positive attitude. Although they found the prosthetics to be useful in enabling participation, many of the participants with trans-femoral level LEAs talked about prosthetic problems that hindered them from doing more walking.

7.5.2 Prosthetic problems

Pain was a common prosthetic problem when walking and standing especially in those with trans-femoral amputations. Pain from the prosthesis was felt to prevent walking both indoors and outdoors. This man reported how it was difficult to continue his rehabilitation at home due to pain and counteracted this by limiting the use of the prosthesis.

> *"... I've got a zimmer in the bedroom and a set of crutches, and I walk up and down the hall but not that often but I have done it, its pain that stops me from doing it more"* (Participant 28)

Another participant also limited his prosthetic mobility due to pain and despite using his prosthesis for going out socially, still had to rely on the wheelchair from day to day.

> *"I still don't use my leg in here, I use my chair, it is just easier. I always say, it is like cheating. I should be putting it on all the time. It [the prosthesis] doesn't help me as much. I don't know. It seems as if I will never get used to it. That is my main aim that I can put it on so I can just walk about as freely as I can"* (Participant 77)

The majority of those with trans-femoral prosthetics were reluctant to wear their limbs and when asked why, one participant talked about pain due to the fit and the weight of the prosthesis.

> *"It's heavy and sore. It hurts me in the groin. They've adjusted it a couple of times, but you get the feeling they have so much work to do they haven't got time"* (Participant 150)

His complaint about the weight of the prosthesis was often an issue for people with trans-femoral amputations. Many felt that the surgeon or health professional were unaware of the impact the weight had on the ability to use their prosthesis and were told that the weight of the prosthesis was the same or lighter than their original limb. This was rebutted by many.

> *"To have my legs back is all I really wish, or to have better, better legs. The legs that we get just now are so heavy, I know they're short of money but the leg: they say it's the same weight as your leg but none of us agree with that, I have never spoke to anybody who agrees with that"* (Participant 112)

Along with the weight of the prosthesis, there was an issue around comfort when wearing it. This caused the length of wearing time to be limited due to pain experienced in the stump.

> *"I mean I could put my legs on and stand up and do that but it's pain, it is really sore so I don't ..."* (Participant 112)

All of the prosthetic limbs require stump socks to be used to adjust for fluctuations in stump volume. The process of putting these on and adjusting them daily can impact on the comfort of the prosthesis as this participant talks about in his dislike for wearing them.

> *"Aye the leg, (pointing to prosthesis) it takes too long to say trying different socks, four socks were on at one time for that leg, eh it's stupid, I'm not going to be doing that when I finish (at the limb fitting centre), putting on four socks every day I should have a sleeve in that (points to prosthesis) that fits"* (Participant 150)

In conjunction with the stump volume changes, those with a trans-femoral prosthesis have to use a total elastic suspension belt around the waist to keep the prosthesis on. Many felt that this was difficult and uncomfortable and limited the time that the prosthesis was worn if at all.

> *"The big plus would be, we hope, this better leg that is on the go now, which doesn't have this incredible corset that's round your waist to hold it on, it's a suction. We hope that that will be wearable for more than an hour in every second day"* (Participant 9)

In addition to the prosthetic problems of pain and comfort, walking with a prosthesis requires more energy if the LEA is at trans-femoral level compared to trans-tibial, due to the loss of the knee joint. Some of the participants who had prosthetic limbs complained that the effort of doing simple tasks in a standing position was too great, and opted to not use their prosthesis, the majority of those were using a trans-femoral prosthesis.

> *"I can get down to the garden and have a walk about, but it's not easy. There's a very slight slope in the back garden, and to walk up that grass – it's not agony. It's so tiring I wonder if I'm going to make it"* (Participant 9)

Although the physical effort of using a prosthesis was discussed, there were some who felt the psychological effort was too great and limited their use of the prosthesis in certain environments, as this lady with a trans-femoral amputation discussed.

> *"If we were going to the likes of the shopping centre, or something like that, there's no way I would trust the environment around me to walk on the leg with sticks. I would be frightened, because you've to concentrate"* (Participant 9)

When discussing all of these prosthetic problems, many participants talked of the state of the art prosthetics that they had observed in the rehabilitation setting, and felt there would be a solution to counteract their problems.

7.5.3 State of the art prosthetics

Many people with amputations attended the limb fitting centre at the same time as other patients with amputations. During these sessions many of them observed ex-military personnel who had amputations due to trauma. Consequently, there was an awareness of the specialist prosthetics that were available. There has also been increased media attention around specialist prosthetics and as such many participants who had had their amputation due to PAOD felt that their prosthetics were sub-standard, inexpensive and lacking the technology to allow them to function optimally. None of the participants had specialist prosthetics and all were using the standard NHS prosthetics.

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One male who had his amputation due to diabetes and PAOD talked about the disparity between the military and the civilian populations.

"I'm looking at these things that I have, these prosthetics, and its 18th, 19th Century technology for the 21st century. It's rubbish. When you see what some people can get if you're in the army, you can get £70,000 leg just like that. I feel like a second-class citizen and, if I want to get to where they are, I'm going to have to pay for that, £70,000 to get that sort of technology" (Participant 99)

There was a sense of dissatisfaction and favouritism toward those with specialist prosthetics, as this female with a trans-tibial prosthesis talked about her disappointment at not having a higher specification prosthetic.

"I am thinking of the technical age, the things that we do for computing and for everything. I also think when you look at these army people you think, now they should have everything they get. They should have absolutely everything. They are young boys. They should have absolutely everything after doing what they have done. But I sometimes think, there should be more to this. I should be able to have a proper picture of my leg. It should properly fit in and everything……. but at the bottom of it I think technology could be better" (Participant 74)

Many suggested the more expensive specialist prosthetics were more comfortable and required less energy to use, although none had tried them. Some felt that there should be more technology in the prosthesis to improve balance and confidence when walking outside instead of avoiding situations. This participant, who had limited use of his bilateral prosthetics, felt that the specialist prosthetics would be lighter, which would help him walk, despite not having any experience of them.

"You see people walking about with nice light legs and you think why do I not get them you know? So either to get my legs back or lighter legs, not the clumpy things that we've got, but I shouldn't complain because I'm lucky enough to get back to walking with those, but they really are heavy, they're terrible, very heavy" (Participant 112)

Suggestions around what could improve the prosthesis tended to centre on the technology available to others, however some of the female participants talked about prioritising the "look" of the prosthesis over functionality. The covering that makes the prosthesis look more real is called the cosmesis, and many participants preferred their prosthetic without the cosmesis as it adds weight and can affect function; therefore the metal pylon is visible. However, this female who had not told many of her friends and family that she had an LEA wanted to have the prosthesis look as similar to her own leg as possible in order to make it more acceptable.

> *"I don't know, I mean when the girls at … (limb fitting centre) said most amputees like the metal showing in their leg I was horrified at that, I was like Oh no, I want it to look real, quite a few younger women up at the gym are happy with it, but no, I wanted it to look as normal as possible"* (Participant 139)

Although pain was associated with some of the prosthetic problems discussed in the interviews, the experience of pain was not isolated to prosthetic users.

7.6 Experience of pain

After an LEA there is a general acceptance that the person will not be completely pain free. Ischaemic pain is often replaced by other types of pain such as phantom pain, stump pain or pain from their remaining limb. All of these experiences of pain were discussed in the interviews in relation to their effect on the participants QoL (discussed above). This participant who had limited use of her prosthesis had ischaemic pain for ten years prior to her LEA. When asked what advice she would give to someone who was thinking of having an LEA she was encouraging of having an LEA as it had reduced her pain and improved her QoL.

> *"don't think twice, definitely do it because I was at the stage I was ready for committing sideyways (suicide) because the pain had just taken over my life, as far as my hubbys concerned he deserves a gold medal I don't know how he's lived with me, he's a saint as far as I'm concerned (laughs), we'll not tell him (laughs), but how that man has put up with me the last two years I do not know because nobody else would have done it I was a totally different person before this operation and if*

anybody was going through the same as I went through I would say don't think twice about it, if I'd of known what was going to happen afterwards I would have got this done years ago, as soon as the pain started..." (Participant 139)

The same participant described the experience of ischaemic pain and went onto talk about how her remaining limb is now painful.

"As far as pain is concerned it's brilliant, because I was in constant pain, there just wasny a minute without pain before it and ischaemic pain is unbearable, absolutely unbearable, so that's the first thing, I'm very glad that I had the amputation, no doubt about that at all, the only problem I've got now is I think I've been leaning on my left leg for so long that the pain is in my left leg now, it's not the same pain, but it's still a pain." (Participant 139)

Although there was relief from the ischaemic pain that often caused the LEA, this was sometimes replaced with severe phantom pain. This participant talked about the phantom pains being so severe that it caused her to injure herself and further reduce her mobility and QoL.

"They said some of it is phantom pain because I still feel as if I've got a leg and a foot. Do you know what I mean? I try to move it and stand on it and whatnot, but it's just not there. See when I was in Inverclyde, I was on the toilet and I was coming off the toilet, which I should have waited until a nurse came. But I thought I still had the full leg, I stood up and bang I went. I broke all my shoulder" (Participant 50)

Phantom pain is common after LEA however it has a tendency to be magnified at night and in this case was severe enough to affect sleep long after the initial surgery.

"I still get a lot of nights where I can't sleep because of the pain, phantom pains basically, which can be a bit annoying to say the least" (Participant 28)

Phantom pain was not the only cause of sleep disturbance as one participant talked about stump pain being worse at night after walking with his prosthesis. He used this as a way of recognising that he had been too active during the day and needed to reduce this the next day.

"If I waken up and I hadn't had a great nights' sleep and my leg was sore say on the stump I would say to myself no, that's just sort of your stump telling me you've done too much the day before, and I would know I had done too much too soon" (Participant 119)

After living with pain prior to the LEA, in some cases years, the pain memory aided the participants to be more aware of looking after their remaining limb. However, for some this caused them to worry and detracted from their QoL.

"When I started walking, even in the gym, I knew that my right leg was going to go because I was having severe pain. I didn't tell them that…. plus, I know the physio, so, for me, I had to hide it. Since then, about eight weeks ago, it was probably longer now, I can't remember, I've had an angioplasty in my right leg and it's worked so I'm now able to walk pain-free. It's fantastic" (Participant 99)

The drive to keep walking despite having pain in the remaining limb or discomfort due to the prosthesis was closely related to the final theme "sense of self", as many related the inability to walk as before to losing their identity or sense of self.

7.7 Sense of self / identity

Throughout the interviews the participants described the "type of person that they were" and how this had changed since their LEA. The opening interview question *"Can you tell me about your life before the amputation and how it compares to now?"* was answered often with a description of the type of person they were and what their role was within their own social situation before their LEA. For example, this 56-year-old man whose QoL score translated to "worse than death", was despondent when he talked about being unable to work anymore due to his trans-femoral amputation. He was now housebound, was only

able to go out when family or friends assisted him, and spent his days in the house alone while his family were at work.

> *"I was a butcher. I had to leave after I got this done (the amputation), that was a big thing in my life. I was on five days a week, always up and getting out at five o'clock. You do your working day and then you are seeing people. It is at a shopping centre and you see and meet a lot of people, different people every day. You are talking to the general public. That was my job. They are coming up to me and then you are talking to customers and advising them and letting them know how you do things. You miss that as well getting out to do that"* (Participant 77).

The loss of employment was more than just financial to this male and many others, it was his way of life. He had been a butcher for 35 years and missed the social interaction and sense of purpose that it gave him. The change in identity and sense of self that the LEA had on the participants' was evident through all the interviews. Many talked of a loss of purpose, anger at their new situation and having to adjust to their new life; whilst others felt their family and friends looked at them differently since their LEA (Figure 7.5).
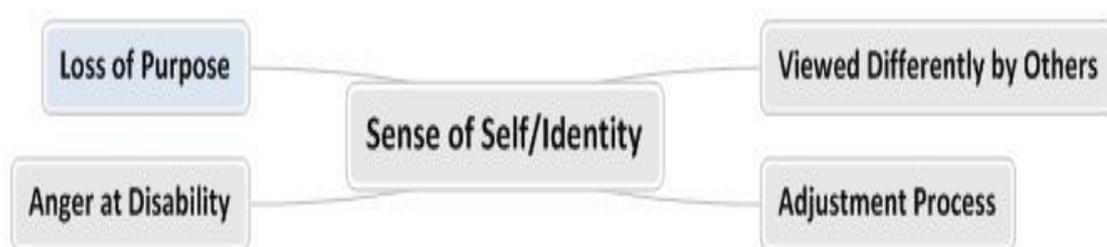
Figure 7. 5 Sense of self / identity.

7.7.1 Loss of purpose

A participant who had retired two years prior to his LEA, immediately spoke of his lack of motivation and loss of purpose to return to his daily routine. He was a 62-year-old man whose QoL score translated to "no quality of life", and was despondent when he talked about his social life and independence prior to his LEA as he was now limited to walking

short distances with his wife for support and unable to go out on his own due to limited mobility.

> *"well my life before was excellent, I could walk the dog, up and about, in the bookies the pub, sneaking out things like that, eh I could do anything, and now it's rubbish, I'm confined but the more it goes on the more you are in , sitting, just a couple of weeks ago she said do you want to go to Clydebank and I said no I can't be bothered, sitting in my pyjamas, I'm usually in my pyjamas I made an effort today and I'm going out later to choose a new couch (laughs) I suppose it's like being in jail you get used to it, I said no I'm not going out, I just sit and you acclimatise (laughs) to sitting in the house, but if the telly is rotten you are sitting looking out the window, I read books, I read a lot, it's a massive difference"*
> (Participant 150)

The contrast to the way people perceived their life before their LEA and six months afterwards was vast. This man had a trans-femoral amputation and no prosthesis and was wheelchair dependent, his house had been reorganised so that he was living in one room and unable to access any other part of his home due to his wheelchair. He was very direct when asked about his situation now compared to before the LEA.

> *"Totally different. You're talking about half a man. Half a man is a fact. You can't even reach up in a cupboard to take a can of beans, that's how bad it is. You can't do anything in the house. Can't even make a bed. That's how bad it is. I'm good being a television controller right now"* (Participant 104)

The inability to do simple tasks and contribute to the chores in the home left him without any satisfaction and he felt as though he was 'half a man'. For many, the fulfilment that employment gave them was now lost, they had limited ability to undertake chores in the home or socialise or do things that were important to them. Some spoke very directly about what they missed about life before the LEA and the change in circumstances was often expressed with anger.

7.7.2 Anger at disability

At the time of the interviews, the participants no longer attended rehabilitation and had been discharged, with or without their prosthesis, this was seen as "successful" in the eyes of the health professionals. However, this was in contrast to the way that the participants talked about the impact that the LEA had on their lives and the sense of anger that they felt at being disabled. The same man who had no motivation to go out and socialise anymore and was dependent on his partner when he walked with his prosthesis, spoke of his anger at people offering to help him.

> *"I didn't want other people in my house, it's so annoying even when you're out and (raises voice) folk come up to you and I am like leave us alone, I hate it, even with my wife I am like I know what I want, I know how to do it, and I know I am going to do it, I'm not a cripple!!! It makes you more self-conscious when people come up to help you and then you start to speed up and then make mistakes…."* (Participant 150)

This participant, who had been distressed by seeing the deprivation of others in the limb fitting centre, was dissatisfied with the help he had been offered during rehabilitation. He had elected to have his LEA due to diabetes and when he looked back on how he felt after coming home from the hospital he was aware that he had been very angry when he met people in shops and was treated differently because he was in a wheelchair.

> *"You become so angry and I think that's part of the problem. There was an awful lot of anger about in me because maybe I'd elected to take it off too early (the LEA) but I wasn't getting out the house anyway and I was fighting that thing about why did I do this? There was a lot of anger in the house because I was angry, very angry with life, the outcome of life. Where was I going to be in six months' time?"* (Participant 99)

In order to move on from the shock and anger of having a LEA participants discussed an adjustment process that was essential.

7.7.3 Adjustment process

Although some had their LEA as elective surgery and had some insight into their future, there was an adjustment process which often meant there were periods of low mood and reflection as to why the LEA had happened. This male with a TTA and a prosthesis scored his QoL as good but still experienced periods of low mood.

> *"It's just one of these things, when you lose your leg, you do your damnedest to get yourself back as well as you can but there are times when you sit and you think to yourself, "Why?" and you feel a bit sorry for yourself. But you've just got to get on with it"* (Participant 83)

The adjustment process was also a time where participants developed coping mechanisms and although no individuals could explain what these were, some expressed a philosophical approach to life since the LEA.

> *"I look at it as another phase in my life, when I had my legs I was out and about constantly, now I don't get out as much so, it's not improved my life, obviously it's not, you know things are never going to be the same…. but I'm…. by now I've sort of basically learned to cope with the situation, that's all I can really do at the end of the day"* (Participant 28)

Alongside the adjustment process that took place after the LEA there was a distinct awareness that a permanent change had occurred not just physically but to their sense of self, the same participant who felt angry at his situation felt that he was no longer the same as everyone else.

> *"I'm not the same person that I was. I know that. I've changed. I wouldn't walk into a crowd anymore. I wouldn't walk into a pub without support. There are a lot of things I wouldn't do. I wouldn't go dancing anymore or clubbing, as they say now. I think you're very much aware of you. Nobody needs to know that I've got a prosthetic leg… but…I have to make them aware that you can't see my disability... but I need to make you aware that I'm not one of you anymore…"* (Participant 99)

This sense of feeling different after an LEA was projected onto the way they felt others viewed them.

7.7.4 Viewed differently by others

Participants felt the physical change after their LEA had caused friends or family to distance themselves. This male had been rehoused to a different area after his LEA however felt that it was not the geographical difference but the actual LEA that caused his friends to not visit him.

> *"...and since this amputation I've lost most of them (friends), most of them they just don't contact me at all, don't contact me at all….because I'm a cripple, I'm in a wheelchair, they don't want to see me in a wheelchair, em it's just how it is as I am in a wheelchair just now"* (Participant 112)

In order to stop friends or family from seeing them differently there was a sense that if they didn't tell them then there would be no change to their relationships. This female who had an elective LEA decided not to tell acquaintances what had happened.

> *"….I don't like, when I'm out with my friend especially, she's got to tell everybody I've had my leg amputated and I don't like that. We were at a few funerals of friends that have passed away recently and nobody knew I was going in for this operation, I kept it quiet it was only my immediate family that knew about it, I didn't want it to be broadcast that I was getting an amputation I wanted to be normal if that's such a thing but when I started to get out and about the people that were stopping me and said I heard you got your leg amputated horrified me absolutely horrified me"* (Participant 139)

It was important that not only did friends and family not see them differently but, discussed in section 7.3.3, many felt that being in a wheelchair changed the way that the public viewed them. This man with a TTA who did get a prosthesis reflected on being outdoors in his wheelchair and being aware of people staring.

"...people, they don't look down at you but they don't take their time it's made me realise how frustrating it must be for folk and when you're in a wheelchair you do see folk look give you a look, a wee sly glance and that kind of thing, the funny thing is seeing how many adults stare and just a few wee weeks ago I noticed two guys and a female just looking at me and I felt like saying, here do you want a photo ? (laughs)" (Participant 119)

7.8 Summary

The purpose of the interviews was to explore the factors that influenced QoL after LEA and all of the participants spoke of the drastic change to their lives since their LEA. Despite many of the participants using humour as a coping mechanism, all of the interviews were tinged with sadness as they spoke of the impact of the LEA on themselves, their family and how they were still adjusting to their life. The interviews were conducted from six months after their LEA and many of the participants were still experiencing problems in their ability to mobilise within their home either with their prosthesis or wheelchair. Many of the participants felt they were not the same as their friends and family after their LEA, and in turn sensed other people viewed them differently. They all talked of their reluctance but necessity to depend upon others on a daily basis and the imposed change that the LEA had on their family, friends or carers. The importance of social support and the negative effects of isolation were evident in all of the interviews. Participants felt that the ability to speak to other people with a LEA was vital to allow them to share knowledge, build friendships and support each other. As most of these interactions occurred in the limb fitting centre there was a lot of discussion around prosthetics, the issues with wearing the prosthesis to carry out tasks and the difference between the specialist prosthetics available to others. The experience of pain was considered to be useful in alerting them to their remaining limb but detrimental in the way it affected their QoL in a daily basis.

In the final chapter, the cohort study results are integrated with the face-to-face interviews and discussed in reference to the background literature and systematic review.

Chapter 8

Discussion

8.1 Rationale for thesis

The aim of the research presented in this thesis was to identify and examine the factors that influence a person's quality of life (QoL) after a lower extremity amputation (LEA) due to Peripheral Arterial Occlusive Disease (PAOD). This mixed methods study had two components; a prospective longitudinal cohort study with follow up questionnaires, and a qualitative analysis of face-to-face interviews. All of the participants in the cohort study had an LEA due to PAOD with or without diabetes. Participants in the face-to-face interviews were selected through maximum variation sampling of their follow up questionnaire scores on QoL completed at 6 months after LEA.

To date there have not been any prospectively conducted longitudinal studies that examine a cohort of patients with a LEA, specifically focussing on QoL, mobility and participation. The ability to examine this population at pre, peri and post LEA phases gives a clearer picture of the patient journey and allows an understanding of the issues faced away from the rehabilitation setting. The following section restates the research questions and how the study addressed each one.

8.2 Research questions and how they were addressed

The primary and secondary research questions were

Primary Research Questions:

    1a) Is QoL affected by an LEA?

    1b) Which factors influence QoL after an LEA?

Secondary Research Questions:

    2. What are the characteristics of the population who have a LEA?

3. What is the mortality rate following LEA and what factors are associated with mortality?

4. Does diabetes influence outcomes after LEA?

5. What are the rates of limb fitting and level of mobility achieved following LEA; and what are the associated factors?

6. What are the views and experiences of people who had a LEA and which factors do they report as influencing their QoL?

To answer these questions, results from the cohort study (which included data from clinical databases and follow up questionnaires completed by participants) and results of the qualitative study with fifteen face-to-face interviews were amalgamated. The cohort study described the socio-demographic characteristics of the 171 participants who underwent a LEA (RQ2), their mortality rate (RQ3) and identified the factors associated with limb-fitting (RQ5). The follow up aspect of the cohort study demonstrated the levels of mobility achieved after limb fitting and how these altered over a twelve-month period (RQ5). Comparisons were made between those with and without diabetes in relation to level of LEA, limb-fitting, QoL, participation and mortality (RQ4). The primary research question focussed on which factors influence QoL and this was answered when results from the cohort study and the face-to-face interviews were integrated (RQ1 and 6).

The following section integrates the results of the cohort study with the findings of the face-to-face interviews to address questions 1 and 6, which have not previously been presented in this way. The findings of the integration of the studies are then discussed with reference to previous studies discussed in the systematic literature review and background literature chapters (Chapter 3 and 2 respectively). Finally, strengths and limitations of this work and the clinical implications are discussed along with the contribution this work has made to the existing evidence base.

8.4 Integration of findings

The rationale for amalgamating the quantitative data from the cohort study with the qualitative aspect data from the face-to-face interviews, was to enrich the findings (Simons

and Lathlean 2010) and provide new knowledge to add to the existing literature (Onwuegbuzie and Leech 2005, Johnson *et al.* 2007). To understand the factors which influenced QoL following LEA, and to enable integration of the results in Chapter 5 and the findings of Chapter 7; the triangulation protocol described in Chapter 6 by Farmer et al (2006) was implemented. Areas of agreement, partial agreement, silence or dissonance were identified and these are defined below (Farmer *et al.* 2006).

I. **Agreement:** factors which were identified in both parts of the study as influencing QoL.

II. **Partial agreement**: factors which were identified in both parts of the study as influencing QoL but were not identified as a key finding.

III. **Silence**: factors which were identified in only one part of the study as influencing QoL.

IV. **Dissonance**: factors where there were conflicting findings between the studies in terms of their influence on QoL.

The findings of the qualitative interviews and the cohort study demonstrated the inter-relationship between factors influencing quality of life and this is summarised in Figure 8.1 presented at the end of Section 8.9. There were no areas of dissonance found between the cohort study and the interviews; the areas of agreement, partial agreement and silence are summarised in Table 8.1.

Table 8.1 Triangulation: areas of agreement, partial agreement and silence between cohort study and qualitative interviews

Agreement		Partial Agreement		Silence	
Cohort	**Interviews**	**Cohort**	**Interviews**	**Cohort**	**Interviews**
Impact of LEA	Impact of LEA	Pain	Pain	Age	
Prosthesis	Prosthesis			Diabetes	
Mobility	Prosthetic Mobility			Gender	
Participation	(i) Interaction with others (ii) Social Support/ Isolation (iii) Sense of Self			Time since LEA	

Abbreviations: LEA=Lower Extremity Amputation, QoL=Quality of Life

The following four sections of the thesis (Section 8.5 to 8.8), describe the areas of agreement, partial agreement and silence found between the cohort study and the qualitative face-to-face interviews (Table 8.1). Each section will include a discussion of how the integrated findings relate to the existing literature.

8.5 Agreement

There was agreement between the cohort study and face-to-face interviews that a LEA had a negative impact on the participant's QoL. The cohort study found that QoL was lower in people with a LEA compared to the general population, the mean health index score following LEA (taken from the EQ-5D-5L, Chapter 4) was substantially lower (0.37) than the UK population as a whole (0.86). The mean age of the cohort was 66.2 years and it is known that increasing age is associated with a lower health index score. However, even when considering the normative values for older people (0.79 for those who are $65 - 75$ years old (Oppe *et al.* 2007) QoL in the cohort was still notably lower. Difficulties were reported in all domains of the EQ-5D-5L measure compared to the population norm, including extreme problems in mobility and usual activities and moderate to severe issues in the domains of anxiety/depression, self-care and pain/discomfort.

In the qualitative study all but one participant spoke about the detrimental impact that the LEA had on their situation. The accounts of difficulties in maintaining a positive sense of self or positive identity (including loss of purpose, anger, and feelings of being viewed differently by others) and feeling isolated by the LEA are discussed in detail in the following section. These, experienced alongside changes in relationships, restrictions imposed by having to use a wheelchair and problems in using prostheses, all combined to and contributed to accounts of low QoL in the face to face interviews as discussed in Chapter 7 and illustrated in Figure 7.1.

The cohort study found that having a prosthesis was positively associated with QoL, furthermore, those who were more mobile with their prosthesis (as measured by the PLUS-M) reported higher QoL than those who were restricted in their prosthetic use. In the qualitative study people who had, and were able to use, a prosthesis spoke of being able to go out on their own when they wanted to, go on public transport and visit friends all of which were viewed as activities that were important to them. Being able to keep up these valued activities seemed to help people to maintain a positive "sense of self" as they were able to do things important to them, depended less on others and were not as socially isolated. Conversely, participants who had limited prosthetic mobility or could only walk with the assistance of someone; spoke of their poor QoL at having little independence for example having to wait for others to take them out for the day.

8.5.1. Impact of a lower extremity amputation on quality of life in previous research

The negative impact of a LEA on QoL, regardless of aetiology, was discussed in several previous studies (Pezzin *et al.* 2000, Davidson *et al.* 2010). The current cohort study added to this evidence with participants reporting extremely low QoL scores 6 and 12 months after LEA (0.37 and 0.33 respectively). These scores were notably lower than the age matched population norm (0.79) (Oppe *et al.* 2007).

The findings of the current cohort are in keeping with a previous Dutch study which reported QoL was poorer for those with a LEA compared to those without an LEA. Their cohort of 82 people with a LEA due to PAOD completed the RAND-36 measure of quality of life and a self-reported form on walking distance, 6 and 18 months after LEA (Fortington *et al.* 2013a). Their cohort was similar to the current cohort study in relation to

age (mean age 67.2 years, which was 1.6 years older than the present study) and proportion of men (67% compared to 79% in the current study). Their assessment points of 6 and 18 months were also similar to the current cohort follow up of 6 and 12 months. The RAND-36 is made up of nine domains that collectively measure QoL, as opposed to the five domains in the EQ-5D-5L. Although there is some overlap between the two measures, e.g. the RAND-36 and EQ-5D-5L include questions in relation to mobility, pain/discomfort and anxiety/depression, however the RAND-36 does not ask about self-care and usual activities but instead asks about social and role limitation. The authors of this Dutch study only reported on 7 of the 9 domains, since data were missing from the remaining two: role-limitation emotional and role-limitation physical. The authors found that those with a LEA had significantly poorer scores in the domains of physical function, social function and pain compared to the age matched norms, which were similar to the poor scores in the domains of mobility and pain/discomfort found in the current cohort study.

Quality of life and prosthetic mobility was also examined in a large study (n=415) of people with a unilateral LEA (Asano *et al.* 2008). These authors used multiple outcome measures including prosthetic evaluation questionnaire and Frenchays' Activity Index (FAI) to ascertain the impact on QoL of a mixed aetiology LEA population. Although their questionnaires were not the same as those in the current cohort study, there were similarities. Asano et al (2008) asked participants to report their ability to use their prosthesis for participation in social activities, which is similar to the Reintegration to Normal Living Index used in the current cohort study. The study found that increased participation in social activities was positively associated with QoL as measured by the Frenchays Activity Index which is similar to the findings of the current cohort study. The main finding from Asano et al (2008) was the strong association between depression (measured by the Centre for Epidemiology Studies Depression Scale) and reduced QoL. In the current cohort study participants reported high levels of depression and anxiety (measured by EQ-5D-5L) at both 6 and 12 months after LEA, which is likely to have detracted from their QoL. Although not directly comparable, there is an association between psychological wellbeing and QoL after LEA in the current cohort study.

Asano et al (2008) also found that other factors such as age, comorbidity, prosthetic mobility, social support and social activity influenced QoL. Their study population was similar to that in the current cohort study as approximately half (53%) of their cohort had a LEA due to PAOD and their participants were only 4 years younger (mean age 61.9 years)

than the current cohort study. However, their cohort had LEAs due to mixed aetiology and had their LEAs 14 years previously, which, may have allowed participants to adjust to their life after LEA, and may explain why the authors found QoL to be higher than they expected. However, Asano et al (2008) did report those with LEAs due to PAOD had a lower QoL than those due to non-vascular aetiologies; which confirms the poor QoL found in the current cohort study.

The lower QoL in those with a LEA due to PAOD concurs with Pernot et al (2000) who examined levels of mobility in a cohort of 164 people with a major LEA (Pernot *et al.* 2000). The mixed aetiology of their cohort allowed the authors to compare those with PAOD, with and without diabetes, to those who had LEA for trauma, tumour or congenital reasons. They used the Sickness Impact Profile as their measure for QoL and function at one year after LEA, and found low QoL was associated with limited mobility.

A large cross-sectional study of those with a LEA in India was conducted to ascertain which characteristics influenced QoL after LEA (Sinha *et al.* 2011). Sinha et al (2011) compared those with a LEA to those without a LEA using the SF-36 QoL measure, however the majority of their study population had LEAs due to trauma (63%) as opposed to PAOD (22%), and their mean age was significantly younger than the current cohort study (47 years) therefore direct comparison are difficult to make. The authors found that amongst 605 participants, factors such as being in employment, fewer co-morbidities and less pain were all positively associated with QoL; the most influential factor was having a prosthesis fitted. This finding supports the current cohort study, which also found that limb-fitting is positively associated with QoL.

In summary, there is agreement between the findings of the cohort study in this thesis and the existing literature that QoL is poor after an LEA. However, the current cohort study has built upon these findings and demonstrated that participants with a LEA report their QoL significantly lower than the age matched population norm.

8.5.2 Prosthesis

The current cohort study found that being fitted with a prosthesis was positively associated with QoL and approximately half of the current participants received a prosthesis (49.7%).

The rate of limb-fitting in the current cohort was relatively high compared to other studies who reported limb-fitting rates in populations with LEAs due to PAOD as low as 26.9% (Pohjolainen *et al.* 1990), 36% (Fletcher *et al.* 2002), 40% (Scott 2012), and 44.8% (Lim *et al.* 2006). In the current cohort study level of LEA was found to have the greatest impact on prosthetic fitting with 50.0% of those with a trans-tibial amputation (TTA) being limb-fitted, compared to only 30.8% of those with a trans-femoral amputation (TFA). Again, this finding that higher proportions of prosthetic fitting occur in those with a unilateral TTA was supported by the literature. Previous studies reported limb fitting rates in those with a TTA to be; 54.9% (Houghton *et al.* 1992), 58.5% (Taylor *et al.* 2005) and 75% (Scott 2012).

The current cohort study found that those with a prosthesis reported higher levels of QoL than those without a prosthesis. It also found participants who had a prosthetic limb reported a lower QoL when their LEA was TFA, compared to those with a TTA (Health Index Score 0.31 and 0.56 respectively) and a statistically significant difference was found between level of LEA and QoL (*p=0.002*). A study by Fortington et al (2013) found that level of LEA also influenced QoL, as those with a TFA or Through Knee Amputation (TKA) reported lower QoL than those with a TTA (Fortington *et al.* 2013a). In addition, these authors reported a positive association between walking distance and QoL occurred in a proportion of their cohort, although the authors did not report exact numbers in their results.

As already discussed the qualitative analysis of the face-to-face interviews (Chapter 7), found the prosthesis was one of the broad themes that influenced QoL. The participants spoke of the increased effort of walking with a TFA prosthesis, which hindered them from being able to perform chores such as making the bed, reaching into cupboards and carrying dishes; often referred to as activities of daily living (ADL). Some of the participants felt these tasks were more difficult due to the weight and discomfort of the prosthesis. One participant spoke of being unable to return to work, while others talked of not being able to continue with hobbies such as rambling, playing snooker or watching their grandchildren play football; as the prosthesis was too heavy and painful to wear.

Prosthetic prescription is mediated by several factors; the primary one being level of LEA (Hagberg 2006), as the preservation of the knee joint following TTA, improves the ability

to walk. Walking with a TTA prosthesis increases the effort required to walk by approximately 25%, while walking with a TFA prosthesis requires approximately 80% greater effort (Waters *et al.* 1976). Hagberg and Branemark (2001) found the TFA prosthesis was difficult to use, in their cross-sectional study of people with a TFA (n=97) in Sweden. Although their cohort did not have PAOD, they found the vast majority of those with a TFA prosthesis (n=92) struggled with the weight and poor fit of the prosthesis along with phantom pain despite them having a LEA between 2 to 52 years prior to the study. The same authors also found a strong association between reduced QoL and prosthetic issues (Hagberg and Branemark 2001). Other studies found similar dissatisfaction with the prosthesis due to poor prosthetic fit, cosmetic problems, and problems carrying out functional tasks (Beekman and Axtell 1987). All of these factors are reported as being more pronounced in those with a LEA at TFA level (Solomon *et al.* 2008). In the current study, participants with a TFA who took part in the face-to-face interviews talked of choosing to use a wheelchair instead of their prosthesis and this was supported by the field notes; as during the interviews none of the participants with a TFA who had been fitted with a prosthesis were wearing it, instead favouring their wheelchair.

Other factors associated with limiting prosthesis use include bilateral LEAs, poor mobility prior to the LEA and reduced muscle strength, cardiovascular fitness or low motivation; all of which impact upon the ability to rehabilitate with a prosthesis. Taylor et al (2005) found those who were not mobile prior to their LEA were 10 times more likely to discontinue prosthetic use and three times more likely to be housebound (Taylor *et al.* 2005). The same authors found being over 60 years old and having ischaemic heart disease as influencing prosthetic fitting.

The impact of not limb-fitting, therefore being wheelchair dependent, has serious effects on morbidity and mortality. The increased time spent sitting in the wheelchair contributes to sedentary behaviour which is exacerbated by the restrictive home environment and the inability to be actively propelling the wheelchair. Existing literature has evidenced the physiological benefits of walking and being upright in terms of cardio-vascular health and conversely the increased mortality for those who are sedentary and sit for longer periods (Chau 2013, Ford 2012).

In the present cohort study the results of the follow up questionnaires at 6 and 12 months, found those who did not have a prosthesis fitted reported lower QoL. There were 13 participants who had not received a prosthesis who completed follow up questionnaires at 6 months and reported their QoL as significantly lower than those with a prosthesis (0.03 (±0.25) and 0.46 (±0.33) respectively). Some participants reported their QoL as worse than death, and reasons for not having a prosthesis were due to their restricted mobility prior to their LEA and issues with their contralateral foot; both impacting upon their cardiovascular fitness and detracting from their limb-fitting potential.

In the qualitative interviews some of those who were fitted with a prosthesis felt it was difficult to use and that with a better, more technologically developed, prosthesis their QoL would be better. There seemed to be a sense however, that 'better' prosthetics were only given to the younger and more able people with LEA i.e. military personnel. This perception is supported by the literature to some extent, as more technological advanced prosthetics have been found to improve mobility and allow many to return to work and participate in sports, although subjects tend to have had their LEA due to trauma and be younger in age than the current cohort (Hafner *et al.* 2007, Kahle *et al.* 2008, Kaufman *et al.* 2008). The association between improved prosthetic technology and QoL was examined in a survey of 33 people with a TFA due to mixed aetiologies. All participants were prosthetic users of a more advanced prosthetic knee joint called a C-leg (microprocessor, controlled prosthetic device), and the study involved the use of the PEQ and the SF-36 QoL measure. The authors found the C-Leg users were more mobile, had fewer falls and were more able to walk up and down stairs, which improved their QoL compared to other studies who had surveyed participants using a standard locking knee (William *et al.* 2013).

8.5.3 Mobility

In the current cohort study there was a decline in mobility from pre LEA to discharge from out-patient rehabilitation with a prosthesis, especially for those with bilateral LEAs as per their Locomotor Capabilities Index score (LCI-5 score -12.7). The change score for those with a unilateral TTA in the present cohort was 0.7, which is close to zero and regarded as "mobility success". This term "mobility success" was coined by Norvell et al (2011) to describe when a person achieves the same as or better mobility after LEA compared to pre

LEA. A positive LCI-5 change score indicates an improvement in mobility, a negative score a deterioration in mobility and a score close to zero, maintenance of mobility from pre to post LEA (Gauthier-Gagnon and Grisé 2006). Norvell et al (2011) conducted a cross sectional review of 87 people with minor (n=27) and major (n=60) LEAs. The authors used the (LCI-5), the same measure that was used in the current cohort study and associated mobility success with an improved QoL as measured with the Satisfaction with Life Survey (SWLS). The authors found that, of those reporting high QoL, 61% had achieved mobility success. Therefore, having a prosthesis and being able to achieve "mobility success" was associated with improved QoL.

Norvell et al (2011) found those with a TTA achieved greater mobility success (-6.4) compared to those with a TFA (-14.9) (Norvell *et al.* 2011). These authors compared the LCI-5 scores from 6 weeks prior to the LEA to those 12 months after LEA (Norvell *et al.* 2011). These are different time points from the present cohort study in which the final LCI-5 score was measured at time of out-patient discharge. In addition none of the participants in the study by Norvell et al (2011) achieved a level of mobility which was the same or better than they had reported pre LEA (Norvell *et al.* 2011). Both Norvell et al (2011) and the current cohort study suggest a deterioration in the person's mobility after LEA.

The follow up questionnaires aspect of the cohort study in this thesis found that mobility levels achieved 6 and 12 months after LEA were relatively poor according to the Prosthetic Limb User Survey of Mobility (PLUS-M). As previously explained, the PLUS-M calculates a t-score which ranges from 21.8 (no mobility at all) to 71.4 (mobile independently over a long distance). This was completed only by those who consented to follow up and had a prosthesis (n=55) and mean scores ranged from 25.9 for those with bilateral LEAs to 42.8 for those with a unilateral TTA 6 months after LEA. The change in mobility over time was also assessed when the same participants were followed up 12 months after LEA, where there was a slight increase in mobility (PLUS-M scores 28.5 to 45.1 respectively). The number of those who completed the follow up questionnaires reduced from 55 to 41 due to mortality and it may be that those with the lowest levels of mobility had died between 6 and 12 months after LEA. Alternatively, the results could suggest that, for some people mobility continues to improve following LEA. This finding was also discussed in the face-to-face interviews when those with a TTA prosthesis who participated spoke of their QoL improving since being able to walk compared to being

wheelchair bound on discharge home from the hospital. Therefore, the findings of this current study contrast with much of the current literature.

The low level of mobility reported 6 and 12 months after LEA on the PLUS-M was one of the novel findings from the current cohort study. Prosthetic mobility (PLUS-M) was shown to have a strong influence on QoL and limb-fitting may be the mediating factor. However, when considering mobility, one consequence of a more proximal LEA is the dependence upon walking aids. One reason for the poorer prosthetic mobility in those with a TFA was examined in a large cohort study (Sinha and Van Den Heuvel 2011). These authors noted that proportionally more of those with a TFA prosthesis were using walking aids to allow them to mobilise; however, they also found that as a consequence completing activities of daily living were more difficult. These authors found that the use of walking aids was a significant factor negatively influencing QoL. Therefore, the relationship between having a prosthesis and good QOL is not direct, instead the level of mobility achieved may influence QoL.

In the face-to-face interviews conducted as part of this thesis, there was clear insight as to how being more dependent upon walking aids, impeded being able to conduct ADLs. One participant who had a TFA prosthesis explained how carrying a cup of tea was impossible to do with two walking sticks therefore relied upon the wheelchair instead (Section 7.5.1).

Similar findings were reported in a large cohort study of people with LEAs, in which authors examined participants' reliance on walking aids and found there was a negative impact on QoL as measured by the SF-36 as they impeded the ability to carry out activities of daily living (Hagberg and Branemark 2001). A more recent cross-sectional study used the SF-36 measure to examine QoL in a large cohort of patients who had their LEA due to various aetiologies (n=368) found a strong association between the ability to walk without walking aids and improved QoL (Sinha *et al.* 2014a). Studies found those with TTAs were more 'successful prosthetic users' as they were more likely to engage in meaningful vocational and social activities as they were less likely to need walking aids (Cox *et al.* 2011, Norvell *et al.* 2011).

Researchers in the USA conducted a qualitative study involving four focus groups with participants who had a major LEA due to PAOD (n=26), and found that mobility, or lack

of, had the greatest influence on QoL (Suckow *et al.* 2015). The same authors reported that those with poorer levels of mobility did not participate in meaningful activities such as visiting family and friends houses due to obstacles they may encounter. These findings by Suckow et al (2015) support the findings in this thesis that poor mobility is associated with poor QoL. The findings in the current cohort study also demonstrate that the ability to mobilise independently is associated with higher levels of participation. Prosthetic mobility measured by the PLUS-M strongly influenced QoL at 6 months after LEA. In addition, the ability to mobilise independently was associated with higher levels of participation.

8.5.4 Participation

Participation was the single most influential factor in relation to QoL at 6 and 12 months, in the current cohort study. Mean scores in the RNLI ranged from 42.2 to 65.3 (max 100), with significantly higher participation levels in those with TTA (*p=0.043*). The RNLI reported how well a participant reintegrated after the LEA by asking about their ability to look after themselves, interact with others and return to usual activities. Throughout the face-to-face interviews, participants talked about the importance of socialising and participating, however several talked of not wanting to do this while being seated in a wheelchair and would prefer to be up standing and walking with a prosthesis.

An earlier study (Fortington et al 2013) found a positive association between the ability to walk and the domain of social function as they found improved mobility positively influenced QoL (Fortington *et al.* 2013a). Fortington et al (2013) surveyed 82 people with a major LEA due to PAOD over an 18-month period and compared their walking distance to their QoL. The authors found that all individuals were able to walk 500 metres pre LEA and 6 months after LEA only 57% were able to mobilise 500 metres. The authors used the RAND-36 QoL tool and the domain of social function encompassed participation (Fortington *et al.* 2013a). Although the current cohort study did not quantitatively measure walking distance after LEA, the PLUS-M assessed functional mobility. Agreement was found between the ability to mobilise, participation and QoL.

Deans et al (2008) performed a cross-sectional study of 25 patients with LEA and found that, for prosthetic users, social integration was more important than physical capability in improving QoL. The authors surveyed a cohort with LEAs due to mixed aetiology with the

WHOQOL-Bref and TAPES outcome measures, and found that participation was positively associated with QoL (Deans *et al.* 2008).

A different methodological design was implemented by MacNeill et al (2008) when they conducted a retrospective case note analysis of 82 people with bilateral TTAs, all of whom had been limb fitted (Mac Neill *et al.* 2008). These authors then invited 32 of this cohort for semi-structured interviews to verify their functional status and found that those who could mobilise independently reported higher levels of QoL (Mac Neill *et al.* 2008). The authors attributed the high levels of QoL within their cohort to the high level of function achieved which enabled participation. In this thesis, data from the questionnaires and interviews demonstrated that the ability to participate after LEA is vital to maintain QoL. The studies in this thesis not only corroborate the evidence in the existing literature but also demonstrate that the level of prosthetic mobility effects QoL through the ability to participate after LEA.

In addition, a finding unique to this study was the associations between social deprivation and participation. The strong link strong between deprivation, participation and QoL was evident in the present cohort study, as those in the poorest areas reported the lowest levels of reintegration (RNLI score 48.2) compared to those in the most affluent areas (RNLI score 73.1). One reason for this may be that those in SIMD 1 or 2 (more socially deprived) had poorer participation and QoL prior to their LEA, compared to those in SIMD 5 (less socially deprived). However, more people in the affluent areas had a TTA and were limb fitted compared to the more deprived areas, and as discussed previously, limb-fitting is imperative to facilitate independent mobility and QoL. In the current cohort study, prosthetic fitting was lower in the more deprived areas despite participants being younger and having similar co-morbidities to those in the more affluent area (SIMD 5). Of significant note, a proportion of participants living in the most deprived areas reported their QoL as worse than death. The reasons for this were unknown but warrant further research into the social inequalities faced by this population.

The observed difference between participation across the socio-economic quintiles was a novel finding in this cohort study. The majority of participants in the current study from SIMD1 and 2 lived in social housing, although the accessibility of the home did not differ significantly across the social deprivation quintiles. RNLI and QoL scores were lower in

areas of social deprivation than the more affluent areas, however, the impact of single room living on these was unknown. The field notes written during the face-to-face interviews conducted in the current study revealed that many of the participants were not able to access their bedroom and instead were living in one room. In some cases, the living room became the participant's bedroom, impacting on all those who lived in the home. The accessibility of the home in relation to participation is an area that has not been researched previously therefore, this study makes a unique contribution to the evidence base.

The interviews in the current study found a large proportion of participants talked about feelings of isolation, despite more than half the cohort (62.6%) living with partners and/or family. Pell and Stonebridge (1999) measured the impact of isolation and similarly found those who lived with others felt isolated following LEA (Pell and Stonebridge 1999).

Asano et al (2008) found that social support influenced QoL in their large cross-sectional study (n=415) of those with LEAs. They therefore identified the importance of improving social relationships after LEA in order to improve QoL (Asano *et al.* 2008).

The current study participants spoke of their relationships changing as they became more reliant on their partners and family to undertake basic tasks such as washing themselves or to assist them in going outside to walk the dogs or go to the shops. Participants spoke of the fear that without this help, there was a sense that they could become more isolated.

Although the current interviews found several participants did not have enough support after their LEA; one female talked of being overwhelmed with support when she was at home, to the point where it held her back from her rehabilitation. This finding was supported in a study that aimed to predict the long term adjustment of an LEA, and found that the level of social support one month after surgery will continue to affect the person 12 and 24 months after LEA (Hanley *et al.* 2004). These authors examined the level of support given to the person and whether they felt supported or helpless as others took over tasks that they were capable of doing. Too much support, lead to feeling helpless and no support caused feelings of isolation; both are extremes in the theme of social support, and it is important to understand that either of these may affect participation and QoL in the long term.

In this thesis, the findings from the face-to-face interviews, under the theme "*interaction with others with an amputation*", provided an insight to why the need to speak to those in the same situation was essential to reduce the feelings of isolation. Participants spoke of sharing experiences and discussions and advice on types of prosthetics and sockets. All of these interactions were in the hospital environment and for those who received a prosthesis these conversations continued once they were home as they would meet and speak to others when attending out-patient rehabilitation. However, these exchanges were finite and would often end on discharge from rehabilitation. During the interviews some participants talked about how important these interactions had been and how the chance to talk about situations that no-one else would understand was vital in their recovery. The impact of peer support on QoL is not well documented in the literature of those with a LEA; however, the Health Foundation supports that when living with a long term condition such as PAOD and/or diabetes being able to speak to others in the same situation has a positive impact on QoL (Wilson and Pratt 1987).

A large proportion of the cohort (79.5%) were housebound after their LEA, and of those a further 64% were restricted to single room living. The inability to access the outdoors and other rooms within their home undoubtedly affected the participants' ability to engage in activities that they felt were important to them. In conjunction with feelings of isolation from their friends and family as they were unable to participate in activities, hobbies and social events; there was an appreciation that there was also a change in the way they felt others viewed them when they were in social situations. These feelings were discussed when participants talked of experiencing a change in body image which prevented them from participating in usual activities. Many felt uncomfortable being around others, especially if they were using their wheelchair and did not have a prosthesis. This was discussed under the theme "*sense of self*" (Section7.7), as it considered the change that the participant felt in themselves since their LEA. The severity of these issues was more apparent in those with a TFA compared to those with a TTA and more so in those who had not received a prosthesis.

Senra et al (2012) conducted semi-structured interviews with a cohort who had a LEA and found that self-identity was altered after LEA beyond their physical appearance. The

authors found that the change in the person's body image caused them to be more aware of their disability which affected their rehabilitation and future goals (Senra *et al.* 2012).

Another study which compared body image, depression and QoL between those with LEAs or mastectomy to healthy controls, found that limb loss or tissue loss was associated with poorer body image, higher levels of depression and lower QoL (Akkaya *et al.* 2011). The presence of anxiety and depression was examined in a cohort of prosthetic users (n=67) and participants were asked to complete several outcome measures: The Trinity Amputation and Prosthesis Experience Scales (TAPES), the Hospital Anxiety and Depression Scale (HADS) and the Self-Consciousness Scale and the Appearance Schemas Inventory (Atherton and Robertson 2006). The authors found almost a third of their cohort (29.9%) were anxious and this was associated with going out in public. A more recent study found that the level of LEA was associated with poorer body image, and those with a TFA reported a poorer body image compared to those with a TTA (Zidarov *et al.* 2009). Zidarov et al (2009) also found that body image was poorer for women compared to men 3 months after LEA (Zidarov *et al.* 2009). They also associated poor body image with lower levels of participation, which in turn, lowered QoL. The face-to-face interviews in this thesis built upon these results under the theme "sense of self". This theme found there was a fundamental change in the participant's overall perception of self as being "disabled" or "vulnerable", not wanting be in the community when people may stare at them and not wanting to be different from others; all of which negatively influenced their QoL.

8.6 Partial agreement

In this thesis, there was only one factor that was found to be in partial agreement between the two studies; the experience of pain. Pain was included in the QoL measure as one of the five domains that participants reported on, however there was not an individual outcome measure that was used to assess pain within the follow up questionnaires in the cohort study. However, the experience of pain was a broad theme that emerged from the face-to-face interviews as influencing QoL.

8.6.1 Pain

In the current cohort study, 6 and 12 months after LEA, pain and discomfort were reported as more problematic compared to the age matched population without a LEA. However, there was no association between the domain of pain in the EQ-5D-5L measure and QoL

of the participant overall. The experience of pain was one of the broad themes identified in the face-to-face interviews, despite no statistical association of pain influencing QoL in the current cohort study. The interviews allowed the experience of pain to be understood in more depth and found that participants were affected by different types of pain and experienced pain at different times. Some participants in the current study reported experiencing pain in relation to their prosthesis whilst others talked about phantom pain affecting sleep. Some spoke of electing to have the LEA due to the pain they were experiencing, while some kept this pain memory as a warning sign to alert them to problems with their remaining limb.

The qualitative study by Suckow et al (2015) discussed earlier, involving 26 people with LEA who participated in focus group discussions, found that the presence of pain negatively influenced QoL (Suckow *et al.* 2015). Suckow et al (2015) reported that although pain was in many cases the reason for the LEA, the resulting phantom or residual limb pain continued to affect sleep, ADLs and social interactions, despite some of the participants having their LEAs up to 27 years previously. This relationship between pain and QoL was also examined in three quantitative studies who all identified an association between lower QoL with increased pain (J. P. Pell *et al.* 1993, Harness and Pinzur 2001, Zidarov *et al.* 2009). Their participants had lived with their LEA from an average of 3 months (Zidarov *et al.* 2009) to 38 months (J. P. Pell *et al.* 1993). The study by Harness and Pinzur categorized pain as residual limb or stump pain, phantom limb pain, contralateral limb pain and bodily pain and found that the presence and experience of any pain was associated with poor mobility and QoL (Harness and Pinzur 2001).

A cross sectional study was more specific reporting phantom limb pain as a negative influence on QoL (van der Schans *et al.* 2002). Van der Schanns et al (2002) examined a cohort of 437 people with a major LEA using the RAND-36 and the Groningen Questionnaire Problems with Leg Amputation (GQPLA). The authors reported that those with phantom limb pain had reduced walking ability and this lowered their QoL.

The results in the current study and the literature discussed in this section are in contrast to a small cross-sectional study by Buijck et al (2012) who found no association between pain and QoL. Buijck et al (2012) asked 27 elderly patients with a LEA due to PAOD to complete the RAND-36 and a questionnaire on bodily pain 3 months after discharge from

rehabilitation, and found no association between pain and QoL (Buijck *et al.* 2012). The methodological difference in the quantitative analysis by Buijck et al (2012) could account for these contrasting findings around pain.

Despite this, pain, has generally been shown to have a negative influence on QoL, as demonstrated within the interviews and supported by the findings from the cohort study. The type of pain is difficult to identify and measure in the population with an LEA and PAOD and warrants further investigation in order to lessen its effect on QoL.

8.7 Silence

Silence was found when only one part of the study reported a factor that influenced QoL. In the cohort study other characteristics were identified as influencing QoL e.g. age, diabetes, gender and length of time since LEA. The qualitative interviews were not set up to systematically investigate differences in experience by these factors and so of course there was silence on these comparisons when comparing cohort with qualitative data. Similarly, that the qualitative interviews identified the importance of sense of self and social support as important to QoL but these were not captured in any of the measures used in the cohort study so again, there was silence on these issues.

8.7.1 Age

In the current cohort study, younger age was positively associated with QoL, 12 months after LEA in those who were limb fitted. However, age was not an influential factor 6 months after LEA, nor did it influence QoL when both limb-fitted and non-limb-fitted participants were analysed together. Studies that associate increasing age with reduced QoL following LEA are scarce. The cohort examined by Fortington et al (2013) had a mean age of 67.8 years (SD 13) and the authors found that those over 65 years of age reported poorer scores within the physical function domain of the RAND-36 QoL ($p<0.001$). Furthermore, those with a TFA reported poorer scores of physical function than those with a TTA ($p=0.007$). The mean age of the participants in the current cohort study was 66.2 years old (SD 11.4) which was similar to other cohort studies who have populations with mean ages of 62 years (SD 10) ((Norvell *et al.* 2011)) and 69.7 years

(Davie-Smith *et al.* 2015). This current study found increasing age was negatively associated with QoL.

8.7.2 Diabetes

Participants with diabetes in the current cohort study reported higher levels of QoL compared to those without diabetes. Multiple regression identified diabetes as a factor that positively influenced QoL 12 months after LEA in those who were limb-fitted.

As previously stated, more participants underwent a TTA compared to TFA on entry to the present cohort study, (60% and 40% respectively; 3:2 ratio). More participants with a TTA, had diabetes (68%) compared to those without diabetes (32%). When categorised by diabetes this TTA: TFA ratio was 3:1 in those with diabetes, and 0.8:1 in those without diabetes. This was similar to Fosse et al (2009) who found that more people who had diabetes had a TTA (21%) compared to a TFA (17%). The same authors observed more people without diabetes had a TFA (31%) compared to a TTA (19%) (Fosse *et al.* 2009). The remaining 12% of their cohort underwent minor LEAs (Fosse *et al.* 2009). The higher numbers of those with a TTA with diabetes and the slightly younger age of those with diabetes, are factors known to improve prosthetic mobility and subsequently QoL which may account for the improved QoL of those with diabetes in the current cohort study.

The higher proportion of TTA in those with diabetes in the current cohort study could be attributed to the more distal disease process in those with diabetes. One study compared the severity of PAOD between those with and without diabetes (Jude *et al.* 2001). The authors examined 136 arteriograms over a 5-year period and found more people with diabetes presenting with the disease process in the foot rather than the proximal larger vessels (Jude *et al.* 2001). In addition, they found those with diabetes had more severe PAOD below the knee than those without diabetes. This may explain why more participants with diabetes underwent a TTA in the current cohort study and subsequently went on to limb-fit which afforded them higher QoL. In the current cohort study, when those who were limb-fitted were examined, diabetes was only influential on QoL 12 months after LEA, therefore, diabetes may not directly affect QoL but indirectly through more proximal amputation and therefore limb fitting. This is in conflict to much of the literature which suggests that the presence of diabetes reduces QoL after LEA due to

diabetes related complications such as poor glycaemic control, loss of vision and renal insufficiency (Glasgow *et al.* 1997, Redekop *et al.* 2002). Although these same complications were observed within the present cohort who had diabetes, only loss of vision was recorded within the Functional Comorbidities Index and so other issues could not be captured here.

In the present cohort study there were no differences in FCI score or the QoL domain of anxiety and depression in the EQ-5D-5L when those with diabetes were compared to those without diabetes. This was unusual as the presence of diabetes has been shown to predispose a person with a LEA to depression and psychological issues more so than those without diabetes (Coffey *et al.* 2009). One reason that no differences were found between the two groups in the current cohort study may be that the FCI only accounts for anxiety and depression if diagnosed within the medical case notes, whereas other studies used self-report tools (Coffey *et al.* 2009, Buijck *et al.* 2012).

Detailed analysis of the present cohort found several significant differences between those with and without diabetes. More than half the cohort had diabetes, and those with diabetes were younger, had more TTAs and achieved successful prosthetic fitting. Their out-patient rehabilitation was longer compared to those without diabetes (147 days and 83 days respectively) and their QoL was higher than those without diabetes. Reasons for the improved QoL may be the longer time those with diabetes had to engage in specialist services thus gaining additional support and information; all of which may improve QoL. Longer out-patient rehabilitation for those who had diabetes may be needed due to delayed wound healing or complications with the contralateral limb; when LCI-5 scores were compared at discharge from rehabilitation those with diabetes were significantly more mobile with their prosthesis than those without diabetes (*p=0.005*). This may be due to the lengthier prosthetic rehabilitation period; the younger age of those with diabetes or the higher numbers of those with a TTA who had diabetes. All of these factors are known to positively affect mobility following LEA, although only the latter was evidenced in the current cohort study and there are no other studies known of that have shown this difference.

8.7.3 Gender

The present cohort study found male gender was positively influenced QoL six months after LEA. This is in contrast to Cox et al (2011) who conducted a cross sectional survey of 87 people, 1-3 years after major LEA, completing the WHO-QOL BREF and the Functional Independence Measure (FIM). The results demonstrated that females reported higher levels of QoL than males however they did not state how many of their cohort had a prosthesis as this is known to impact on QoL (Cox et al. 2011).

Three quarters of the participants in the present cohort study were male (75%), which reflects the higher percentage of males in the general population with PAOD (Criqui 2001). Although this follows the trend of LEAs being more prevalent amongst men, it was higher than reported in earlier studies 51.4% and 60.9% (Izumi *et al.* 2009, Johannesson *et al.* 2010). Furthermore it was higher than the large study (n=1739) of all those with a LEA due to PAOD in Scotland who reported 63.9% of their cohort were male (Davie-Smith *et al.* 2015).

8.7.4 Time since amputation

The current cohort study found that self-reported QoL at 6 months after LEA predicted QoL at 12 months. There is no clear or consistent pattern in existing literature in terms of the change in QoL over time following LEA. A study that examined QoL in shorter time frames e.g. admission for LEA, discharge home and again 3 months after LEA; found that QoL remained stable throughout their study period (Zidarov *et al.* 2009). Fortington et al (2013) refuted this and found that QoL gradually improved over 18 months after LEA (Fortington *et al.* 2013a). They measured QoL at similar time points to the current cohort study and found most change in QoL occurred in the first 6 months; thereafter it was not as significant an improvement. In contrast, Norvell et al (2011) found QoL deteriorated over the 12 months, after LEA, however their cohort reduced over that time period due to mortality (Norvell *et al.* 2011).

The interviews in the current study found participants talked of a change in their QoL over the period of leaving the hospital setting until the time of interview (6 months after LEA). Some felt that their QoL deteriorated when they were discharged from the hospital setting to their home as they became housebound. Others felt their QoL improved during this same period as their prosthetic rehabilitation progressed and they became independently

mobile. The influence of time on QoL then appears to vary according to individual circumstances such as rehabilitation progress and environmental restrictions. These findings from the interviews may go some way to explaining the differing results from other quantitative studies, which examined QoL over time. Additionally, the increasing age and the progressive nature of PAOD in this population may negatively affect QoL over time. As previously discussed prosthetic use is positively associated with QoL. However, over time people may reduce the use of their prosthesis because of arthritis in the contralateral limb, cardiac and/or respiratory issues and stump pain (Gauthier-fiagnon *et al.* 1998) or due to a decline in cognitive function in some participants, as prosthetic use is known to deteriorate with cognitive impairment (Hanspal *et al.* 1995).

Additionally, there may be a reduction in motivation to use their prosthesis at home or within their community, once they have left the supportive rehabilitation environment. Taylor et al (2005) found the home environment to be an influential factor in maintaining prosthetic mobility for those with a TFA, as the ability to undertake activities of daily living with their prosthesis was vital to continuing mobility (Taylor *et al.* 2005). It is also possible that the prosthetic mobility skills gained from rehabilitation may not transfer to the real life environment where skills such as walking on different surfaces or uneven terrain may be required. A study of people with bilateral TTAs has shown that suitable accommodation and social support are also crucial in maintaining prosthetic use (Hunter and Holliday 1978). If transference of prosthetic skills to appropriate accommodation and social circumstances is achieved, then long term prosthetic use and sustaining good QoL may be more likely.

8.8 Dissonance

There were no conflicting results from the cohort study and face-to-face interviews therefore dissonance was not found.

8.9 Summary and conceptual model

The integration of the findings of the cohort study and the interviews led to the development of a conceptual model, which provided a better understanding of the complex relationship within and between the factors identified as having an influence on QoL after

an LEA. The conceptual model illustrates that the factors influencing QoL were inextricably linked. Male gender, younger age and presence of diabetes all increased the likelihood of having a prosthesis fitted. While having a prosthesis did not determine QoL per se, those with greater levels of mobility were more likely to be able to participate, feel less isolated and require less social support which afforded them greater levels of QoL. Conversely, those who were wheelchair dependent or had poorer levels of prosthetic mobility reported lower levels of QoL; which was associated with dependence on social support, feelings of isolation and changes in the way they feel about them self (Figure 8.1).
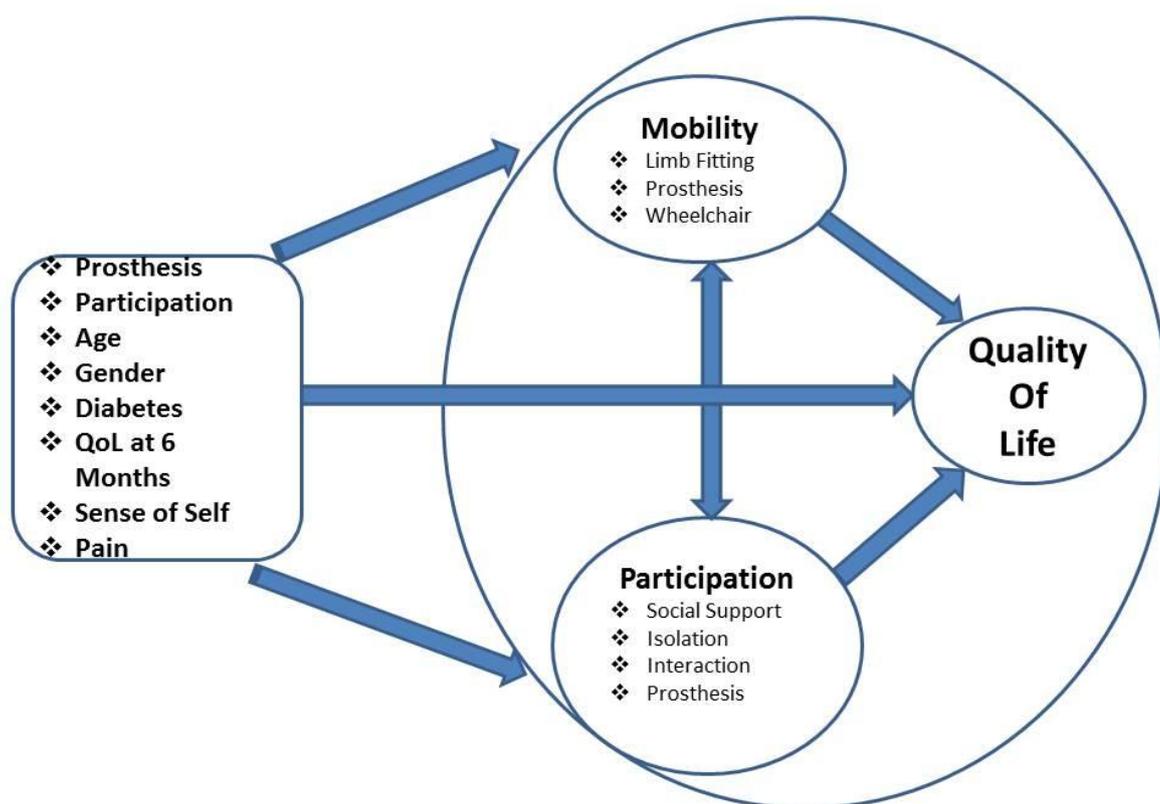
Figure 8.1 Conceptual model of factors influencing quality of life after lower extremity amputation.

8.10 Other key findings

The following section will discuss other key findings highlighted within the cohort study with reference to the existing literature, which were not included within the triangulation protocol. Following this, limitations of the current work and the implications of the findings for the clinical setting and future research will then be discussed.

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8.10.1 Social Factors

The current cohort study examined the participants' social factors i.e. type of housing, accessibility and whom a person lived with at time of LEA. A high proportion of participants lived in social housing (52.3%) compared to those who owned their home (38%); this was interesting as the majority of the cohort lived in the most deprived areas and there is a known link between social housing and lower socio-economic status (Malpass 2008). Indeed, a significantly greater number of people lived in social housing in SIMD 1 compared to SIMD 5 (*p<0.001*).

Irrespective of type of housing and SIMD quintile, a high proportion of participants (77.2%) in the current study were housebound after their LEA. Restricted access due to stairs and/or rooms with narrow doorways, meant that, due to their wheelchair two-thirds (67%) were confined to single room living i.e. one room with a bed, toileting equipment, kitchen accessories and TV. Indeed, three of the fifteen interviews conducted in this thesis took place in this type of room. The impact of living in such a restrictive environment and the implications for the physical and psychological wellbeing of a person were witnessed first-hand. Many of the participants were unable to be physically active which is likely to have further impacted on their quality of life. The social model of disability suggests that disablement is influenced not by the inability to participate but instead the restrictive environment that prevents a person from socially interacting or doing things important to them (Thomas 2010). In the context of this study many of the participants were housebound or single room living, and it was this that prevented them from being able to take part in activities that they felt important to them.

As a large proportion of the cohort were confined in their home, they reported being more reliant upon others which had grave consequences for their psychological wellbeing and changed the dynamics of relationships. A small study (n=25) of prosthetic users reported a strong association between social relationships and QoL (Deans *et al.* 2008). Strong associations were found between scores in the environmental domain of the WHO-QOL-BREF and social subscale score of the TAPES measure, suggesting a link between restrictions of the environment and QoL in those with a LEA (Deans *et al.* 2008). No literature to date has highlighted the single room living aspect after LEA and its long term

consequences on the person, making the findings in this thesis novel in their contribution to the literature.

There has been no research to date on associations between social deprivation and QoL after LEA. In the present cohort study, over two thirds of participants lived in the two most deprived areas of Greater Glasgow and Clyde (SIMD 1 and 2). Furthermore, those in the poorest area (SIMD1) reported the lowest QoL and those in the most affluent area reported the highest QoL. Although there were no statistically significant differences when all five quintiles were compared, there was a noticeable difference between the characteristics of these groups. The population in SIMD 1 (poorest area) were on average 13 years younger than those in SIMD 5 (affluent area), and there were more participants with a TFA in SIMD 1 compared to SIMD 5, proportionally fewer people were limb-fitted in the poorest area. This data on age and social deprivation suggests that LEAs occur in the young/ poor or the elderly/ wealthy. Social deprivation is known to be strongly linked to life expectancy with those in more affluent areas living up to 15 years longer than those in more deprived areas within Greater Glasgow and Clyde (GG&C) (Gray and Leyland 2009). The link between social deprivation and poor health is well documented in medical literature and previous research has specifically identified an association between social deprivation and rates of LEA (Ferguson *et al.* 2010). Ferguson et al (2010) studied 327 people who underwent a LEA in a 6-year period in one area of England and found the two most deprived areas were over-represented compared to the most affluent areas. These findings support the high numbers of LEAs in SIMD 1 and 2 in the current cohort study.

Although the prevalence of diabetes was similar between the SIMD quintiles in the present study; there may be an increased risk of LEA for those with diabetes living in a socially deprived area. Weng et al (2000) retrospectively examined a large cohort (n=610) of people in London, who had attended a diabetes clinic 10 years previously and using medical case notes were able to calculate how many had gone on to have a LEA, diabetic foot ulcer, other complications or died within the 10-year period. The authors concluded that those with diabetes who had poor glycaemic control, were older, smoked and lived in socially deprived areas, had more microvascular complications which were more likely to cause diabetic foot disease and increase their risk of a LEA (Weng *et al.* 2000). Furthermore, a Scottish study of people with Type II diabetes examined a population of 216,652 and found that social deprivation was inextricably linked to increased mortality

from heart disease and that with increasing deprivation the risk of mortality was greater in those with diabetes compared to those without diabetes (Jackson *et al.* 2012).

Despite research into the prevalence of LEAs and increased mortality in more deprived areas there has been no research published highlighting the link between poor QoL and social deprivation in those with a LEA as was found in this thesis.

8.10.2 Limb salvaging surgery

In the twelve months prior to LEA, 56% of participants in the present cohort had limb salvaging surgery. This is higher than an American study which reported 43.6% of their cohort had limb salvaging surgery prior to LEA (Abou-Zamzam *et al.* 2003). These authors performed a retrospective analysis over three years and observed that limb salvaging surgery was generally performed within 15 months of LEA. However they did not report associations between limb salvaging surgery and level of LEA (Abou-Zamzam *et al.* 2003).

In the present cohort study there were as an observed association between those who had limb salvaging surgery and level of LEA. Participants who had limb salvaging surgery prior to LEA were more likely to have a TTA compared to TFA (*p=0.016*). No other studies were found that made this observation. Limb salvaging surgery rates have increased in the past decade and in some countries this is associated with a decrease in the rates of major LEAs (Goodney *et al.* 2009). Goodney et al (2009) reviewed incidence of limb salvage surgeries in a 10-year period from 1996 to 2006 and found and decrease in lower extremity bypass surgery (219 to 126 per 100,000) and an increase in endovascular interventions (138 to 455 procedures per 100,000). Over the same period there was a clear reduction in LEAs (263 to 188 amputations per 100,000). Although it was not possible to perform a cause analysis, there was an increase in limb salvaging procedures and reduction in LEAs. An earlier study reported an increase in limb salvaging procedures over a seven-year period in their cohort and a slight decline in LEAs, however they also observed that open arterial bypasses decreased (77 to 61 per 100,000) as the first option of limb salvage and instead endovascular procedures were more prevalent (59 to 75 per 100,000) (Al-Omran *et al.* 2003). Their cohort was comparable to the current study as their mean age was 67.5 years, and there were more TTAs compared to TFAs. This finding suggests that

improving the circulation has some benefit as even though an LEA may still be required, it will likely be at a more distal level and thus the knee joint is saved and limb fitting is more likely.

8.10.3 Contralateral foot

Once a LEA has been performed for PAOD with or without diabetes the participant is at high risk of losing their contralateral limb (Pinzur *et al.* 1991). Fifty percent of the participants in the current cohort had contralateral foot issues' and during the initial in-patient admission, 2.9% went on to have a LEA of their contralateral limb. This number rose to 3.7% at 6 months and 4.0% at 12 months after LEA. Alongside this there was an increasing number of re-amputations to a higher level on the same side. In the current cohort, bilateral LEAs increased from 19.3% at baseline to 24.8% at 6 months and 31.4% at 12 months. The findings in the current cohort study support the existing literature and highlight the high risk these participants have of losing their remaining limb. A large retrospective analysis of lower extremity bypass surgeries (n=228), found that limb salvaging surgery performed on the remaining limb was more likely to fail and lead to a second LEA or graft occlusion within 12 months (Baril *et al.* 2011). Further amputation whether to a more proximal level or leading to the loss of both limbs has a significant impact on the individual and reduces the possibility of being limb-fitted, and lowers QoL, demonstrating the importance of looking after the contralateral foot to prevent the need for limb-salvaging surgery or further LEAs.

Maintaining good condition of the contralateral (CL) foot is vital for a person with a LEA due to PAOD as when they walk with their prosthesis they will be more dependent on their CL limb than their prosthetic limb (Pinzur *et al.* 1991, Robert Gailey PhD 2008). Approximately 30% of patients with a LEA due to PAOD report pain in their contralateral foot; due to ischaemia, ulcers or Charcot arthropathy, which will affect their ability to weight bear correctly and use their prosthesis effectively (Pinzur *et al.* 1991). More than 50% of the current cohort had contralateral foot issues and during the interviews, two participants talked of having pain in their remaining limb that prevented them from walking any distance with their prosthesis. Good care of the remaining limb is vital in being able to continue to mobilise with the prosthesis.

8.10.4 Cognition

Less than a quarter of the current cohort was diagnosed with a cognitive impairment (22.8%) at time of LEA by the medical or therapy staff. This figure was lower than expected however, as deteriorating cognitive ability may have been one reason for the low levels of mobility observed.

An earlier study found that cognitive integrity was associated with continued prosthetic use in a cohort of elderly patients with a LEA who were purposively selected (Bilodeau *et al.* 2000). All of their cohort had one LEA due to PAOD, lived at home, were over 60 years old and had a prosthesis. Eighty-one percent wore their prosthesis every day and 89% of this group for more than 6 hours a day. Other factors that influenced prosthetic use were prosthetic satisfaction and not possessing a wheelchair. The authors suggested that cognitive decline has an impact on the participant's ability to put on and take off the prosthetic limb safely. Another study of those with unilateral LEAs due to PAOD found a highly significant correlation between prosthetic mobility and cognitive intellect, as measured by the psychomotor test from the Clifton Assessment Procedure for the Elderly (CAPE) (Hanspal and Fisher 1991). Hanspal et al (1991) found that cognitive function had a greater influence on prosthetic mobility than level of LEA.

People with a diagnosis of PAOD, have a higher risk of being diagnosed with vascular dementia, therefore it may be that some participants in the current cohort study were living with vascular dementia in its early stages may but had not been clinically diagnosed (Rockwood *et al.* 1997). In the current cohort study, those who had a cognitive deficit and were unable to consent to follow up questionnaires were not included in the analysis of QoL. Although cognition was documented at enrolment into the current cohort study it was not reassessed at the different study time points, therefore there is no evidence to suggest that cognition had an effect on QoL or mobility after LEA.

8.10.5 Co-morbidities

The participants in the current cohort study had an average of five co-morbid conditions at time of LEA. These conditions were associated with a range of signs and symptoms including reduced cardiorespiratory function and pain, which, in isolation or in combination may adversely affect mobility, especially when considering the increased

energy requirement of walking with a prosthesis (Schmalz *et al.* 2002). The presence of co-morbid conditions along with increasing age, deteriorating cognition and poor balance were all found previously to negatively affect prosthetic use12 months after LEA in a cohort of people with unilateral LEAs (Schoppen *et al.* 2003). The general health of a person who has a LEA due to PAOD has a strong influence on the ability to use their prosthesis; as one study found the fewer co-morbid conditions that a person with a LEA has, the better their ability to walk (Sinha *et al.* 2014b). Several other studies also found a negative relationship between number of co-morbid conditions and QoL (Abdelgadir *et al.* 2009, Akkaya *et al.* 2011, Laiteerpong *et al.* 2011). In terms of individual co-morbidities; hypertension, alcohol dependence, anxiety and depression all negatively influenced QoL (Norvell *et al.* 2011).

No associations were found between co-morbidities and outcomes such as limb-fitting, mortality or level of LEA in the current cohort study. Additionally, there was a question in the face-to face interviews that asked the participant about their health, yet the answers were not found to relate to QoL when thematic analysis was conducted. This would suggest that in the current study co-morbidities and poor health did not influence QoL after LEA. This is in contrast to one study who reported co-morbidities such as diabetes was associated with lowered QoL, and the longer the duration of diabetes and the associated side-effects, the poorer the QoL (Abdelgadir *et al.* 2009). Reversing co-morbidities may not be achievable in this population; however, the primary and/or secondary prevention of developing further co-morbidities and effectively managing existing co-morbidities may help maintain levels of mobility and QoL over time following LEA.

In the current cohort, participants reported higher levels of anxiety/depression (mean score 2.6±1.0) compared to the population norm (mean score 1.7) indifferent of diabetes status. The higher levels of anxiety/depression reported in the current cohort study may go some way to explaining the poor QoL and participation scores. A larger cross sectional study of people following LEA found lower QoL was associated with high levels of depression/anxiety as reported in the mental component of the SF-36. The same authors also noted less social restriction and the absence of co-morbid diseases improved QoL (Sinha *et al.* 2014b). Buijck et al (2012) also suggested a strong association between QoL and depression (Buijck *et al.* 2012).These studies support the theory that poor QoL is

associated with higher levels of depression and anxiety as found in the current cohort study.

8.10.6 Mortality

The 30-day mortality rate of 5.8% in the current cohort study was the lowest of all the studies examined in the literature review who reported 30-day mortality rates ranging from 6.9% (Abou-Zamzam *et al.* 2003) to 18% (Campbell *et al.* 2003). Of relevance however the participants in the study by Campbell et al had a median age of 76 years, 10 years older than the present study. Pell and Stonebridge (1999) reported 12% mortality prior to discharge from hospital and their population had a median age of 73 years which is more than six years older than the current cohort study. Aulivola et al (2004) reported a 30 day mortality rate of 8.6% when they examined a large cohort (n=788) of those with major LEAs over an 11 year period (Aulivola *et al.* 2004). They also found that 30-day mortality was higher for those with a TFA (16.5%) compared to a TTA (5.7%) (*p<0.001*). A similar observation was made in the current cohort study with more of those with a TFA dying within 30 days (4.1%) compared to those with a TTA (1.7%). Thus the present study adds to the evidence which suggests that advancing age and more proximal levels of LEA are both associated with higher mortality rates at 30 days after LEA (Pell and Stonebridge 1999).

Many of the papers reporting mortality following LEA are more than 10 years old and advances in anaesthetics and surgical care over the 10 years since these other studies were reported may explain the lower 30-day mortality in the current cohort. Although the cohort study found that those who died within 30 days were on average 3.2 years older than the mean age of 66 years, this was still younger than the other studies reviewed. One reason for this may be that those in Glasgow undergo a LEA at a younger age compared to other parts of the world. Another more recent study by Fortington et al (2013) reported a 30-day mortality of 22%, the mean age of their sample was 74.1 years and all LEAs were due to PAOD and / or diabetes. (n=299). The authors suggested the reasons for this high mortality rate at 30 days was due to the frailty of their cohort and the existing cerebrovascular or renal disease (Fortington *et al.* 2013b).

At 6 months after LEA, the mortality rate in the current study increased to 17.5%, which is again, lower than other studies such as Pell and Stonebridge who reported a 6 month mortality of 29% (Pell and Stonebridge 1999). At one year after LEA the mortality rate in the current study was 30%, again, lower than that observed in the study by Fortington et al who reported a 44% mortality rate 12 months after LEA.

At all-time points, of those who died more had a TFA compared to a TTA. This higher mortality with proximal LEAs is an indication of the aggressive process of PAOD, which has a wider effect on the major organs and co-morbid disease (Thorud *et al.* 2016).

Although mortality rates were no different between those with and without diabetes, 6 and 12 months after LEA, as already discussed, those with diabetes are more likely to have distal LEAs and hence higher limb fitting rates compared to those without diabetes. The association between mortality and not limb-fitting was high, with a seven times higher mortality rate for those who did not limb-fit (OR 7.14). The association between not limb-fitting, therefore being wheelchair dependent (Section 8.5.2) and mortality requires further exploration.

The social isolation that participants spoke of in the interviews may also have a link to the high mortality rate in the cohort study. Feelings of social isolation or loneliness are known to be negatively associated with QoL (Hawton *et al.* 2011). Isolation can have as great an impact on mortality as other modifiable factors (Steptoe *et al.* 2013) Risk factors for increased mortality such as such as smoking, lack of exercise and increased alcohol excess are comparable with social isolation in the elderly (Dickens 2011).

8.11 Limitations

The findings of this cohort study have contributed significantly to the evidence base in terms of our understanding of QoL following LEA due to PAOD. It has provided novel findings on QoL, reintegration and mobility over a one-year period after LEA. Despite this, there were some limitations to the study design and implementation, which will now be discussed.

The number of participants in the cohort study was high (n=171) for a one-year data collection period in one region of the country. However, the numbers who consented to follow up questionnaires and then completed these were lower than expected (n=67), this was in part due to the poor health of the cohort. At the start of the study only 60% were able to consent to follow up, the remaining 40% unable due to poor general health and cognitive issues. Of those who consented to follow up, the response rate was relatively low with 34 participants who initially consented, not returning questionnaires, partly due to hospital admissions or mortality.

Participants with a through knee LEA were examined within the trans-femoral group due to their similar prosthetic needs which increased numbers of TFAs slightly, and the different levels of bilateral LEAs meant some of the analysis was not possible as numbers were small in these groups,

Quality of life was not measured prior to the LEA, nor at baseline (time of surgery), therefore it is difficult to ascertain the change in quality of life due to LEA. The nature of the disease process of PAOD means that many of the participants were not aware that a LEA was imminent therefore it would not have been appropriate to recruit participants to a study about LEAs when they had not been consented or fully aware that they were going to have this surgery. Also a measure of QoL immediately pre-op or post-op would not provide an accurate reflection of a person's QoL.

8.12 Clinical implications and future research

This study has shown that prosthetic use, mobility and participation all have a strong association with quality of life after LEA. Mortality was seven times higher in those not limb fitted; while the association between limb fitting and mortality may not be a direct one but rather a reflection of poorer general health, the results of this cohort study suggest that limb fitting improves QOL after LEA. Only 49.7% of participants in this study were fitted with a prosthetic limb. Clinical decision making in terms of limb fitting occurs on a case by case basis and is determined by factors such as physical capability, cognition, co-morbidities and the condition of the remaining limb. More needs to be done to optimise these areas in readiness for prosthetic rehabilitation. Further research is required to determine the factors which influence limb fitting and the effectiveness of rehabilitation to

address these factors to ensure that optimal rehabilitation strategies can be implemented. For example, prehabilitation in the form of cardiovascular conditioning exercise before LEA may improve the likelihood of limb fitting post LEA.

The study also found that, although limb fitted, a significant proportion of the cohort did not use their prosthetic limb. The continuing use of the prosthesis and issues with the weight, fit, suspension and knee joint mechanisms need to be addressed. The improved prosthetic technology that is available to military personnel is slowly filtering through to those in the NHS. Many of these new prosthetics have improved fit and suspension along with providing anti-stumble knee mechanisms (Hong-Liu *et al.* 2011) and energy saving feet (Kobayashi *et al.* 2014). These advances in technology may be of value in improving and maintaining the mobility of the less active participant with PAOD, allowing them to improve their function, avoid social isolation and improve QoL. However, the use and health economic impact of state of the art prosthetic technology have not been evaluated in those with PAOD.

A LEA has a devastating effect on a person's physical and psychological well-being, and the importance of prosthetic fitting is only one part of the rehabilitation process. Prior to a LEA, the patient should be advised of the implications that the level of LEA, their home environment, remaining foot, pre LEA mobility and general health will have on their long term outcome and QoL. As many of the participants were single room living and stayed in social housing, the rehabilitation process should include a robust review of their social/housing situation to increase use of their prosthesis once they are home, and there should be a drive to ensure that rehousing to wheelchair accessible homes is a priority for housing associations. There is also potential to utilise third sector resources to assist in improving and sustaining good quality of life after LEA.

8.13 Summary and conclusions

To date no other mixed methods studies have observed the participant's journey from LEA up to 12 months after a LEA. This study has produced strong evidence that participants with an LEA due to PAOD with or without diabetes, report poorer quality of life than the age matched population norm. It also identified that the key factors influencing QoL following LEA were being limb-fitted and the level of mobility and participation achieved

after LEA. This was also the first study to demonstrate the association between social deprivation, low prosthetic use and poor QoL in people with a LEA due to PAOD. Interestingly the presence of diabetes positively influenced QoL at 12 months after LEA in those with a prosthesis, probably related to the higher proportion of TTA in people with diabetes.

This study also found that participation and level of prosthetic use was strongly associated with QoL after a LEA. Mortality was seven times greater in those who did not achieve prosthetic fitting. Levels of prosthetic mobility achieved after TFA were poorer than those with TTA and there was a deterioration in mobility six months after LEA. Despite this, the ability to mobilise with a prosthesis is imperative in order to participate within the community and improve QoL.

It is vital that clinical services aim to increase the proportion of people who receive a prosthetic limb after LEA and that those who receive a prosthesis are able to walk and participate in activities that are fulfilling, in order to achieve a good QoL. Therefore, emphasis should be on continuing prosthetic use once discharged from rehabilitation services and targeting these services in the more deprived areas. The ability to access improved prosthetic technology in this population was introduced in Scotland one year after this study was conducted through the Murrison Report (Murrison 2011). The impact that prosthetic limbs with advanced technology may have on those with a LEA due to PAOD and /or diabetes has yet to be researched but may well improve QoL as many of the participants in this study had felt it would.

For those not felt to be appropriate to proceed to limb fitting, and therefore wheelchair dependent, it is important that social care and housing associations deliver services to optimise functional ability, facilitate participation and prevent them from feeling that their QoL is "worse than death", otherwise the often lifesaving procedure of an LEA is futile in the long term. The higher proportion of the cohort who were discharged home to single room living highlights the serious consequences that the LEA has on social isolation and health, and was a novel finding from this study. Legislation integrating health and social care was passed by the Scottish Parliament in February 2014 and was implemented in April 2016 which was after the last participant had been followed up for 12 months (Wainwright and Waring 2015). The £8 billion spend on the partnership between NHS and

social care is of particular relevance in those who have undergone an LEA as is evidenced by the findings of this thesis.

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Appendix I

NHS Greater Glasgow and Clyde   **University of Glasgow**

Participant Information Sheet

For the study entitled:
Rehabilitation & functional outcome following lower limb amputation: the influence of diabetes.

This study is being undertaken in collaboration with NHS Greater Glasgow & Clyde and the School of Nursing and Healthcare within the University of Glasgow.

Before you decide whether or not to take part it is important for you to understand why the research is being undertaken and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Thank you in advance for taking the time to read this and to decide whether or not you wish to take part.

Part 1: Basic study information

What is the purpose of the study?
No matter what the reason for having an amputation, rehabilitation focuses on fitting a person with an artificial limb in order to walk, remain independent and keep active. All of this can help to improve a persons' quality of life, however the decision to receive an artificial limb is dependent on many factors. Some people are unable to receive an artificial limb and are wheelchair dependent after an amputation, others make the decision later once home and some decide not to use the artificial limb, once fitted with it, preferring to use their wheelchair instead. Each individual is fully entitled to make the decision that is right for them however there are some factors that can influence the decision such as whether the person has diabetes, how their walking was prior to amputation and whether they have support at home or not. Research suggests that having diabetes can cause other health problems and can make it more difficult to remain mobile with an artificial limb or prevent the person from using one in the first instance. This study aims to compare those with diabetes to those without diabetes in order to see if there are other factors that influence the decision to receive and use an artificial limb.
This study is in two parts. The first part involves the researcher examining your medical case notes and following these over a period of 18 months from the date of amputation. The second part is a telephone questionnaire asking two or three sets of questions at 6 months, 12 months and 18 months after your amputation. These questions will ask about your quality of life, how you are coping since the amputation and, if you have an artificial limb, then how your walking is. The telephone call will take no more than 15 minutes to complete and will be digitally recorded.

Why have I been chosen?
As you have undergone a major amputation of your leg, your physiotherapist has informed the researcher that you may be eligible to participate in this study. All people undergoing a major amputation in Greater Glasgow & Clyde from 01.03.14 until 28.02.15 will be asked if they would like to participate in this study.

Do I have to take part?
Taking part in research is entirely voluntary; therefore it is up to you to decide. You should read this information leaflet and when you come to your first appointment we will describe the study to you and go through this information leaflet again and answer any questions you may have.

Whilst in hospital, following your amputation, the researcher will be introduced to you by your physiotherapist. The researcher will discuss the study with you and you will be asked to sign a consent form to show that you agree to take part. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not have any effect on the standard of care you receive.

What will happen to me if I take part?
Your telephone contact information will be taken by the researcher.

What do I have to do?
The researcher will contact you 6 months after your amputation to arrange a suitable time to conduct the telephone questionnaire. You will receive paper copies of the questionnaires by post to make it easier to answer whilst on the telephone. This same telephone questionnaire will be repeated at one year after the amputation and again at 18 months after the amputation. Along with the telephone questionnaire the researcher will review your medical case notes at these same time points.

What are the possibly disadvantages or risks of taking part?
There are no risks, side effects or disadvantages expected from taking part in this study.

What are the possible benefits of taking part?
This study will not benefit yourself directly, however the information collected will be used to assess whether there are changes required to the delivery of the rehabilitation services in the future.
What happens when the research study stops?
A written summary of the study results will be posted to you if you wish.

Will my taking part in this study be kept confidential?
Yes, all information collected from you during the study will be kept strictly confidential and treated with normal ethical and legal practice for data collection. With your consent we will inform your own GP about your involvement in this study.

If the information in Part 1 interests you, and you are considering taking part please read the additional Part 2 information.

Part 2: Additional Information

What will happen if I don't want to continue in the study?
You can withdraw from the study at any time and the information collected from you will still be used.

What If there is a problem?
Should you have a concern about any aspect of the study you should contact the researcher (see contact details below) in the first instance, she will do her best to answer any questions. If this does not resolve the issue, and you would like to formally complain you can do this through the NHS Complaints Procedure on tel: 0141 201 4500 or e-mail: complaints@ggc.scot.nhs.uk. You can also visit the Greater Glasgow & Clyde NHS website at www.nhsggc.org.uk for more information. Independent advice about the study can be obtained from Margaret Sneddon, department head at the University of Glasgow, Tel: 01413302071.

What happens to the results of the research study?
This study is part of a PhD which the researcher is undertaking. It is intended that the results of the study will be published in reports; all data will be anonymised before this. Should you wish to know the results of the study then we will send you a copy of the main findings once the research is complete.

Who is organising funding the research?
This study is funded by Diabetes UK

Who has reviewed this study?
All research in the NHS is looked at by the Research Ethics committee, an independent group of people who aim to protect patient safety, rights, well being and dignity. This study has been reviewed and given favourable opinion by the West of Scotland Research Ethics committee.

Participation, further information and contact details.
Should you wish to take part in this study or if you require any further information about this research study, want further advice as to whether you should participate or have any concerns during the study please do not hesitate to contact the Principal Investigator on the number below.

Fiona Smith
Research Physiotherapist
Nursing and Healthcare School, MVLS
59 Oakfield Avenue
University of Glasgow
G12 8L

Tel: 0141 330 7154
Email f.smith.3@research.gla.ac.uk

Thank you for taking the time to read this information sheet.

Appendix II

NHS Greater Glasgow and Clyde

University of Glasgow | Nursing & Health Care

Patient Identification Number for this study:

STUDY CONSENT FORM

Title of Project: Rehabilitation & functional outcome following lower limb amputation: the influence of diabetes

Name of Researcher: Fiona Smith

Please initial boxes

1. I confirm that I have read and understand the participant information sheet (version 1 dated 30.12.13) for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data Collected during the study may be looked at by individuals from NHS Greater Glasgow & Clyde or from regulatory authorities. I give permission for these individuals to access my records.

4. I understand that agreeing to take part in this study will involve a telephone interview asking 2 – 3 questionnaires, lasting approximately 15 minutes in duration.

5. I agree to the telephone interview being digitally recorded.

6. I agree that I can be contacted by the researcher to complete a telephone interview at 6, 12 and 18 month intervals.

7. I agree to my GP being informed of my participation in this study.

8. I agree to take part in the above study.

_____   _____   _____

Name of Participant   Date   Signature

_____   _____   _____

Researcher   Date   Signature

*1 copy for participant; 1 copy for researcher and 1 (original) to be kept in the medical notes.

Appendix III

Participant Identification Log

Site: Chief/Principal Investigator: Fiona Smith

Participant number	Name	Site	Date Of Amputation	CHI Number	Phone Number	Consent to Telephone & Date to call

Appendix IV

University of Glasgow

Date:

Re:

Dear Doctor

I am writing to inform you that the patient named above has consented to take part in a study named "Rehabilitation & Functional Outcome following Amputation: The influence of Diabetes". The study is being conducted by myself, a PhD student at the University of Glasgow and is funded by Diabetes UK.

The project will compare those with diabetes to those without diabetes in terms of pre-operative surgery, level of amputation and limb fitting post amputation. This project is being conducted in order to ascertain whether diabetes influences the outcome post amputation and if so will enable a service model to be devised that is person centred and evidenced based. This project will gather routinely collected data on all persons who undergo a lower limb amputation in Greater Glasgow & Clyde over one year commencing 01.03.14., in addition your patient has consented to a follow up telephone interview at 6, 12 and 18 months following amputation.

The participants will have given consent to this project whilst an in-patient in the acute setting. The participant's details such as level of amputation, reason for amputation and other factors such as socio-economic status will be collected from the case notes at time of amputation and then at 6 monthly intervals until 18 months post amputation. Along with this the participant will be contacted by telephone at 6, 12 and 18 months post amputation by the researcher and asked 2 or 3 questionnaires depending on limb fitting status. These questionnaires will pertain to quality of life, and reintegration to normal living following amputation. If limb fitted with a prosthesis the third questionnaire will relate to the person's mobility.

I have attached a patient information sheet for your information. The patient is aware you have been informed and has given their consent for this letter to be sent. If you require any further information please do not hesitate to contact me.

Yours faithfully,

Mrs Fiona Smith
Research Physiotherapist
PhD Student
0141 330 7154
f.smith.3@research.gla.ac.uk

Appendix V

Functional Co-morbidities Index

Arthritis (rheumatoid and osteoarthritis)	Yes		No	
Osteoporosis	Yes		No	
Asthma	Yes		No	
Chronic Obstructive Pulmonary Disease, Acquired Respiratory Distress Syndrome, Emphysema	Yes		No	
Angina	Yes		No	
Congestive Heart Failure (or heart disease)	Yes		No	
Heart Attack (myocardial infarction)	Yes		No	
Neurological disease e.g. Multiple Sclerosis or Parkinson's	Yes		No	
CVA or TIA	Yes		No	
Peripheral Arterial Disease	Yes		No	
Diabetes Type I and II	Yes		No	
Upper gastrointestinal disease (ulcer, hernia, reflux)	Yes		No	
Depression	Yes		No	
Anxiety or panic disorders	Yes		No	
Visual impairment (cataracts, glaucoma, macular degeneration)	Yes		No	
Hearing impairment (very hard of hearing even with hearing aids)	Yes		No	
Degenerative disc disease including, back disease, spinal stenosis or severe chronic back pain	Yes		No	
Obesity and/or BMI > 30 (Pre-op weight in Kg/height in metres ^{2}) Weight ……… (Kg) Height …….. (metres) BMI = …………	Yes		No	
Please see Guidance Notes **Score** (Yes = 1, No = 0)	/ 18			

Appendix VI

Locomotor Capabilities Index - 5

The coding (0- 4) is as follows:
0- No
1- Yes, if someone helps
2- Yes, if someone is near
3- Yes, alone with walking aid(s)
4- Yes, alone **without** walking aid

Were you able to do the following activities 6 months before the amputation? Are you able to do them wearing your prosthesis at final discharge?

Activity REMEMBER when scoring: 3 = with walking aid 4 = <u>without</u> walking aid	6 months pre-admission	Final Discharge
Basic Activities		
Get up from a chair		
Walk indoors		
Walk outside on even ground		
Go up the stairs with a hand-rail		
Go down the stairs with a hand-rail		
Step up a kerb		
Step down a kerb		
TOTAL		
Advanced activities		
Pick up an object from the floor when standing		
Get up from the floor (e.g. after a fall)		
Walk outside on uneven ground (e.g. grass, gravel, slope)		
Walk outside in bad weather (e.g. rain, wind, snow)		
Go up a few steps without a hand-rail		
Walk down without a hand-rail		
Walk while carrying an object		
TOTAL		
OVERALL TOTAL		
CHANGE of overall total from 6 months preadmission to final discharge		

Appendix VII

EQ-5D-5L Quality of Life Measure
Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ❑

I have slight problems in walking about ❑

I have moderate problems in walking about ❑

I have severe problems in walking about ❑

I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑

I have slight problems washing or dressing myself ❑

I have moderate problems washing or dressing myself ❑

I have severe problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑

I have slight problems doing my usual activities ❑

I have moderate problems doing my usual activities ❑

I have severe problems doing my usual activities ❑

I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑

I have slight pain or discomfort ❑

I have moderate pain or discomfort ❑

I have severe pain or discomfort ❑

I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑

I am slightly anxious or depressed ❑

I am moderately anxious or depressed ❑

I am severely anxious or depressed ❑

I am extremely anxious or depressed ❑

We would like to know how good or bad your health is TODAY.
This scale is numbered from 0 to 100.
100 means the <u>best</u> health you can imagine.
0 means the <u>worst</u> health you can imagine.
Mark an X on the scale to indicate how your health is TODAY.
Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health
you can imagine

— 100
— 95
— 90
— 85
— 80
— 75
— 70
— 65
— 60
— 55
— 50
— 45
— 40
— 35
— 30
— 25
— 20
— 15
— 10
— 5
— 0
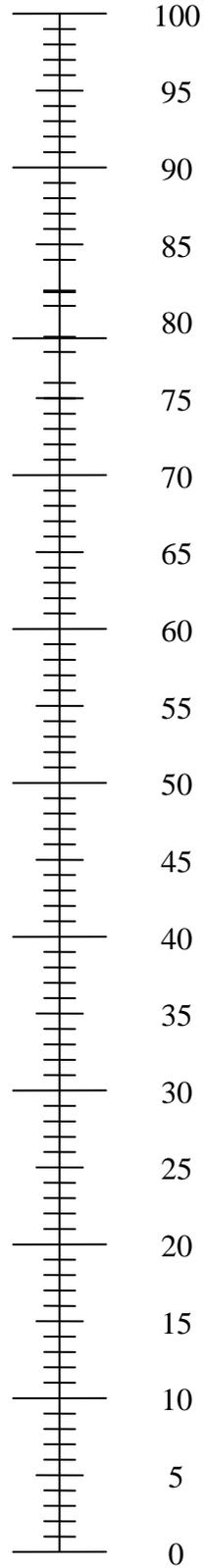
The worst health
you can imagine

Appendix VIII

Reintegration To Normal Living Index (RNLI)

Please use this visual scale to give a number to how you answer the following questions:

(1) I move around my living quarters as I feel necessary.

----

(2) I move around my community as I feel necessary.

----

(3) I am able to take trips out of town as I feel are necessary.

(4) I am comfortable with how my self-care needs (dressing feeding toileting bathing) are met.

----

 (5) I spend most of my days occupied in work activity that is necessary or important to me.

----

(6) I am able to participate in recreational activities (hobbies crafts sports reading television games, as I want to.

----

(7) I participate in social activities with family friends and/or business acquaintances as is necessary or desirable to me.

----

(8) I assume a role in my family which meets my needs and those of other family members.

----

(9) In general I am comfortable with my personal relationships

10

9

8

7

6

5

4

3

2

1

0

Not Able

----
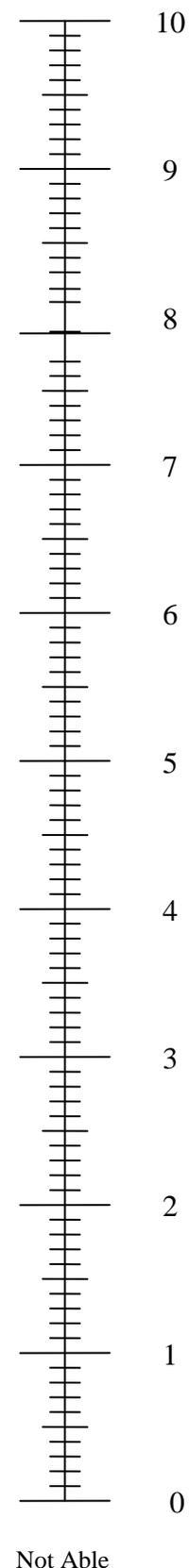
(10) In general I am comfortable with myself when I am in the company of others.   -

----

(11) I feel that I can deal with life events as they happen.

Appendix IX

Prosthetic Limb User Survey of Mobility (PLUS-M)

PLUS™
Mobility Short Form v1.1

Name: _____   Date: _____

Instructions: Please respond to all questions as if you were wearing the prosthetic leg you use most days. If you would normally use a cane, crutch, or walker to perform the task, please answer the questions as if you were using that device.

Please choose "unable to do" if you:
- Would need help from another person to complete the task,
- Would need a wheelchair or scooter to complete the task, or
- Feel the task may be unsafe for you

Please mark one box per row.

Question	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
1. Are you able to walk a short distance in your home?	☐ (5)	☐ (4)	☐ (3)	☐ (2)	☐ (1)
2. Are you able to step up and down curbs?	☐ (5)	☐ (4)	☐ (3)	☐ (2)	☐ (1)
3. Are you able to walk across a parking lot?	☐ (5)	☐ (4)	☐ (3)	☐ (2)	☐ (1)
4. Are you able to walk over gravel surfaces?	☐ (5)	☐ (4)	☐ (3)	☐ (2)	☐ (1)
5. Are you able to move a chair from one room to another?	☐ (5)	☐ (4)	☐ (3)	☐ (2)	☐ (1)
6. Are you able to walk while carrying a shopping basket in one hand?	☐ (5)	☐ (4)	☐ (3)	☐ (2)	☐ (1)
7. Are you able to keep walking when people bump into you?	☐ (5)	☐ (4)	☐ (3)	☐ (2)	☐ (1)
8. Are you able to walk on an unlit street or sidewalk?	☐ (5)	☐ (4)	☐ (3)	☐ (2)	☐ (1)
9. Are you able to keep up with others when walking?	☐ (5)	☐ (4)	☐ (3)	☐ (2)	☐ (1)
10. Are you able to walk across a slippery floor?	☐ (5)	☐ (4)	☐ (3)	☐ (2)	☐ (1)
11. Are you able to walk down a steep gravel driveway?	☐ (5)	☐ (4)	☐ (3)	☐ (2)	☐ (1)
12. Are you able to hike about 2 miles on uneven surfaces, including hills?	☐ (5)	☐ (4)	☐ (3)	☐ (2)	☐ (1)

www.plus-m.org

PLUS-M™ 12-item Short Form (v1.1)
© 2014 University of Washington

Appendix X

Date:

Dear …………………..

I am writing to you regarding the study "Rehabilitation & Functional Outcome following Amputation: The influence of Diabetes". Six months ago I spoke with you about participating in a follow up telephone conversation, where you gave written consent to me phoning you in order to gain your answers to the questions enclosed in this envelope.

I have enclosed the questionnaires that I will be asking you about and appreciate you taking the time to think upon your answers to these. I will call you in one week and if it is not a suitable time to speak with you, I will leave you a message and look forward to hearing from you at your earliest convenience. You can contact me or leave a message on my phone on either number below.

The study is being conducted by myself, Fiona Smith, physiotherapist, as part of my PhD at the University of Glasgow and is funded by Diabetes UK.

Many thanks in anticipation,

Yours faithfully,

Mrs Fiona Smith
Research Physiotherapist
PhD Student
0141 330 7154
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Appendix XI

Excluded from Cohort Study

Reason Excluded From Cohort	n=12
Failed orthopaedic joint replacement	4
Paraplegia	2
Congenital Abnormality	1
Chronic Regional Pain Syndrome	1
Trauma	1
Injection of Steroids into Groin	1
Intravenous Drug Abuse	1
Idiopathic Dystonia	1

Appendix XII

Renal Function Pre LEA

Renal Function eGFR (ml/min)	Whole Cohort (n=171)	NDM (n=80)	DM (n=91)	p value
eGFR>60	72.5% (n=124)	91.3% (n=73)	56.0% (n=51)	*<0.001*
eGFR 30-60	13.5% (n=23)	3.7% (n=3)	22.0% (n=20)	
eGFR 15-30	4.6% (n=8)	3.7% (n=3)	5.5% (n=5)	
eGFR <15	2.4% (n=4)	0% (n=0)	4.4% (n=4)	
RRT		1.3% (n=1)	7.7% (n=7)	
Renal Tx		0% (n=0)	4.4% (n=4)	

Abbreviations: eGFR=Glomerular Filtration Rate, *DM=Diabetes, NDM=No Diabetes, RRT=Renal Replacement Therapy, Tx=Renal Transplant

Appendix XIII

Diabetes Treatment

Medication	All with DM (n=91)	Type I (n=17)	Type II (n=74)	p value
Insulin	48.3% (n=44)	88.2% (n=15)	39.2% (n=29)	*p=0.002*
Insulin & OHA	22.0% (n=20)	5.9% (n=1)	25.7% (n=19)	
OHA	25.3% (n=23)	0% (n=0)	31.1% (n=23)	
Diet	4.4% (n=4)	5.9% (n=1)	4.0% (n=3)	
Suplhenylurea	23.1% (n=21)	0%	28% (n=21)	
Pancreatic Tx	4.4% (n=4)	5.9% (n=1)	4% (n=3)	

Abbreviations: OHA=Oral Hypoglycaemic Agent, DM = Diabetes, Tx=Transplant