FOOT AND ANKLE IMPAIRMENTS AFFECTING MOBILITY IN STROKE

ALISON ROGERS

U0959508

A thesis submitted in partial fulfilment of the requirements of the University of East London for the degree of

Doctor of Philosophy

April 2019

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ABSTRACT

Introduction:

Altered foot characteristics are common in people with stroke, with a third presenting with abnormal foot posture which is associated with ambulatory difficulties. Understanding the relationship between measures of foot and ankle impairment and their association with mobility and balance outcomes is therefore important; however, poor clinimetric properties of foot and ankle measures after stroke precludes evaluation of these relationships. Therefore, this research, undertaken as part of a multicentred research project, had the following aims:

Study 1: To evaluate the clinimetric properties (feasibility, test–retest reliability, and clinical relevance) of measures of foot and ankle impairments, for application in people with stroke.

Study 2: To examine how these measures differ between people with stroke and normal controls; and whether they are associated with mobility and balance outcomes.

Methods:

In Study 1, community-dwelling people with stroke, able to walk 10 m (metres), attended two testing sessions to evaluate the clinimetric properties of different foot and ankle measures. These included: static foot posture and dynamic foot loading (peak plantar pressure, PPP, contact area, CA and centre of pressure, CP) using a plantar pressure mat; isometric muscle strength using a hand-held dynamometer (HHD); peak ankle and hallux dorsiflexion and stiffness using bespoke rigs; and ankle plantarflexion spasticity using the Tardieu scale. Statistical analysis used intraclass correlation coefficients ($ICCs_{(3,1)}$), standard error of measurement (SEM) and Bland–Altman plots.

In Study 2, measures identified as reliable from Study 1 were incorporated in a cross-sectional study design. Participants were recruited from acute and community neurological services in East London and North Devon. Statistical analysis tested the

differences between groups and between affected limbs in people with stroke. Impairment measures were evaluated using multivariate regression analysis for their association with functional outcomes: walking speed (over 10 m); Timed Up and Go (TUAG), Forward Functional Reach Test (FFRT) and presence of falls (> 1 in the last 3 months).

Results:

In Study 1, 21 people with stroke tested the measures. These were found to be feasible and easy to administer, although loss of data (up to 33%) was observed. All measures had moderate to excellent test–retest reliability (coefficients 0.50–0.98), except ankle plantarflexion stiffness ($ICCs_{(3,1)} =$ 0.00–0.11).

In Study 2, there were significant differences in all measures between people with stroke (n = 180) and controls (n = 46), apart from static foot posture (p = 0.670), toe deformity (p = 0.782) and peak hallux dorsiflexion (p = 0.320). Between limb differences were identified for all measures except foot posture (p = 0.489) and foot CA (p > 0.05). Multicollinearity analysis found 10 measures appropriate for multivariate regression which identified the following R^2 and variance explained: 59% walking speed (R^2 = 0.543); 49% TUAG (R^2 = 0.435); 36% FFRT (R^2 = 0.285) and 26% for Falls Presence.

Conclusion:

The study demonstrated that seven foot and ankle measures of impairment after stroke were clinically feasible, reliable *and* associated with mobility and balance outcomes. The measures were ankle and foot isometric muscle strength, sway velocity, PPP (RFT and FFT), CA (MFT and FFT) and peak ankle dorsiflexion. These measures can now be incorporated into research to examine methods to improve the treatment of foot and ankle after stroke.

DECLARATION

I declare that this work is entirely my own.

FUNDING

Initial funding was provided by the Scholl fund in March 2012. Additional funding was secured to complete the remaining parts of the project; this was approved as of January 2015 through to September 2015.

WORD COUNT

86,102

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GLOSSARY

Agreement	a term used in context of reliability, meaning the extent to which values produced by a measurement tool are similar. Quantified by statistical measures such as correlation coefficients and Bland–Altman plots.
Balance	maintenance of equilibrium of body segments within a base of support (Everett, 2010).
Centre of force/pressure	a way of representing the summative neuromuscular response that controls the centre of mass, which in turn controls forward progression and balance. On a pressure mat this represents the point at which the line of gravity pierces the floor.
Clinical relevance	or significance. A clinimetric property of a measurement tool when it is able to distinguish clinical meaningful changes, this usually requires use of statistical analysis such as standard deviation, standard error of the mean and minimal clinically important differences for an impairment.
Contact area	the total area in contact with the pressure mat/supporting surface during stance. This may be divided into subsections of stance by time/subphase/foot region.
Fall	an event where an individual inadvertently comes to rest on a lower surface (World Health Organisation, 2012).
Feasibility	the applicability of methods to their clinical context and whether the results can be sustainable and relevant (Bowen *et al.*, 2009).
Mobility	the ability to move around with ease in one's own environment, enabling individuals to carry out everyday activities (Everett, 2010; Webber *et al*., 2010).
Peak pressure	where the maximal pressure value exerted on a single cell during loading of the foot is recorded.

Prevalence	the proportion of a population who have a specific characteristic in a given time period.
Reliability	the ability of a measure to differentiate among subjects or scores (Kottner *et al*., 2011); an attribute of a measure which means it is consistent and/or free from error and yields consistent results over different time frames and between different raters (Portney and Watkins, 2009).
Repeatability	the degree of how close scores, or ratings, obtained under similar conditions are (Kottner *et al*., 2011).
Severity	the degree of, or range of differences, in an illness/impairment, separate to 'presence' which is the frequency of having a particular characteristic or characteristics.
Stroke	a neurological deficit of cerebrovascular origin that persists beyond 24 hours (World Health Organisation, 2013).
Test–retest reliability	synonymous with intra-rater reliability, where one tester repeatedly assesses an outcome at a minimum of two time points, addressing the ability of consistently obtaining the same results on repeated occasions (Sim and Wright, 2000). Can also be termed repeatability.
Walking or gait	a specific aspect of mobility defined as a repetitious sequence of limb movement to simultaneously move the body forward while maintaining stance stability (Perry and Burnfield, 2010).

LIST OF ABBREVIATIONS

AR	Alison Rogers
ARNI	Action for Rehabilitation after Neurological Injury
AS	Ashworth scale
BBS	Berg Balance scale
BOS	base of support
CA	contact area
CASP	Critical Appraisal Skills Programme
CBF	cerebral blood flow
CI	confidence interval
COF	centre of force
COP	centre of pressure
CoV	coefficient of variation
CP	contact pressure
df	degrees of freedom
DF	dorsiflexor
DFL	dynamic foot loading
EMG	electromyography
F10MWT	Fast 10-Metre Walk Test
FAC	functional ambulatory category
FAiMiS	Foot and Ankle impairments affecting Mobility in Stroke
FES	Falls Efficacy Scale
FFRT	Forward Functional Reach Test
FFT	forefoot
FPI	foot posture index
GRF	ground reaction force
GRRAS	Guidelines for Reporting Reliability and Agreement Studies
HHD	hand-held dynamometer
HHT	Hitchhiker's toe
HV	hallux valgus
ICA	internal carotid artery
ICC	intraclass correlation coefficient
ICF	International Classification of Function
IPJ	interphalangeal joints
LA	less-affected
LFF	lateral forefoot
LMF	lateral mid-foot
LOA	limits of agreement
LRF	lateral rearfoot
LTD	lesser toe deformity
LToes	lateral toes
MA	more-affected

MAS	modified Ashworth scale
MC	Mary Cramp
MCA	middle cerebral artery
MCID	minimal clinically important difference
MD	mean difference
MFF	medial forefoot
MFT	mid-foot
ML	medio–lateral
MMF	medial mid-foot
MMT	manual muscle testing
MRC	Medical Research Council
MRF	medial rearfoot
MTH	metatarsal head
MToes	medial toes
MTPJ	metatarsal phalangeal joint
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NM	neuromuscular
PASS	postural assessment scale
PCA	posterior cerebral artery
PF	plantarflexor
PICO	Population, Intervention, Comparison, Outcome
PPP	peak plantar pressure
PTI	pressure–time integrals
RA	rheumatoid arthritis
RCP	Royal College of Physicians
RFT	rearfoot
ROM	range of motion
SD	standard deviation
SEM	standard error of measurement
SOP	standard operating procedure
TAS	tone assessment scale
TG	Terry Gorst
TIA	transient ischaemic attack
TSS	time since stroke
TT	ankle joint
TUAG	Timed Up and Go
UEL	University of East London
UK	United Kingdom
UL	upper limb
UMNL	upper motor neurone lesion
v.	versus
VAS	visual analogue scale
VIF	variable inflation factor

WIS	Walking Impact Scale

Units	
cm	centimetre
kg	kilogram
kPa	kilo pascal
m	metre
N	newton
Nm	newton metre
s	second

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First, I would like to thank my supervisors, Dr Mary Cramp, Dr Stewart Morrison and Dr Kellie Gallagher, who have given me the opportunity to do this piece of work and have steered and supported me through this PhD programme.

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Finally, and most importantly, I want to thank my God and Saviour for His steadfast love and His grace, which were evident to me throughout this research and thesis completion. He has given me wisdom, taught me the value of committing my plans to Him, and 'numbering my days'.

DEDICATION

This thesis is dedicated to the people who have had a stroke and live daily with the impairments this brings. I hope that through this research and future associated research many people with stroke will live with improved function and quality of life.

Chapter 1: INTRODUCTION

This introductory chapter will outline the purpose, background and scope of this research. Furthermore, the overarching aims will be presented, with a brief review of the relevant literature, to be expanded in later chapters. Finally, the expected novel aspects will be presented.

1.1 PURPOSE OF STUDY

Stroke is defined as a neurological deficit of cerebrovascular origin that persists beyond 24 hours (World Health Organisation, 2013). In the United Kingdom (UK), just over 100,000 people suffer a stroke annually (Intercollegiate Stroke Working Party, 2016; National Health Service, NHS, Digital, 2017). Those affected are primarily older adults, with the average age of first stroke reported as 77 years (Royal College of Physicians, RCP, 2017). Stroke is recognised as the largest cause of complex disability with approximately 1.2 million people currently living with the long-term consequences of this condition in the UK (Stroke Association, 2018).

Following a stroke, a wide range of impairments occur, including muscle weakness, altered muscle coordination, reduction in range of motion (ROM), and gait and balance deficits (Bohannon, 2007; Lamontagne *et al*., 2002; Dorsch *et al*., 2012; Walsh *et al*, 2017). Foot and ankle impairments have also been recognised; in particular, ankle muscle weakness, reductions in ankle passive and active ROM (dorsiflexion–plantarflexion and inversion–eversion) (Dorsch *et al*., 2016) and altered muscle activity, including ankle PF spasticity (Lamontagne *et al.,* 2002; 2001). Furthermore, abnormal foot posture and asymmetries between more- and less-affected limbs within the same person with stroke have been reported (Forghany *et al*., 2011). Despite the presence of these deficits, few feasible and reliable clinical tools are available to measure these characteristics (Keenan *et al.*, 2007; Pandyan *et al.*, 2005; Keating *et al.*, 2000). Having feasible, reliable and clinically relevant measures is key to a thorough evaluation of the presence of foot and ankle impairments and their importance to recovery and function after stroke. Therefore, robust clinical measurement tools are required to adequately quantify this after stroke.

To date, links between stroke-related impairments and problems in mobility and balance have been partially explored, demonstrating associations with deficits in muscle strength (Dorsch *et al*., 2016; Bohannon, 2007), spasticity (Lamontagne *et al*., 2002) and foot posture (Kunkel *et al*., 2017). Mobility is known as the ability to move oneself by changing body position or location, or by moving from one place to another, by walking, use of assistive devices or transportation (Everett, 2010; Webber *et al*., 2010). Mobility is limited after stroke with only 41.4% of people reported to be able to walk outside with an aid (Lord *et al.*, 2004), and a comfortable walking speed of 0.84 $m{\cdot}s^{-1}$ (Severinsen *et al.*, 2011) is significantly lower than the 1.4 $m{\cdot}s^{-1}$ in people without stroke (Bohannon and Williams Andrews, 2011). Balance is in part defined as the maintenance of equilibrium of body segments within a base of support (Kell, 2010). Up to 80% of people with stroke demonstrate poor balance (Tyson *et al.*, 2006), with this often leading to a fall; 20–50% of stroke survivors experience one or more falls (Walsh *et al.*, 2017; Lim *et al.*, 2012; Ashburn *et al.*, 2008). As foot and ankle impairments are key considerations for maintaining mobility and balance in older adults (Spink *et al.*, 2011, Menz and Morris, 2006), it is plausible that these impairments may be important clinical predictors of deficits in mobility and balance outcomes for people after stroke.

Thus, the purpose of this work is to explore the characteristics of foot and ankle impairments in people after a stroke, primarily to ascertain whether any of the impairments assessed are associated with mobility and balance deficits so commonly observed in stroke patients. It is hoped that this research will enhance clinical understanding and recognition of the foot and ankle impairments that impact on balance and mobility post-stroke. This research may support the development of targeted and appropriate multidisciplinary rehabilitation care after stroke as well as influence both local and national policies for stroke rehabilitation.

1.2 FOOT AND ANKLE IMPAIRMENT AFFECTING MOBILITY IN STROKE (FAiMiS) STUDY

The research programme presented in this thesis is a part of a wider research project named ‘Foot and Ankle impairments affecting Mobility in Stroke’ (FAiMiS). The original justification for the FAiMiS project was based on a review of current research (completed

in 2012). This demonstrated that limited mobility and poor balance, which is common after stroke, may be caused by multiple factors, including foot and ankle dysfunction (Forghany *et al*., 2011 and Spink *et al*., 2011). Yet, the impact of specific foot and ankle impairments following stroke received little attention. Therefore, the purpose of the FAiMiS project was to study foot and ankle problems after stroke and examine the effects on mobility and balance in community-dwelling people with stroke. The project had the following aims:

1) Explore how individuals with stroke perceive the impact of foot and ankle impairments on their life after stroke; and determine the (foot and ankle) factors which they believe affect their mobility and balance.
2) Evaluate the psychometric and clinimetric properties of a range of tests of foot and ankle impairments in order to develop a battery of tests suitable for use in routine clinical practice.
3) Use this test battery to determine the key (foot and ankle) predictors of mobility and balance post stroke.

These aims defined the three phases of the FAiMiS study which will be discussed in the following paragraphs, highlighting which aspects were used in this current thesis. Two research assistants were employed to work on the FAiMiS project – Terry Gorst (TG) based in North Devon and Alison Rogers (AR) based in East London – their roles are outlined below[1]. Figure 1.1 shows the elements taken from the FAiMiS project and used in this thesis and Figure 1.2 shows the timelines of both pieces of work.

Phase one was conducted by TG in North Devon. Semi-structured interviews with a group of 13 people with stroke explored perceptions of foot and ankle impairments and their impact on mobility and balance impairments (Gorst *et al.*, 2016). Results highlighted a number of impairments including foot pain, sensory impairments and muscle weakness (Gorst *et al.*, 2016). These impairments were integrated with other impairments found when AR reviewed evidence for Phase 2. This culminated in a final FAiMiS assessment battery that included foot pain, lower limb sensation, foot posture, toe deformity, dynamic foot loading (DFL), isometric muscle strength, peak ankle and hallux dorsiflexion angle and ankle spasticity. Phase 1 was not included as part of the thesis as this forms the PhD thesis of TG.

[1] Researcher profiles are found in Appendix 26

Phase two (thesis Study 1) was conducted by AR in East London. Using the literature review and key papers presented in Figure 1.1 it explored the feasibility and reliability and clinical relevance of measures of these foot characteristics and neuromuscular impairments in a small cohort of people with stroke (n = 21). Notably foot pain and lower limb sensation were not included as part of the thesis Study 1, this is discussed in Section 1.2.1. Subsequently, measures that were deemed feasible, reliable and clinically relevant were selected for inclusion in the final, third phase of the work.

In Phase three (thesis Study 2), in a cross-sectional study of 180 people with stroke impairments, relationships with mobility and balance outcomes were explored using multivariate regression analyses. This was conducted by TG and AR. To ensure impairments were characteristic of people with stroke, comparisons were conducted with an age- and gender-matched control group (n = 46).

1.2.1 Distinctives of this Thesis Compared to the FAiMiS Project

This thesis has focused on foot characteristics and neuromuscular impairments, not including sensation and foot pain, taken from the second and third phase of the FAiMiS project. While the role of sensation and foot pain are crucial to understanding functional outcomes in older people (Spink et al., 2011), these phenomena were excluded from this current thesis. Underpinning this focus was:

- the interlinked nature of muscle strength, joint motion and muscle resistance after stroke (Lamontagne *et al*., 2002; 2001);
- associations between plantar pressure and spasticity, and neuromuscular impairments found after stroke (Meyring *et al*., 1997);
- associations with foot posture and ankle muscle weakness, joint motion, spasticity and functional outcomes in people with stroke (Forghany *et al*., 2011; Dorsch *et al*., 2012).

This permitted dedicated attention within this thesis on clinimetrics and on advancing understanding of measuring three foot characteristics (foot posture, toe deformity and

DFL) and three neuromusculoskeletal impairments (muscle weakness, joint range of motion and spasticity). Specifically, this required establishing clinically feasible and relevant tools which were reliable and yielded robust results. These could then be used in the final phase (Phase 3) of the FAiMiS project and in Study 2 of this thesis. Furthermore, as the FAiMiS project had two research assistants, research could be expanded, resulting in publications related to developing sensory assessment tools for use in neurological populations (Gorst, *et al*., 2019a and Gorst, *et al*., 2019b) and the repeatability of plantar pressure analysis in stroke (Rogers *et al*., 2020). Potential limitations of excluding sensation and foot pain despite its justification are discussed in Chapter 6. Of note, all variables (including sensation) are included in the power calculation for the FAiMiS analysis.

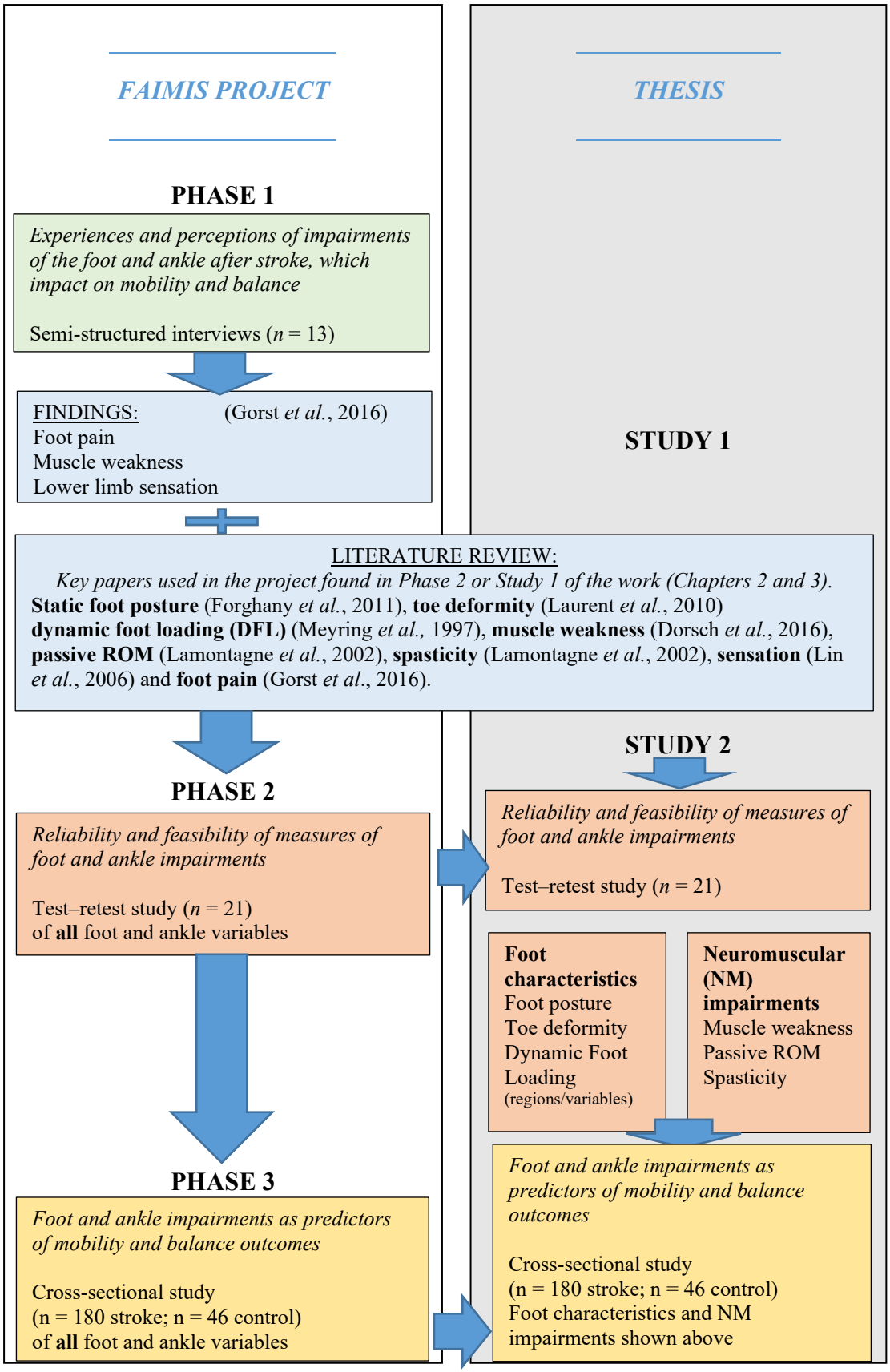


Figure 1.1 Flow Diagram: Overview of FAiMiS Project and Thesis, Phases and Studies
(impairments shown in bold were used in the thesis).

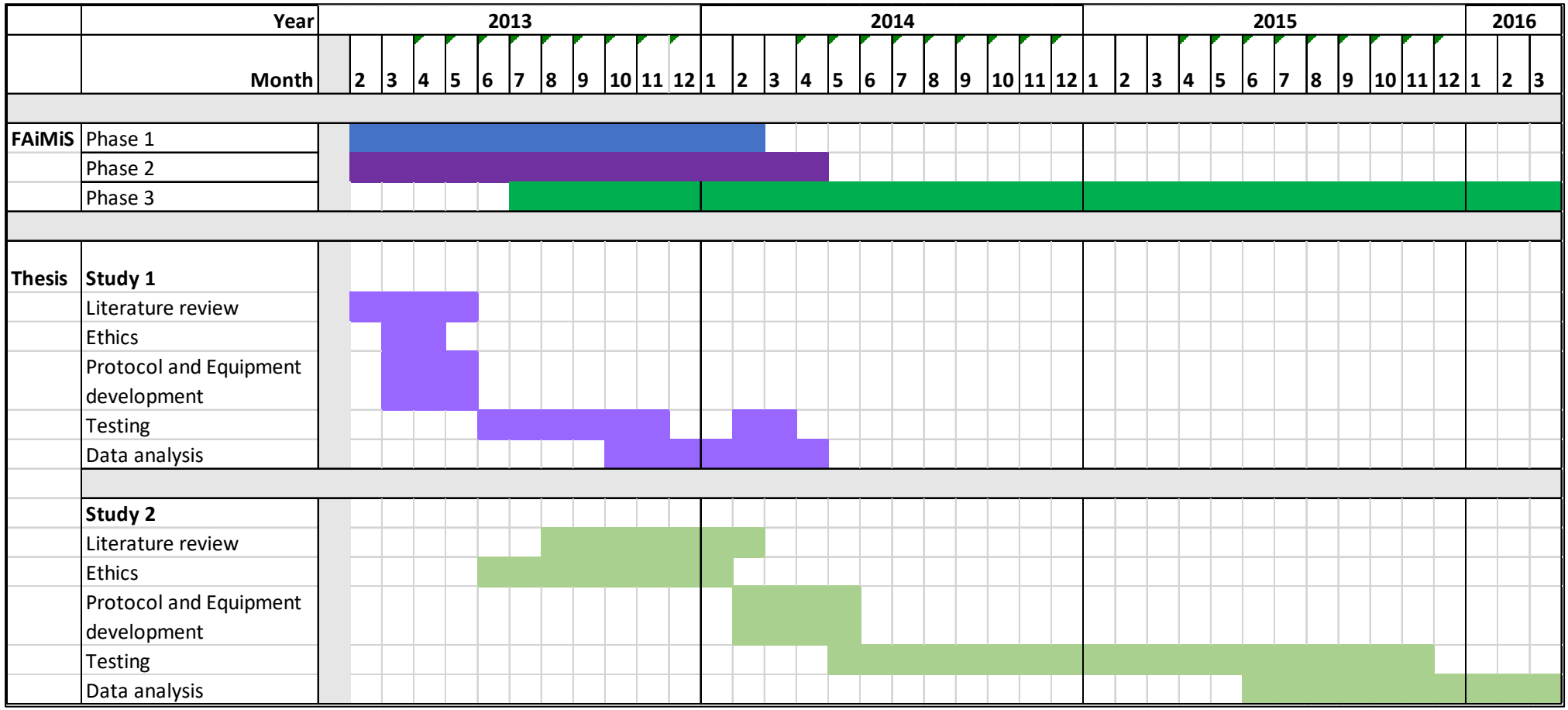


Figure 1.2 Timeline of FAiMiS Phases and Thesis Studies

NB: data analysis for Study 2 of the thesis continued into until Summer 2017, to enable the chart to fit the page. Phase 2 = Study 1 and Phase 3 = Study 2.

1.3 STROKE

1.3.1 Background

Stroke is a common and complex pathology; it is defined as:

a clinical syndrome consisting of rapidly developing clinical signs of focal or global (in case of coma) disturbances of cerebral function lasting more than 24 hours or leading to death with no apparent cause apart from vascular origin.
(*World Health Organisation, 2013*)

The length of time of the disruption to cerebral blood flow is a key distinguishing feature of a stroke with any disruption lasting less than 24 hours reported as a transient ischaemic attack (TIA). Age is the single most important non-modifiable risk factor, with gender and ethnicity also contributory factors (RCP, 2017; Stroke Association, 2018). Modifiable risk factors include hypertension, smoking, diet and physical inactivity (Stroke Association, 2018; Boehme *et al*., 2017). The average age of first stroke differs between male and females; Lee *et al.* (2011) reports that the average age of first stroke in women is higher at approximately 80 years and lower for men at 74 years (Stroke Association, 2018). Despite this, stroke is reported in younger people (Stokes and Stack, 2011), with up to 40,000 strokes occurring a year in the UK in people below 65 years of age (Different Strokes, 2018). Worldwide evidence shows that the prevalence of stroke is 41% higher in males than females (Appelros, 2009); UK data for number of strokes per year reports a 0.84 male to female ratio, which is mainly influenced by women who live longer (Stroke Association, 2018).

Stroke is the second most common cause of death in Europe and across the world (World Health Organisation, 2017) and is the fourth single largest cause of death in the UK (Stroke Association, 2018). Stroke is recognised as the largest cause of complex disability in the UK, with two thirds of all people with stroke leaving hospital with a disability (Stroke Association, 2018). Consequently, the immediate costs to the National Health Service (NHS) for stroke care over a year are enormous, at approximately £1.07 billion (RCP, 2017). Compounding this is the large number of people with stroke having significant long-term health care needs (The National

Institute of Health and Care Excellence, NICE, 2013b). Costs of social care double when comparing the first year to subsequent years after stroke from £2.3 to £4.6 million) (Stroke Association, 2018). Direct stroke treatment amounts to 5% of the total UK NHS costs and the remainder is accounted for by informal care costs, loss of income and £800 million for benefit payments (Saka *et al.*, 2009). There are personal, professional and economic repercussions, with more than 40% of people with stroke failing to return to work (Daniel *et al.,* 2009). Work conducted by Wang *et al.* (2014) reported that disability linked to stroke severity was the most consistent negative predictor of return to work. Thus, disability and the economic consequences are substantial. Lower limb function, such as mobility and balance, links not only to return to work outcome and quality of life but may also influence national economic factors (Westerlind *et al*., 2017).

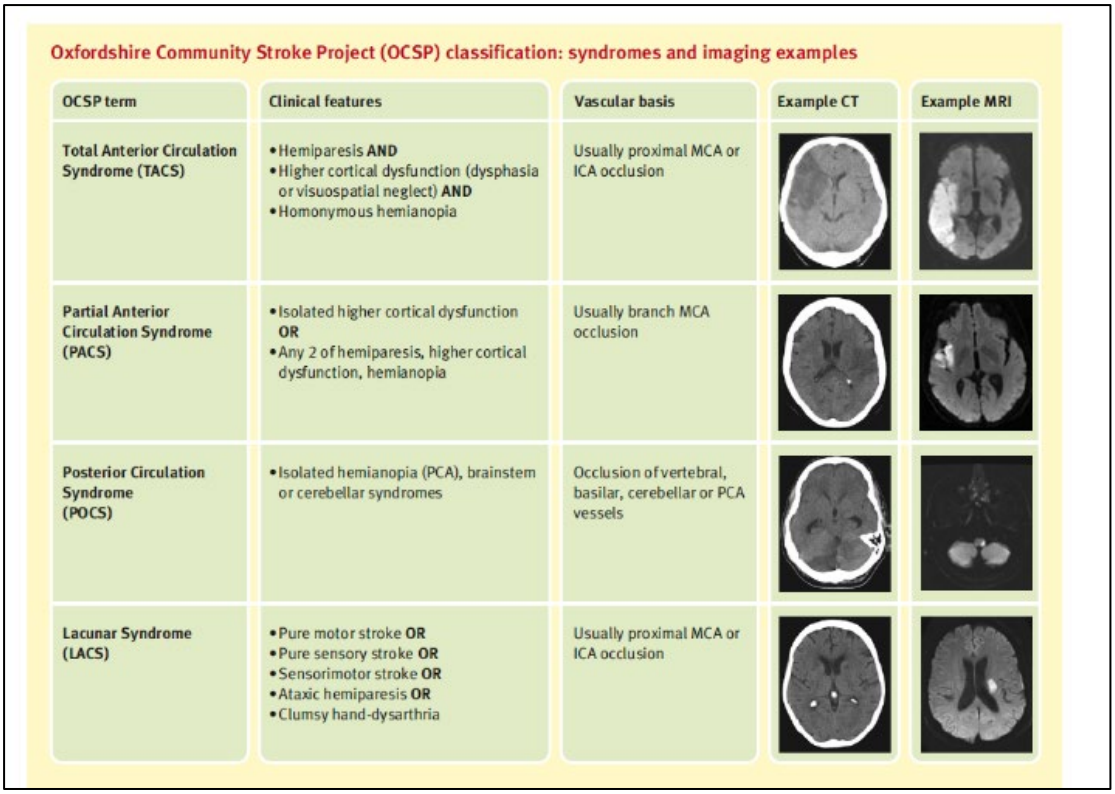
1.3.2 Types and Classification of Stroke

Stroke can be broadly categorised into two types: ischaemic or haemorrhagic. Approximately 85% of stroke events are due to ischaemia, the remaining 15% are haemorrhagic (RCP, 2017). In the case of an ischaemic stroke, a stenosis reduces or completely stops the flow of blood through cerebral arteries. This is caused by either an occlusion, which accounts for 50%, or an embolism, which accounts for 25%; these may be produced by vessel narrowing such as atherosclerosis (Derdeyn, 2007; Adams *et al*., 1993). Despite the extensive provision of cerebral blood flow (CBF) to the brain by the Circle of Willis and distal blood vessels, the disruption or alteration of blood flow will impact on the perfusion and functioning of the cerebral tissue (Paciaroni *et al*., 2009). In a stroke, the fall in CBF deprives the brain of oxygen, which leads to a cascade of events resulting in an accumulation of toxic compounds such as calcium, which causes neuronal damage, and apoptosis or programmed cell death (Endres *et al*., 2008).

Haemorrhagic strokes are caused by the rupture of blood vessel walls in the area of a weakened wall such as an aneurysm, or arteriovenous malformation, which results in blood leaking into the brain tissue (Rymer, 2011). These may typically be intracerebral, but subarachnoid haemorrhages may occur and account for 1 in 20

strokes (NHS Direct Wales, 2015). The ruptured blood vessels following the burst of an aneurysm, or any other weakening of the cerebral blood vessel wall, allows blood into the brain tissue – intracerebral, intraventricular and/or subarachnoid spaces (An *et al*., 2017). The blood-occupied space causes shift and/or compression of brain tissue. The blood and plasma cause vasogenic and cytotoxic oedema, neuronal damage and necrosis (Rymer, 2011; An *et al*., 2017).

One classification system, known as the Oxfordshire Community Stroke Project (Bamford) Classification system (Bamford, 1992), is based on clinical presentation of the stroke and is used internationally to report the number and type of strokes. Figure 1.3 shows how the functional organisation of the cerebral cortex and surrounding subcortical and brainstem regions relate to deficits and functional outcome following a stroke. It also demonstrates how clinical signs are dependent on the location and extent of the vascular accident (Ward, 2012; Bamford, 1992). These classifications are: total anterior circulatory stroke (TACS), partial anterior circulatory stroke (PACS), lacunar stroke (LACS) and posterior circulatory stroke (POCS). Stroke can also be categorised by the area of the brain where the lesion is as well as the associated clinical presentation, e.g. intracerebral, or it can be categorised according to the circulatory vessels affected, e.g. small vessel occlusion (Stroke Association, 2015). Clinical presentation is further discussed in Section 1.3.4.



Oxfordshire Community Stroke Project (OCSP) classification: syndromes and imaging examples

OCSP term	Clinical features	Vascular basis	Example CT	Example MRI
Total Anterior Circulation Syndrome (TACS)	• Hemiparesis **AND** • Higher cortical dysfunction (dysphasia or visuospatial neglect) **AND** • Homonymous hemianopia	Usually proximal MCA or ICA occlusion		
Partial Anterior Circulation Syndrome (PACS)	• Isolated higher cortical dysfunction **OR** • Any 2 of hemiparesis, higher cortical dysfunction, hemianopia	Usually branch MCA occlusion		
Posterior Circulation Syndrome (POCS)	• Isolated hemianopia (PCA), brainstem or cerebellar syndromes	Occlusion of vertebral, basilar, cerebellar or PCA vessels		
Lacunar Syndrome (LACS)	• Pure motor stroke **OR** • Pure sensory stroke **OR** • Sensorimotor stroke **OR** • Ataxic hemiparesis **OR** • Clumsy hand-dysarthria	Usually proximal MCA or ICA occlusion		

Figure 1.3 Oxfordshire Community Stroke Project (Bamford) Classification
(adapted by Muir, 2013 from Bamford, 1992; used with permission).

Abbreviations: MCA = middle cerebral artery; ICA = internal carotid artery; PCA = posterior cerebral artery.

1.3.3 Stroke Management

Developments in early detection, such as the Act FAST campaign (Gov.uk, 2014), diagnosis and medical management of stroke using thrombolysis interventions, has culminated in increased survival and outcome rates (RCP, 2017). For ischaemic stroke, mortality is approximately 26% (Andersen *et al*., 2009). For haemorrhagic stroke, the pathophysiological effects are often larger and more sustained, with mortality 10–15% in the first 24 hours and increasing to 50% after three months (RCP SNNAP, 2014; Andersen *et al*., 2009). Further evidence from the UK reports that 13–18% of all strokes are fatal (Lee *et al.*, 2011), with UK statistics reporting 55% of those surviving having slight to severe disability at six months based on the modified Rankin scale (RCP, 2017). This suggests a high rehabilitation burden to healthcare services.

Management of stroke has been influenced by streamlined stroke pathways developed in accordance with NICE guidelines (NICE, 2013b). These guidelines state the need for: early assessment with stroke patients assessed by all the multidisciplinary team within 72 hours; rehabilitation provided via the multidisciplinary team in a specialist inpatient ward; and rehabilitation intervention lasting for 45 minutes a day, five days a week (RCP, 2017; NICE, 2013b). Early supported discharge is frequently used to enable patients to return to the home environment as quickly as possible (RCP, 2017; NICE, 2013b). Rehabilitation outcomes are thought to be maximised in the home environment (Langhorne *et al.*, 2009; Mayo *et al.*, 2000). The final phase of the stroke pathway highlights ongoing long-term support both for social and health care needs (NICE, 2013b). Rehabilitation therapists are critical in providing targeted assessment and management that is both effective and timely at all stages of the stroke pathway.

Stroke rehabilitation of the foot and ankle complex has received limited attention. Key foci of UK national stroke guidelines for rehabilitation (NICE, 2013b) include upper limb rehabilitation and return to function or mobility. There has been less focus on specific lower limb deficits. Despite widely self-reported foot problems (Bowen *et al.*, 2016), the under-representation of lower limb deficits in stroke management to date has been reported to be up to 74% (Jordan *et al.*, 1997). Looking at the foot and ankle specifically, references are made to the treatment/interventions around the foot and ankle such as use of orthoses and electrical stimulation to aid stabilisation of the ankle and prevent foot drop, a commonly observed post-stroke deficit (NICE, 2013b). Foot drop has been reported in 14–20% of people with stroke (Jakubowitz *et al*., 2017; Wade *et al*., 1987). Signposting for a podiatry assessment is recommended (NICE, 2013b). A previous inquiry into stroke services in Wales used evidence from the All Wales Podiatrists Stroke Group for National Assembly of Wales, (2009). This report outlined the importance of podiatry involvement in gait deficits and wound care problems following a stroke (National Assembly for Wales, 2010). As 20% of the stroke population have diabetes, wound management and skin integrity is a significant concern (Jorgensen *et al.*, 1994). Furthermore, the report outlined the need for podiatry involvement in extrinsic and intrinsic foot and ankle problems, naming footwear and foot pain, respectively, to reduce falls risk. This demonstrates the potential need of people with stroke for detailed assessment and management of the foot. Appendix 1

provides a summary of the normal anatomy and function of the foot and ankle. Changes found at the foot and ankle after stroke are explored further in Section 1.3.4.1.

1.3.4 Clinical Presentation

Stroke can cause a wide range of symptoms including motor weakness, sensory disturbances, altered muscle activity, cognitive deficits and perceptual difficulties (Nudo, 2013; Ward 2012; Bohannon, 2007; Bear *et al*., 2007). Motor weakness is the main symptom and has a predominantly one-sided presentation, with the clinical symptoms observed on the contralateral side to the location of the stroke in the brain. This is due to the decussation of neural information in the brain stem (Lindsay and Bone, 2004). The one-sided presentation is termed either hemiparesis (where *hemi* = half and *paresis* = absence) or hemiplegia (where *plegia* = partial reduction) (Stokes and Stack, 2011); however, both sides tend to be affected, as the neural tracts do not entirely decussate and thus cause ipsilateral deficits. In particular, the cortico-spinal tract, which partially decussates (80:20 split at the medulla) (Tortora and Derrickson (2014) leaving the distal regions such as the foot and ankle vulnerable to ipsilateral deficits (Gracies, 2005b; Sheean, 2002). Additionally, anatomical lateralisation of the brain, where specific functional regions, such as Broca's area used for speech production, are found in one hemisphere only, result in some deficits being specific to the hemisphere affected. Thus, functional deficits are dependent on the location and side of the lesion.

Recovery post-stroke is variable and unpredictable in nature (Kwakkel and Kollen, 2013). Natural neurological recovery, i.e. that which is intrinsic and spontaneous, is reported to occur in the first three months and then plateaus the following three months (Kwakkel and Kollen, 2013). Secondary changes will also occur from a combination of disuse, plastic adaptations of mutable tissues and altered cortical activity. As an upper motor neurone lesion (UMNL), stroke is characterised by both positive signs, such as spasticity, and negative signs, such as weakness (Goldstein, 2001). This is attributed to two key types of responses from the nervous system. On the one hand, muscle overactivity or spasticity results from a response to peripheral stimulation or abnormal sensory awareness (Kwakkel and Kollen, 2013; Ward, 2012). On the other hand, negative signs such as weakness is thought to be due to a loss of cortical

stimulation (Kwakkel and Kollen, 2013; Ward, 2012). While there is much debate as to how altered sensori-motor control following a stroke impacts on muscle activity, symptomatically there is a loss of activity being stimulated and activity being inhibited resulting in altered levels of muscle activity (Pandyan *et al*., 2005).

Along with other long-term neurological conditions, impairments found after stroke can be considered using the International Classification of Function (ICF). The ICF classification was first proposed by the World Health Organisation (2001) and defines health status based on levels of impact on: body structure and function (e.g. muscle weakness), activity (e.g. walking) and participation (e.g. attending a social gathering). Applying this to people with stroke, impairments of body structure and function would include muscle weakness, altered muscle activity or spasticity, passive ROM, and foot characteristics. Activity descriptors include mobility, balance, falls, perceptions of fear of falling and impact of stroke on walking. Participation descriptors incorporate involvement in daily life such as accessing the local community and engaging in social events. These constructs will be considered in the following sections.

1.3.4.1 Body Structure and Function

In a large cohort of British people with stroke (n = 1259), Lawrence *et al.* (2001) found that common impairments, three months after stroke, included weakness of lower limb (75%), weakness of upper limb (77.4%), urinary incontinence (48.2%), impaired consciousness (44.7%), dysphagia (44.7%) and impaired cognition (43.9%). Furthermore, 60% had visual problems and many reported fatigue (Lawrence *et al.*, 2001). This demonstrates the wide-ranging nature of impairments following stroke.

A plethora of foot and ankle impairments are reported post-stroke. This includes the following: foot drop due to muscle weakness in the pre-tibial muscles (Carr and Shepherd, 2010), stiffness of movement (Gorst *et al.*, 2016), loss of awareness of the foot when walking (Gorst *et al.*, 2016), altered proprioceptive sensation (Lin *et al.*, 2006), altered light touch and pressure (Bowen *et al.*, 2016) and pain (Bowen *et al.*, 2016; Gorst *et al.*, 2016). Jordan *et al*. (1997) reported an array of foot problems including poor alignment, arterial or venous insufficiency and nail and skin problems. Similar localised issues such as chronic oedema, ulcer formation, corns/callous, lack

of fatty padding and foot deformity have been reported by Laurent *et al.* (2010). A similar array of problems was reported by Jordan *et al*. (1997), which included poor alignment, arterial or venous insufficiency, as well as nail and skin problems. These multisystem impairments found after stroke are also reflected in an inquiry conducted by a podiatrist regarding stroke services in Wales (All Wales Podiatrists Stroke Group for National Assembly of Wales, 2009). Furthermore, a reduced ability to self-care compounds management of associated foot issues, such as difficulties in selecting appropriate footwear and support for acquiring appropriate footwear (Bowen *et al*., 2016). Research by Bowen *et al.* (2016) explored foot problems and issues with footwear in a group of 145 people with stroke and found several self-reported foot problems, itemised in rank order in Figure 1.4 below.

Weakness and limited movement in feet/ankles

Loss of sensation

Drop foot

Low arch/flat foot

Bunion

Ingrown toenails

Corns/callus

Toes curl up/under

Lesser toe deformity

Fungal infections

Problems with nail growth

Arthritis

Cramp

Plantarfascitis

Problems due to differences in leg length/foot size/shoe size

Figure 1.2 Foot Problems Reported by People with Stroke in Rank Order (Bowen *et al*., 2016)

To elucidate stroke-related problems around the foot and ankle, Forghany *et al.* (2011) focused on changes in foot posture and clinical impairments. In a cross-sectional study of 72 stroke participants, they examined muscle strength using the Motricity Index, spasticity using the modified Ashworth scale (MAS), and observed foot posture using the foot posture index (FPI) (for more information on the FPI see Appendix 1, Sections 2.3.1 and 3.4.1). They found that asymmetrical foot posture was common; approximately 30% of participants demonstrated changes that deviated from neutral foot posture with both pronated and supinated postures equally present. Abnormal foot posture was reported to be more frequent in people whose mobility is limited to indoor walking as opposed to community ambulation. This illustrates a link between foot posture and functional ability.

1.3.4.2 Activity: Mobility, Balance and Falls

The complex impairments following stroke, can have a devastating impact on activities such as gait and balance (Tyson *et al.*, 2006; Olney and Richards, 1996b). As such, gait and balance deficits remain among the key problems experienced by people with stroke. *Mobility* enables movement in one's own environment, to carry out everyday activities (Everett, 2010; Webber *et al*., 2010). Walking or *gait* is a specific aspect of mobility defined as a repetitious sequence of limb movement to simultaneously move the body forward while maintaining stance stability (Perry and Burnfield, 2010). *Balance* is a dynamic process requiring sensory perception of body movements, integration of sensorimotor information within the central nervous system, and establishing an equilibrium between destabilising and stabilising forces due to the execution of appropriate musculoskeletal responses (Peterka, 2002). Balance may be referred to as either static or dynamic. Static balance is the ability to maintain postural stability and orientation with centre of mass over the base of support and body at rest; dynamic balance achieves this while the body parts are in motion, for example during reaching (O'Sullivan and Portney, 2014). Balance is often linked with falls. A *fall* is described as an event where an individual inadvertently comes to rest on a lower surface, such as the ground or floor (World Health Organisation, 2012; NICE, 2013a). These descriptions will be used throughout this thesis to frame the research work.

People with stroke have poor mobility, walking ability and balance (Stokes and Stack, 2011; Carr and Shepherd, 2002; Michael *et al.*, 2005). Reductions in gait speed have been reported post-stroke (Severinsen *et al.*, 2011) and have been found to be determinants of long-term outcomes in stroke (Schmid and Rittman, 2007), levels of community ambulation (Lord and Rochester, 2005) and clinically meaningful change in functional recovery (Schmid and Rittman, 2007). Furthermore, gait outcomes impact on participation level tasks such as mobilising around one's own home, accessing local amenities, as well as returning to work (Lord *et al*., 2004; Vestling, 2003). Given the high occurrence of lower limb weakness and the range of impairments which occur following a stroke, it is surprising that following a stroke, up to 75% patients will walk again (Hendricks *et al*., 2002). Although work by Preston *et al.* (2011), which incorporated people with stroke from both acute and rehabilitation settings, was more conservative than Hendricks *et al*. (2002), and reported that 39–60% are able to walk again.

Walking ability at six months after stroke can be predicted using muscle strength in the hemi-paretic leg and sitting balance in the second to fourth week after stroke (Kwakkel and Kollen, 2013). In addition, cardiovascular capacity, balance and paretic limb strength have been found to be associated with walking speed and distance (Patterson *et al.*, 2007). Recent work has found that foot and ankle impairments, such as abnormal foot posture and reduced ankle ROM, have been found to be associated with impaired mobility (Forghany *et al.*, 2014, Forghany *et al.*, 2011). Furthermore, ankle plantarflexor (PF) stiffness and ankle dorsiflexor (DF) weakness have been highlighted as limited progression of gait (Lamontagne *et al.*, 2002). Lamontagne *et al.* (2002) focused on the ankle complex and examined the role of muscle weakness, muscle stiffness and spasticity around the ankle during gait in a cohort of 30 participants who were less than six months post-stroke. They found that the reduced peak ankle PF moments on paretic and non-paretic sides were positively related to gait speed, with 50% of the variance explained by peak activation of a key muscle in the calf complex medial gastrocnemius; however, the evidence is limited. Together these suggest that abnormal foot posture and/or the factors predisposing some people with stroke to it could affect mobility, balance and function.

Up to 80% of people with stroke demonstrate poor balance (Tyson *et al.*, 2006). Deficits, such as difficulty maintaining static balance, responding to external perturbation in both static and dynamic positions and in postures of sitting and standing, are reported to be present after stroke (Tyson *et al.*, 2006; Marsden *et al.*, 2005). Loss of balance may eventually lead to a fall. Falls are common, with approximately 20–50% of people with stroke classed as fallers, in both inpatient and community settings (Walsh *et al.*, 2017; Kunkel *et al*., 2017; Lim *et al.*, 2012; Ashburn *et al.*, 2008; Hyndman *et al.*, 2002). Multiple causes are cited for this: severity of stroke, poor balance, reduced lower limb strength and sensory disturbances, notwithstanding the considerable psychological impact (Walsh *et al.*, 2017; Ashburn *et al.*, 2008; Tyson *et al.*, 2006). Xu *et al*. (2018) found that both impaired mobility and reduced balance are risk factors for falls after stroke (OR 4.36; 95% CI 2.68–7.10; OR 3.87; 95% CI 2.39–6.26). Additionally, motor impairment was also found to have an affect (OR, 1.75; 95% CI 0.98-3.12); however, this was statistically non-significant.

Foot and ankle changes have been reported to contribute to a greater risk of falls, although it is acknowledged further work is required to elucidate the causes for this (Weerdesteyn *et al.*, 2008). Contributory factors are multifaceted and include both *intrinsic* and *extrinsic* foot and ankle factors. Intrinsic factors reported in stroke and linked to falls are a pronated foot posture (Kunkel *et al.*, 2017), trunk and lower limb function (evaluated by the Rivermead leg and trunk score) (Ashburn *et al.*, 2008) and balance control (Ashburn *et al.*, 2008). Extrinsic factors studied have found footwear to influence falls (Bowen *et al.*, 2016). The intrinsic factors will be explored further in Chapter 2.

While there is some information about the role of foot and ankle impairments in gait changes, balance and falls, further work is needed to provide more comprehensive understanding. Relationships between several factors influencing mobility and balance outcomes have been established in older people (Spink *et al.*, 2011). These include ankle PF strength, hallux and ankle inversion range of motion, which explained 25% of the variance in these scores ($p < 0.01$). Whether similar relationships exist in people with stroke is yet to be explored. To date there has been limited exploration of the sequelae of impairments affecting the foot and lower limb and their impact on mobility and balance problems.

1.3.4.3 Participation: Quality of Life, Self Esteem and Employment

Very little work currently exists to demonstrate the specific role of the foot and ankle in participation after stroke. Reports exist about issues with footwear and self-esteem, with perceived physical appearance shown to be a strong predictor of general self-esteem (Howes *et al.*, 2005). As in other conditions, changes in footwear and views on footwear may impact on a person's self-esteem and compliance with interventions after stroke (Naidoo *et al*., 2011). Unsurprisingly, Gorst *et al*. (2016) found negative perceptions associated with altered gait patterns, footwear and orthotic use after stroke.

More generally, previous studies have found that declines in mobility and balance outcomes have an impact on participation level tasks such as mobilising around one's own home, accessing local amenities, as well as returning to work (Vestling, 2003). Park and Kim (2019) found that after stroke weight-bearing distribution and balance outcomes (using the Berg Balance scale) were positively correlated with quality-of-life measures. Similarly, Martino Cinnera *et al*. (2020) found a positive correlation between balance skills and quality of life measures. Muscle strength also contributes to participation; Wang *et al.* (2014) reports that muscle weakness was the most consistent negative predictor of return to work. Cohen *et al*. (2018) also found that post-stroke total paretic limb strength, as well as mobility outcomes (6 m Walk Test and TUAG), were significant predictors of quality of life and reintegration into the community. Westerlind *et al*. (2020) found that 50% of people with stroke return to work within three months and 80% within two years post-stroke. Factors that hindered this included higher stroke severity, increasing age and poorer self-expectation. Fear of falling, which often accompanies or precedes a fall itself, precipitates a downward spiral of decreasing mobility, loss of muscle strength and activity- and participation-limiting behaviours, all of which are reported after stroke (Andersson *et al*., 2008). Thus, disability and the economic consequences are substantial and lower limb function affects not only quality of life and a return to work outcome, but may also influence national economic factors.

1.3.4.4 Summary

This section has described what stroke is and its accompanying symptoms, outlining the significant number of survivors living with long-term mobility problems. It has highlighted the lack of focus on the foot and ankle in rehabilitation research and clinical management. The thesis aims to address gaps in current understanding and the aims and structure of this thesis are described below.

1.4 OVERARCHING AIMS

This thesis addresses the question:

'Are foot and ankle impairments associated with mobility and balance outcomes after stroke?'

This question was established at the outset of the current work, derived directly from the FAiMiS study. In order to answer this research question, two overarching research aims are addressed in two main studies. These two study research aims are as follows:

1. To evaluate the clinimetric properties (feasibility, test–retest reliability, and clinical relevance) of measures of foot characteristics and neuromuscular foot and ankle impairments, for application in people with stroke (**STUDY 1**).

2. To explore whether foot characteristics and neuromuscular foot and ankle impairments identified following stroke differ from normal controls; and whether these are associated with mobility and balance outcomes (**STUDY 2**).

Study 1 evaluates the feasibility, reliability (test–retest) and clinical relevance of protocols for measurement of static foot posture and DFL. It establishes a standardised protocol and methods of analysis of specific DFL variables, including the optimal number of regions to characterise the foot. Additionally, isometric muscle strength testing of the ankle and hallux using a HHD, and a newly developed tool to measure peak ankle and hallux dorsiflexion, are assessed.

Study 2 characterises the differences between a stroke and an age- and gender-matched control population. This provides a clear outline of the prevalence of foot and ankle impairments of people with stroke and whether these differ from those without stroke. Study 2 also ascertains which foot and ankle impairments are associated with mobility and balance outcomes. The knowledge gained from the results of this study should aid assessment and management of the foot and ankle after stroke.

Further specific aims and research questions will be presented following the literature reviews in Chapters 2 and 3.

1.5 THESIS STRUCTURE

This thesis contains five further chapters; the content of these chapters is outlined below. As this programme of research is divided into two linked studies, the structure reflects this. Two literature review chapters covering foot and ankle impairments after stroke and their measurement will be followed by two chapters reporting the methods and results of Study 1 and Study 2.

Chapter 2: Literature Review A: The Impact of Stroke on the Foot and Ankle
In the first literature review, clinical impairments found at the foot and ankle after stroke will be explored, along with their association with mobility and balance deficits. Normal anatomy and biomechanics of the foot and ankle will be presented, followed by an explanation of the rationales for exploring foot and ankle impairments after stroke.

Chapter 3: Literature Review B: Clinical Measures of Foot and Ankle Impairments After Stroke
A second literature review will describe, analyse and critique measurement tools currently in use for quantifying foot and ankle impairments. This will include those used in stroke populations and other neurological populations. Consideration of tools used in similar populations, such as older adults, and how these may be translated into stroke populations, will also be referred to.

Both chapters will highlight the gap within the literature to warrant the current research programme and support the aims and research questions for each study being presented.

Chapter 4: Study 1: The Development, Feasibility and Reliability of Measurement Tools Used to Assess Foot and Ankle Impairments After Stroke

Chapter 4 will report Study 1, including its study design, recruitment, protocols and procedures, development of tools and their feasibility and reliability. It will end with a discussion of the findings prior to Study 2, summarising the measures to be taken forward into the next stage of the research.

Chapter 5: Study 2: Foot and Ankle Impairments as Predictors of Mobility, Balance and Falls Outcomes

Chapter 5 will introduce new protocols and procedures used in Study 2, not previously used in Study 1. The chapter will include a large, detailed results section demonstrating both the prevalence of foot and ankle impairments after stroke and their influence on chosen outcomes. A discussion will be included within the chapter to enable the reader to understand and explore the findings.

Chapter 6: Conclusion

Finally, the conclusion will explore and synthesise the findings across the two studies and examine these considering the current literature and management of people with stroke. Implications for clinical practice will be outlined and avenues for further work suggested.

1.6 SUMMARY

The current thesis is a clinically relevant, evidence-based, robust research programme. The novelty of the work is presented in Section 3.7. It is expected that findings will contribute to the management of the foot and ankle of people with stroke, improving mobility and balance outcomes.

Chapter 2: THE IMPACT OF STROKE ON THE FOOT AND ANKLE

2.1 AIMS AND OBJECTIVES

This chapter will critically appraise foot characteristics, neuromuscular foot and ankle impairments, and any associated mobility and balance deficits after stroke, with the following aim of Study 2 in mind:

To explore whether foot characteristics and neuromuscular foot and ankle impairments identified following stroke differ from normal controls; and whether these are associated with mobility and balance outcomes.

The purpose is to present the critical value of the foot and ankle to everyday activity after stroke, its influence on activity and function, and the limitations of current understanding and research into this area. Thus, this chapter will provide a rationale for the focus on the foot and ankle post-stroke and justification for the research. This chapter will elucidate the following key points: firstly, the foot and ankle characteristics and impairments after stroke and which ones will be explored and used to form the focus of this research; secondly, what current and past literature has ascertained and where the gaps in knowledge are; and thirdly, whether these impairments hold promise of being useful clinical indictors of post-stroke mobility and balance.

2.2 LITERATURE REVIEW STRATEGY

2.2.1 Questions Guiding the Search Strategy

Chapter 2 is derived from literature identified in searches guided by the following two questions. The questions were based on the aim of Study 2 referred to above.

1 *What is the prevalence of clinically measurable foot characteristics and neuromuscular impairments found after stroke: specifically, static foot posture, toe deformity, DFL, isometric muscle weakness, joint ROM and spasticity?*

2 *Are these clinically measurable foot characteristics and neuromuscular impairments associated with mobility, balance and falls outcomes?*

2.2.2 Search Strategy

Two searches were conducted to answer the above questions and inform the literature review. Search engines PubMed and Google Scholar were utilised, as well as scientific databases BMJ clinical evidence, CINAHL, EBSCO, EMBASE, MEDLINE, OVID, PEDro, PLoS, and PSYCHINFO. The search terms used are shown in Appendix 2. Search MeSH headings and Boolean logic were employed using AND, NOT and OR. Titles and abstracts were reviewed by the researcher, AR, and all relevant literature (full papers/conference reports) was obtained to review in full. Reference lists were also searched for eligible papers. To evaluate study quality, Critical Appraisal Skills Programme (CASP) checklists (CASP, 2019) appropriate to the study design were used to inform critical evaluation of the literature. The checklists helped to ascertain the application of the study design including participant recruitment, bias, confounding factors, follow up, as well as results and their application to the literature review. The use of the checklists was not formally recorded as the intention was not to conduct a systematic review. The searches took place between February 2013 and September 2018. Sources were selected from the 1990s until 2018. This was to ensure that seminal work and developments in instrumentation and measurement of foot and ankle characteristics could be appraised. Full search details are found in Appendix 2.

2.2.3 Inclusion and Exclusion:

Inclusion of papers was based on Population, Intervention, Comparison, Outcome, Study type (PICOs) (Akobeng, 2005):

- Population: adult stroke survivors (three or more months post-stroke), adults with neurological condition, older adults[2];
- Intervention: None;
- Comparison: None/control group;
- Outcomes: impairments as specified in question 1 and valid and reliable outcomes related to gait and/or balance and/or falls, for example walking speed;
- Study type: cohort, observational, case control, cross-sectional, repeated measures.

2.2.4 Key Papers

The papers identified in the literature searches and used within this literature review are summarised in Table 2.1 and organised by impairment categories. Appendix 3 shows the full table of literature identified and included where relevant.

[2] *If no studies were found within a population the search was expanded to include older adults without any neurological deficit (> 65 years) and in some cases children with neurological deficits (e.g. cerebral palsy).

Table 2.1 Key Papers from Literature Search 1 and Search 2

Impairment	Author and date	Study design	No. and condition of participants	Relevance	Key results
Static foot posture	Forghany *et al.* (2011)	Cross-sectional	*n* = 72 stroke Age: 68.3 ±12.6 years TSS: 16.4 ±53 months	I + F	Using age-adjusted FPI scores[3], 30% of participants deviated from normal posture on the more-affected side: • pronated (16%) • supinated (13%) Abnormal foot posture more frequent in people limited to indoor walking, FAC ($p < 0.01$).
	Kunkel *et al.* (2017)	Cross-sectional	*n* = 23 stroke Age: 75.09 ±7.57 years TSS: 8 years (±6.38) *n* = 16 controls, Age: 73.44 ±8.35 years	I + F	This study explored differences between (eight) foot and ankle characteristics of stroke patients and healthy controls and whether these foot and ankle problems differ between stroke-fallers and non-fallers. Foot posture: • Greater pronation in stroke (compared to controls) ($p = 0.08$) (8 FPI v. 4.5). • Greater pronation in fallers (compared to non-fallers) ($p = 0.027$).
Toe deformity	Kunkel *et al.* (2017)	Cross-sectional	(See entry above)	I + F	Toe deformity: HV found in 57% stroke and 81% controls, no differences found between fallers ($n = 12$) and non-fallers ($n = 11$) ($p > 0.05$).

[3] FPI = foot posture index, age-adjusted scores (Section 4.3.1.1, Table 4.3).

Impairment	Author and date	Study design	No. and condition of participants	Relevance	Key results
	Laurent *et al.* (2010)	Prospective	*n* = 39 stroke Age: 58.4 years TSS: 0 months	I + F	46% (18/39) of people with a unilateral stroke, who demonstrated active toe clawing during standing or walking up to three months post-stroke. 15 out of 18 (83%) regained average functional capacities (Barthel[4]: 30–70, PASS[5]: 15–33, FAC[6]: 3–4) and were significantly linked to equinus and/or varus foot ($p < 0.0001$).
	Yelnik *et al.* (2003)	Case series	*n* = 450 stroke Age: 51.7 ±8.8 years (*n* = 11) TSS: from admission to hospital	I	Hitchhiker's Toe is seen in approximately 2% (11/450). Of these 11: • 36% had foot pain (4/11), • 100% had shoe difficulties, e.g. difficult to put on (11/11), • 55% had abnormal posture of the foot (6/11).
Plantar Pressure Analysis	Meyring *et al.* (1997)	Cross-sectional/ cohort study; empirical descriptive study	*n* = 18 stroke Age: 50.2 ±16.4 years TSS: not specified *n* = 111 control Age: 27.2 ±8.4	I	Peak pressures in the stroke group were found to be statistically significantly different from the control group (retrospective cohort of 111) for 3rd and 5th MTH (where 3rd MTH 286 (173) kPa stroke v. 361 (162) kPa control, and 5th MTH 150 (l00) kPa stroke v. 213 (125) kPa control, $p < 0.05$).

[4] Barthel Index used to evaluate motor impairment of the leg and patients' functional abilities.
[5] PASS = postural assessment scale for stroke patients to evaluate balance function
[6] FAC = Functional ambulatory classification to evaluate mobility function.

Impairment	Author and date	Study design	No. and condition of participants	Relevance	Key results
					Hemiparetic cohort was stratified according to spasticity rating using the AS[7] and found only peak pressures for AS = 2 at the 3rd MTH were found to be significantly different (AS 0: 395 (163) kPa; AS 1: 275 (144) kPa; AS 2 146 (l00) kPa, $p < 0.05$). Overall, lower peak pressures were found under the lateral forefoot ($p < 0.05$).
	Forghany *et al.* (2015)	Cross-sectional	$n = 20$ stroke $n = 15$ controls *Age and TSS data not available.*	I + F	People with stroke bore greater pressure on the affected side through the lateral heel and lesser toes ($p = 0.01$) and less through the medial and central fore foot ($p = 0.05$) areas than healthy controls. Regression analysis demonstrated that those with higher medial heel pressures were more likely to be household walkers (odds ratio = 1.11, $p < 0.05$).
	Mickle *et al.* (2011b)	Cohort	$n = 312$ older people, fallers HV ($n = 36$) Age: 71.9 ±6.7 years HV control ($n = 36$)		Altered plantar loading profiles in those with a history of falls (toe deformities contributed to altered plantar pressure distribution with higher pressure found in the location of the deformity, e.g. HV had increased over first and second metatarsals) reported higher PPP under second–fifth metatarsals in those with lesser toe deformities.

[7] Ashworth scale (AS) = 0–2 rating sale for severity of spasticity

Impairment	Author and date	Study design	No. and condition of participants	Relevance	Key results
			Age: 71.9 ±6.6 years LTD (n = 71) Age: 73.2 ±6.9 years LTD control (n = 71) Age: 73.1 ±6.9 years		PPP: statistically significant differences ($p < 0.05$) were found between HV and controls at 1st MTH, 2nd MTH and between LTD and controls at 2nd MTH, 3rd MTH, toes 2 and toes 3–5. Almost all PP were higher in the toe deformity group (excluding HV toes 3–5). PTIs were also explored: statically significant differences ($p < 0.05$) found between HV v. control, at 1st MTH; and between LTD v. control at 2nd MTH, 3rd MTH, toes 2 and toes 3–5.
Muscle Weakness	Lamontagne *et al.* (2002)	Cross-sectional	n = 30 stroke Age: 57.8 ±10.8 years TSS: 44–153 days n = 15 healthy controls Age: 59.1 ±9.8 years	I	Muscle weakness during walking using 3D motion analysis, force plate analysis, electromyography and isokinetic dynamometry. Reduced peak ankle PF moments during the stance phase of gait, reported on both paretic and non-paretic sides, with paretic sides demonstrating greater deficits. Swing phase peak DF angle tended to be reduced (not significantly) on the paretic side of the patients compared with control values. This reduction was neither associated with excessive antagonist coactivation nor to PF hyperactive stretch reflexes, but rather to an increased PF passive stiffness.
	Dorsch *et al.* (2012)	Cross-sectional observational	n = 60 stroke Age: 69 ±11 years TSS: 1–6 years	I + F	Muscle strength (N) measured by HHD: • ankle PF 93 ±53 (0–239), • ankle DF 66 ±37 (0–189), • ankle invertors 66 ±41 (0–158), • ankle evertors 55 ±40 (0–136). Positive association with walking speed: • ankle DF (r = 0.50, p = 0.00),

Impairment	Author and date	Study design	No. and condition of participants	Relevance	Key results
					• ankle PF ($r = 0.29$, $p = 0.03$), • ankle evertors ($r = 0.33$, $p = 0.01$). Found that (together with hip flexor strength) ankle dorsiflexion accounted for 31% of the variance found in walking speed ($p < 0.01$) with poor to moderate associations with ankle dorsiflexion, plantarflexion and eversion and walking speed.
	Dorsch *et al.* (2016)	Cross-sectional observational	$n = 60$ stroke Age: 69 ±11 years TSS: 1–6 years $n = 35$ controls Age: 65 ±9 years	I + F	Evaluated maximal isometric strength of 12 muscle groups in lower limbs using a HHD. The affected lower limb of the participants with stroke was significantly weaker than that of the control participants for all muscle groups ($p < 0.01$). Strength (adjusted for age, sex and body weight) was 48% (range, 34%–62%) of that of the control participants. The most severely affected muscle groups were hip extensors (34% of controls), ankle DFs (35%), and hip adductors (38%), and the least severely affected muscle groups were ankle invertors (62%), ankle PFs (57%) and hip flexors (55%). The intact lower limb of the participants with stroke was significantly weaker than that of the control participants for all muscle groups ($p < 0.05$) except for ankle invertors ($p = 0.25$). Strength (adjusted for age, sex and body weight) was 66% (range, 44%–91%) of that of the control participants. The most severely affected muscle groups were hip extensors (44% of controls), ankle DFs (52%) and knee flexors (54%).

Impairment	Author and date	Study design	No. and condition of participants	Relevance	Key results
Reduced ROM	Schindler-Ivens *et al*. (2008)	Cohort	*n* = 17 chronic hemiparetic stroke Age: 58.7 ±9.0 years TSS: 6.3 ±4.5 years *n* = 15 able-bodied participants Age: 51.9 ±14.5 years	I	Evaluated ankle dorsiflexion passive ROM among other lower limb ROM using a biodex dynamometer. Ankle DF ROM was 12.78° in the paretic limb and 15.28° in the non-paretic, although this was not significantly different from controls (11.55°). Ankle DF stiffness, as a derivative of maximum angle and torque required, was 0.61 in the paretic limb and 0.57 in the non-paretic limb. This was the highest reported stiffness value evaluated, however, no significant differences were found between any variables.
	Lamontagne *et al.* (2000)	Cross-sectional descriptive	*n* = 14 stroke Age: 54.7 ±10.9 years TSS: 93.7 ±26.4 days *n* = 11 healthy controls Age: 50.6 ±11.6 years	F	Paretic side, passive stiffness contributed more (16.8%; range 2.9–49.6%) to total PF stiffness during gait compared ($p = 0.01$) with both the nonparetic side (7.3%) and control values (5.9%). Cause: large muscle tendon passive stiffness, a decreased active muscle contribution, or both. The contribution of passive stiffness was not significantly ($p > 0.05$) related to gait speed in both the patients and the controls.
	Kunkel *et al.* (2017)	Cross-sectional	(See previous entry)	I + F	Evaluated first MTPJ ROM in people with stroke and found this to be significantly reduced ($p < 0.025$) in comparison to age-matched controls; however, this was not found to relate to falls.

Impairment	Author and date	Study design	No. and condition of participants	Relevance	Key results
Spasticity	Watkins *et al.* (2002)	Cohort study	*n* = 106 stroke Age: 69.9 ±11.3 years TSS: 12 months	I + F	Increased muscle tone (spasticity) was present in 29 (27%) and 38 (36%) of the 106 patients when measured using the MAS and TAS, respectively. Combining the results from both scales produced a prevalence of 40 (38%). Those with spasticity had significantly lower Barthel scores at 12 months ($p < 0.0001$).
	Lin *et al*, (2006)	Cross-sectional	*n* = 68 stroke Age: 61.69±13.97 years TSS: 3.91 ±5.87 years	I + F	Spasticity index (%/l·s^{-1}) 8.56 ±6.72 (range 0.49–35.55). Passive stiffness (deg): unaffected 4.52 ±4.86 (range 0.00–15.01) v. affected 5.48 ±4.72 (0.00–17.82), no significant difference between sides ($p = 0.41$). Dynamic ankle spasticity inputted into regression analysis was the most important determinant for gait spatial symmetry $R^2 = 0.53$ ($p < 0.001$).
	Hsu *et al.* (2003)	Descriptive analysis of convenience sample	*n* = 26 Stroke Age: 54.2 ±10.9 years TSS: 10.3 ±12.0 months	I + F	Spasticity of the affected PFs was the most important independent determinant of temporal and spatial gait asymmetry during comfortable-speed walking ($R^2 = 0.76$ for temporal asymmetry; $R^2 = 0.46$ for spatial asymmetry) and fast-speed walking ($R^2 = 0.75$ for temporal asymmetry; $R^2 = 0.45$ for spatial asymmetry).

Abbreviations: TSS = time since stroke; Relevance: I = impairment or F = function; DF = dorsiflexor; FAC = functional ambulatory category; FPI = foot posture index; HHD = hand-held dynamometer; HV = hallux valgus; LTD = lesser toe deformity; MAS = modified Ashworth scale; MTH = metatarsal head; MTPJ = metatarsal phalangeal joint; PF = plantarflexor; PP = peak pressure; PTI = pressure–time integrals; ROM = range of motion; TAS = tone assessment scale.

2.3 FOOT CHARACTERISTICS

Foot characteristics can be considered as static and dynamic components; static components will be explored first.

2.3.1 Static Foot Posture

Static foot posture describes the way in which the foot is held by both soft tissues and bony structures in specific positions. Typically, this is done in standing. Foot posture type may determine muscle activation in the lower limb during walking and running in people without neurological disease (Murley *et al*., 2009). The FPI developed by Redmond (2005) is a measure which is widely utilised to characterise the foot in an upright weight-bearing static position. It categorises the foot into one of five types: highly supinated (−12 to −5), supinated (−4 to −1), normal (0 to +5), pronated (+6 to +9) and highly pronated (10 to 12), using six observable foot characteristics, as shown in Appendix 1 and Section 3.4.1.

The FPI has been used in three research studies to describe static foot posture after stroke (Forghany *et al*., 2011, Jang *et al*., 2015 and Kunkel *et al*., 2017). Two papers, Jang *et al*., 2015 and Kunkel *et al*., 2017, reported FPI using the total score (−12 to 12). Jang *et al.* (2015) compared three static foot posture tests including the FPI in a group of 31 people with stroke. They found mean FPI scores of −0.25 and 1.74 for paretic and non-paretic sides, respectively, which were statistically significant from the score of 2.12 reported for the 32 control participants ($p < 0.05$). There were some concerns about the statistical approaches that did not account for the nature of the FPI data and therefore their findings should be treated with some caution. Kunkel *et al.* (2017) explored foot problems after stroke in a cross-sectional study of 23 people with stroke and compared them with 16 control participants. They used the median FPI total score and found greater pronation was demonstrated when compared to healthy control groups (FPI score 8 v. 4.5, $p = 0.008$) with no significant difference between sides in the stroke group. The differences in total FPI scores between Jang's and Kunkel's work may have been influenced by the older group (63.4 years v. 75 years), as age is known to increase pronated foot types in healthy older adults (Menz, 2015). In a cross-sectional study of 72

people with stroke, Forghany *et al.* (2011) explored the frequency and nature of static foot posture after stroke. They found altered static foot posture using the FPI; their scoring used an age-adjusted total score and abnormal/normal foot posture categories (Section 3.4.1 and 4.3.1). Asymmetry between feet was reported in 30% of participants. Findings demonstrated deviations from typical posture on the more-affected side with both 'abnormally' pronated (15%) and supinated (13%) postures almost equally present. Whether these findings differ to Jang's or Kunkel's cannot be appraised as no median total scores were presented in Forghany's work.

Forghany *et al.* (2011) also explored static foot posture in relation to clinical impairments and functional ability. They reported that 'abnormal' pronated/supinated foot posture was found to be more frequent in people whose mobility was limited to indoor walking as opposed to community ambulation, as reported by the functional ambulatory category (FAC)[8] ($p < 0.01$). Thus, an 'abnormal' foot posture is associated with reduced indoor walking suggesting a potential link between foot posture and functional ability (Forghany *et al.*, 2011). Further insight into whether these pronated and supinated foot postures are found in indoor walkers may be indicative of a severe stroke, as the level of disability after stroke has been shown to limit walking ability (Aaslund *et al*., 2017); however, whether severity of stroke or level of disability played a role in total scores recorded by Jang *et al*. (2015) is not clear as the functional capacity of the participants was not reported, and therefore a comparison cannot be made. Kunkel *et al*. (2017) evaluated FPI in subgroups of fallers ($n = 12$) and non-fallers ($n = 11$). Fallers had greater pronation than non-fallers ($p = 0.027$), suggesting a potential link with dynamic balance. No specific mechanisms were postulated by the authors, however the association with functional outcomes is of clinical importance, especially as functional deficits are often reported after stroke and limit participation (Walsh *et al*., 2017). Forghany *et al*. (2011) conducted a thorough analysis which explored relationships with muscle weakness or spasticity but found no association. Age was an independent predictor of abnormalities ($p < 0.001$), explaining 24% of a total 37% variance by all demographics; notably, the average age was 68.3 years. Jang *et al.* (2015) found that with more severe spasticity, measured by MAS, greater supination (i.e. a more negative FPI score) was present

[8] Functional Ambulatory Category used to classify walking ability, (Appendix 11: Functional Ambulatory Classification (FAC)).

($r = 0.78$). This change in FPI score may demonstrate that foot posture changes arise alongside spasticity, yet Forghany's work would not support this. Whether spasticity or other neuromuscular deficits are key contributors to these structural changes, is as yet unclear.

Therefore, so far, the evidence demonstrates that static foot posture is altered after stroke and results in functional consequences (Kunkel *et al*., 2017; Jang *et al.*, 2015; Forghany *et al.*, 2011). The type and role of static foot posture may be crucial to characterising the foot after stroke and may focus clinical management of functional goals.

2.3.2 Toe Deformity

Toe deformities of the hallux or lesser toes are commonly observed as part of a clinical foot assessment, where they are often found to lead to functional deficits and footwear problems (Menz, 2015; Mickle *et al.*, 2009). Toe deformities are frequently observed in older people (Menz, 2015; Mickle *et al.*, 2009), where it is thought their presence is due to age-related muscle weakness and imbalance (Menz, 2015). Deformities include: hallux valgus (HV), defined as displacement of the hallux toward the midline of the foot at the metatarsal phalangeal joint (MTPJ); claw toe/s, defined as flexion of both the MTPJ and interphalangeal joints (IPJs) in the lesser toes; and hammer toe, defined as flexion of the IPJs of the lesser toes (Apley and Solomon, 2010). However, there is some evidence of exploring their presence in people with stroke.

2.3.2.1 Hallux Valgus

Hallux valgus may arise due to genetics, type of footwear, pes planus, arthritic or neurological origin (Fraissler *et al*., 2016). HV was evaluated by Kunkel *et al*. (2017) in 23 people with stroke and 16 healthy controls as one of eight selected foot characteristics. HV was assessed using the Manchester scale, which evaluates hallux position ranking it from not present, mild, moderate or severe using clinical photographs of the hallux (Section 3.4.1). Kunkel and colleagues (2017) found that 57% of people with stroke had HV (median score 2, range 1–4), whereas 81% of controls had HV (although they had the same median score 2, range 1–4); however, this was not a statistically significant

difference ($p > 0.05$), thus leading to the conclusion that this deformity arose due to age rather than stroke. This would appear plausible, however Mickle *et al*. (2009) found moderate to severe HV in only 12% (36/312) of their cohort of older people. Moderate to severe categories were not separately analysed in the Kunkel paper, limiting comparisons. Kunkel *et al*. (2017) also explored differences between the presence of HV in stroke fallers ($n = 12$) versus stroke non-fallers ($n = 11$) but did not find any differences. Spink *et al*. (2011), in their cross-sectional study of older people, similarly found that HV was present in 122/305 (40%) and affected function, with statistically poorer performance on lateral stability and coordinated stability tests ($p < 0.05$). Therefore, HV does not appear to directly influence function after stroke; rather it is related to older age when it does appear to influence function. Whether this is the case with other toe deformities found after stroke is not clear.

2.3.2.2 Toe Clawing

Toe clawing is thought to result from altered modulation of the foot grasp reflex and long toe flexor muscle overactivity (Laurent *et al.*, 2010; Barnes *et al.*, 2003) as a cutaneous response to normal sensory input (Manfredi *et al*., 1975). Cohen and Iannone (1967) originally described it as:

> *"an involuntary plantar flexion of the toes which continues for many seconds after withdrawal of an evoking stimulus is occasionally observed in patients with diffuse brain lesions or focal lesions involving the frontal lobe".*

No updated definition exists. In their prospective study, Laurent *et al*. (2010) evaluated incidence of toe clawing along with presence of equinus or varus foot deformity and functional activities using the Barthel Index. Toe clawing was reported in up to 46% (18/39) of people with a unilateral stroke, who demonstrated active toe clawing during standing or walking up to three months post-stroke (Laurent *et al.*, 2010). Interestingly, this was significantly linked with equinus and/or varus foot deformity ($p < 0.0001$): 83% regained functional activity. Yet this study was focused on the acute stages after stroke, up to three months post-stroke. The association of toe clawing with disease severity was not explored and remains an area for research. Reynard *et al*. (2009) reported frequent

foot dysfunction during the swing phase of gait. Using a group of 20 people with varus foot deformity during swing phase, the researchers evaluated participants with video analysis and surface electromyography. They observed 13/20 (65%) with combined foot varus, ankle plantarflexion and claw toes; 5/20 (25%) with foot varus and ankle plantarflexion and 2/20 (10%) with foot varus dysfunction only. Notably Reynard's sample did not state the total range of time since stroke although the average time was 21 months (interquartile range 43). This demonstrates a more chronic population than the work by Laurent *et al*. (2010) suggesting this phenomenon may persist sometime after the initial stroke lesion. No other studies report toe clawing prevalence in stroke; however, an old study in 100 people with spinal cord injury or multiple sclerosis by Rivera-Dominguez *et al.* (1979) found toe clawing and/or pes cavus (an exaggerated longitudinal arch) was present in 10% of people and suggested spasticity and ankle PF spasms as the cause. Similar findings to Rivera-Dominguez are unlikely to be found after stroke as, due to the altered pathological drivers, the spasticity observed is different, originating in the spinal cord rather than cortical areas.

In a group of 312 older people, Mickle *et al.* (2009) found that toe deformity was associated with hallux muscle strength. Participants who displayed moderate–severe HV ($n = 36$) or a lesser toe deformity, such as claw/hammer toes ($n = 74$), had significantly reduced strength of the respective toe muscles, i.e. hallux and lesser toes, compared to those without these foot problems ($p < 0.01$); however, in a diabetic population with claw toe deformity, an intrinsic muscle atrophy score based on MRI images was not found to correlate with toe deformity (Bus *et al.*, 2009). Mickle's work also found that severe HV and lesser toe deformity was more likely in fallers (relative risk [*RR*] = 2.36; 95% confidence interval [CI] = 1.03–5.45; *RR* = 1.32; 95% CI = 1.04–1.69; $p < 0.01$, respectively); those with lesser toe deformity were 2.1 times more likely to fall ($p = 0.01$) (Mickle *et al.,* 2009). In a later published work, Mickle *et al.* (2011b) evaluated toe deformity in relation to gait and balance in the same cohort of 312 older people (as in the study reported in 2009); they stated significantly altered variability of gait speed for lesser toe deformity versus controls, 6.2 ±2.6 cm^{-1} compared to 5.1 ±2.0 cm^{-1} ($p < 0.05$). Yet this was the only spatiotemporal aspect of gait (1 out of 12 measured) which changed. As toe clawing in older adults and diabetics has a different pathophysiology than that found after stroke, parallel findings are unlikely. Yet, understanding the presence of toe clawing

after stroke may have useful functional clinical relevance in the management of impaired mobility, falls and balance deficits found after stroke.

2.3.2.3 Hitchhiker's Toe

Hitchhiker's toe (HHT) is a toe deformity described as hyperextension of the first MTPJ caused by prolonged overactivity of the extensor hallucis muscle (Yelnik *et al.*, 2003). This hyperextension of the extensor hallucis longus muscle may be found following multiple conditions disrupting sensorimotor control of the central nervous system (Gaber *et al*., 2011); however, it is rarely observed or described after stroke (Yelnik *et al*., 2003). It is elicited by pressure to the sole of the foot even when the participant is supine, similar to the Babinski sign (Yelnik *et al*., 2003), and/or a tonic ambulatory foot response, which occurs while walking or standing (Iwata *et al.*, 2003). Allart *et al*. (2015) found a range of triggering features in a study of 20 neurological participants with extensor hallucis longus overactivity. They categorised HHT as permanent, or intermittent when either standing or walking. The severity of HHT varied from mild to severe, but no reputable scale was utilised to classify this.

Specialist centres in the UK treating HHT reported 62% (18/29) of cases related to stroke pathology (Gaber *et al*., 2011). Similarly, in France, Allart *et al*. (2015) reported 60% (14/20) of their HHT participants had a diagnosis of stroke. Despite this HHT is rare, with approximately 2% (11/450) of people with stroke being affected (Yelnik *et al.*, 2003). The HHT deformity is clearly disabling; Yelnik *et al*. (2003) reported multiple accompanying effects including foot pain 36% (4/11), shoe difficulties 100% (11/11) and abnormal posture of the foot 55% (6/11). Additionally, Gaber *et al*. (2011) found that 55% (16/29) of their participants also had associated foot drop or equino varus deformities. This may suggest that HHT is often present alongside other toe and foot deformities, similar to that found by Laurent *et al*. (2010) for toe clawing; however, work by Gaber *et al*. (2011) was not conducted exclusively in people with stroke. Apart from the work by Yelnik *et al.* (2003), Gaber *et al*. (2011) and Allart *et al.* (2015), few reports of HHT after stroke currently exist; hence its association with mobility and balance outcomes has not been explored.

The toe deformities reported here may influence function; recent research in older adults has identified toe clawing as a risk factor for impaired balance (Spink *et al*., 2011; Mickle *et al*., 2009) and walking ability (Mickle *et al.*, 2011a). While caution is necessary with the extrapolation of these findings to people with stroke, its evidence suggests that further research is required to inform our understanding of altered muscle activation of the foot and ankle post-stroke. Furthermore, while toe deformities have been associated with abnormal reflexes and foot positions (Iwata *et al.*, 2003; Laurent *et al*., 2010), reports remain anecdotal and descriptive in nature. Whether deformities are due to passive contracture and/or active reflex activity has not been ascertained. (It is acknowledged that this cause of toe deformity may be neuromuscular in nature and therefore the presence of toe deformity may be considered part of a non-neural presentation of stroke or may also be attributed to altered sensorimotor control.) Further work is required to determine the link between spasticity after stroke and its impact on function, and to establish and differentiate the contributory factors involved.

2.3.3 Dynamic Foot Loading

Alongside changes to foot posture and toe deformity, DFL is an emerging interest. Evaluation and reporting of DFL using plantar pressure analysis has advanced clinical understanding of the foot in recent decades (Orlin and McPoil, 2000). The use of clinical measures, such as plantar pressure analysis, offers a means to evaluate the function of the foot in healthy and diseased populations (Giacomozzi, 2011). Measurement of foot loading aims to characterise how the individual structures of the foot are loaded throughout the gait cycle using specially designed pressure-sensitive mats (Orlin and McPoil, 2000). Potential mechanisms for how dynamic foot structure and function may be related to changes in plantar pressure were proposed by Morag and Cavanagh (1999) based on a study of 55 healthy participants (20–70 years old) walking barefoot at normalised walking speed (0.78 $m \cdot s^{-1}$) across a pressure mat (Figure 2.1). They found that foot structure and function predicted 50% variance in peak plantar pressure[9] (PPP) and peak force[10]. PPP under the mid-foot and first metatarsal head (MTH) was predicted by foot structure, e.g. calcaneal inclination, age, weight, soft tissue, arch index; whereas

[9] Peak plantar pressure = the maximal pressure value exerted on a single cell during loading of the foot are recorded.
[10] Peak force = the maximal force value recorded on a single cell during loading of the foot.

both foot structure and function were important for heel and hallux PPP, e.g. gastrocnemius muscle activity, bony alignment, hallux range of motion, amongst others. Figure 2.1 demonstrates both foot characteristics and neuromuscular elements that may be deficient in people with stroke, and thereby influence plantar pressures. This provides

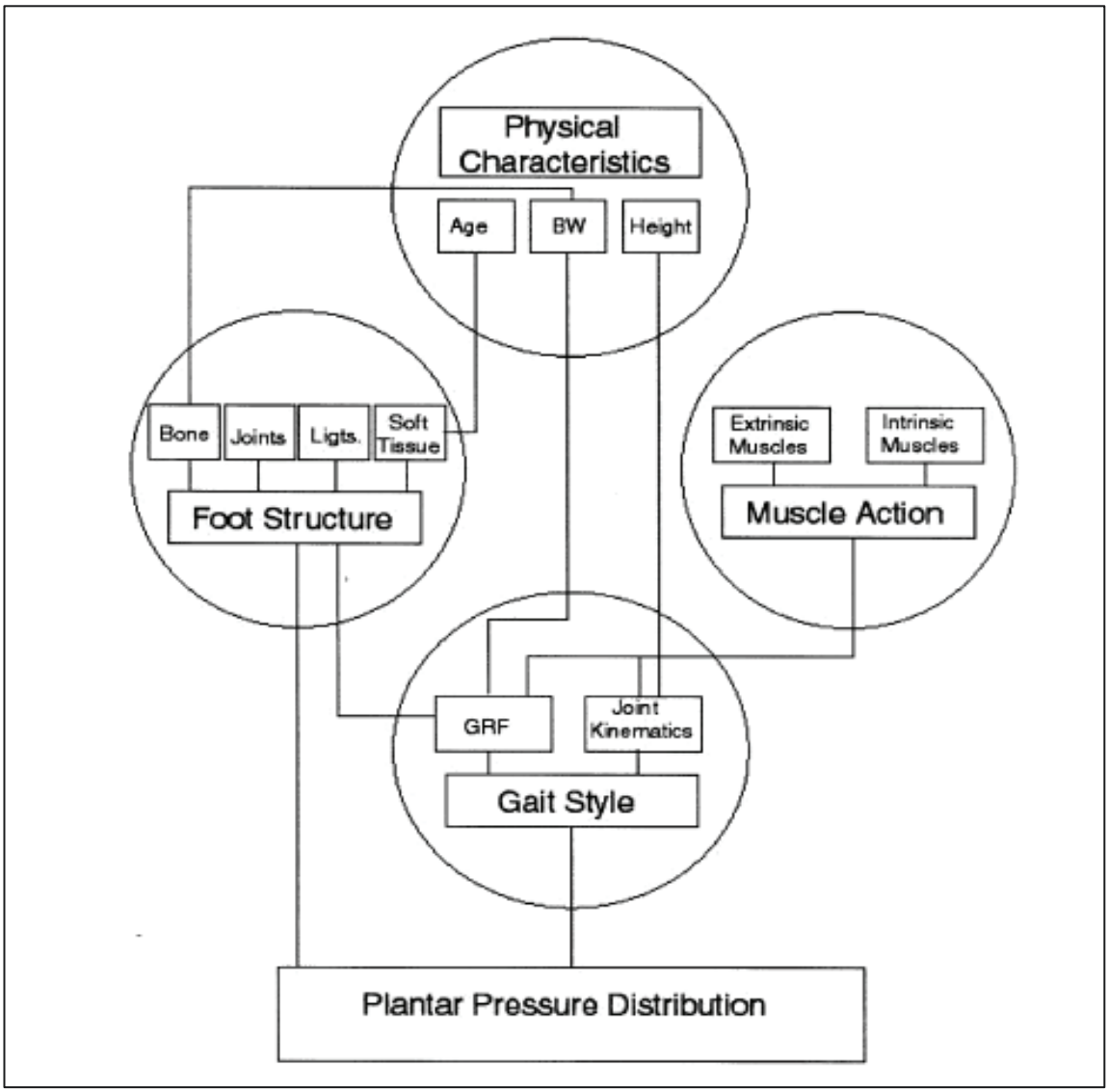


Figure 0.1 Conceptual Model Used to Predict Plantar Pressure (Morag and Cavanagh, 1999)

a theoretical justification for exploring plantar pressure characteristics in this population, despite the work using a non-clinical population.

Evaluating DFL may hold promising clinical relevance within the stroke population, as work conducted in other patient cohorts suggests. Research in rheumatoid arthritis (RA) and people with diabetes has linked altered plantar pressures to reduced functional outcomes (Giacomozzi, 2011). Menz and Morris (2006) conducted a large cross-sectional

trial exploring foot loading characteristics during walking in 172 older people and their relationship to clinical symptoms such as muscle weakness, sensation, pain and falls incidence/history. Overall, 13–53% and 4–40% of variance in maximum force and peak pressures, respectively, were explained by clinical factors such as hallux muscle strength, MTPJ ROM, foot posture and toe deformity. Salient research has also been conducted in older people (> 65 years) with the presence of toe deformity and history of falls (Mickle *et al.*, 2011b). Increased plantar pressures were found during stance phase of gait, with altered plantar loading profiles through the forefoot and toes in those with a history of falls. It was suggested that toe deformities contributed to altered plantar pressure distribution with higher pressure found in the location of the deformity, e.g. HV had increased over first and second metatarsals ($p < 0.01$). Mickle *et al.* (2011b) also reported higher peak pressure under second and third metatarsals and second–fifth toes in those with lesser toe deformities. This may have been due to reduced contact of the toes, as they were pulled back, shifting weight bearing to the forefoot and away from the toes. Interestingly, this was not shifted medially, however results from the rest of the foot regions were not presented or discussed. Therefore, consideration of foot loading using plantar pressure analysis may be crucial to the understanding of foot and ankle impairment after stroke, and any possible association with falls and impaired mobility.

A small number of observational studies evaluating plantar pressure in stroke exist. Some of the earliest work exploring foot loading characteristics during barefooted walking in people with stroke was conducted by Meyring *et al.* (1997). In their empirical, descriptive study, they evaluated dynamic plantar pressure distribution in 18 hemiparetic patients using a capacitive EMED-F01 system (Novel®). Peak pressure values during stance phase of gait during the first step from double support were explored across seven regions of the foot: medial heel; lateral heel; midfoot; first, third and fifth MTHs; and hallux. Peak pressures were found to be statistically significantly different from the control group (retrospective cohort of 111) for third and fifth MTHs (286 ±173 kPa stroke v. 361 ±162 kPa control and 150 ±l00 kPa stroke v. 213 ±125 kPa control, respectively, $p < 0.05$). Overall, peak pressures were lower by 40% under the lateral forefoot on the affected side. The rationale proposed for this was a reduction of vertical force, from weight shifting to the affected side, and a lateral shift during stance favouring medial maintenance of centre of gravity. These are all characteristics frequently observed in walking after stroke (Beyaert *et al*., 2015; Olney and Richards, 1996a). The lower midfoot pressures suggested

an alternative cause whereby increased intrinsic foot muscle activity had potentially resulted in a more rigid foot with a higher arch (Meyring *et al.*, 1997); however, foot posture deformity was not evaluated to establish this. Hillier and Lai (2009)[11] used an in-shoe system to measure plantar pressure in 15 people with stroke. They found that contact pressure (CP) and contact area (CA) values were similar between feet for easier tasks; however, when challenged using harder tasks there was greater pressure on the less-affected foot (4 kPa) compared to the more-affected foot (3.3 kPa). Despite this, areas of high peak CP on the more-affected foot were found for several participants. Similar to Meyring *et al*. (1997), there was a redistribution of contact/weight toward the lateral border of the more affected foot in most, but not all, subjects. Results from this study however were not statistically analysed for interlimb differences.

More recent work conducted in people with stroke includes a cross-sectional study by Forghany *et al.* (2015) who recruited 20 stroke and 15 healthy gender- and age-matched participants to observe plantar pressure using a pressure mat system (TekScan®, F-scan). Their findings differed to those of Meyring and colleagues (1997); they reported that people with stroke bore greater pressure on the affected side through the lateral heel and lesser toes ($p = 0.01$) and less through the medial and central forefoot areas ($p = 0.05$) than healthy controls. No data was presented regarding inter-limb differences. Given these conflicting findings further work is required to determine a consensus in altered foot loading after stroke.

The association between loading and clinical impairments after stroke has been evaluated by Meyring *et al*. (1997). The hemiparetic cohort was stratified according to spasticity rating using the Ashworth scale (AS), where scores range from zero to four. Only peak pressures for AS = 2 at the third MTH were found to be significantly different from the AS = 0 group ($p = 0.05$); however, this analysis only included five and eight participants in each group, respectively, limiting broader generalisations. Despite this, the change in PPP suggests changes in the presence of spasticity after stroke. The forefoot, especially, may be a useful region to evaluate due to its key role during push off in gait. Meyring's work is limited by the use of a retrospective convenience sample of a young control group with a mean age of 27 years compared to the stroke group mean age of 50 years. This

[11] Information for paper found in Table 3.2, Section 3.3.2.

difference in age may have inflated statistical comparisons that may not have been found in an age- and gender-matched control group; however, it emphasises the influence neuromuscular effects, such as spasticity in the foot and ankle, may have on DFL outcomes after stroke and reinforces the use of foot loading characteristics.

Forghany *et al*. (2015) did not explore whether the changes found were a risk to tissue integrity or related to other impairments at the foot and ankle, i.e. spasticity, abnormal foot posture or isometric muscle weakness. They conducted a regression analysis to evaluate the functional relevance of altered plantar pressure loading. They demonstrated that those with higher medial heel pressures were more likely to be household walkers (odds ratio = 1.11, $p < 0.05$). Further criticisms of this work relate to the application of the pressure mat. The regions identified were not justified in terms of their clinical applicability, which is an issue raised by Giacomozzi, who recommends clinical justification should be included in reports of plantar pressure analysis (2011). Additionally, the sampling rate of the plantar pressure mat was 20 Hz, which is below the recommended minimum of 50 Hz therefore reducing the quality of the data capture (Giacomozzi, 2010; 2011). No other work conducted in stroke using pressure mats exists for comparison.

Work looking at centre of pressure (COP) during foot loading using pressure mats in stroke is limited to a few studies, despite a wealth of literature evaluating COP using force plates. Chisholm *et al.* (2011) proposed COP excursion as a way of representing the summative neuromuscular response that controls the centre of mass, which in turn controls forward progression and balance. On a pressure mat, this represents the point at which the line of gravity pierces the floor. In a group of 57 people with stroke, walking 7 m over a pressure-sensitive mat GAITRite® at preferred and fastest speed, Chisholm *et al.* (2011) found asymmetrical AP-COP (AP = anterior–posterior) displacement for 43/57 participants in preference of the non-paretic limb and a positive moderate association between foot and leg function (measured by the Chedoke McMaster Stroke Assessment) and AP-COP displacement: $r = 0.521$, $p < 0.0001$ and $r = 0.485$, $p < 0.001$, respectively. This suggests improved foot and leg function corresponds with increased forward COP translation during stance phase. They also found reduced or absent forefoot COP time indicating limited forward progression and altered foot function during end of stance. Additionally, asymmetry in COP excursion was significantly associated with reduced

forward progression during gait ($p < 0.05$). Lastly, ML-COP (ML = medio-lateral) variability was greater under the non-paretic limb, possibly suggesting difficulty with paretic limb swing phase. As changes were found in the non-paretic side, both limbs may be of importance. Hillier and Lai (2009) also found COP motion was markedly reduced on the more-affected lower limb with a mean of 0.3 cm versus 0.5–3.8 cm for the other lower limb, however with a small sample size and no statistical analysis it is difficult to further analyse these findings alongside Chisholm's. A more recent study by Kim *et al*. (2013) evaluated COP sway using a pressure-sensitive mat (F-Scan) in a group of 36 people with stroke. COP sway improved after a four-week training protocol to strength ankle dorsiflexors and was statistically significantly different between pre- and post-training ($p < 0.01$); however, differences in COP sway amplitude between training conditions were not found ($p < 0.05$). Further work is required to ascertain the clinical relevance of DFL variables, peak pressure and COP excursion in both limbs after stroke.

2.3.4 Links between Static and Dynamic Foot Measures

Static measures of the foot, such as foot posture and toe deformity, are often viewed clinically as useful indicators of dynamic function of the foot which may be measured by plantar pressure analysis. To date, the association between static foot posture measures and dynamic measures such as peak pressures are weak to moderate ($r = -0.17$ to 0.41) in 92 healthy adult volunteers during standing and walking (Jonely *et al.*, 2011). Lower arch foot postures are associated with greater pressures under the hallux and medial mid-foot ($r = -0.25$ to 0.41) and lower pressures under the medial forefoot ($r = -0.10$ to -0.26, $p < 0.05$), with associations stronger in standing (Jonely *et al.*, 2011). Razeghi and Batt (2002) critically reviewed methods of foot type classification and concluded that only combined foot structure and function in dynamic loading closely related to functional behaviour of the foot during locomotion. Some work has explored the links between static and dynamic measures. Sanchez-Rodriguez *et al.* (2012) evaluated whether the FPI can predict dynamic plantar pressures in 10 regions using the Footscan® system. In their sample of 400 healthy subjects, lower pressures were found in the toe regions of supinated feet; conversely higher pressures were found in toe regions in pronated feet ($p < 0.001$). The opposite trend was found for the fifth MTH. Notably, talar head palpation and malleolar curvature did not predict plantar pressures. Talonavicular prominence was the

most influential criterion, predicting 11% of fifth MTH pressure (Sanchez-Rodriguez *et al.*, 2012). Therefore, specific aspects of the FPI are more sensitive at picking up possible plantar pressure changes. Whether this is the case in people with stroke and whether foot posture correlates with foot pressures is currently unknown. Work conducted by Buldt *et al.* (2015) compared a range of static foot measures in 97 healthy adults to ascertain whether these measures predicted dynamic foot posture during barefoot locomotion. While assessing a battery of anthropometric, spatiotemporal and static foot posture measures, these only contributed up to a maximum of 22% of the variance seen in dynamic kinematic outcomes during walking. The FPI was the most significant predictor among the measures, but it did not differ notably from other measures in the amount of variance it could predict. Thus, while other measures are available, the FPI provides an assessment of foot posture in various planes that may indicate specific dynamic changes. Links between static and dynamic measures of foot structure and biomechanics are plausible, although not fully understood (Cavanagh *et al*., 1997). Whether any association exists between static and dynamic measures at the foot in people after stroke is yet to be established. Clinically, these findings may help guide assessment, treatment and management of the foot after stroke.

2.3.5 Summary

Foot characteristics display altered severity after stroke with some associations made with common post-stroke impairments and functional deficits. Overall, abnormal static foot posture (pronation and supination, or asymmetry between feet), toe deformities and altered DFL during gait have been found. Currently, there is limited data available for these characteristics within stroke, and as such it remains an area requiring research, especially as the role of foot contact during weight-bearing tasks cannot be overlooked (Forghany *et al.*, 2011). Overall study quality and strength of evidence varied, with some papers presenting robust findings applicable to the focus on this research; these key papers were highlighted in Table 2.1.

2.4 NEUROMUSCULAR IMPAIRMENTS AT THE FOOT AND ANKLE AFTER STROKE

In older adults, foot and ankle impairments have been shown to be associated with poorer mobility and balance outcomes as well as falls history (Menz et al. 2005; Spink *et al*., 2011; Mickle *et al.*, 2011a); specifically, research suggests reduced hallux muscle strength (Mickle *et al*., 2009; Mickle *et al*., 2011b) and passive ankle ROM (Spink *et al*., 2011) contribute to these changes. Therefore, altered foot function after stroke may be mediated by ankle and hallux muscle weakness, reduced ROM, and by spasticity (Jang *et al*., 2015, Laurent *et al*., 2010). Attention will now turn to these neuromuscular impairments at the foot and ankle regions, aiming to evaluate their severity and influence on function after stroke.

2.4.1 Muscle Weakness

Muscle strength is defined as the ability of a muscle to generate tension in response to an internal or external load, which may be either moving or static (Sharp and Everett, 2010). Muscle strength generation must be enough to resist the mass of the limb speed and direction in which it may be moving and, if applicable, any additional load (Sharp and Everett, 2010). Muscle strength after stroke is frequently diminished or even absent, with its reduction well documented in stroke patients since the 1980s (Bonita and Beaglehole, 1988; Bohannon, 1989; Bohannon, 2007). It is due to the immediate impaired neural activation of muscle or even total denervation from descending motor control arising in the cortex to the corresponding area of the body (Stokes and Stack, 2011). The almost immediate reduction in, or complete loss of, muscle activity leads to *post-stroke weakness,* which comprises of impaired force magnitude and difficulty producing force for function (Patten *et al.*, 2004; Lieber, 2010). Muscle weakness is accompanied by ensuing structural and mechanical changes including reduction in muscle mass, fibre length and pennation angle, and increased tendon compliance, all of which influence force generation (Lieber, 2010). Muscle weakness has been reported in over 70% of people with stroke, apparent as both upper limb (77%) and lower limb (72%) weakness (Lawrence *et al.*, 2001).

Post-stroke weakness is reported as being present bilaterally; being greatest in paretic limbs (Adams *et al.*, 1990; Lamontagne *et al.*, 2002); being greater proximally than distally; and with deficits being greater in lower limb muscles than upper limb muscles (Andrews and Bohannon, 2000). Post-stroke weakness will now be explored, with a focus on the ankle PFs, DFs, invertors, evertors, as well as hallux and foot muscles, and their influence on mobility and balance.

Ankle PF muscle strength is critical for push off and ankle DFs are utilised to achieve ground clearance and foot loading. Both are affected in stroke (Lamontagne *et al.*, 2002; Ada *et al.*, 2003). Weakness of the ankle DF muscles has been reported in 14–20% of people with stroke and is observed clinically as a 'dropped foot' (Ring *et al.*, 2009; Jakubowitz *et al*., 2017). In 55 ambulatory people with stroke, greater motor impairment, PF spasticity and ankle muscle weakness were found in those with dropped foot compared to those without (Chisholm *et al*., 2013). Andrews and Bohannon (2000) evaluated the distribution of static muscle strength impairments in a group of 48 stroke patients in an inpatient rehabilitation setting, testing eight muscle groups bilaterally using hand-held dynamometry at two time points since stroke (initial: 9.6 ±5.8 days and final: 25.9 ±13.5 days). Comparing isometric muscle strength to previous normative data between limbs, they found that static ankle DF muscle strength measured 32.2% of the normative value on the more-affected side (74.9 N m compared to 181.1 N m) and 75.8% of the normative value on the less-affected side. At the final assessment, values were 44.3% for the more-affected side and 83% for the less-affected side (106.2 N m and 198.8 N m, respectively). Thus, significant muscle weakness was observed in ankle DFs, with the effects greatest on the more-affected side. Despite authors often citing marked distal weakness (Bohannon, 2007; Patten, 2004), in the data reported by Andrews and Bohannon (2000), ankle DFs were ranked as second weakest after knee extensors in the lower limb; however, this evidence was with people less than three months after stroke and may not demonstrate ongoing weakness at later stages after stroke.

Research by Lin *et al*. (2006) involving 68 participants 3.91 ±5.87 years post-stroke also used a HHD to evaluate maximal isometric strength of ankle plantarflexion and ankle dorsiflexion. They found that as percentage of body weight, ankle PF strength was significantly different on the more-affected side (37.16 ±19.13 %BW) than the less-affected side (50.04 ±16.63 %BW, $p < 0.000$). Ankle DF strength also showed changes

between limbs: more-affected (22.32 ±13.85 %BW) versus less-affected (34.57 ±9.84 %BW, $p < 0.000$). More recent work by Dorsch *et al.* (2012) in their observational study of a group of 60 people with 1–6 years history of stroke found similar changes. They evaluated lower limb peak isometric muscle strength tested using a HHD, including ankle PFs, DFs, invertors and evertors. They found that the more-affected side isometric muscle strength measurements were as follows: ankle PFs 93 ±53 N (0–239), ankle DFs 66 ±37 N (0–189), ankle invertors 66 ±41 N (0–158), ankle evertors 55 ±40 N (0–136). No comparisons were made with the less-affected side to determine deficits due to the stroke. Additionally, comparisons cannot be made with previous work by Andrews and Bohannan (2000) as measurement units differ (torque, N m, versus force, N); however, in a later report, Dorsch *et al*. (2016) reported strength of ankle PFs, DFs, invertors and evertors of the same cohort as their 2012 paper, with an additional age-matched control group ($n = 35$). They found that the more-affected side was significantly weaker than controls ($p < 0.01$). Represented as a percentage of stroke muscle strength (N m) compared to control group, muscle strength was, in descending order: ankle invertors 62%, ankle PFs 57%, ankle evertors 54%, ankle DFs 35%. Strength deficits were also found on the less-affected side. These values demonstrated the profound nature of distal weakness after stroke, similar to that reported by Andrews and Bohannon (2000). Apart from the work by Dorsch *et al.* (2012) and Dorsch *et al.* (2016), little research is available reporting muscle strength of ankle invertors and evertors. Furthermore, none is available reporting isometric hallux or lesser toe muscle weakness in people after stroke.

Muscle weakness has also been evaluated in relation to other stroke sequelae such as limited ROM and spasticity. Lamontagne *et al*. (2002) evaluated muscle weakness, co-activation and spasticity during gait using 3D motion analysis, force plate analysis, electromyography and isokinetic dynamometry in 30 people with stroke (time since stroke > 6 months) and compared them with 15 healthy controls. They found reduced peak ankle PF moments during the stance phase of gait reported on both paretic and non-paretic sides, with paretic sides demonstrating greater deficits ($p = 0.01$). Swing phase peak tibialis anterior activation was reduced on the paretic side of people with stroke compared with the non-paretic side and controls ($p < 0.05$ and $p < 0.01$, respectively). This reduction was neither associated with excessive antagonist coactivation nor to PF hyperactive stretch reflexes, but rather to an increased PF passive stiffness. The role of muscle stiffness or reduced ROM will be discussed further in Sections 2.4.2 and 2.4.3.

Foot and ankle muscle weakness is reported to influence functional outcomes after stroke including mobility, balance and falls. In particular, using gait kinematics and kinetics, ankle DF weakness after stroke has been shown to have a negative impact on gait speed, by limiting power generation in response to speed increases (Jonkers *et al.*, 2009; Nadaeu *et al.*, 1999). Other studies using a HHD reflect this. Lin *et al*. (2006) used multivariate regression to demonstrate that ankle DF strength was the most important factor determining gait velocity ($R^2 = 0.30$, $p < 0.01$), taking account of other post-stroke clinical impairments. Dorsch *et al.* (2012) found that, together with hip flexor strength, ankle DF strength accounted for 34% of the variance found in walking speed, measured at comfortable speed over a distance of 10 m. Ankle DF strength alone significantly correlated with walking speed, accounting for 31% of the variance ($p < 0.001$). Furthermore, poor to moderate positive associations with walking speed were found for ankle DFs ($r = 0.50$, $p < 0.00$), ankle PFs ($r = 0.29$, $p = <0.03$) and ankle evertors ($r = 0.33$, $p = 0.01$) of specific muscle groups, demonstrating that ankle muscle strength in multiple muscle groups surrounding the ankle influences gait speed Dorsch *et al.* (2012).

The ankle and foot are foundational to balance and control of stability, and of particular importance for the first of three key balance reactions, the ankle strategy (Shumway-Cook and Woolacott, 2011). There are numerous studies evaluating interventions targeting ankle muscle strength to improve balance, but few studies report the association between isometric ankle muscle strength and balance outcomes. Hyndman *et al*. (2002) reported that of 41 community dwelling stroke survivors, 21 reported falling. Of these 21, feet dragging during walking was reported 11 times by fallers as leading to falls, alluding to ankle weakness as a precipitating factor; however, this was not explicitly explored in the study. Kligyte *et al*. (2003) quantified isometric muscle strength using a HHD in the lower limb and evaluated its relationship to dynamic balance outcomes. In 30 people with stroke, they found moderate significant ($p < 0.05$) correlations to the functional reach test with ankle inversion on the unaffected side, $r = 0.53$; ankle eversion on the unaffected side, $r = 0.45$; ankle dorsiflexion on the unaffected side, $r = 0.44$; and ankle plantarflexion on the impaired side, $r = 0.38$. Interestingly, both limbs were similarly correlated with the

TUAG (r = −0.40–0.58) for all four ankle muscle groups evaluated; however, the control group (n = 30 healthy adults) demonstrated moderate to good correlation between ankle muscle groups and the TUAG (r = 0.51–0.86). Therefore, loss of muscle strength would appear to negatively impact on the ability of people after stroke to maintain their balance.

Turning attention to evidence of functional consequences of hallux and toe weakness from older people, aged 65 years or more, Spink *et al.* (2011) reported that strength in the ankle invertors, ankle evertors and the hallux PFs accounted for 25% of the variation seen in the functional mobility outcomes. Hallux PF strength has been shown to impact on gait in older people and as such is a predictor of poor mobility (Menz *et al.*, 2005). The predictive value is less than that found at the ankle PFs in stroke (31%) (Dorsch *et al*., 2012). Yet these studies suggest the possible contribution that smaller muscles of the hallux may have on mobility outcomes after stroke and thus the importance of evaluating this.

2.4.2 Reduced Passive ROM

Limitation in available joint ROM is commonly reported after stroke (Gracies, 2005a; Vattanasilp *et al*., 2000). This restriction in motion is usually influenced by several factors including neural hypertonicity, muscular weakness (neural and non-neural) and soft tissue changes in foot and ankle muscles. Deficits may be in *active* ROM, where muscle contraction moves the limb, or *passive* ROM, where an external force moves the limb (Everett, 2010). Loss of active ROM after stroke arises due to muscle weakness and/or alterations in motor control, such as overactivity of muscle contraction. This results in difficulty moving the foot and ankle through full available *active* ROM. Conversely, *passive* ROM examines the non-neural elements of the foot and ankle joints such as the joint capsule, ligaments and skin changes and swelling (Ryder, 2001). Limited passive ROM may be secondary to soft tissue changes and altered muscle activity reducing the intricate multi-planar biomechanics of the ankle during function. This section will consider the presence and potential functional impact of reduced ankle and hallux passive ROM.

2.4.2.1 Ankle Dorsiflexion/Plantarflexion

Active ankle DF ROM is required to reach 12–22º for normal gait (Weir and Chockalingam, 2007). Despite this, few papers report its severity after stroke, although many document limitations in ROM. Hence, it is a crucial area for consideration after stroke. Schindler-Ivens *et al*. (2008) evaluated ankle dorsiflexion passive ROM along with other lower limb joint ROM in a group of 17 chronic hemiparetic stroke and 15 able-bodied participants. They found mean ankle DF ROM was 12.78° in the paretic limb and 15.28° in the non-paretic; this was not significantly different from the controls (11.55°). Lin *et al.* (2006) explored PF passive stiffness in relation to function in 68 post-stroke participants. They reported similar average *passive* ankle DF ROM, 15.39° on the paretic side and 17.56° on the non-paretic side, which were within the functional range for gait. No statistical comparison of actual ROM available between limbs was reported and only standard error was reported. Yet, Lin and colleagues postulated that the reduction in ankle DF ROM may be due to stiffness and spasticity of PFs, ankle joint pathology and DF weakness (Lin *et al.*, 2006). Interestingly, both papers report mean values that would allow normal gait (Weir and Chockalingam, 2007), although it remains unclear to what extent impaired lower extremity passive ROM deficits occur in community ambulating people with stroke (Schindler-Ivens *et al.*, 2008).

Functional consequences of reduced ankle ROM were examined in a cross-sectional study by Forghany *et al.* (2014) using 3D motion capture. They explored foot structure and function in 20 people with stroke and 15 age- and gender-matched controls. Participants attended a single session and walked barefoot at a comfortable walking speed at least 10 times. All participants could walk independently without an aid for at least 10 m. Deficits were reported during stance phase in all three planes of movement, rather than the commonly reported sagittal plane deficits in the ankle region, i.e. ankle plantarflexion and dorsiflexion, and reported for rearfoot, forefoot and whole foot. The findings showed small but significant overall changes between stroke and control groups in whole foot total ROM (20.2 ±3.78° and 23.4 ±4.78°, respectively, $p < 0.02$) and other reported variables. Largest differences were seen in the following three regions in the sagittal plane of the foot: rearfoot ankle plantarflexion at toe off (−3 ±6.98° and −8.8 ±4.38°, respectively, $p < 0.003$), forefoot range of final ankle plantarflexion motion (1.9 ±2.18° and 4.6 ±3.38°, respectively, $p < 0.008$), and whole foot late stance ankle PF ROM (15.9

±6.58° and 23.1 ±4.78°, $p < 0.001$). (Findings in other planes are discussed in subsequent sections.) These values show in detail reduced movement at the ankle and foot during stance, smaller overall ROM and less plantarflexion. Interestingly limitations in dorsiflexion were not found during stance, perhaps due to the passive nature of motion during this phase. The results of the binary regression models revealed that rearfoot movements were most closely related to walking ability. Stroke survivors with a less plantarflexed (odds ratio = 1.30, $p = 0.005$) or less inverted (odds ratio = 1.70, $p = 0.004$) rearfoot at toe off, or a less adducted rearfoot in late stance (odds ratio = 0.65, $p = 0.02$), were more likely to be limited to walking indoors (so called household walkers). Recent work by Kunkel *et al*. (2017) evaluated active ankle DF ROM using goniometry and found that angles reached median scores of 9.5° (range 0–19°) on the affected side, and 10.3° (range 0–21°) on the unaffected side; this was not statistically different at $p > 0.05$. Neither was the control group at 10.5° (range 0–24°), $p > 0.05$. Notably this study evaluated *active* ROM and both groups were community mobile, despite the recorded ROM being lower than that stated as a threshold for normal gait (12°, Weir and Chockalingam, 2007); however, no association with falling was found. Whether this is due to the lack of impact that loss of ROM has on falls or due to the type of assessment used (goniometry, not 3D motion analysis) is unclear. Both these studies partially demonstrate the functional limitations of ankle DF ROM.

2.4.2.2 Ankle Inversion/Eversion

Typical passive/active ankle inversion and eversion ROM is 35° and 20°, respectively (Palastanga *et al*, 1989). Ankle inversion and eversion ROM may be limited and affect the ability of the foot to contact the floor and respond to uneven surfaces. In their experimental cohort study, Youberg *et al.* (2005) used a 3D motion capture system to explore the amount of rearfoot motion used during stance phase of walking in a group of 40 healthy adults. They reported that dynamic rearfoot motion was 68.1% of available passive eversion ROM and 13.2% of the available passive inversion ROM. This research indicates that individuals regularly utilised the outer range of eversion during function. Forghany *et al.* (2014) demonstrated a reduction of rearfoot inversion in the stroke group (−5.4 ±4.48° versus −9.6 ±3.4°, $p < 0.002$) with abduction/adduction showing less movement (by approximately 2.6°). Furthermore, decreased rearfoot supination

influenced limited walking ability (inversion, odds ratio = 1.70, $p = 0.004$; adduction, odds ratio = 0.65, $p = 0.02$). This shows that post-stroke impairments, especially those affecting active motion, may play a role in altering foot biomechanics. Additionally, Forghany's work highlights that ankle inversion and eversion are of potential interest when exploring or evaluating foot and ankle function, particularly in functional tasks such as gait.

2.4.2.3 Hallux Dorsiflexion

Hallux dorsiflexion ROM is vital during the late stages of stance phase, with any decrease in ROM influencing mobility and balance. Hopson *et al.* (1995) reported that 65° of MTPJ toe extension is required for walking. Similarly, Perry and Burnfield (2010) stated 70° was required. Kunkel *et al.* (2017) recorded active first MTPJ ROM in people with stroke with median of 27° (range 0–64°) on the more-affected side compared to 38.7° (range 0–68°) on the less-affected side ($p < 0.025$); however, pooled median values were not significantly different to age-matched controls. Reductions in first MTPJ extension ROM were found to be concurrent with reduced sensation (Kunkel *et al.*, 2017). Whether these reductions are seen in larger cohorts or to correlate with other stroke impairments has yet to be explored.

Few research studies of hallux passive ROM examine a link to function. Kunkel *et al.* (2017) evaluated first MTJP ROM in relation to falls but did not find an association; however, in 71 older people, HV was associated with reduced gait velocity and step length ($p < 0.01$ and $p < 0.02$, respectively) demonstrating instability which may lead to falls (Menz and Lord, 2001). While this does not relate specifically to the issue of hallux dorsiflexion, it shows the importance of joint position and foot structure in the role of maintaining balance.

2.4.3 Spasticity

Spasticity is a key example of a 'positive' neural component of an upper motor neurone lesion. It is broadly defined as an increased resistance to rapid stretch of a muscle (Lance, 1980). This definition has been expanded to describe the contributory physiological mechanisms by the SPASM consortium, which describes spasticity as:

"disordered sensori-motor control resulting from an upper motor lesion presenting in either intermittent or sustained involuntary activation of muscle"
(Pandyan *et al*., 2005).

Spasticity has been attributed to a loss of supraspinal control from the cerebral cortex (Sheean, 2002). This leads to resistance to agonist muscle activity, thus slowing or stopping movements. The alteration in the supraspinal control on excitatory and inhibitory spinal pathways can result in complex variations of symptoms, with location of the lesions having a large effect (Ward, 2012). Spasticity is not only caused by neural factors but is compounded by non-neural or adaptive features attributed to changes in mechanical muscle fibres, collagenous tissue and tendon properties, resulting in 'increased tone' (Ward, 2012; Kilbride and Cassidy, 2011).

Spasticity throughout the limbs after stroke has been reported frequently in the literature, yet figures are not consistent and vary from 4% to 38% at one-year post-stroke (Lundstrom *et al.*, 2008; Watkins *et al*., 2002). Watkins *et al.* (2002) conducted a longitudinal observational study of 106 people up to a year post-stroke. Spasticity was explored based on the Lance spasticity definition using the tone assessment scale (TAS)[12] and the MAS, (Bohannon and Smith, 1987). Spasticity was found to be present in approximately 38% of people one-year post-stroke onset (39% in first strokes and 44% in recurrent strokes). Sommerfeld *et al.* (2004) found spastic limbs in 19% of their cohort at three months post-stroke using the MAS. The disparity is perhaps due to the earlier timing of data collection from time since stroke (one month versus one year).

[12] TAS evaluates posture and associated reaction after stroke on a scale of 0–5 for 12 items. However, its reliability is not as strong that for the MAS (k = 0.22–0.50 v. k = 0.79–92), Gregson *et al*. (1999).

Spasticity in the ankle region is thought to arise due to the combination of overactivity within the individual muscles exacerbated by weakness in the antagonist muscle group, i.e. the ankle DFs (Carr and Shepherd, 2002). It is chiefly caused by gastrocnemius, soleus and toe PF muscles which cause the ankle to plantarflex, and by posterior tibialis which increases inversion/adduction (Lamontagne *et al*., 2001; 2002). These may lead to atypical foot postural patterns including plantarflexion, inversion and toe flexion and adduction, often known as equinovarus deformity (Barnes, 2008; Laurent *et al*., 2010). Equinovarus deformity has been reported as present in 18% of people after stroke (Verdie *et al.*, 2004). Using results from Watkins *et al.* (2002), the presence of ankle PF spasticity, measured by the MAS, was observed in 36% of 106 participants at one year post-stroke. Yet Wissel *et al*. (2010), in their prospective observational trial, found spasticity using the MAS at the ankle was present in 66% of 103 participants at 12–24 weeks after stroke; however, Welmer *et al.* (2010) reported spasticity assessed by the MAS in only 3% of a group of 66 people at 18 months post-stroke. An additional six people had clonus. Therefore, it appears that there is little consensus regarding the presence of ankle PF spasticity, despite studies using the same measure. Ankle spasticity may vary with time since stroke as onset of ankle PF spasticity following stroke is highly variable (Malhotra *et al.*, 2009; Ward, 2012). Establishing the severity of spasticity is also problematic. It is important that time points for the measures must be stipulated and evaluation using appropriate definitions and/or tools is required to ascertain the severity of spasticity after stroke.

The influence of spasticity on muscle structure and activation consequently influences joint movement (Kilbride and Cassidy, 2011; Lamontagne *et al*., 2002; Lin *et al*., 2006). Links between spasticity after stroke and difficulties with walking and activities of daily living have been found. Lin *et al*. (2006) reported an ankle spasticity index (measured by EMG activity and muscle-lengthening velocity) of 8.56 ±6.72 (0.49–35.55) $\%/l \cdot s^{-1}$ in a group of 68 ambulatory stroke participants. When included in a regression analysis, ankle dynamic spasticity was the most important determinant for gait spatial symmetry, with $R^2 = 0.53$, $p < 0.001$, evaluated using the GAITRite system. Similarly, work by Hsu *et al.* (2003) found that, in a smaller group of 26 people with mild to moderate stroke, spasticity measured by the MAS in the more-affected ankle PFs was a primary factor influencing gait asymmetry with a moderate correlation with comfortable walking speed ($r = -0.47$, $p \leq 0.05$), single support time asymmetry ($r = -0.57$, $p < 0.01$) and step length

asymmetry ($r = -0.53$, $p < 0.01$). Watkins *et al.* (2002) reported that poorer functional outcomes measured by the Barthel Index were associated with spasticity ($p > 0.0001$) in 106 people with stroke; however, multiple muscle groups were examined (two upper- and five lower-limb muscles), which may have affected this finding. Conversely, Sommerfeld and colleagues (2004) found the association between spasticity and the TUAG and Barthel Index were poor. The lack of consensus in some of these research findings could demonstrate that spasticity may not be the only factor contributing to functional outcomes after stroke.

2.4.3.1 Muscle Stiffness

Stiffness is a term used to encompass both neural (or hypertonic) and non-neural characteristics observed clinically in the presence of spasticity. Stiffness can be quantified from change in ROM and change in torque required to move the joint between two positions (Marsden *et al.*, 2013; Schindler-Ivens *et al*., 2008). In early work by Thilman *et al.* (1991), resistance to passive movement of the ankle was measured in both hemiparetic and control participants. They found that ankle dorsiflexion in the more-affected limb was significantly stiffer than the less-affected side, with no change in ankle plantarflexion. This was attributed to loss of compliance of the Achilles tendon, with the role of passive stiffness in triceps surae also thought to contribute. Lamontagne *et al.* (2002) found that ankle PF stiffness was significantly higher, compared to controls at normal walking speed; however, links with gait speed were not explored by Lamontagne *et al.* (2002). They found that PF passive stiffness was associated with swing phase ankle DF peak ROM, but, in this instance, it did not preclude function as tibialis anterior (TA) activation overcame the stiffness. Lamontagne *et al*. (2000) found that total PF stiffness contributed most to gait (16.8%; 2.9–49.6%, $p < 0.01$); however, the contribution of passive stiffness was not significantly related ($p < 0.05$) to gait speed in both the patients and the controls. Stiffness, as a derivative of maximum angle and torque required, as explored by Schindler-Ivens *et al*. (2008) was 0.61 in the ankle DFs of the paretic limb and 0.57 in the non-paretic limb. This was the highest reported stiffness value out of three muscle groups (hip extension, hip flexion and ankle dorsiflexion) evaluated by Schindler-Ivens *et al.* (2008). No significant differences were found between any ankle variables. In a cross-sectional study by Rahimzadeh *et al*. (2017), 27 individuals with stroke were

placed in a high (MAS Score ≥ 2) or low (MAS score< 2) spasticity group and completed standing trials with both eyes open and eyes closed. They found that COP excursion was impaired in the medial–lateral plane, and was further reduced during eyes closed condition; this suggested a stiffening strategy in ankle PFs along with proximal muscles, and that ankle stiffness has a role in impaired balance after stroke.

2.4.3.2 Contracture

Stiffness over time may lead to contractures (Ward, 2012; Barnes and Radermacher, 2001; O'Dwyer *et al.*, 1996). This is defined as shortening of muscle length and reduction of muscle compliance, where muscle length is fixed and does not change with passive movement reducing available ROM (Barnes, 2008; O'Dwyer *et al.*, 1996). Fixed ankle PF contracture is reported in a third of people with stroke (Vattanasilp *et al.*, 2000). Fixed contracture of ankle PFs can limit passive and active ROM leading to impaired function of the ankle during gait (Olney and Richards, 1996a; Forghany *et al.*, 2014). There are many possible mechanisms for this. First, the limitation in the eccentric lengthening of the calf complex may inhibit the lowering of the heel to the floor during standing and walking (Barnes, 2008). Second, fixed contracture limits the amount of concentric activity to enable propulsion, thus adding inertia to swing phase of gait (Barnes, 2008). Finally, changes at the foot and ankle cause compensations proximally in the kinetic chain. For example, reduced ankle plantarflexion and inversion ROM (Barnes, 2008) cause the lower limb to become 'functionally' longer resulting in increased knee flexion and hip flexion during standing and hip circumduction and gait (Barnes, 2008). Contracture, enhanced passive stiffness or spasticity in the ankle PFs may limit the range of ankle dorsiflexion during stance and swing phase and thus the progression of the body over the foot, stride length and walking speed (Lamontagne *et al.*, 2001; 2002); however, as has already been presented, there is limited evidence about restriction of ankle ROM.

2.4.3.3 Toe region

The biomechanical impact of spasticity after stroke on the foot can be appreciated through structural foot changes such as toe deformity, exhibited as HHT and claw toe. This was discussed in Section 2.3.2 where links with functional outcomes, such as falls, were drawn

and contributory factors, such as intrinsic muscle weakness, were highlighted. Furthermore, changes in foot posture have also been attributed to the presence of spasticity following stroke and have been associated with structural foot deformities (Forghany *et al.*, 2011; 2014).

2.4.4 Summary

Neuromuscular changes found after stroke often combine and result in altered functional ability. These deficits include profound weakness in ankle muscles, loss of passive ROM at the ankle, and increased ankle PF stiffness and presence of spasticity. Impairments in ankle invertor/evertor and hallux DF/PF strength and ROM are rarely reported after stroke and hence require further research.

2.5 OVERVIEW OF THE LITERATURE

This chapter has presented a wide-ranging critical review of the impairments that occur after stroke. This has focused specifically on the foot and ankle both in static and dynamic function at three or more months post-stroke. There are still gaps in current knowledge and further work focusing on the measurement of impairments and characteristics, as well as their link to mobility and balance outcomes, is required. Appendix 3 includes tables used by the author to summarise the current literature and emerging gaps.

The key questions in relation to the current research are:

- What is the range of differences in static foot posture and toe deformity after stroke in comparison with age- and gender-matched controls?
- What is the range of differences in dynamic plantar foot loading after stroke in comparison with age- and gender-matched controls?
- What is the range of differences in altered DFL deficits at its clinical interpretation after stroke in comparison with age- and gender-matched controls?
- What is the range of differences in ankle and hallux isometric muscle weakness after stroke in comparison with age- and gender-matched controls?

- What is the range of differences reduced ROM in the ankle and hallux including inversion and eversion, and dorsiflexion after stroke in comparison with age- and gender-matched controls?
- What is the range of differences ankle PF spasticity after stroke in comparison with age- and gender-matched controls?

Furthermore, the literature has demonstrated that, for many of the impairments, association with functional outcomes is unclear or has not been fully established. Whether these impairments at the foot and ankle are predictive of mobility and balance outcomes requires exploration. The emerging gaps are whether:

- static foot posture and toe deformity are associated with mobility and balance outcomes after stroke;
- DFL characteristics are associated with mobility and balance outcomes after stroke;
- ankle and hallux isometric muscle weakness (single or composite) is associated with mobility and balance outcomes after stroke;
- ankle and hallux passive ROM are associated with mobility and balance outcomes after stroke;
- ankle PD spasticity is associated with mobility and balance outcomes after stroke.

These gaps explain the aim of Study 2 which is as follows:

> *To explore whether foot characteristics and neuromuscular foot and ankle impairments identified following stroke differ from normal controls; and whether these are associated with mobility and balance outcomes.*

Study 2 will address the following key questions:

1) Are there differences between people with stroke and age- and gender-matched controls in the severity of foot characteristics and neuromuscular impairments?
2) Are there differences between the more- and less-affected limb in people with stroke in the severity of foot characteristics and neuromuscular impairments?
3) Are foot characteristics and neuromuscular impairments at the foot and ankle associated with mobility and balance in people with stroke?

Given the potential functional importance and clinical relevance of these foot and ankle impairments after stroke, it is important that this research uses feasible, valid and reliable measures to quantify them. Chapter 3 will critically explore measurement tools for these impairments at the foot and ankle.

Chapter 3: CLINICAL MEASURES OF FOOT AND ANKLE IMPAIRMENTS AFTER STROKE

Chapter 2 outlined specific foot and ankle characteristics and neuromuscular impairments, and their severity and association with mobility and balance outcomes. A variety of measurement tools and approaches exist that can quantify foot and ankle impairments; however, not all are applicable to people with stroke, or are suitable for use in a clinical setting. Clinically applicable tools, which are feasible, reliable and relevant for use in people with stroke are required to inform understanding of the functional implications of these deficits and address the aim of Study 2.

3.1 AIMS AND OBJECTIVES:

The aim of this chapter is to provide theoretical justification for Study 1 of the research programme. The aim for Study 1 is:

To evaluate the clinimetric properties (feasibility, test–retest reliability, and clinical relevance) of measures of foot characteristics and neuromuscular foot and ankle impairments, for application in people with stroke.

This chapter outlines current measurement tools used to measure foot and ankle impairments; particularly in reference to their feasibility, reliability and relevance in a clinical environment. This will include measures of foot characteristics (static foot posture, toe deformity and DFL) and neuromuscular impairments (isometric muscle strength, passive ROM and spasticity). To do so, the characteristics required of measurement tools to ensure robust findings will be explained. Literature exploring feasibility, reliability and clinical relevance of measures of foot and ankle impairments following stroke will be critically analysed and, where applicable, the theoretical underpinning for the development and evaluation of measurement tools of foot and ankle impairments in people with stroke will be explained. The chapter will conclude with key findings and aims, which will be explored in Study 1 of this research programme.

3.2 MEASUREMENT

Measurement of impairments in body structure and function, activity and participation-level characteristics, are essential to the rehabilitative process following a stroke (NICE, 2013b). The term 'measurement' is used to describe the quantification of an observation made against a set standard (Everett, 2010; Wade, 1992). Tools are the resources that are used to gain these measures. The term clinimetric properties refers to the characteristics of a measurement tool that make it suitable for use in evaluation of a clinical phenomenon (Fava *et al.*, 2012; Streiner, 2003). Measurement tools as part of their clinimetric properties must possess feasibility, validity and reliability and be clinically relevant and appropriate. These properties can be ascertained through research (Fava *et al*., 2012). Valid, reliable and responsive tools inform clinical and multidisciplinary management after stroke (NICE, 2013a). Assessments are interpreted measurements (Ward, 1992), and form the basis of clinical intervention. Assessments and/or measurements may be used to establish an initial diagnosis or a clinical baseline; as a comparator to demonstrate deviation from normal and/or expected outcomes and progression of treatment; or to monitor a process relating to, or research into, a specific problem. Measurement therefore forms a foundation to treatment and may have an ability to predict recovery and guide service delivery models.

3.2.1 Feasibility

Feasibility is not often reported in the literature but is a valued attribute of a clinical measurement tool. Feasibility relates to the applicability of methods in the clinical context and whether their use is sustainable (Bowen *et al.*, 2009). Feasibility is a broad term that includes availability of time, capacity or other resources, as well as financial and technical demands of a measure (Bowen *et al*., 2009). As such, measures must be feasible for use in the specific environment and with the intended population to be able to collect data from most people. Evaluation of feasibility is complex and thus far not clearly defined; however, it encompasses assessment of process/es, recourses, management and scientific basis (Thabane *et al*., 2010; Tickle-Degnen, 2013). Examples of this include time to complete, ease of use and available data. In this thesis, the aim is that measures will be

used in a clinical setting for people with stroke and therefore need to be feasible to use in this context and with this population.

3.2.2 Validity

Measurement tools should establish validity, i.e. the tool measures what it should (Portney and Watkins, 2009). Validity is assessed by evaluating facets of validity such as face validity, content validity, criterion validity and construct validity (Portney and Watkins, 2009). Portney and Watkins (2009) describe them as follows:

- *face validity* specifies that an instrument appears to test what it is supposed to test;
- *content validity* requires the items that make up the test to adequately sample the content of the variable being measured;
- *criterion validity* shows that the outcomes of a measure can be used as a suitable measure of the target test; this can either be concurrent or predictive;
- *construct validity* indicates the capability of the measure to measure a construct and the amount that it reflects the components of the construct.

If a tool is valid, it can be used to discriminate between individuals, evaluate change and make predictions related to the specific characteristics being measured (Portney and Watkins, 2009), like the FFRT and falls risk (Duncan *et al*., 1990). Not all types of validity are relevant to measurement tools. Given the measures of interest in Study 1, face and construct validity are most relevant.

3.2.3 Reliability

Reliability is another important clinimetric attribute demonstrating whether a measure is consistent and/or free from error and yields consistent results over different time frames and between different raters (Portney and Watkins, 2009). Reliability is the ability of a measure to differentiate among subjects or objects (Kottner *et al*., 2011), it is therefore linked to variability in subjects. Two key types of reliability exist: intra-rater and inter-rater reliability. Inter-rater reliability is the stability of a measure across different raters, e.g. different clinicians. Intra-rater reliability is the consistency of one tester to obtain similar results where they repeatedly assess an outcome. This may often be termed repeatability (Sim and Wright, 2000). As such, the characteristic being measured is

expected to be stable during the allotted time frame without any intervention. A test–retest design is recommended to evaluate intra-rater reliability by eliminating systematic error and only evaluating error due to chance and/or change in the phenomena being measured (Portney and Watkins, 2009).

Reporting of reliability is outlined in the article 'Guidelines for Reporting Reliability and Agreement Studies' (GRRAS) by Kottner *et al.* (2011). These guidelines highlight best practice in reporting for a variety of measures analysing both reliability and the concept known as agreement. Agreement is an attribute relating to the degree to which scores of a measure are identical (Kottner *et al*., 2011). Reliability and agreement are not fixed but are an interaction between tools, subjects and the context of assessment. Therefore, reporting of study methods and their results must be included to properly ascertain the reliability of a tool. Table 3.1 outlines methods for analysing reliability for specified data types, including: ICC (for ratio/interval data), kappa statistics (for ordinal data) and 95% confidence intervals (for ratio/interval and ordinal data). The guidelines also stipulate that specific calculation models should be explained. An ICC model should be outlined as one way (1), two way (2) or mixed (3) together with its form, i.e. the number of measures taken (e.g. $ICC_{(2,k)}$, where k = number of measurements taken). For agreement: Bland–Altman plots, limits of agreement, coefficient of variation (CoV) and SEM are used. Analysis of these statistics enables conclusions to be drawn about the overall reliability of the tool. Details on the interpretation of ICC scores is found in Section 4.5.3.

Table 3.1 Statistical Methods for Analysing Inter- and Intra-rater Reliability and Agreement Studies (used with permission, Kottner *et al*., 2011)

Level of measurement	Reliability measures	Agreement measures
Nominal	Kappa statistics	Proportions of agreement Proportions of specific agreement
Ordinal	Ranked intraclass correlation Matrix of kappa coefficients Weighted kappa	Proportions of agreement Proportions of specific agreement
Continuous	Intraclass correlation coefficients	Proportions of agreement (ranges) Proportions of specific agreement (ranges) Standard errors of measurement Coefficients of variation Bland–Altman plots and limits of agreement

3.2.4 Clinical relevance

Clinical relevance or significance is challenging to define. Nonetheless, measures must be able to detect clinical meaningful changes for several stakeholders (Armijo-Olivo *et al*., 2011); this often involves evaluating the responsiveness of the measure or whether it demonstrates deviation from expected results. This is related to the term minimal clinically important difference (MCID), which is defined as the smallest change in a treatment outcome that an individual patient would identify as important and which would indicate a change in the patient's management (Portney and Watkins, 2009). MCID encapsulates:

1. a minimal amount of patient reported change;
2. something significant enough to change patient management (Cook, 2008).

However, this is often challenging as MCIDs often do not exist for measures as they may be specific to a person or population (Page, 2014). Also, calculating clinically important changes in outcomes or indeed in a measure is challenging and using confidence intervals of statistical results is recommended where MCIDs are not available (Page, 2014). A clinically relevant measurement tool is therefore one which makes the associated costs inconveniences, and even makes associated harms worthwhile (Armijo-Olivo *et al*.,

2011). Clinical relevance facilitates the understanding and interpretation of results for clinicians, assisting the transfer of knowledge into clinical practice (Armijo-Olivo *et al*., 2018). These attributes will be borne in mind when considering clinical relevance in this thesis but it is not a key focus, rather the appropriateness of clinical measures.

3.3 LITERATURE REVIEW STRATEGY

3.3.1 Question Guiding Search Strategy

The research questions guiding the literature search are based on the aim of Study 1:

How are clinically measurable foot characteristics and neuromuscular impairments evaluated/assessed? Are they feasible, reliable and clinically relevant? This relates specifically to static foot posture, toe deformity, DFL; isometric muscle strength, joint range of motion and spasticity.

3.3.2 Search Strategy

One search was conducted to answer question 3 and to provide a literature review. The search was conducted as per Section 2.2.2 using terms outlined in Appendix 2, Search 3. Study quality was evaluated using the GRRAS guidelines (Kottner *et al.*, 2011), shown in Appendix 4. These helped to determine inclusion in the literature review. Further search details are found in Section 2.2.2 and Appendix 2.

Study selection was broadly based on the following criteria:

- population: adult stroke survivors (three or more months), adults with neurological conditions[13];
- outcomes of interest: feasibility and reliability of relevant measurement tools;

[13] If no studies were found within a population the search was expanded to include older adults without any neurological deficit (> 65 years) and in some cases children with neurological deficits (e.g. cerebral palsy).

- study type: repeated measures, validity, reliability (test–retest), feasibility.

3.3.3 Search 3 Key Papers

Table 3.2 displays key papers used within this literature review.

Table 3.2 Key Papers for Literature Review for Study 1

Impairment	Author and date	Study design	No. and condition of participants	Feasibility/ reliability/ clinical relevance	Key results
Static Foot Posture	Menz and Munteanu (2005)	Concurrent validity study	*n* = 95 older adults Age: 78.6 ±6.5 years	Validity and Reliability	Compared three clinical measures of static foot posture. Intra-rater reliability was also explored for FPI and reported as moderate with an ICC of 0.61. Three clinical measures demonstrated significant associations with each of the radiographic parameters (p = 0.01). The FPI demonstrated weaker correlations with the radiographic parameters (r = 0.42–0.59). FPI was a valid measure of medial arch height when compared with radiographs with navicular height and arch index showing differing aspects.
	Lee *et al*. (2015)	Reliability	*n* = 22 stroke No info available for age and TSS.	Reliability	Evaluated FPI use in a group of people with stroke and reported high intra- and inter-rater reliability with ICCs of 0.81–0.88. Intra-percentage agreement was high (88.6%). **NB: Abstract only.**
Toe deformity	No studies found for clinimetric properties of toe deformity measures in stroke.				

Impairment	Author and date	Study design	No. and condition of participants	Feasibility/ reliability/ clinical relevance	Key results
Dynamic Foot Loading	Zammit *et al.* (2010)	Repeated measures	*n* = 30 healthy asymptomatic adults Age: 28.2 ±6.1 years	Reliability	Found moderate to good intra-rater reliability with $ICC_{(3,1)}$ of 0.44–97 (95% CI 0.10, 0.99), with most variability and lower ICCs in midfoot and lesser toe regions (second–fifth toe). 0.44 (0.10–0.69). TekScan® MatScan™ system demonstrates generally moderate to good reliability.
	Brenton-Rule *et al*. (2012)	Repeated measures	*n* = 23 older people with RA Age: 69.74 ±10.1 years	Reliability Feasibility	TekScan® mat system had excellent intra-rater reliability during three stance sway trials with eyes open and eyes closed conditions (anterior–posterior, medial–lateral dimensions), with reported $ICCs_{(2,1)}$ above 0.84 and moderate SEM of 1.27 to 2.35 mm. Feasibility was described as portable and easy to use, suitable for research and clinical settings.
	Hillier and Lai (2009)	Test–retest	*n* = 15 stroke Age: 54 to 83 years TSS: 0.5–13 years	Reliability Relevance	Evaluated whether F-Scan insole produced reliable data between trial 1 and trial 2 for the parameters of CP and CA. 30 mins between trials. Four different stance positions: feet together, with eyes open or eyes closed, and feet apart with eyes open or eyes closed. Good to excellent inter-trial reliability: *r* = 0.704–0.986. • CP: easy task – mean hemiparetic 3.6 kPa v. non-hemiparetic 3.7 kPa; harder task – mean hemiparetic 3.3 kPa v. non-hemiparetic 4 kPa. • CA: redistribution of contact on the lateral border of the more affected foot. • COF: motion was reduced on the more affected lower limb with a mean of 0.3 cm v. 0.5–3.8 cm for the other lower limb.

Impairment	Author and date	Study design	No. and condition of participants	Feasibility/ reliability/ clinical relevance	Key results
Muscle Weakness	Bohannon 1986	Retrospective study	*n* = 30 neurological patients Age: 51.9 years	Reliability	HHD was reliable for measuring ankle muscle strength in a neurological population, with excellent test–retest reliability for ankle PFs and DFs between 3 raters: $r = 0.97–0.99$, $p < 0.01$.
	Yen *et al*., (2017)	Pilot reliability study Test–retest	*n* = 15 stroke Age: 56.6 ±12.9 years No TSS data.	Reliability	Isometric muscle strength using HHD in a supine position in the acute hospital setting. $ICCs_{(3,1)}$ of 0.93 and 0.96 (95% CI 0.815–0.987, SEM 1.23–1.30) were reported for ankle DFs. Units of muscle force not stated, no validation of muscle testing between sitting and supine positions.
	Spink *et al.* (2010)	Reliability	*n* = 36 young adults Age: 23.2 ±4.3 years *n* = 36 older healthy adults Age: 77.1 ±5.7 years	Reliability	Used HHD in older people. Inter-rater reliability $ICCs_{(3,1)}$ of 0.77–0.88, intra-rater ICCs were higher, $ICC_{(3,1)}$ 0.78–0.94, for all ankle and foot muscle groups, including the lesser toes.
	Mickle *et al.*, (2006)		*n* = 6 young adults	Reliability	Used paper grip test. Showed excellent ICCs of 0.93 and 0.92, respectively, for hallux and toes in standing.

Impairment	Author and date	Study design	No. and condition of participants	Feasibility/ reliability/ clinical relevance	Key results
Reduced ROM	Keating *et al.* (2000)	Test–retest reliability	*n* = 21 stroke Age: 75.4 ±8 years No TSS data.	Reliability	Analysed ankle DF passive ROM in stroke patients while applying a standardised force (14 N). ROM was determined using a goniometer on a photograph of the joint ROM. The Lidcombe plate measured ankle DF ROM and was highly reliable ($r > 0.92$) in both unimpaired and impaired lower limbs.
	Paton (2006)	Cohort	*n* = 24 healthy adults Age: 21–40 years	Feasibility	Has been used successfully to measure passive hallux dorsiflexion in sitting in diabetic participants. No statistics reported.
Spasticity	Patrick and Ada (2006)	Cross-sectional study	*n* = 16 stroke (3 years post) Age: 63 ±7 years TSS: 1.2–5years	Validity	Explored whether the Tardieu scale can distinguish contracture. Agreement of 100% was found between Tardieu scale and EMG of ankle PFs, Agreement between MAS and EMG activity, ($r = 0.15$), with the Tardieu scale exhibiting clear relationships, $r = 0.62$. The MAS overestimated the spasticity present in those with contracture. However, the relationship between the angle of muscle reaction at V3 was only significantly related to the angle at which fast stretch-induced EMG activity occurred in the elbow flexors ($r = 0.78$, $p = 0.04$), not in the ankle PFs ($r = 0.57$, $p = 0.14$). This suggests that the grade of muscle reaction (X) during the fast velocity stretch (V3) is the most appropriate measure of spasticity from the Tardieu scale.

Impairment	Author and date	Study design	No. and condition of participants	Feasibility/ reliability/ clinical relevance	Key results
	Mehrholz *et al*. (2005)	Cross-sectional comparison study	n = 30 severely brain injured patients Age: 63.9 ±12.9 years	Reliability	Evaluated test–retest reliability using MAS at the ankle with knee extended and flexed. Test–retest reliability MAS - knee extended was κ = 0.47 - knee flexed was κ = 0.62, with low standard error (0.02–0.04). Test-retest reliability Tardieu scale - knee extended κ = 0.72 - knee flexed κ = 0.82, still with low standard error reported Statistically significant difference ($p < 0.001$). Inter-rater reliability was only poor to moderate (κ = 0.14–0.47) although significant differences were still found between reliability scores.

Abbreviations: TSS = time since stroke; CA = contact area; CI = confidence interval; CIA = ; C1MA = ; COF = centre of force; CP = contact pressure; DF = dorsiflexor; ICC = intraclass correlation coefficient; EMG = electromyography; FPI = foot posture index; HHD = hand-held dynamometer; HV = hallux valgus; MAS = modified Ashworth scale; NHr = ; PF = plantarflexor; RA = rheumatoid arthritis; ROM = range of motion; SEM = standard error of measurement.

3.4 FOOT CHARACTERISTICS

This section will provide a review of the current measures of foot characteristics and their possible application to people with stroke. Chapter 2 demonstrated links with foot posture, isometric muscle weakness, passive ROM and spasticity with functional outcomes such as walking (Forghany *et al.*, 2011; Bohannon, 2007; Dorsch *et al*., 2012; Lamontagne *et al*., 2002), balance (Bohannon, 2007) and falls (Kunkel *et al.*, 2017) after stroke. Therefore, this section will address pertinent clinimetric properties of measurement tools used, focusing on feasibility and reliability. Particular attention is paid to DFL as a key novel area of this thesis.

3.4.1 Static Foot Posture

As complex changes to foot structure following stroke are reported (Bowen *et al.*, 2016; Jordan *et al.*, 1997) it is pertinent that these changes can be assessed using clinically feasible and reliable tools. Characterising the static foot is not without its challenges. There is an abundance of individual measures that assess static foot posture including footprint parameters, navicular tuberosity position or height, rearfoot angle measurement, (medial) arch index, malleolar valgus index and the FPI (Langley *et al*., 2016; Billis *et al.*, 2007; Evans *et al*., 2003). Yet, there is little consensus on the best measure to use due to the lack of comparative studies between the multiple approaches to measurement (Langley *et al*. 2016; Billis *et al.*, 2007; Evans *et al*., 2003); however, the FPI is increasingly utilised in clinical and research practice as it is the only multiplanar evaluative static foot posture tool (Menz and Munteanu, 2005, Langley *et al*., 2016). The scale, feasibility and reliability of the FPI will now be explored.

The FPI is a tool developed to characterise the foot using six observable features (Redmond, 2001). These features are scored between –2 to +2 and the total of all features is categorised as five foot types: highly supinated (–12 to –5), supinated (–4 to –1), normal (0 to +5), pronated (+6 to +9) and highly pronated (10 to 12) (Redmond *et al.*, 2008), see Appendix 12. Use of the FPI varies with either the cumulative scores recorded for each foot, or the categories indicated by the score being reported. Age-related adjustments have also been proposed, accounting for changes in foot structure with age (Menz, 2015). Normal values have been reported by Redmond *et al.* (2008) from over 600 participants,

and a U-shaped relationship was found with age; young and older adults showed higher values, indicating more pronation. The results indicated the FPI was sensitive to detect a pathological population based on the FPI score (defined in the paper as over two standard deviations from the mean, with a mean of +4). Notably, neurogenic pes cavus and a supinated foot posture were identified in the pathological population. Given this sensitivity, the FPI is a promising assessment tool for use in people with stroke.

Reliability of the FPI using total scores has been established in children, adolescents and adults, with moderate results for inter-rater reliability between four raters ($ICC_{(2,4)} = 0.58$) and excellent intra-rater reliability found among four different raters with an average $ICC_{(3,1)}$ of 0.81 (0.72–0.86) (Evans *et al.*, 2003). The FPI was found to possess better reliability than other current measures of static foot posture except for navicular height (normalised to foot length). The FPI has also been widely used in older adults and found to be reliable (Menz and Munteanu, 2005). Menz and Munteanu (2005) compared three clinical measures of static foot posture in 95 older adults and found the FPI to be a valid measure of medial arch height when compared with radiographs with navicular height and arch index showing differing aspects. Intra-rater reliability was also explored for the FPI and reported as moderate with an $ICC_{(3,1)}$ of 0.61, (95% CI 0.27–0.81). No other reliability statistics were presented; however, similar to Evans *et al.* (2003), Menz and Munteanu (2005) found navicular height was the most useful clinical measure, being simple, easy to perform and an accurate representation of the medial arch. Yet, it is not descriptive of other features of static foot posture. More recently, Langley *et al*. (2016), reported the FPI as a reliable multiplanar measure ($\kappa_w = 0.92$) in a group of 30 healthy adults over two sessions. FPI's evaluation of static foot posture using six multi-planar characteristics makes it a desirable measure, supported by acceptable reliability.

The FPI is increasingly being used in neurological populations (Kunkel *et al.*, 2017; Jang *et al.*, 2015; Forghany *et al.*, 2011) thus demonstrating it is feasible to use for people with stroke. Lee *et al*. (2015) evaluated reliability of the FPI in a group of 22 people with stroke and reported high intra- and inter-rater reliability with ICCs of 0.81–0.88 (model not stated) and intra-percentage agreement of 88.6%; however, little detail can be extracted for critique as only the abstract was available in English. To date, the reliability of the FPI has not been widely reported for people with stroke.

3.4.2 Toe Deformity

Despite toe deformity being frequently reported after stroke (Kunkel *et al.*, 2017; Bowen *et al.*, 2016; Laurent *et al*., 2010; Jordan *et al.*, 1997), as yet no established measure exists to record deformities in the hallux or lesser toes, such as claw toes, hammer toes or HHT. Indeed, these impairments appear to have clinical relevance being associated with reduced function (Laurent *et al*., 2010; Mickle *et al*., 2009). Validated, reliable ordinal measures exist to quantify HV, such as the Manchester scale (Garrow *et al.*, 2001). The Manchester scale uses four images of the hallux to grade the extent of HV on a scale 0–3. Garrow *et al*. (2001) found excellent inter-rater reliability, ($\kappa = 0.86$). The Manchester scale has been used in older people (Menz and Munteanu, 2005) and people with stroke (Kunkel *et al.*, 2017) to assess HV. Although the Manchester scale is a reliable and suitable tool to observe HV, HV deformity was not identified as a key area for further evaluation and development. Kunkel and colleagues (2017) found no significant differences in HV presentation between stroke and control group; although HV presentation was lower in the stroke group. Reliability of the Manchester scale in people with stroke has not been reported.

No measures comparable to the Manchester scale are reported for other toe deformities that may be found after stroke, such as HHT. Consequently, other toe deformities need scales developing to enable evaluation of the presence and extent of the deformity. Toe deformities after stroke are caused by disordered sensorimotor control resulting from changes in body position, such as moving from and through sit, stand and walk (Laurent *et al*., 2010). Laurent *et al*. (2010) evaluated claw toe presence when the ankle was positioned at plantigrade, first while sitting down, brushing the foot on the floor, second standing up into a loading position and finally during gait; however, reliability of this approach was not evaluated. Yelnik *et al.* (2003) found HHT presence by observation and video analysis although no reliability work supported this assessment approach. Given the disordered sensorimotor control, adequate assessment would require EMG and joint ROM assessment to be able to distinguish whether deformity was due to passive or active causes, a strategy recommend by Pandyan *et al.* (2005); however, this would not be clinically feasible. Therefore, a less technical approach, such as visual observation, and a rating scale, like the Manchester scale, may provide a promising alternative. Thus, further work is required to develop and evaluate a feasible way of reporting these toe deformities.

3.4.3 Dynamic Foot Loading

Dynamic foot loading using plantar pressure analysis was explored in Chapter 2 in relation to its potential importance in understanding the foot post-stroke. In older adults, increased PPP is associated with falling (Menz and Morris, 2006; Mickle *et al.*, 2010; Spink *et al.*, 2011). In people with diabetes, changes in plantar pressure indicate tissue damage (Fernando *et al.*, 2014; Barn *et al.*, 2015); in people with RA, changes in plantar pressure demonstrate altered foot loading (van der Leeden *et al.*, 2007). To date, research in people with stroke has evaluated plantar pressures in small cohorts and found altered loading patterns when compared to the contra-lesional foot or control participants (Meyring *et al*., 1997; Hillier and Lai 2009; Forghany *et al*., 2015) and an association with mobility outcomes (Forghany *et al*., 2015). Thus, plantar pressure analysis is clinically relevant, as understanding the impact of stroke on the foot and ankle may aid effective management. Plantar pressure analysis provides quick, easily interpreted data to allow clinicians to focus their treatment. The methods used to analyse foot-floor interaction are crucial. Here the instrumentation, feasibility, reliability and clinical relevance of plantar pressure systems will be explored, specifically including the protocols employed and variables produced.

3.4.3.1 Assessment of Dynamic Foot Loading

Dynamic foot loading in people with stroke may be explored using many types of instrumentation including 3D motion analysis (Forghany *et al.*, 2014; Dean and Kautz, 2015), video analysis (Saleh and Murdoch, 1985) and plantar pressure systems (Nolan *et al.*, 2015; 2008). 3D motion analysis and the use of force plates are reported to be reliable for analysis of gait and are referred to as gold standard for motion analysis. 3D motion capture has been used recently in the stroke population, highlighting deficits in inversion and eversion ROM resulting in a pronated foot during gait (Forghany *et al.*, 2014). While detailed biomechanical data from 3D motion analysis is valuable, in a clinical environment inadequate space and financial constraints often preclude its use. Furthermore, multiple trials (up to 10) are required for reliable data (Monaghan *et al*., 2007), and large amounts of time to process and interpret the data mean that it is best utilised for research purposes. Video analysis on the other hand is instantaneous and can

provide valuable feedback for patients and clinicians alike; however, it does not demonstrate the interaction between foot-floor contact surfaces during the gait cycle. Visual observation is similarly instantaneous but is unreliable with approximately 80% of observations being incorrectly identified (Saleh and Murdoch, 1985). This is unsurprising as gait is inherently complex and foot loading is challenging to interpret and quantify (Rosenbaum and Becker, 1997). Plantar pressure systems may provide an excellent alternative to these methods.

Plantar pressure systems demonstrate the interaction between the foot and the floor during static and DFL (Orlin and McPoil, 2000). They provide detailed quantitative data for each region of contact, reflecting the distribution of pressure over the sole of the foot (Rosenbaum and Becker, 1997). Dynamic plantar pressure analysis distinguishes normal from abnormal foot loading (Rosenbaum and Becker, 1997), thereby evaluating the biomechanical function of the foot (Giacomozzi, 2011; Morag and Cavanagh, 1999). Clinical assessment using plantar pressure analysis can aid diagnosis, treatment selection, prognostic indicators and assess disease severity (Orlin and McPoil, 2000), as such it is a promising tool for application in stroke. Plantar pressure systems are easy to use and set up and require little space, suggesting they are potentially feasible to use in a clinical setting. They enable standardised data collection and extraction protocols (Giacomozzi., 2011; Orlin and McPoil, 2000), thereby enhancing data reliability and validity. Furthermore, plantar pressure systems can be tailored to the target population though the selection of protocols, variables and foot regions. Many plantar pressure systems are available, including mat and in-shoe systems. Mat systems are often wireless and cheaper than in-shoe systems and thus are used clinically. In-shoe systems are expensive, as they require individual insoles for each participant and are more often used in research. Manufacturers of plantar pressure systems include TekScan®, Vista Medical, NOVEL, Parotec and EMED among others (Giacomozzi, 2011; Razak *et al.*, 2012). These systems vary in specification of sensor size, number of sensors, range of measurement (kPa), frequency of sampling (Hz) and amount of hysteresis (Giacomozzi, 2011; Orlin and McPoil, 2000). Given the versatility of plantar pressure systems, careful consideration of methods of data collection and data analysis is required; this will now be discussed.

3.4.3.2 Feasibility

Feasibility has not been frequently researched; however, Brenton-Rule (2012) in a study of older people with RA using a mat system, described plantar pressure analysis as portable and easy to use, suitable for research and clinical settings. Later work by Gurney *et al*. (2017) studied 38 diabetics using a mat and an in-shoe based system and found positive self-reported experience from participants when implemented into a clinical setting. The median time for pedobarographic testing was 25 minutes (including study introduction and consenting) and no adverse events were reported. Therefore, plantar pressure systems appear feasible for clinical use, although this has not been explicitly established in stroke.

3.4.3.3 Reliability

To date, limited research reporting the reliability of plantar pressure systems for the stroke population is available. Hillier and Lai (2009) used an in-shoe plantar pressure system F-Scan (Tekscan^{TM}) to evaluate reliability for CP and CA, with a 30-minute time difference between repeated trials. In 15 people with stroke, four different stance positions were explored: feet together with eyes open or eyes closed, and feet apart with eyes open or eyes closed. Good to excellent inter-trial reliability was found (r = 0.704–0.986). This is promising, however, similar work has yet to be conducted during stance phase of gait and using a pressure mat.

Further research exists using mat systems in the older adult population and those with conditions such as RA and diabetes. Reliability of peak force, peak pressure and average pressure variables using the TekScan® mat system was evaluated in 30 healthy older people by Zammit *et al.* (2010). Over three barefoot walking trials using a two-step gait protocol, they found moderate to good inter-session reliability with $ICC_{(3,1)}$ of 0.44–97 (95% CIs 0.10–0.99) for mean values, across the seven regions. Most variability and lower ICCs were found in the mid-foot region (ICC = 0.49, 95% CIs 0.10–0.69) and metatarsophalangeal joint region with the CoV ranging from 5 to 23%. In the diabetic foot, Gurney *et al.* (2013) evaluated intra-rater reliability in a small cohort of 10 participants in mid-stance over five trials using a mid-gait protocol and analysed across

10 foot regions using an EMED platform. They found ICCs of 0.76–0.99 with a CoV of 4–13% for plantar pressure variables (peak pressure, maximum force, force time integral and contact time), demonstrating higher reliability than Zammit *et al*. (2010); however, the ICC model used was not stipulated, and a smaller cohort may have caused inflation of ICC values. Two different platforms were also utilised. Hafer *et al*. (2013) compared different mats and systems in 22 healthy adults and found $ICCs_{(2,1)} > 0.7$ for mats produced by the same manufacturer (i.e. two Emed X Plates and two MatScans) and by different manufacturers (i.e. Novel and TekScan®). Therefore, when using standardised protocols, use of alternative brands of instrumentation is not critical. Reliability of plantar pressure analysis has been evaluated by Brenton-Rule *et al.* (2012) in older people with RA. They found the TekScan® mat system had excellent intra-rater reliability during three stance sway trials with eyes open and eyes closed conditions (anterior–posterior, medial–lateral dimensions), with reported $ICCs_{(2,1)} > 0.84$ and moderate SEM of 1.27–2.35 mm. Therefore, in healthy young and older adults, and in those with RA, the use of plantar pressure analysis is reliable.

Due to the heterogeneity of plantar pressure system protocols that exist (Giacomozzi, 2011), protocols for collecting and analysing data must be standardised in relation to the number and speed of steps, and to system requirements. Key protocols for evaluating foot loading use one-, two- or three-step protocols; from their standing position, the participant's 1st, 2nd or 3rd step is evaluated as it loads onto the pressure mat system. A further protocol is the mid-gait protocol where loading is evaluated during steady gait (i.e. not acceleration or deceleration phases). Work comparing protocols has been conducted and found to have comparable reliability as reported by Zammit *et al.* (2010) (citing Bryant *et al*., 1999; Bus and Lange, 2005 and van der Leeden *et al*., 2007). Yet, Zammit *et al*. (2010), using a two-step protocol, and Gurney *et al*. (2017), using a mid-gait protocol, reported different reliability (ICCs of 0.44 v. > 0.7, so careful consideration is required when selecting gait protocols. Reliability of plantar pressure measurement is also influenced by the number of steps in the trial (Giacomozzi, 2011). The number of steps within trials range from 3–10 steps using the in-shoe system (Menz and Morris. 2009; Mickle *et al.* 2011b; Hafer *et al*., 2013). Using a mat system, an average of three steps is used by Menz *et al.* (2009) and Mickle *et al.* (2011b). Hafer *et al*. (2013) found that all parameters reached a value within 90% of an unbiased estimate of the mean within five trials. Speed of walking over the mat is also crucial and higher speeds result in higher

pressures (Giacomozzi, 2011). Therefore, using a standardised assessment protocol is paramount to maintain reliable outcomes when using dynamic plantar pressure.

3.4.3.4 Clinically Relevant Parameters

Planter pressure systems are sophisticated devices that produce a large range of variables (Hafer *et al.*, 2013; Giacomozzi, 2011). Yet, no consensus exists about the optimal variables to use for clinical practice or research purposes. Researchers' choice of variables must be tailored to the needs of the cohort under evaluation and their expected deficits (Giacomozzi, 2011). While being a pragmatic approach, this may result in clinically meaningless data, thus a theoretical underpinning is required for each variable. Conventional variables reported in the literature outlined by Giacomozzi (2011) are shown in Table 3.3. These variables all quantitatively describe DFL; clinical relevance was discussed in the literature review in Chapter 2, Section 2.3.3. The changes observed after stroke in these variables may help show deficit and/or recovery after stroke. For clinicians, such as podiatrists and physiotherapists, involved in managing the foot and ankle in people with stroke, having clinically relevant parameters is essential. Knowing which variables indicate improved or worse function, such as gait, may aid prioritisation of problems in body structure and function to be identified during clinical assessment; therefore, treatment can be tailored more effectively. So far changes in these variables are not fully understood and what pressures demonstrate recovery after stroke is unclear.

Table 3.3 Plantar Pressure Parameters (adapted from Giacomozzi, 2011)

Parameter	Definition	Clinical relevance	Comments
Peak pressure (kPa, PSI, $N \cdot cm^{-2}$, bar)	Highest pressure value experienced during measurement.	Potential skin damage, loading pattern (Forghany *et al*., 2015; Spink *et al*., 2011). Lower pressures found on affected limbs after stroke.	Can be displayed as a spatial map; utilises absolute values.
Mean pressure (kPa)	The pressure value at each sensor averaged over the measurement period.	Skin damage.	Time period of averaging must be stated.
Pressure-time integral/ impulse (PTI) (kPa)	Area under peak pressure curve.	Altered loading pattern (Nolan *et al.,* 2015), may indicate area(s) of/at risk of skin damage.	Relevant for assessment issues – compare directly with curve value with force platform.
Force-time integral, (%N)	Calculating area under force curve.	Same as above but no research exists demonstrating this.	Uses the force curve.
Contact area (CA) (cm^2)	Instantaneous value of loaded area on the pressure device surface.	Loading pattern, amount of foot contact (Yang *et al.*, 2014). Reduced CA = less foot contact especially found in mid-foot regions. CA not analysed in relation to recovery or level of function after stroke.	

Centre of force (COF)/pressure trajectory (cm/mm)	2-dimensional array utilising COF coordinates for the whole measurement period.	Loading pattern, postural sway/stability, motor control at the foot and ankle (Chisholm *et al*., 2011; Nolan *et al.*, 2015; Hillier and Lai, 2009). Increased sway during static tasks = poor balance control and risk of falls. Reduced COF trajectory length during static trials (2.5–5.3 non hemiparetic v. 0–3.2 cm hemiparetic).	Vector expressed as a single value

NB: Other measures include pressure curve, force curve, COF/CP velocity or acceleration, pressure gradients. Types of maps, such as the pressure integral map: the computation of PTI as the area under the curve of peak pressure curve; actual mean pressure; values averaged over the period of measurement frame of each sensor activity; and leading time map: load data with time and space included).

As clinical relevance is an important factor in selection of variables, defining which characteristics relate to impairments found after stroke is key. PPP (Forghany *et al*., 2015; Yang *et al*., 2014; Nolan and Yarossi, 2011; Hillier and Lai, 2009), contact area (Meyring *et al.*, 1997; Yang *et al*., 2014; Hillier and Lai, 2009) and centre of force (COF) (Nolan *et al.*, 2015; 2008; Hillier and Lai, 2009; Nolan and Yarossi, 2011; Chisholm *et al.*, 2011) have been used to evaluate foot characteristics as described in Chapter 2, Section 2.3.3. In addition, other parameters such as maximum force, pressure time integral (PTI) and contact time have been explored by some authors (Gurney *et al.*, 2013; Nolan *et al.*, 2008). For example, in stroke survivors, Nolan *et al.* (2008) reported statistically significant increases in PTIs in the medial arch area demonstrating increased loading of the foot; however, in diabetics, Bus and Waaijaim (2013) found that PTIs would indicate tissue at risk of damage, but did not add further benefit to ascertaining ulceration above peak pressure data. This is relevant as diabetes is a risk factor for stroke (Stroke Association, 2018) and ulceration is a common clinical symptom in diabetes and may affect the foot after stroke. Later work reported COF values for both anterior–posterior and medial–lateral directions (Nolan *et al.*, 2015, Nolan and Yarossi, 2011) to evaluate changes in foot function using an orthotic.

From Table 3.3 and discussion in this section, the following variables may best illustrate clinical changes after stroke:

- peak pressures may demonstrate altered foot loading and may be associated with walking speed (Forghany *et al*., 2015; Chen *et al*., 2007; Meyring *et al.*, 1997);
- foot contact area may be related to foot posture, spasticity and walking speed (Forghany *et al*., 2015; 2011);
- COF may indicate stability of foot loading during stance, indirectly measuring balance (Chisholm *et al*., 2011; Nolan *et al*., 2015; 2008; Hillier and Lai, 2009).

3.4.3.5 Foot Regions of Interest

Definition and number of foot regions used in analysis is an important consideration for plantar pressure data collection and extraction (Giacomozzi, 2011). The range of region utilisation varies in non-stroke populations from 3–12 as plantar pressure systems software often extracts pre-selected variables from particular foot regions. The number of regions often rely on pre-selected algorithms of the plantar pressure system software. For example, some software programmes use 11 e.g. TekScan® (TekScan, 2012). A geometrical approach or an anatomical approach may be used for identification of foot regions. Geometrical approaches are based on the longitudinal bisection of the footprint from the mid posterior heel through to the top of the second toe and then transverse lines roughly corresponding to anatomical structures such as the length of tarsal bones. Anatomical approaches employ kinematic measurements to apply anatomical landmarks to the foot (Giacomozzi, 2011). Studies do not often provide a rationale for their choice (Giacomozzi, 2011), as is the case in the research conducted in stroke populations, where the number of regions also varies: from three or four (Yang *et al.*, 2014; Chisholm *et al.*, 2011; Chen *et al.*, 2007) to seven (Meyring *et al.*, 1997) and even 12 regions (Nolan *et al.*, 2008). Too few or too many may risk loss of a clinically meaningful representation of foot regions. Therefore, like the choice of variables, the number of regions must be based on hypotheses underpinned by theories that are being explored by researchers (Giacomozzi, 2011). To date, there is no consistent procedure for footprint regionalisation, and/or the number of foot regions, based on clinical relevance when evaluating people with stroke.

3.4.4 Summary of Foot Characteristics

Foot characteristics appear to be feasible, reliable, valid and clinically relevant for use in the stroke population; however, this has yet to be fully established. The FPI, visual observation of toe deformity and plantar pressure systems appear to be key tools. Dynamic assessment of plantar pressure necessitates consideration of the clinical relevance of parameters, including PPP, CA and COF. Furthermore, regional definition requires evaluation to enable an appropriately optimised number of regions in order to analyse clinically relevant changes for people with stroke; specifically, evaluation is required for whether using four regions to represent rearfoot, mid-foot, forefoot and toe regions, or eight regions to appreciate additional medial and lateral differences.

3.5 NEUROMUSCULAR IMPAIRMENTS

3.5.1 Muscle Weakness

In Chapter 2, reduced neural activation of muscle resulting in muscle weakness in the lower limb, was cited as a significant deficit after stroke (Bohannon, 2007; Eng *et al.*, 2002; Lawrence *et al.*, 2001). Isometric muscle strength is defined as a muscle contraction in which the length of the muscle stays static during a contraction (Kisner and Colby, 2017). This differs from isotonic muscle strength where muscle force is generated throughout available joint ROM, and from isokinetic muscle strength where force is generated at a constant speed during motion (Kisner and Colby, 2017). This work focuses on isometric muscle strength for two reasons: first, this type of contraction can be assessed using tools in the clinical assessment of people with stroke; second, it is a good representation of isotonic muscle strength after stroke (Stark *et al.,* 2011). The focus in this section will be on measures of isometric muscle strength to critically evaluate the feasibility, reliability and clinical relevance of tools. This will include manual testing, isokinetic and isometric dynamometry, with consideration of force values representing a single muscle group or composite muscles (limb or body segment).

Isometric muscle strength is typically expressed as a unit of force, in kilograms (kg), where distance from the fulcrum/axis is not considered (Everett, 2010); or it can be

represented in newton metres (Nm) where the moment arm (distance from the fulcrum) is included. Isometric muscle strength is often 'normalised' to standardise the measures taken across a heterogeneous sample or groups. This neutralises anthropometric differences between participants, making measures comparable (Jaric, 2002). This can be done by normalising to body mass (kg), height (m) or limb length (m). Multiple approaches to quantifying isometric muscle strength exist; these vary from clinically applicable measures like manual muscle testing, to highly specialised equipment, such as isokinetic devices. Sophistication and quality of the measurement tools, along with their clinical utility, varies. Limitations of isometric muscle strength testing may arise due to a lack of standardisation in testing procedures, poor quality of muscle contraction, or absence of data management procedures (e.g. normalisation). Measures to assess isometric muscle strength at the foot and ankle, suitable for use in the clinical setting, will now be critically reviewed, with a focus on hand-held dynamometry.

3.5.1.1 Tools

Manual Muscle Testing

Many manual muscle testing (MMT) scales are available, with the Oxford scale or Medical Research Council (MRC) scale used frequently (Mendell and Florence, 1990). The MRC scale is easy to follow, quick to administer and requires no equipment (Petty and Moore, 2001; Clarkson, 2000). This MMT scale classifies muscle activity in relation to gravity, throughout muscle range of action, on an ordinal scale from zero–five in increments of one[14]; it is therefore unable to detect small changes. Efforts to improve discrimination between grades using '+' or '–' as Kendall *et al*. (1993) suggested, have been adopted into clinical and research practice (Florence *et al.*, 1992). Positioning of participants for testing throughout range and against gravity can also present challenges, thus tests are not feasible. Additionally, the MRC scale is reported to have poor reliability in both intra- and inter-rater reliability in neurological patients (Cuthbert and Goodheart, 2007). Furthermore, the MRC scale has limited validity in the foot and ankle region where gravity has less influence on limb movement.

[14]0: None – no visible or palpable contraction; 1: Trace – visible or palpable contraction with no motion; 2: Poor – full ROM gravity eliminated; 3: Fair – full ROM against gravity; 4: Good – full ROM against gravity, moderate resistance; 5: Normal – full ROM against gravity, maximal resistance.

Dynamometry

Highly instrumented and standardised equipment such as isokinetic dynamometry, e.g. the Kin-Com dynamometer, measure muscle strength outputs at set ranges over constant speeds and a known force. Isokinetic dynamometers are considered gold standard measures of muscle strength due to their high reliability post-stroke for most muscle groups (ICCs 0.61–0.99, Kristensen *et al.*, 2017). Isokinetic dynamometry yields good to excellent reliability of ankle muscles in neurological populations with $ICCs_{(3,1)}$ of 0.74–79 (Hsu *et al.*, 2002); and $ICCs_{(1,1)}$ of 0.88–0.97 (Eng *et al.*, 2002). Pohl *et al*. (2000) evaluated the reliability of lower extremity isokinetic strength testing in a small cohort of 10 adults with stroke and compared this to a healthy control group (n = 10). Using a test–retest design, knee extension and flexion (60°/second) and ankle PFs (30°/second), were found to be reliable (ICCs of 0.8–0.9). Whether the testing speed accounted for spasticity is not clear and this may have contributed to the broad confidence intervals reported (ICCs of 0.3–0.9). This highlights the need for protocols which include strategies to mitigate the effects of confounding factors such as levels of spasticity. Practically, however, healthcare resources and infrastructure often preclude the use of isokinetic dynamometry. In the clinical setting this is due to the high costs and available space, and in the community its instrumentation is too cumbersome. Furthermore, isokinetic dynamometry has limited use at the foot and ankle. While it can measure ankle dorsiflexion and plantarflexion, it is rarely used for inversion and eversion (Aydog *et al.*, 2004) and cannot be applied to the toe muscles due to its bulky instrumentation.

3.5.1.2 Hand-Held Dynamometry

Simplistic instrumented dynamometric or myometric devices, such as a HHD, are commonly used to measure muscle strength in the clinical setting. It can quantify isometric muscle strength produced using force gauges integrated into the devices (Li *et al.*, 2006; Bohannon, 1986; Eng *et al.*, 2002). The key criticism of a dynamometry device is that the force measured cannot be quantified over a dynamic ROM and is limited to isometric testing (Le-Ngoc and Janssen, 2012); however, in their systematic review, Stark *et al.* (2011) explored correlation between isokinetic and HHD measures of muscle strength from 17 papers. They found that considering the portability of a HHD, ease of

use, cost and compact size compared with isokinetic devices, a HHD yielded minimal differences and therefore considered it a feasible, valid and reliable tool. Yet few studies evaluated ankle muscle groups (Stark *et al.*, 2011). One study by Li *et al.* (2006) evaluated a new HHD able to test at a variety of joint motions including ankle plantarflexion and dorsiflexion in 28 healthy adults and compared this with an isokinetic device (KinCom) during isometric muscle contractions of lower limbs muscle groups. It was found to be valid, with a correlation of $r = 0.97$ between the HHD and KinCom of pooled muscle strength data ($r = 0.93$ for ankle plantarflexion, and $r = 0.60$ for ankle dorsiflexion). Hence, a HHD is a feasible, valid and reliable tool in adults; however, its validity has not been evaluated in ankle muscles in people with stroke.

Literature in neurological populations demonstrates convincing reliability. In the 1980s, Bohannon (1986) standardised protocols for measuring isometric muscle force using a HHD on a participant in a supine position, including ankle DFs and ankle PFs for people with stroke. Bohannon (1986) reported that a HHD was reliable for measuring isometric ankle muscle strength (kg) in a neurological population ($n = 30$). They reported excellent test–retest reliability ($r = 0.97$–0.99, $p < 0.01$), despite not normalising the data. More recently, Yen *et al.* (2017) found isometric muscle strength using a HHD in a supine position to be reliable in a small group of 15 people with stroke in the acute hospital setting. Excellent $ICCs_{(3,1)}$ of 0.93 and 0.96 (95% CI 0.815–0.987, SEM 1.23–1.30) were reported for ankle DFs; however, the units of muscle force were not stated (although they are assumed to be in pounds, lbs), data was not normalised and they did not validate muscle testing between sitting and supine positions. Hence, despite the lack of normalisation, a HHD appears to be a reliable tool for use at the ankle in people with stroke, specifically in supported positions.

Aside from ankle DF and PF muscle strength, literature in neurological cohorts is sparse when considering other foot and ankle muscle groups. Reliable protocols have been developed for measuring and reporting muscle weakness of individual lower limb muscle groups, including ankle invertors/evertors and hallux PFs and DFs, in healthy young or older cohorts (Kelln *et al.*, 2008; Spink *et al.*, 2010; Moraux *et al.*, 2013). These protocols used a supported position and a minimum of three trials during testing; no normalisation of measures was conducted. Spink *et al.* (2010) studied a group of 36 older people and

36 young people using a HHD and found inter-rater reliability $ICCs_{(3,1)}$ of 0.77–0.88 (95% CI 0.67–0.94 and CoV 8.5–15.5%). Intra-rater ICCs were higher – $ICCs_{(3,1)}$ of 0.78–0.94 (95% CI 0.70-0.93 and CoV 11.3–14.7%) – for isometric muscle strength in ankle DFs, PFs, invertors, evertors and PFs of hallux and lesser digits. Kelln *et al.* (2008) performed strength testing using a HHD for all muscle groups around the ankle and the hallux in a young healthy population and found good to excellent repeatability ($ICCs_{(2,k)}$ of 0.8–0.98) and low SEM values 0.01–0.83 kg; however, for ankle eversion, intersession reliability had an SEM of 2.23 kg. In a cohort of 76 healthy subjects (5–80 years old) Moraux *et al.* (2013) found ankle DF/PF isometric muscle strength using a HHD (in Nm) had excellent reliability, with ICCs of 0.94 and 0.88 (SEM 3–11 Nm and limits of agreement 8.4–30.6 Nm), respectively. This illustrates that good reliability is achievable for ankle dorsiflexion/plantarflexion, ankle inversion/eversion and hallux PF/DF isometric muscle strength testing across all age groups in healthy people. Moraux *et al*. (2013) also evaluated feasibility of their protocol in nine people with muscle dystrophy at the ankle and found that even very weak participants could be tested (detecting values up to 1.1 Nm). So, while hand-held dynamometry may appear feasible, care should be taken for movements that are difficult for the tester to control due to participant strength or mechanical advantage, e.g., ankle plantarflexion (Kelln *et al*., 2008) as forces greater than 120 N are reported to influence outcomes (Wikholm *et al*., 1991). Whether this is a concern when testing people with stroke is unknown.

Toe muscle strength has also been evaluated using indirect methods such as the paper grip test (de Win *et al*., 2002). Participants are placed in a seated position and activate their hallux PF muscles to resist a piece of paper being pulled away by the tester from under their toes[15]. The paper grip test was shown to have moderate to good intra and inter-rater reliability ($\kappa = 0.56$; $\kappa = 0.61$–87 respectively) in 20 leprosy patients (de Win *et al*., 2002). The test has been adapted by using a pressure mat underneath the hallux to evaluate hallux PF strength. Menz *et al*. (2006) reported ICCs of 0.87 for lesser toes and 0.88 for greater toes in 40 young people when using the paper grip test and plantar pressure combined; however, the paper grip test is an indirect measure of muscle strength, and its reliability has only been established in a small sample. Only recently, this tool has been

[15] Paper Grip Test (PGT) developed by W. J. Theuvenet and P. W. Roche from The Anandaban Leprosy Hospital, The Leprosy Mission, Nepal, in 1990.

reported as valid when compared with hand-held dynamometry in 69 people with diabetic neuropathy (Healy *et al*., 2018). No work exists establishing reliability of HHD in stroke survivors for these muscle groups, revealing a gap in current knowledge and practice.

3.5.1.3 Single versus Composite Measures

Lastly, despite the large body of literature exploring isometric muscle weakness after stroke, there is little consensus on reporting composite or single muscle strength. Most literature reports a single functional muscle group of muscle strength, e.g. ankle DFs (Dorsch *et al*., 2012), or muscle groups at a particular joint, e.g. ankle DFs and PFs (Bohannon, 2007); however, Li *et al*. (2006) used pooled data across muscle groups to evaluate HHD validity in comparison to isokinetic strength testing. Some literature has used ankle and larger lower limb muscle groups as predictors for gait and mobility outcomes (Lamontagne *et al.*, 2002; Dorsch *et al.*, 2012) but these studies have solely evaluated strength impairments. Thus a composite value may be of use in elucidating the role of the foot and ankle in mobility and balance outcomes. The limitation with single measures is that they may preclude use in multivariate regression modelling, as keeping the number of variables proportional to sample size is key (1 variable to 10 cases). With all muscle groups in the lower limb having demonstrated excellent reliability in healthy and older populations, as well as ankle muscle groups in people with stroke (Bohannon, 2007), whether inclusion of the smaller hallux muscle groups in a combined measure will influence this is not yet known. Therefore, further information is needed to determine whether it is beneficial to combine hallux with ankle muscle groups to use as a composite score in regression modelling.

3.5.1.4 Summary

Understanding isometric muscle weakness is crucial to predicting post-stroke morbidity and recovery (Kwakkel and Kollen, 2013). This section has explored muscle strength measurements that are highly instrumented and reliable and yet not clinically applicable. Of the clinically applicable tools, hand-held dynamometry has higher reliability than MMT (Bohannan and Smith, 1987) and is validated against ‘gold standard’ isokinetic tools (Stark *et al*., 2011). Hence the use of HHD for ankle and hallux muscle groups

would appear justified; however, protocols for hand-held dynamometry have not been explored in the stroke population for *all* lower limb muscle groups (Bohannon, 2007), namely ankle inversion/eversion and hallux plantarflexion/dorsiflexion, despite hand-held dynamometry being used in older people (Spink *et al.*, 2010). Normalisation, while advised, has not been applied in the reliability studies reported. Furthermore, no guidance exists as to whether measures can be reported as a composite value for regression analyses. Evaluation of ankle and hallux hand-held dynamometry, use of single and composite scores, as well as their predictive ability in balance and mobility outcomes, is required.

- hand-held dynamometry of ankle muscles appears feasible in stroke; however, this has not been established for hallux muscles.
- hand-held dynamometry of ankle dorsiflexion/plantarflexion: reliable after stroke and in older adults (Bohannon, 1986; Yen *et al*., 2017).
- hand-held dynamometry of ankle inversion, eversion: reliable in young people, adults and older adults (Spink *et al*., 2010; Kelln *et al*., 2008), not yet found to be reliable after stroke.
- hand-held dynamometry of hallux dorsiflexion/plantarflexion: reliable in young people, adults and older adults (Spink *et al*., 2010; Kelln *et al*., 2008), not yet found to be reliable after stroke.
- hand-held dynamometry of single v. composite scores: no studies explore the use of single or composite scores.

3.5.2 Reduced Passive ROM

Deficits in passive ROM are frequently reported due to muscle stiffness, spasticity, contracture and muscle weakness after stroke (Chapter 2, Section 2.4.2). Ankle DF ROM has been measured for decades using goniometers (Gatt and Chockalingam, 2011) or visual estimation (Youdas *et al.*, 1993); however, other tools and approaches including inclinometers (Harvey *et al.*, 2003), specifically designed equinometers or rigs (Keating *et al.*, 2000) have been used. A large proportion of studies of ankle and hallux passive ROM measures have focused on methods in healthy populations (Zhang *et al.*, 2014; Gatt and Chockalingam, 2011; Martin and McPoil, 2005). This section will critically evaluate

a range of tools and methodological considerations including the use of standardised loads and optimal positioning.

3.5.2.1 Measurement of Passive Ankle DF ROM

Goniometry

Goniometry is a simple, easily applied technique used to measure joint angles by applying a goniometer, a plastic dial measuring 360° with a stationary and moveable arm attached at a fulcrum. It is frequently used in clinical practice although reliability is often thought of as dubious. A paper by Martin and McPoil (2005) reviewed ankle goniometric measurement and selected articles based on their data analysis processes, including ICC and SEM data. They found 11 articles from a range of pathologies; four studies were found demonstrating types of reliable ankle ROM measurement tools in neurological conditions, including stroke (Martin and McPoil, 2005). Their review revealed mixed reliability for ankle dorsiflexion intra-rater reliability. In a group of people with spinal cord injury, head trauma and stroke, Elveru *et al.* (1988) reported an $ICC_{(1,1)}$ of 0.95. Pandya *et al*. (1985) found an ICC of 0.90 in a group with Duchene muscular dystrophy; however, both of these studies are old, and retests were conducted on the same day which may have produced higher ICCs. The two other studies were more recent and had three or more days between test and retest. Fosang *et al*. (2003) reported an ICC of 0.81 for intra-rater reliability in 18 people with spastic cerebral palsy; however, a large SEM of 4.8° was reported. In a group of 10 children with spastic paresis, Kilgour *et al*. (2003) found that $ICCs_{(2,1)}$ ranged 0.63–0.90 between sessions with either knee flexed or extended. Thus, time between testing may reduce reliability so it is important that this mirrors the clinical context. Inter-rater reliability for these studies was lower although still good, with ICCs ranging from 0.73–0.77: $ICC_{(1,1)}$ 0.77 (Elveru *et al*., 1988); ICC 0.75 (Fosang *et al*., 2003), ICC 0.73 (Pandya *et al*., 1985).

In more recent work, Popoff *et al.* (2012) evaluated intra- and inter-rater reliability of goniometric measurement of ankle dorsiflexion over one week in 28 people with stroke. Moderate to good ICCs (0.50–0.78) were achieved using standard application of ankle goniometry. The use of imposed landmarks did not improve this and yielded poor to moderate reliability (ICCs 0.36–0.66) (Popoff *et al.*, 2012). Thus, the standard method

was more reliable; however, ICC models were not described. As goniometry is renowned for being unreliable (Gatt and Chockalingam, 2011), a recent systematic review in non-neurological populations found that, while reliability coefficients were high across 10 different methods there were often quality deficits, such as lack of testing in pathological groups and a lack of reliability statistics. Overall, the evaluation of ankle ROM using goniometry was challenging (Martin and McPoil, 2005; Gatt and Chockalingam, 2011). Studies have explored reliability of a variety of alternative ROM measures, these will now be evaluated.

Lunge Test

One commonly used test for ankle ROM is the lunge test, where participants in step-stand load the anterior leg and measures are taken from the posterior leg using the angle created between the floor and the fibular head. Three studies evaluated the lunge test for passive ankle dorsiflexion test–retest and found good to excellent reliability. In 31 older adults, Menz *et al.* (2003) used a modified lunge test while supported by a wall and measured the angle between the lateral malleolus to the head of fibular. Test–retest reliability was high with an $ICC_{(3,1)}$ of 0.87 and a low CoV of 3.5% demonstrating excellent reliability. Similarly, Munteanu *et al.* (2009) measured ankle DF passive ROM in 30 healthy adults (mean age 22.1 ±5.6 years) during a weight-bearing lunge test with high intra- and inter-rater reliability using either an inclinometer ($ICC_{(2,2/4)}$ ranged between 0.77–0.88) or a specialised plastic rig with 2-degree increments ($ICCs_{(2,2/4)}$ of 0.89–0.97). Limits of agreement reported were narrow with both techniques, showing ankle ROM may not vary with the equipment used (Munteanu *et al*., 2009). O'Shea and Grafton (2013) used a tape measure to indirectly measure ankle DF ROM with 13 healthy subjects (mean age 39 ±14.5 years). Excellent intra- and inter-rater reliability was found with $ICC_{(3,k)}$ of 0.98–0.99, with low SEM of 0.3–0.4 (95% CI −0.3 to 1.2). Despite this, the protocol was not well described, limiting comparison with previous work, and a non-significant sample size was utilised meaning results cannot be generalised. A concern with the lunge test is its feasibility for use after stroke, where people often have impaired balance and limited posterior calf complex flexibility which may limit the safety and efficacy of testing ankle DF ROM in this position. Furthermore, the lunge test does not assess the effect of gastrocnemius on limitation of ankle ROM because it does not have the knee in extension.

Lastly, authors refer to this measure as ankle flexibility rather than ankle DF ROM (Menz *et al.*, 2005). Use of the lunge test has not been reported on post-stroke populations. While the lunge test appears to be an easily applied technique it has not been evaluated in neurological cohorts, reasons for this may be due to reduced balance of people with stroke therefore rendering the test unsafe.

Equinometers/Lidcombe Plate

Equinometers are specifically designed rigs, comprising of a plate, inclinometer and a load cell. They require a force application and rotate around the approximate axis of the joint, e.g. the ankle joint (Figure 3.1). Due to the effects of altered muscle tone in neurological conditions, it has been proposed that standardised loads should be applied for assessment of passive ROM (Ada and Herbet, 1988). The rationale for application of a load appears to be multifactorial (Gatt and Chockalingam, 2011). First, it may allow calculation of passive stiffness using change in torque/force and change in angular displacement (Marsden *et al*., 2013). Second, it reduces variability in examiner force

Figure 1. The Lidcombe System.

A: a footpiece attached to a perspex sheet ruled with parallel lines
B: a spring attached to the footpiece
C: a force gauge attached to the spring that indicates the level of force (kilograms) applied to the spring
D: a handpiece attached to the force gauge
E: swivel connecting piece
F: straps around the thigh
G: roll under the knee

Figure 3.1 Lidcombe Plate (Keating *et al*., 2000)

application and readings (Gatt and Chockalingam, 2011). This improves further the standardisation of protocols and reliability of results, as examiners may apply variable amounts of force when testing (Moraux *et al*., 2013). Third, it removes the natural alterations in stretching characteristics of a muscle which may fluctuate due to environmental causes, such as temperature (Gatt and Chockalingam, 2011), or intrinsic proprieties, such as muscle spasticity (Ada and Herbert, 1988). Notably the distinction between passive stiffness and passive ROM is conceptual and therefore needs to be considered when applying the results of measurement tools.

A rig called the Lidcombe plate was first used in work by Moseley and Adams (1991) in people with stroke. This adopted the application of load when measuring passive ankle DF ROM and reported an inter-rater reliability $ICC_{(2,1)}$ of 0.97. The same rig was used by Keating *et al.* (2000) to analyse ankle DF passive ROM in stroke patients while applying a standardised force (14 N). ROM was determined using a goniometer on a photograph of the joint ROM. The Lidcombe plate measured ankle DF ROM and was found to be highly reliable ($r > 0.92$) in both unimpaired and impaired lower limbs (Keating *et al.*, 2000). The use of a standardised force application of 14 N was deemed suitable to overcome any resistance from muscle stiffness. Additionally, the use of a load also improved reliability outcomes. Non-neurological populations have also found high reliability, with Scharfbillig and Scutter (2004) using forces of 8.2 kg in a group of healthy children and reported exceptionally high ICCs at 0.99 for both intra- and inter-rater reliability. Therefore, the use of a standardised load appears to be feasible and highly reliable, although exact loads are yet to be established (Gatt and Chockalingam, 2011).

Another application of standardised load is to measure muscle stiffness. Muscle stiffness is a way of evaluating a combination of reflex activity and non-neural changes. Marsden *et al*. (2013) employed two loads in a group of spastic paraparesis patients and used this to measure stiffness, using a simple calculation of change in torque over change in angle applied[16]. No reliability statistics were reported. It seems plausible that this approach could be used effectively after stroke, but it has not yet been evaluated.

[16]Stiffness = change in torque (N m)/change in position (degrees) (calculation taken from Marsden *et al.,* 2013).

Inclinometers

Inclinometers (similar to a digital protractor or spirit level), once attached to the limb, can be used to measure joint angle with measurements in a variety of positions. These are useful when goniometers are impractical or not feasible to use, especially when requiring passive ROM, as they allow measurement to be relatively 'hands-free'. Some authors have reported that digital inclinometers were more reliable than goniometry for passive ankle DF ROM in the lunge position, with ICCs of 0.96, SEM 1.3–1.4, and a minimal detectable change value of 3.7–3.8º (Konor *et al.*, 2012); however, by being positioned on the limb the readings do not reflect specific ankle DF ROM. Studies have been conducted evaluating the reliability of inclinometers for ankle DF ROM with ICCs up to 0.95 reported (Munteanu *et al.*, 2009; Bennell *et al.*, 1998). Harvey *et al.* (2003) used a pulley system with an integrated inclinometer in group of neurological patients and found excellent intra-rater reliability with an $ICC_{(2,1)}$ of 0.95 (95% CI 0.91–0.98). This tool demonstrates excellent reliability of measuring ankle DF passive ROM indirectly. Therefore, whether a clinically feasible and reliable measurement for use in a stroke population could combine an inclinometer and a standardised force (such as the Lidcombe plate) for use in a supine/long-sitting position after stroke is of interest.

3.5.2.2 Measurement of Passive Ankle Inversion–Eversion ROM

Measuring ROM of ankle inversion and eversion is less widely reported, perhaps due to the complex multi-planar motion available at the ankle and foot. Use of goniometers is widespread clinically but modifications to position of testing and placement of the goniometer are necessary (Menadue *et al.*, 2006). Reliability in older adults varies, with high values for intra-rater reliability and low to moderate values for inter-rater reliability testing. Menadue *et al*. (2006) assessed *active* ankle inversion and eversion ROM in both sitting and prone positions using goniometry in a group of 30 older adults. They found $ICCs_{(2,1)}$ of 0.82–0.96, SEM 1.0–2.2, for sitting, and ICC of 0.42–0.80, SEM 2.8–4.6, for prone. Youberg *et al.* (2005) evaluated *passive* ankle inversion and eversion ROM in 40 healthy volunteers using electromagnetic sensors with the foot positioned with the calcaneus perpendicular to the board and the lower leg positioned with the tibial tuberosity bisecting the long axis of the foot. Readings were taken while in sitting and in

a non-weight bearing position. Passive eversion and inversion ROM was 9.0 ±3.5 and 30.5 ±6.8°, respectively, and reliability reached an $ICC_{(2,k)}$ of 0.98 over five trials (ICC > 0.91 for one trial). There are some limitations of this work and application to a neurological population as the system developed did not account for varying resistance from the passive movement that could be produced by spasticity. To date, there is no clinically feasible and reliable tool that quantifies ankle inversion and eversion passive ROM that standardises the force applied in a supine position against a stabilised foot with a known axis of rotation.

3.5.2.3 Measurement of Passive Hallux DF ROM

Similar to ankle inversion and eversion, hallux ROM tends to be clinically quantified by goniometers, which are typically limited by a lack of standardised force. Less work has been conducted in clinically applicable methods, with none reporting reliability in people with stroke. Jones and Curran (2012) compared visual estimation and goniometry of photographed MTPJ ROM and found intra- and inter-rater reliability with ICCs > 0.95 in experienced examiners; however, this was only moderate in less experienced examiners, demonstrating how goniometry can be influenced by level of clinical experience. Highly instrumented and reliable methods for specific toe deformities hallux rigiditus, hammer toe and hallux limitus have been studied. Vulcano *et al.* (2016) used radiographs to examine hallux rigitus and found excellent inter-rater $ICCs_{(3,1)}$ of 0.87–0.95 and intra-rater $ICC_{(1,1)}$ of 0.88–0.94. Kwon *et al.* (2009), utilising a 3D digitiser and CT scan, likewise reported excellent $ICCs_{(3,1)}$ of 0.95–0.96 (95% CI 0.90–0.98, SEM 2.64–3.3.5); and an $ICC_{(3,1)}$ of 0.99 (95% CI 0.98–0.99, SEM 1.42–1.47), respectively. While excellent reliability has been reported in these studies, methods are not clinically feasible due to the instrumentation required. Smart phones have also been employed for first MTPJ joint ROM demonstrating good intra- and inter-rater reliability, with an $ICC_{(2,k)}$ of 0.86 and 0.71, respectively, and low SEM (1.4–1.7) across three different raters; however, this was conducted in healthy students only and results varied between the devices compared (goniometry versus smart phone) (Otter *et al.*, 2015).

Kunkel *et al*. (2017)[17] used methods outlined by Hopson *et al*. (1995) to measure first MTPJ active ROM using goniometry. Hopson *et al*. (1995) compared four passive measurement techniques of 1st MTPJ ROM in 20 healthy subjects and reported excellent intra-rater reliability. ICCs ranged from 0.91 to 0.98 across static non-weight-bearing, partial-weight-bearing and step-weight-bearing conditions with low SEM of 0.8–1.38. Although significant differences were found between mean MTPJ ROM for all conditions ($F = 132.1$; degrees of freedom [df] $= 4, 76$, $p \leq 0.0001$), with significant post hoc comparisons between all static conditions versus the dynamic condition ($p < 0.05$), reliability was not reported for the dynamic condition. A specialised rig designed by Paton (2006) has been used successfully to measure passive hallux dorsiflexion in sitting in diabetic participants. This simple, quick and cheap device lends itself to a clinical setting and is shown in Figure 3.2 below. A goniometer is attached on the axis of rotation of the ankle using a spring for a hinge. A force of 1.76 N was applied to achieve hallux dorsiflexion; however, reliability was not reported, and the tool has not been used in a neurological population. Thus, a feasible, reliable tool for the clinical assessment of passive ROM of the hallux DF in a stroke population is still required.

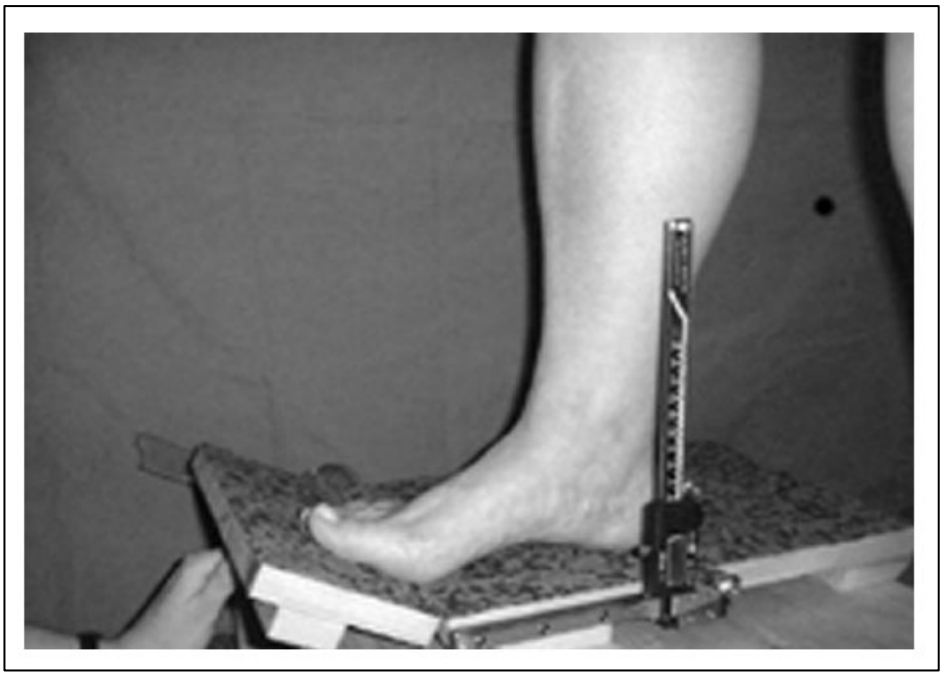


Figure 3.2 Hallux dorsiflexion measuring rig

[17] Table 2.1 in Section 2.2.3 for paper details.

3.5.2.4 Summary

In summary, there are ongoing challenges with the feasibility, reliability and accuracy of clinical assessment of ankle ROM especially, and hallux and lesser-toe passive ROM.

- Measurement of ankle and hallux passive ROM demonstrates potential feasibility and reliability, with ankle inversion and eversion being the most challenging motion to assess.
- The tools need to use standardised forces making them suitable to use with people with stroke (Keating *et al*., 2000; Paton, 2006).
- Measures need to be undertaken in a clinically feasible position to allow for repeated testing in a neurological population.

Thus, further work is required to establish standardised equipment and protocols that can reliably quantify peak ankle dorsiflexion, ankle inversion, eversion and hallux dorsiflexion range.

3.5.3 Spasticity

Despite spasticity being central to a physiotherapeutic stroke assessment, little development of tools to measure spasticity has been undertaken (Ward, 2012; Pandyan, 2005). Difficulties in measurement arise due to the complexity of spasticity and its different definitions and interpretations (Mehrholz *et al.*, 2005). Key pathophysiological features contributing to spasticity are activation of the tonic stretch reflex, phasic stretch reflex and reflex patterns such as flexor withdrawal (Wood *et al.,* 2005). Therefore, measurements needed to encompass all aspects to be valid; however, measures of spasticity rarely combine all aspects and rather often only assess one feature of spasticity (Sheean, 2002). Furthermore, studies measuring spasticity seldom define spasticity or which component of spasticity is being measured (van der Krogt *et al*., 2012; Malhotra *et al.*, 2008; Sheean, 2002). Research has demonstrated a gap in the concurrent assessment of neural and non-neural aspects of spasticity (van der Krogt *et al*., 2012). Discussion between authors has culminated in recommendations that to adequately assess spasticity, variables and features of spasticity need to be reflected (van der Krogt *et al*., 2012; Malhotra *et al.*, 2008; Mehrholz *et al.*, 2005; Sheean, 2002). These include quality of movement, reflex activity, latency of reaction, amplitude of reaction, range of onset or duration, speed, force or torque required for response (Pandyan *et al*., 2005); however,

these require a complex arrangement of measurement devices not suitable for clinical use. As robust clinical measures are not yet available for measuring spasticity, one way of simplifying this complex phenomenon is by encompassing all aspects contributing to spasticity, both neural and non-neural, as resistance to movement. Clinical practice reflects this lack of clarity, where simply the resistance to passive movement is the way of quantifying spasticity (Haugh *et al.*, 2006). Two frequently used and highly recommended clinical scales for spasticity are MAS (Bohannon and Smith, 1987; Ashworth, 1964) and Tardieu (Boyd and Graham, 1999; Tardieu, 1954; Held and Pierrot-Deseilligny, 1969).

The modified Ashworth scale (MAS) ranks resistance to passive movement on a scale of zero–four[18] (Bohannon and Smith, 1987; Ashworth, 1964). It is quick and easy to administer, using three repeated passive movements through available ROM at a standardised speed (using a count of 1001); however, intra- and inter-rater reliability has been found to range from poor to excellent, 0.4–0.8 for the MAS (Bohannon and Smith, 1987). Vattanasilp *et al*. (2000) has suggested that the Ashworth scale, while able to examine muscle stiffness, does not differentiate between neural and non-neural factors; however, the Ashworth scale does not have point 1+ on the scale (Morris, 2002) included in the modified scale and is therefore not directly comparable. Further criticism has suggested that the MAS, which is conducted in a relaxed position (usually supine or long sitting), qualifies results with speed of limb excursion (Pandyan *et al.*, 1999). Furthermore, the scale is limited by its ordinal level of measurement.

The Tardieu scale is frequently used in clinical practice and has been deemed more sensitive to changes in spasticity (Haugh *et al.*, 2006), as it quantifies spasticity by measuring the intensity of muscle reaction at specific velocities (Morris, 2002). The Tardieu scale measures spasticity in three categories: quality of movement (X) ranked

[18] Modified Ashworth scale: 0 = no increase in muscle tone; 1 = slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of ROM when the affected part(s) is moved in flexion or extension; 1+ = slight increase in muscle tone, manifested by a catch, followed by resistance throughout the remainder (less than half) of the ROM; 2 = more marked increase in muscle tone through most of the range of movement, but affected part(s) moved easily; score being a valid and ordinal measure of spasticity; 3 = considerable increase in muscle tone, passive movement difficult; 4 = affected part(s) rigid in flexion or extension.

from 0–5[19], that is, no resistance to unable to move; ROM at onset and termination of resistance or 'catch'; and finally, speed of movement from slow to fast[20] (Boyd and Graham, 1999; Tardieu *et al.*, 1954; Held and Pierrot-Deseilligny, 1969; Glinsky, 2016). A key benefit of the Tardieu scale is the ability to assess quality of movement at three different velocities and to note the point of catch at two parts of the ROM; with the difference between these being important in measuring the extent of spasticity. Additionally, it measures clonus and immobility, i.e. contracture, of a joint as well as resistance to passive movement. Excellent intra-rater reliability across two sessions in elbow flexors and ankle PFs (ICCs of > 0.85) has been found (Singh, 2011). Furthermore, Fosang *et al.* (2003) reported reliability of the Tardieu scale in children with cerebral palsy: three muscle groups involving the ankle PFs reached ICCs of 0.55–0.97 and had a SEM of 2–9°. Despite this, queries regarding the reliability and validity led the authors to conclude that further research should be conducted to ascertain this.

Haugh *et al.* (2006) conducted a systematic review to determine the Tardieu scale's validity and reliability as a clinical measure of spasticity, as defined by Lance[21]. They found 31 studies exploring the use of the Tardieu scale; however only two studies evaluated the reliability of the Tardieu scale in cerebral palsy and one paper explicitly evaluated the use of the Tardieu scale in adults with stroke. The quality of the muscle reaction was not considered. Haugh and colleagues (2006) concluded the Tardieu scale was more sensitive and reliable than the Ashworth scale, although details on reliability and validity were not presented. This may be due to inherent differences in the scale, i.e. more attributes accounted for in the Tardieu scale. In a literature review Morris (2002) explored the clinical relevance of the MAS and Tardieu scale in adults with neurological conditions and recommended that the Tardieu scale was a more useful measure of spasticity, with an ability to distinguish between contracture and spasticity. This was attributed to the standardised speed of movement and inter- and intra-rater reliability and

[19] Tardieu scale: 0 = no resistance throughout course of the passive movement; 1 = slight resistance throughout the course of passive movement, no clear catch at a precise angle; 2 = clear catch at a precise angle, interrupting the passive movement, followed by release; 3 = fatigable clonus <10 seconds; 4 = unfatigable clonus >10 seconds when maintaining pressure and appearing at a precise angle; 5 = joint is immobile. Researchers and clinicians use the 0–4 scale, either appear acceptable (Glinsky, 2016).
[20] V1 = as slow as possible; V2 = speed of limb segment falling under gravity; V3 = as fast as possible.
[21] Lance definition of spasticity = Spasticity is a motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motoneuron syndrome (Lance, 1980).

content validity (Morris, 2002). Patrick and Ada (2006) explored whether the Tardieu scale can distinguish contracture. An exact agreement of 100% was found between the Tardieu scale and EMG of ankle PFs; little agreement or relationship was found between MAS and EMG activity, $r = 0.15$, with the Tardieu scale exhibiting clear agreement or relationship, with $r = 0.62$ demonstrating moderate to good proportion of agreement. Interestingly, the MAS overestimated the spasticity present in those with contracture. Mehrholz *et al.* (2005), in a group of 30 severely brain injured patients, found that test–retest reliability using MAS at the ankle with knee extended was poor to moderate with $\kappa = 0.47$ and with knee flexed was $\kappa = 0.62$; there was a low SEM (0.02–0.04). Higher test–retest reliability was found for the Tardieu scale with knee extended $\kappa = 0.72$ and knee flexed $\kappa = 0.82$, again with low standard error reported; however, inter-rater reliability was only poor to moderate ($\kappa = 0.14$–0.47) although significant differences were still found between reliability scores. No other statistics presenting spread of error or agreement between scores was presented. Thus, the reliability of the Tardieu scale is still to be convincingly evaluated at the ankle region; however, its ability to distinguish contracture and provide valid results, where EMG activity is synonymous with spasticity, appear superior to the MAS.

No measure exists to quantify spasticity in the (long) hallux or toe flexors or extensors, which may be exhibited as claw toes or HHT.

3.6 OVERVIEW OF THE LITERATURE

In summary, this chapter has demonstrated a critical analysis of measures of static foot posture, toe deformity, DFL, as well as ankle and hallux isometric muscle weakness, passive ROM and spasticity found after stroke. As such, it has found that while many reliable and valid measures exist for clinical measurement of static and DFL, FPI and plantar pressure have yet to have their feasibility, reliability and clinical relevance in people with stroke determined. Additionally, few clinically feasible tools for isometric strength, passive ROM and spasticity consider the complexity of positioning for stroke assessment, the varied clinical environments, and financial constraints. Tools or scales that possess good or excellent reliability are rare for ankle dorsiflexion, plantarflexion, inversion and eversion, with even fewer for hallux dorsiflexion and plantarflexion. The literature presented has not always adhered to standards set by GRAAS with few reporting

Bland–Altman plots and statistics related to agreement. Thus, this chapter highlights the need for reliable measures to be established and underlines gaps in the current literature. Appendix 5, includes tables used by the author to summarise the current literature and emerging gaps.

Therefore, this thesis plans to explore the following questions in order to address gaps highlighted in this chapter:

Foot characteristics:

- **Static**

1) Is static foot posture using the FPI assessment feasible and reliable in people with stroke?
2) Is toe deformity classification feasible in people with stroke?

- **Dynamic**

3) Are plantar pressure variables feasible, reliable *and clinically relevant* to represent DFL characteristics during stance phase of gait in people with stroke?
   In particular:
   a. which variables are clinically relevant to represent DFL characteristics (i.e. peak plantar pressure, foot contact area, centre of force)?
   b. what number of regions are feasible and reliable to obtain data from?

Neuromuscular foot and ankle impairments:

4) Are clinical measurements of foot and ankle isometric muscle weakness using a HHD feasible and reliable in people with stroke?
5) Are single or composite measures of ankle and hallux muscle weakness appropriate for use as predictive measures of balance and mobility outcomes in people with stroke?
6) Is it feasible and reliable to measure peak[22] ankle dorsiflexion, ankle inversion and eversion, and hallux dorsiflexion through application of two standardised forces in people with stroke?

[22] The term 'peak' has been used to add clarity, it is not total joint ROM that will be evaluated but peak angle of dorsiflexion reached at the two loads.

7) Is ankle PF muscle stiffness, through application of two standardised forces, feasible and reliable to measure in people with stroke?
8) Is the Tardieu scale a reliable measure of ankle PF spasticity in people with stroke?

These questions form the basis of Study 1 in Chapter 4.

3.7 NOVELTY OF THE WORK

This thesis differs from previous work by proposing feasible, reliable and clinically relevant measurement tools and protocols that will enhance and/or refine assessment of foot and ankle impairments in people with stroke. Currently, few clinically established tools or protocols exist for examining the impairments at the foot and ankle following stroke. It is possible that these measurement tools and protocols have the potential to allow for more effective assessment of foot and ankle impairments, enabling Allied Health Professionals to establish accurate measurement findings on which to support their interventions. Research has, in the main, explored neuromuscular impairments, rather than foot characteristics, in relationship to mobility after stroke. Some studies have observed links to mobility outcomes between ankle DF and PF muscle strength (Bohannon, 2007; Lamontagne *et al.*, 2001; 2002), altered muscle activity (including spasticity) and foot posture asymmetry (Forghany *et al.*, 2011). Consequently, exploring the prevalence of multiple foot characteristics, together with neuromuscular impairments, is novel. Additionally, exploring their combined association with mobility, balance and falls outcomes for people with stroke will provide new understanding of their influence. It is expected that a targeted assessment and intervention of the foot and ankle of these patients will improve functional outcomes for people with stroke, thus resulting in improved community ambulation, balance and reduction in falls. Findings from Study 2 will help inform multidisciplinary rehabilitation pathways included in clinical assessment protocols for Allied Health Professionals involved in the care of patients following stroke.

The novel aspects are:

- development and evaluation of feasible, reliable and clinically relevant tools and/or protocols for quantifying neuromuscular impairments after stroke at the foot and ankle;
- evaluation of the feasible, reliable and clinically relevant use of foot posture and plantar pressure analysis to quantify foot characteristics;
- evaluation of the differences in prevalence of foot and ankle impairments between stroke and age- and gender-matched controls;
- analysis of the predictive ability of multiple variables (foot characteristics and neuromuscular deficits) at the foot and ankle with mobility, balance and falls outcomes.

Chapter 4: STUDY 1: THE DEVELOPMENT, FEASIBILITY AND RELIABILITY OF MEASUREMENT TOOLS USED TO ASSESS FOOT AND ANKLE IMPAIRMENTS AFTER STROKE

4.1 INTRODUCTION

This chapter presents methods, results and discussion for Study 1 of the research programme. Evidence reviewed in Chapter 2 demonstrated that there are current limitations in the understanding of the association between foot characteristics and foot and ankle neuromuscular impairments after stroke. This is precluded by the lack of feasible and reliable methods for measurement of foot characteristics and foot and ankle neuromuscular impairments after stroke. Therefore, robust measures were required to investigate the effects of foot and ankle impairments on mobility and balance. Building on existing evidence, Study 1 has evaluated the feasibility and reliability of foot characteristics and neuromuscular foot and ankle impairments and, where necessary, included development and evaluation of new measurement tools.

Chapter 3 outlined current knowledge about suitable tools to assess foot and ankle impairments that are feasible, reliable and clinically relevant. The chapter demonstrated that there are gaps for tools applied in the stroke population, with some impairments not routinely measured, e.g. isometric hallux muscle weakness. Some pathology-related characteristics, such as difficulty in limb positioning and management of resistance to movement, along with the requirement of tools to be clinically feasible, make this challenging. Thus, careful consideration in the development and standardisation of measurement tools and procedures are required to enable robust assessment of foot and ankle impairments. Table 4.1 outlines the purpose of testing in relation to the Chapter 3 literature review; evidence supporting the decision to test feasibility and/or reliability for each variable/tool combination is included.

Table 4.1 Overview and Purpose of Testing in Study 1

Variable		Tool – position	Feasibility	Reliability	Clinical relevance	Evidence/comments
Foot characteristics	**Foot posture**	Foot Posture Index – standing	Yes	Yes	No	No feasibility or reliability reports in stroke. Reliable in children through to older adults (Evans *et al.,* 2003; Redmond *et al*., 2008).
	Toe deformity	Observation – sit/stand/walk	Yes	No	No	No standard measure exists for use in stroke. Post hoc decision to not explore this as no retest data was gathered.
	Dynamic foot loading - COF sway velocity and path length	Plantar pressure mat – quiet standing	Yes	Yes	Yes	No feasibility reports in stroke, although used in multiple papers (Nolan *et al*., 2008; Meyring *et al.*, 1997). Good to excellent reliability in older people, those with RA and diabetics (Brenton-Rule, 2012; Gurney *et al*., 2013; Hafer *et al*., 2013)
	Dynamic foot loading - plantar pressure and contact area	Plantar pressure mat – walking, stance phase	Yes	Yes	Yes	

Neuro-muscular impairments	**Ankle and hallux muscle strength (single and composite)**	Hand-held dynamometer – long sitting	Yes	Yes	No	Feasibility assumed; however, not established for ankle inversion/eversion and foot muscles. Reliable for ankle dorsiflexion/plantarflexion/inversion/eversion (Bohannon, 1986; Andrews and Bohannon 2000) but not for hallux dorsiflexion/plantarflexion in stroke.
	Peak ankle and hallux dorsiflexion (low and high force)	Bespoke rig – long sitting	Yes	Yes	No	Feasibility assumed; however, not established for ankle and foot muscles. Reliable for ankle dorsiflexion (Keating *et al*., 2000) but not for ankle inversion/eversion and hallux dorsiflexion/plantarflexion in stroke.
	Ankle and hallux passive stiffness*	Calculation†	Yes	Yes	No	No measures for stiffness of hallux dorsiflexion in stroke. Only ankle DF stiffness available (Schindler-Ivens *et al*., 2008). No feasibility or reliability testing available.
	Ankle PF spasticity (quality of muscle reaction)	Tardieu – long sitting	No	Yes	No	Feasibility is implied by previous studies but not reported. Reliability established in stroke. Good to excellent reliability reported Singh *et al.*, 2011; Mehrholz *et al*., 2005); however, quality of movement has not been convincingly established despite some reliability work (Haugh *et al*., 2006)

*measured at the same time as peak ROM angles. † Equation 4.1 in Section 4.4.2.6 (Marsden *et al*., 2013).
Abbreviations: COF = centre of force; DF = dorsiflexor; PF = plantarflexor; RA = rheumatoid arthritis.

Outlined below are impairments requiring suitable measurements which have little or no established feasibility, reliability and, in some cases, established clinical relevance; and which have a bearing on post-stroke mobility and balance outcomes.

Static Foot Characteristics:

- **Static foot posture using the FPI.** Static foot posture may influence DFL (Forghany *et al.*, 2015) and abnormal foot type is associated with reduced walking speed (Forghany *et al.*, 2011). No feasibility or reliability is reported in the literature specific to stroke, although the FPI has been shown to be reliable in older adults and people with diabetes (Menz and Munteanu, 2006; Brenton-Rule *et al*., 2012).
- **Toe deformity (type and nature).** Toe clawing appears to be associated with lower functional ability after stroke (Laurent *et al*., 2010). HV is present after stroke, however no significant differences in HV have been found to date between stroke and age- and gender-matched controls (Kunkel *et al.*, 2017). No feasibility or reliability of toe clawing or other toe deformity has been reported in stroke.

Dynamic Foot Characteristics:

- **Dynamic foot loading using plantar pressure analysis, peak pressure, contact area and centre of force.** Plantar pressure analysis appears to demonstrate changes in foot loading after stroke (Meyring *et al*., 1997); however, to date (summer 2013), plantar pressure has not been used to explore association with mobility and balance outcomes after stroke. No feasibility or reliability is currently reported using this system in stroke. Good to excellent reliability (ICCs > 0.7) has been reported in other populations including older adults (Hafer *et al.*, 2013). No evaluation of the number of regions or types of variables and their clinical relevance has yet been explored in stroke.

Neuromuscular impairments:

- **Foot and ankle muscle weakness:** Isometric muscle weakness using a HHD of: ankle dorsiflexion, ankle plantarflexion, ankle inversion, ankle eversion, hallux

DF and hallux plantarflexion. Isometric ankle DF muscle strength is associated with walking speed after stroke (Dorsch *et al*., 2012). Data is available on the reliability of ankle DF and ankle PF isometric muscle strength using a HHD in people with stroke (Andrews and Bohannon, 2000; Yen *et al*., 2017); however, this does not include ankle invertors/evertors, hallux dorsiflexion and plantarflexion. Additionally, no work evaluates the use of single muscle group values and combined, or composite, muscle group values.

- **Foot and ankle passive ROM:** Peak ankle dorsiflexion, ankle inversion, ankle eversion, hallux dorsiflexion angle. Ankle ROM has been shown to limit gait speed and progression after stroke (Lamontagne *et al.*, 2002; 2001). No association has been found between hallux dorsiflexion and mobility and balance outcomes in stroke to date. Limited sources demonstrate feasibility and reliability of a clinical tool for ROM using a standardised force, nor what force is most reliable. Furthermore, no tools exist for measurement of ankle inversion, ankle eversion or hallux DF ROM using a standardised force.
- **Ankle PF spasticity**
    - **Stiffness in ankle DF and hallux DF movements.** Stiffness may be associated with mobility and balance outcomes. Measurement of stiffness in stroke has not been feasibly or reliably demonstrated to date.
    - **Quality of muscle reaction.** The reliability of the Tardieu scale is still to be convincingly evaluated at the ankle region, despite being used extensively in neurological populations and demonstrating good reliability at the upper limb. No research convincingly reports reliability of the quality of movement component.

4.1.1 Aims and Research Questions

The aim of this study is:

To evaluate the clinimetric properties (feasibility, test–retest reliability and clinical suitability) of measures of foot characteristics and neuromuscular foot and ankle impairments, for application in people with stroke.

This work will answer the following research questions.

Foot characteristics:

- **Static**

1) Is static foot posture using the FPI assessment feasible and reliable in people with stroke?
2) Is toe deformity classification feasible in people with stroke?

- **Dynamic**

3) Are plantar pressure variables feasible, reliable *and clinically relevant* to represent DFL characteristics during stance phase of gait in people with stroke?
   In particular:
   a. which variables are clinically relevant to represent DFL characteristics, i.e. peak plantar pressure, foot contact area, centre of force?
   b. what number of regions are feasible and reliable to obtain data from?

Neuromuscular foot and ankle impairments:

4) Are clinical measurements of foot and ankle isometric muscle weakness using a HHD feasible and reliable in people with stroke?
5) Are single or composite measures of ankle and hallux muscle weakness appropriate for use as predictive measures of balance and mobility outcomes in people with stroke?
6) Is it feasible and reliable to measure peak ankle dorsiflexion, ankle inversion and eversion, and hallux dorsiflexion through application of two standardised forces in people with stroke?
7) Is ankle PF muscle stiffness, through application of two standardised forces, feasible and reliable to measure in people with stroke?
8) Is the Tardieu scale a reliable measure of ankle PF spasticity in people with stroke?

The following sections, Sections 4.2–4.4 will outline the design, materials and procedures utilised, including the development of novel bespoke tools essential to this project and methods for calibration. A detailed battery of clinical measures for the

evaluation of the foot and ankle impairments in stroke participants was developed to answer the research questions that were proposed. Standard operating procedures (SOPs) are provided in Appendices 13–17. The clinical measures reported were included as part of a larger study assessment battery in the FAiMiS study (Chapter 1, Figure 1.1.).

4.2 METHODS

4.2.1 Design

To enable evaluation of the reliability of measurement tools, this study adopted a test–retest study design. The test–retest study design is the recommended design to assess reliability of a tool and/or protocol over time (Portney and Watkins, 2009). This design also allows for feasibility to be evaluated by implementing the protocols and reporting feasibility of use in relation to time to complete, ease of use and available data. This design also meant feasibility and clinical relevance of DFL could be evaluated as discussed in Section 4.5. Clinical relevance, especially of DFL, was highlighted as an area of interest and so data for both the more-affected and less-affected side was collected to enable its evaluation. In this work, only intra-rater reliability could be evaluated due to the FAiMiS study design.

As previously mentioned, inherent to exploration of reliability is that the tools used within a research study have systematic error minimised as much as possible; thus, an appropriate equipment calibration must be carried out. This can be done in three ways. First, to ensure that systems/tools are working in their defined parameters, calibration of the tools is conducted. Natural phenomena that may influence variables, such as hysteresis and drift which are common in plantar pressure and force measurement, are omitted as much as possible. Therefore, in this study, force transducers, inclinometers and pressure mats were calibrated in line with the manufacturer's guidelines and maintained within acceptable parameters (Sections 4.3 and 4.4). Second, standardised protocols must be formulated and adhered to by the tester. Thus, any resulting changes in measurements could be attributed to changes in the phenomena being measured, along

with that due to systematic or random error. Third, conducting multiple tests (texts suggest three or more, Portney and Watkins, 2009) and using an average. This allows for the inherent fluctuations in physical phenomena (such as ROM and muscle strength) to be minimised, thus recorded values are close to the true value and not due to chance (Portney and Watkins, 2009).

As evaluating feasibility of measures was part of this study, all the testing was conducted in a clinical laboratory setting, similar to the clinical environment. This allowed testing procedures to be designed and implemented as they would be in the clinical setting, therefore being reproducible in clinical settings such as physiotherapy gyms and podiatric clinics. This approach was consistent with the clinical focus of the research programme, thus ensuring the development of the measures and protocols, and enabling feasibility to be evaluated.

4.2.2 Sample Type and Size

Inherent within reliability testing is the concept of population specific testing (Bruton *et al*., 2000), which is crucial for Study 1 as the reliability of tools must be evidenced within stroke participants. The study, therefore, only included participants who had had a stroke. Chronic stroke participants of three months or more after stroke were selected to ensure stability of measurement by avoiding improvements made by spontaneous recovery (Kwakkel and Kollen, 2013).

Two factors guided the sample size for this work: participants and time points (Sim and Wright, 2000). In most cases, practicalities often limit numbers due to the number of raters available and the tolerance of participants being tested (Sim and Wright, 2000). Walter *et al.* (1998) recommend a sample size of 19 to achieve a reliability coefficient of > 0.7 at two specified time points ($n = 2$) with an acceptable reliability of $p_0 = 0.7$; expected reliability $p_1 = 0.9$; power $(1 - \beta) = 0.8$; and significance level ($p = 0.05$). This study aimed to recruit 22 participants to allow for attrition (Sim and Wright, 2000).

4.2.3 Participant Recruitment

Ethical approval from the University of East London (UEL) Research Ethics Committee was gained before commencing the work (March 2013, Appendix 6). Participants were recruited from local stroke groups in Northeast London, identified through the Stroke Association website (www.stroke.org.uk/finding-support), as well as website advertisng i.e. Action for Rehabilitation after Neurological Injury (ARNI). The groups were attended by the researcher (AR) who presented the study in layman's terms to the attendees; interested volunteers were given a letter of invitation (Appendix 7). Participants were then contacted by the researcher (AR) and screened using the inclusion and exclusion criteria below. If these criteria were met, they were invited to attend two data collection sessions at UEL.

Inclusion criteria:

- three or more months after a diagnosed stroke;
- able to walk 10 m independently with or without an aid;
- living in the community;
- over 18 years old;
- able to give informed consent (no significant cognitive/behavioural/language barrier).

Exclusion criteria:

- any significant co-morbidity affecting the foot and ankle (e.g. rheumatoid arthritis);
- any recent surgery (e.g. hip or knee replacement) or any other neurological condition (e.g. Parkinson's disease).

Participants were given an information sheet regarding the study (Appendix 8) and gave their informed consent to participate (Appendix 9).

4.2.4 Testing Procedures

Testing for this study was undertaken in the Human Motor Performance Laboratory at UEL. An overview of the tests is shown in Table 4.1. Due to the long assessment battery and to ensure that participants were able to participate optimally during the test, tests were conducted on both the more-affected and less-affected limbs. These were tested for isometric muscle strength and peak ankle and hallux angle. All assessment methods were fully explained, each participant's comfort was maintained throughout with regular questions to ascertain discomfort and/or pain. The order of testing is shown in Table 4.2. This was organised for ease of testing and positioning of the participant, and to reduce possible fatigue experienced by the participant. For all the measures, three trials were performed, where applicable, with the less-affected side being tested before the more-affected side. All data collected was recorded in a data collection form (Appendix 10) with exception of DFL, which was recorded in a TekScan T-Scan^{TM} software database (v7.0) on the project laptop (Toshiba Pro OA Windows® 7). In accordance with national and local governance and data protection, records were kept in a secure location, in a locked room and cupboard, and data files were password protected and encrypted (University of East London (UEL) Data Management Guidance and Good Clinical Practice by the National Institute of Heath Research (NIHR)). Retest sessions (test 2) were conducted in the same location, on average 15.64 ±11.64 days after test sessions (test 1) and utilising the same assessment battery conducted in the same order. Time during the day of testing varied with participants and this was not controlled and therefore mimicked the clinical environment. No blinding occurred between measures as only one researcher conducted the protocols and recorded the findings. Informal piloting of procedures was conducted amongst the FAiMiS research team (Mary Cramp, TG and AR). The following sections include equipment, calibration and experimental testing protocols.

Table 4.2 Order of Testing for Study 1

Order	Measurement (position)	Tool	Variable [units] (*n*)
1	Peak ankle dorsiflexion angle (long sitting)	Bespoke rig	Peak angle [°] at low force and high force (2)
2	Ankle isometric muscle strength (long sitting)	HHD	Individual and all ankle summed [kg] (2)
3	Ankle PF spasticity (long sitting)	Tardieu scale	Severity of spasticity Presence of spasticity (2)
4	Peak hallux dorsiflexion angle (sitting on edge of plinth)	Bespoke rig	Peak angle [°] at low force and high force (2)
5	Hallux isometric muscle strength (sitting on edge of plinth)	HHD	Individual and all hallux summed [kg]
6	Static foot posture (standing)	FPI	Abnormal/normal Foot posture category FPI score (2)
7	Toe deformity	Observation	Toe deformity present Fixed/mobile (2)
8	Dynamic foot loading (standing and walking)	TekScan® HR mat	Peak plantar pressure [kPa], Contact area [cm^2], COP velocity [cm^2/sec], COF path length [cm] (4)

Abbreviations: COP = centre of pressure; FPI = foot posture index; HHD = hand-held dynamometer; PF = plantarflexor.

4.2.5 Participant Demographics

4.2.5.1 Participant information

As part of the initial data collection, specific questions were asked of the participant to gather information about the following (Appendix 10):

- Date of birth (DD/MM/YYYY)
- Time since stroke (months)

- Type of stroke (haemorrhagic/ischaemic)
- Location of stroke (cerebral, cerebellar, brain stem, unknown)
- Side of stroke (right or left)
- Dominant side (lower limb)
- Falls in the last three months (yes/no, and number)
- Any current treatment (specific to stroke, e.g. physiotherapy, changes in medication)
- Functional ambulatory classification scale (FAC) (Holden *et al.*, 1984). (Appendix 11)

4.2.5.2 Anthropometric Measures: Weight and Height

Body weight was measured using seca® scales. These were calibrated with known 10 kilogram (kg) weights (range 10–100 kg) prior to the start of the study. Anthropometric measures were taken with shoes off but no clothing was removed. Height was measured using a seca® height stadiometer (maximum height 205 cm) and recorded to one decimal place. Calibration was completed using calibrated rod lengths 150 cm and 200 cm. This was completed on a weekly basis during the three-month testing period. Participants were asked to step onto the scales and wait until their weight was recorded. Likewise, they were asked to step under the height measure and have their height recorded. Where necessary, the participant was assisted by the researcher (AR) to step onto the scales or to turn to have their height measured. These measures took two to five minutes.

4.3 CLINICAL MEASURES: FOOT CHARACTERISTICS

4.3.1 Static Foot Posture

The SOPs are found in Appendix 13.

4.3.1.1 Equipment

Static foot posture was assessed using the FPI-6 standardised assessment proforma (Redmond, 2005) found in Appendix 12. The FPI-6 consisted of six constructs: the talar

head palpation; supra- and intra-lateral malleolar curvature; calcaneal frontal plane position; prominence of region of talonavicular joint; congruence of the medial longitudinal arch; abduction/adduction of the forefoot on the rearfoot. Each construct was scored on a scale from −2 to +2 and were summed to give a multiplantar score of foot posture (−12 to +12) for each foot. The FPI was used 30 times by the researcher under supervision of an experience podiatrist, as recommended by Redmond (2005), prior to the start of Study 1[23].

4.3.1.2 Protocol

During testing, participants were asked to stand, barefoot, with their feet shoulder width apart and level with each other. If required, minimal support was offered by their walking aid. The protocol was applied as per the FPI-6 instructions: observing each construct; then deciding whether the feature was highly supinated, supinated, neutral, pronated or highly pronated. It took between two to five minutes to complete all six constructs for both feet.

4.3.1.3 Measures

Feasibility was evaluated by the completeness of data available, and the researcher reported ease of conducting and time taken to complete the test. Scores from the FPI were recorded for each construct and totalled for each foot giving a total score between −12 to +12 for each foot. Reliability was evaluated for the more-affected side using the scores in the original FPI categories, age-adjusted categories and normal/abnormal classification as per Redmond *et al.* (2008), see Table 4.3. Original scores in this table were based on five categories: highly supinated = −12 to −5; supinated = −4 to −1, normal = 0 to +5; pronated = +6 to +9; highly pronated 10+. Adults aged 60 years or more had scores adjusted to account for foot posture changes over this age (Menz, 2015). Normal and abnormal classification was included in line with Forghany *et al*. (2011) to allow comparisons between studies.

[23] Data was not kept for evaluation.

Table 4.3 Foot Posture Normal/Abnormal Classification Across Age Ranges (Redmond *et al*., 2008; Forghany *et al*., 2011)

Category	Abnormal		Normal	Abnormal	
	1 Highly Supinated	2 Supinated	3 Normal	4 Pronated	5 Highly pronated
Original	−12 to −5	−4 to −1	0 to 5	6 to 9	10 to 12
Normal adults	−12 to −4	−3 to 0	1 to 7	8 to 10	11 to 12
Adult > 59 years	−12 to −4	−3 to 0	1 to 8	9 to 11	12

4.3.2 Toe Deformity

4.3.2.1 Equipment

No equipment was required as visual observation and palpation was used.

4.3.2.2 Protocol

Toe deformity was evaluated by visual observation by the researcher (AR) of toe position on the more-affected side of participants. This was conducted in three positions: *in sitting*, on a standard chair with arms, with feet resting on the floor; *in standing*, with feet shoulder width apart and if necessary stabilised using a walking aid; and *in walking*, observing stance phase only. Using palpation of the joint movement and end feel, the deformity was classified as fixed or mobile and then recorded. Fixed deformity was where the joint could not be moved, and mobile was where movement was available.

Toe deformities recorded were:

- HHT: defined as extension of the hallux MTPJ;
- Claw toe/s: defined as flexion of both MTPJ and interphalangeal joints (IJPs) in the lesser toes;
- Hammer toe: defined as flexion of the IPJs in the lesser toes (Apley and Solomon, 2010).

4.3.2.3 Measures

Feasibility was evaluated by the completeness of data available, and the researcher reported ease of conducting and time taken to complete the test. Presence of deformity was reported as a dichotomous variable (Yes or No), and mobile or fixed deformity type was further described where deformities occurred. Where more than one deformity was present this was recorded in addition.

4.3.3 Dynamic Foot Loading

The SOPs are found in Appendix 14.

4.3.3.1 Equipment

Plantar pressure data collection was conducted utilising a high-resolution pressure mat, TekScan HR Mat™, Research v.6.70, as shown in Figure 4.1. The 0.5 m^2 low profile (0.57 cm) mat is comprised of 268 0.1 mm flexible sensors. The tool differs from other instrumentation, such as force platforms, in that it is relatively cheap, highly portable and easy to use (Giacomozzi, 2011; Orlin and McPoil, 2000). It also has good repeatability reported for non-stroke populations, with peak pressure over three trials (ICCs 0.65−0.92) (Zammit *et al.*, 2010). The mat was set up, connected to a power source via the USB computer input cable. Sensor boxes were attached to the mat via 25-foot cuff cables. The proprietary software package, FootMap™, was set up on the project laptop, ready for step calibration and participant data recordings.

Figure 4.1 Pressure Mat

4.3.3.2. Protocol

In accordance with guidelines by Giacomozzi (2010), calibration was conducted routinely to ensure that the pressure mat function was stable for testing purposes. The two-point calibration test was conducted before data collection commenced. This used known weights, which were sequentially loaded onto the mat and readings recorded; using raw sum data, a line of best fit was calculated and used to calibrate readings (TekScan, 2012, pp. 125–128). This technique incorporated assessment for drift and plateau of the pressure cells loading and therefore allowed for hysteresis and creep to be accounted for as the weights were applied sequentially over time (TekScan, 2012, pp. 129–132). Step calibration was used at the start of the test session for each participant prior to their data collection. This required participants to step with one foot at a time onto the mat. This is recommended as the most accurate calibration for research purposes (TekScan, 2012, p. 129). The TekScan HR Mat^{TM} trigger was set at > 2 kPa and the sampling rate was 50 Hz as recommended by Giacomozzi (2010).

Recordings were taken in standing and walking. To provide a representation of neuromuscular control of the ankle during standing, recordings of COF, or sway, were taken with participants standing on the mat for up to 400 frames, i.e. 20 seconds duration. This was completed with eyes open, with feet shoulder width apart and without use of an aid to stabilise. Sway recordings were kept short to minimise fatigue felt by the participants. Walking recordings were taken from a standing position following a two-step protocol (Menz and Morris, 2006; Zammit *et al*., 2010), where the second foot fall landed on the mat. The intention with this protocol was to account for the variability in gait following stroke (Patterson *et al.*, 2008) and to balance this with having to keep to a limited testing time frame. Participants were instructed to walk barefoot at a self-selected comfortable walking speed over the mat. If ankle-foot orthoses or similar aids were worn, these were removed. Three trials with complete loading of the foot on the more-affected side on the mat during stance were collected. The more-affected side was chosen to ensure that foot loading on the side more-affected by stroke was analysed for reliability and so that participants did not become fatigued during testing.

4.3.3.3. Measures

Feasibility was evaluated by reviewing data loss, and reasons for this, as well as anecdotal comments by participants of their experience of the testing, the number of trials and complete foot loads for each limb, were recorded, and time to collect and extract data was accounted for. Following critical analysis of plantar pressure variables in Chapter 3, the following variables were selected for analysis:

From standing trials:

Sway velocity and path length: COF trajectory velocity (cm^2/sec) and path length (cm) during static trials with eyes open during quiet standing. This was defined as rate of movement of the COF.

A diagrammatic representation of the COF path is shown in Figure 4.2. Data was extracted from ASCII files using a predetermined protocol (Appendix 18) and MATLAB® script (Appendix 19). Both path velocity and length vectors, as well as *x* (anterior–posterior) and *y* (medial–lateral) values, were extracted and used for analysis.

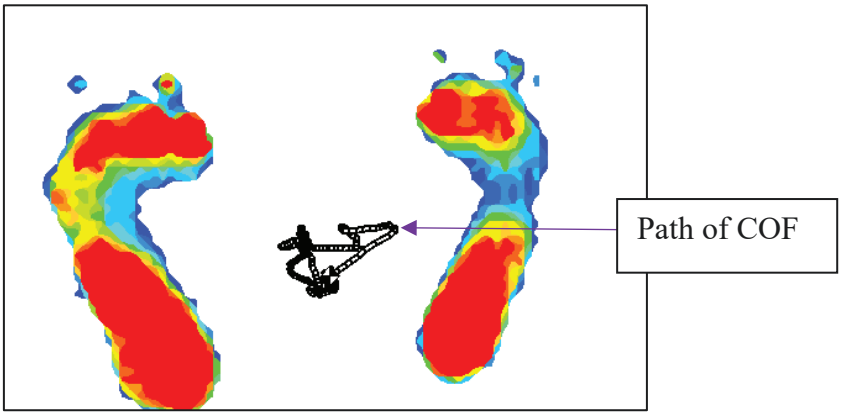


Figure 4.1 Peak Stance Centre of Force Path (Participant 12, Study 2), COF is denoted by black and white line, indicated by arrow.

From walking trials:

- **Peak plantar pressure (kPa):** defined as maximal pressure recorded during stance through one region of the foot;
- **Contact area (cm^2):** defined as the area in contact with the mat during stance.

From the walking trials, PPP (kPa) and regional CA (cm^2) values were evaluated, using two different plantar-foot region protocols involving four or eight regions. Region definition can be based on either anatomical or geometric regional maps (Giacomozzi, 2011) and a range of foot masks with the number of regions ranging from three to eleven has been used in the literature (Yang *et al.*, 2014; Chisholm *et al.*, 2011; Chen *et al.*, 2007). Geometric regional analysis does not require the use of kinematic measurements (Chapter 3, Section 3.4.3) and therefore it has been used in this work. It is based on mathematically calculated areas that include the anatomical regions of interest (Giacomozzi, 2011). Four and eight region maps were applied to the footprint. 'Four-region' analysis included rearfoot (RFT), mid-foot (MFT), forefoot (FFT) and toes regions. The foot was divided into equal thirds of total foot length (cm), defined as the distance from posterior mid-heel to the tip of second MTH. The toe region comprised of

the hallux and lesser toes, separate from the FFT, as reliability of plantar pressure analysis of the toe region has been reported as low (Pataky *et al.,* 2008). The four regions are shown in Figure 4.3.

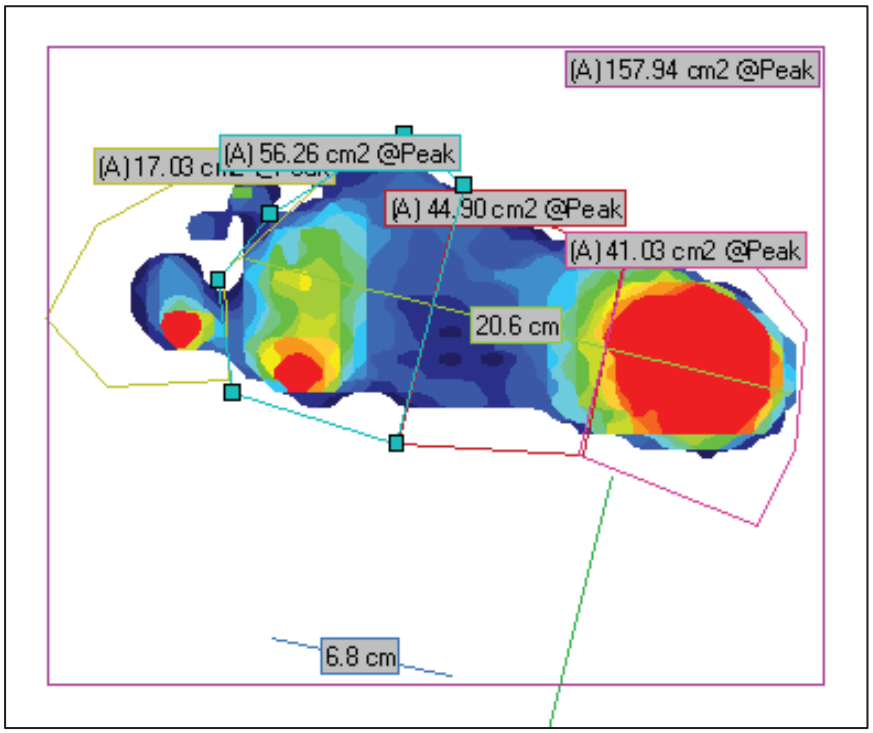


Figure 4.2 Four-Region Analysis

For the eight-region analysis (Figure 4.4), the foot was further bisected by a line from the posterior calcaneus to the second metatarsal head; the eight regions were lateral rearfoot (LRF), medial rearfoot (MRF), lateral mid-foot (LMF), medial mid-foot (MMF), lateral forefoot (LFF), medial forefoot (MFF), lateral toes (LToes) and medial toes (MToes). This was to ensure that changes on both the lateral and medial side of the foot could be evaluated as differences had been noted in previous studies (Meyring *et al*., 1997; Forghany *et al*., 2015).

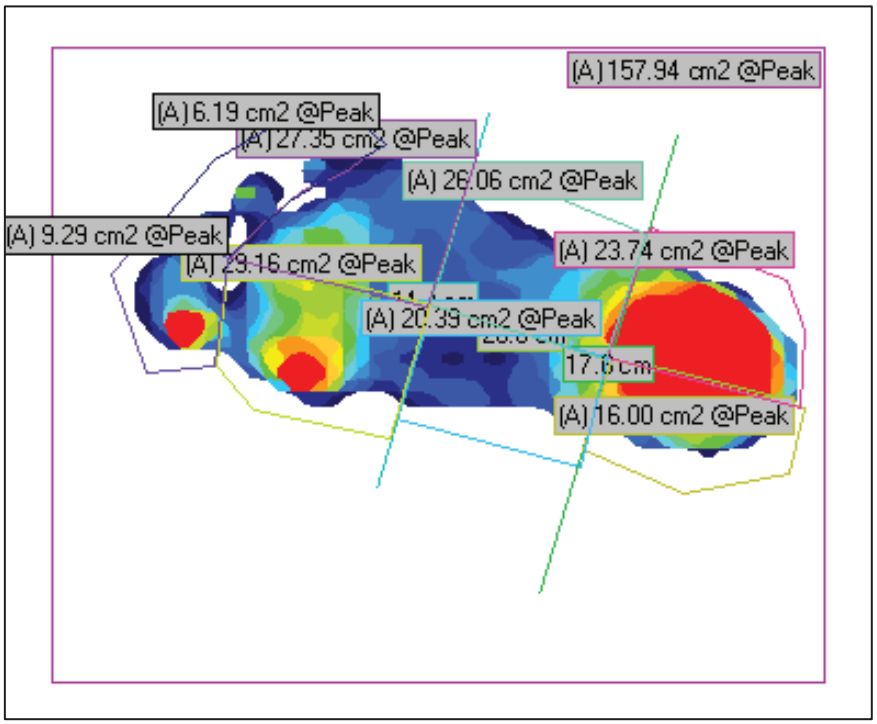


Figure 4.3 Eight-Region Analysis

Values for peak pressure and CA data for the foot and for each region were extracted as ASCII files and inputted into Excel files. The protocols for this can be found in Appendix 20; these were used in addition to the manufacturer's protocols (Tekscan HR Mat™ User Manual).

4.4 CLINICAL MEASURES: NEUROMUSCULAR IMPAIRMENTS

4.4.1 Ankle and Hallux Muscle Strength

The SOPs are found in Appendix 15.

4.4.1.1 Equipment

The Lafayette® (Nicholas) Manual Muscle Testing system is a HHD that is designed to measure isometric muscle strength. It has a resolution of 0.1 kg and a range of 0–136 kg, and it has attachments/heads suitable for small, medium and large surface areas. It was used to quantify isometric muscle force produced by six specific muscle groups: ankle dorsiflexion/plantarflexion/inversion/eversion, and hallux dorsiflexion/plantarflexion.

Use of a HHD in stroke has been established in the ankle (Bohannon, 1986; Riddle *et al.*, 1989) but not for ankle inversion and eversion and hallux muscle groups. It was calibrated using known weights attached via the hook and evaluated as a pull force.

*4.4.1.2 Protocol for **Ankle** Muscle Groups*

Participants were positioned in long sitting on a plinth, with the lower limb being tested placed on dense foam and with a 15 cm diameter roll under the knee being tested. Three large Velcro® adjustable straps were used to stabilise the pelvis, thigh and calf during this test. Participants were asked to actively resist the direction of force applied by the researcher. This was provided in the opposite direction (180°) of the resultant muscle group movement, e.g. for ankle dorsiflexion, force was provided on the dorsal aspect of the foot (axis of rotation through the malleoli). Standardised verbal encouragement was given to participants: "*keep pulling/pushing until I say relax"*. This was repeated throughout the test. Peak muscle force (kg) for the ankle DFs, PFs, invertors and evertors, from contractions held for five seconds, were recorded. Thirty-second rests were given after each contraction and each test was repeated three times. Further details are provided in Table 4.4.

Table 4.4 Testing Information for HHD at the Ankle

Movement	Head size*	Participant	Tester
Ankle dorsiflexion	Large, curved head, additional one layer of foam (7 mm thick).	On the centre of the dorsum of the foot, just proximal to the MTHs.	Positioned at the end of the bed facing the participant and in a wide step stance position with the plinth approximately hip height to allow good biomechanical advantage for the tester. Upper limbs will be neutral at shoulder region and 90° at the elbow with the wrist flexed, and hands grasping the HHD. Resistance will be given in a plantarflexion direction in line with the mid shaft of the tibia using body weight as necessary.
Ankle plantarflexion	Large, curved head, additional one layer of foam (7 mm thick).	Place the HHD on the centre of the plantar aspect of the foot over the MTH.	In the same position as above but with wrists extended and resistance offered in a DF direction.
Ankle inversion	Medium, flat circular head, additional one layer of foam (7 mm thick).	Place the HHD on the medial aspect of the foot halfway down the shaft of the 1st MTH.	Positioned still facing the participant and in step stance, upper limbs in a slightly flexed, abducted and internally rotated, wrist extended position. Position should enable force given to oppose inversion movement. For left foot, this will be the right UL. For right foot; the left UL.
Ankle eversion	Medium, flat circular head, additional one layer of foam (7mm thick).	On medial aspect of the foot, 5th MTH (mid-point).	Positioned with the opposite upper limb holding the HHD and opposing eversion.

*Head fixed to the HHD. Available head sizes were: large, slightly curved; medium, flat circular; small round. Abbreviations: HHD = hand-held dynamometer; MTH = metatarsal head; PF = plantarflexor; UL = upper limb.

*4.4.1.3 Protocol for **Hallux** Muscle Groups*

Participants were seated on the edge of the plinth, with the plinth at a height of 30 cm to accommodate a stool under the plantar surface of the feet, and to ensure a comfortable position for the researcher (AR). Participants were permitted to use their upper limbs to stabilise their trunk as necessary. The hallux MTPJ was placed on the edge of the stool. Additional support was provided by the researcher's hand over the dorsum of the foot to stop the foot from moving. Once in this position, the HHD was used to measure hallux dorsiflexion/plantarflexion by placing the head of the HHD on the distal phalanx of the hallux; this was on the opposite surface of the direction being tested. Further information is provided in Table 4.5.

Table 4.5 Testing Information for HHD at the Hallux

Movement	Head size*	Participant	Tester
Hallux dorsiflexion	Small diameter head, with foam layer.	On top of nail using the head.	Positioned kneeling on the floor. One hand holding the HHD and the other stabilising the foot, with web space round ankle.
Hallux plantarflexion	Small diameter head, with foam layer.	On centre of toe pad using the head.	Positioned kneeling on the floor. One hand holding the HHD, the other stabilising the foot.

*Head fixed to the HHD. Available head sizes were: large, slightly curved; medium round; small round.

4.4.1.4 Measures

Feasibility was evaluated by the completeness of data available, and the researcher reported ease of conducting, any equipment issues and time taken to complete the test. Three peak isometric force measurements were taken and recorded as kg force. A moment arm was defined as the length from lateral malleolus to the tip of the hallux and an average of 0.1 m (based on average height of 1.7 m and foot size of 8) was defined. The mean of the three values was calculated and used in data analysis. The mean of peak muscle strength was analysed for single individual muscle groups: ankle dorsiflexion, plantarflexion, inversion, eversion; and hallux dorsiflexion and plantarflexion. Additionally, to evaluate reliability and consider fit for the predictor model, composite (summated) values for ankle region (dorsiflexion, plantarflexion, inversion and eversion), hallux region (dorsiflexion and plantarflexion) and all muscle groups (ankle dorsiflexion,

plantarflexion, inversion, eversion and hallux dorsiflexion and plantarflexion) were calculated.

4.4.2 Peak Passive Ankle and Hallux Dorsiflexion Angle

The SOPs are found in Appendix 16.

*4.4.2.1 Tool Development: Peak **Ankle** Dorsiflexion Angle*

As presented in Chapter 3, using a standardised force is paramount in order to minimise the influence of soft tissue resistance on the ROM measured. No commercially available tool existed that applied a standardised force for measuring ankle dorsiflexion, so a bespoke rig was developed similar to features of the Lidcombe plate and procedure utilised by Keating *et al.* (2000). The key requirements identified from the literature were:

- To be able to passively measure peak ankle dorsiflexion.
- To be able to apply a low and high standardised force.
- To be appropriate for clinical use.

The bespoke tool (Figure 4.5) incorporated these features as outlined below:

- A digital inclinometer was employed to measure joint angle. A digital inclinometer was considered a more reliable method than goniometry (Konor *et al.*, 2012; Sidaway *et al.*, 2012). The digital inclinometer (Wixey WR365) used a 'Dead Level™ [24] system to establish the angles in a sagittal plane, which was only suitable for ankle DF/PF motion. The inclinometer had a 0.1 degree resolution with a range of −180/+180° and a digital display with a hold button and zero button to allow for calibration to any surface. The inclinometer was fixed to the ankle dorsiflexion measurement tool via a magnetic metal base. It could then also be attached to the hallux DF tool using the double-sided tape.
- To ensure a standardised force was input by the tester, a force transducer (Sauter FK250) was incorporated into the tool. The Sauter FK250 is a 15 cm long gauge

[24]Dead Level is the absolute level with respect to the centre of the earth.

with a steel fixture at the distal end and a digital display at the top; it measures linear forces using either a hook or a magnetic screw fitting at a rate of 1000 Hz.

- Finally, to position the participant's foot, a rigid plastic foot plate was used. A wooden handle and Velcro® straps were added to aid ease of use and stable fixation on the participant. Additionally, magnetised metal fixing points to attach/remove the strain gauge and inclinometer were added. Hygiene was maintained using alcohol-free wipes between users and comfort was ensured with the use of foam pads at the heel.

Modifications were required on the peak ankle DF rig to ensure that the ankle and foot were held firmly in place and the joint for the force transducer was sturdy. This meant a viable tool was not ready until the testing was halfway through Study 1.

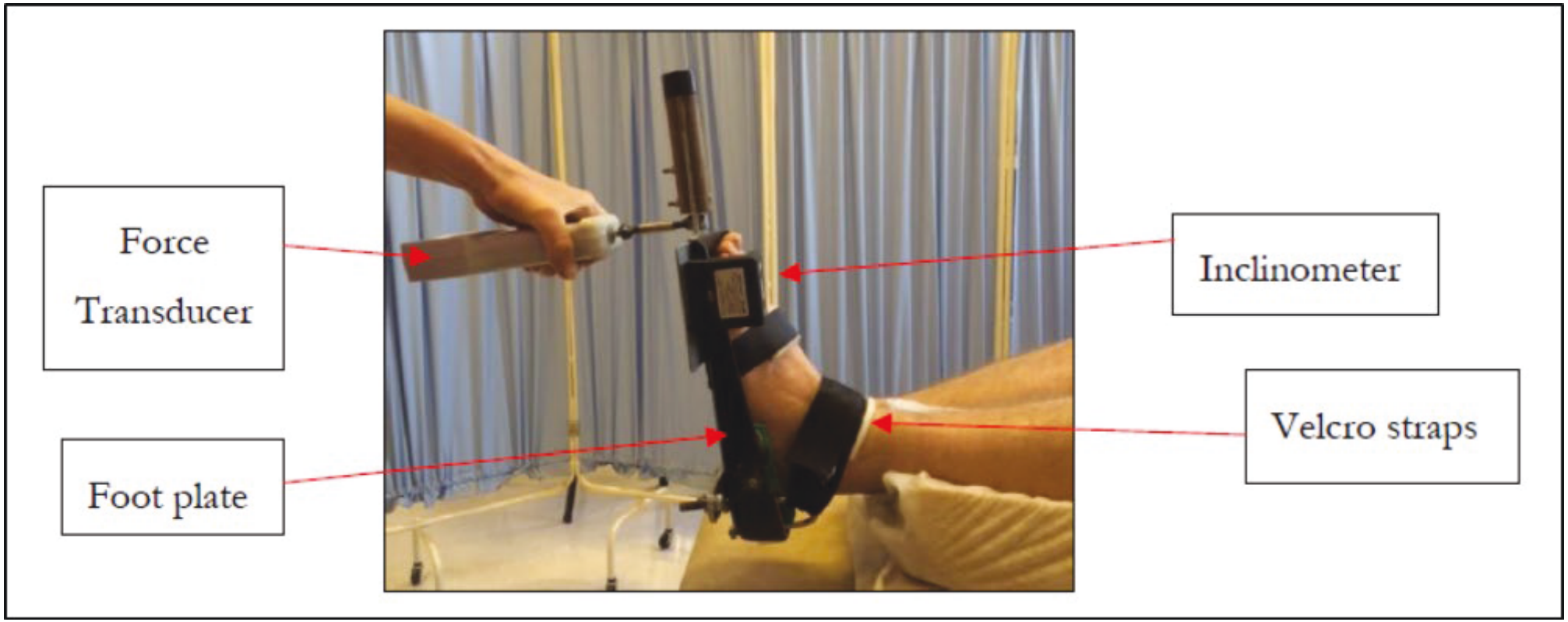


Figure 4.4 Peak Ankle Dorsiflexion Tool

*4.4.2.2 Equipment: Peak **Ankle** Dorsiflexion Angle*

Calibration of the force transducer was conducted using calibrated weighing scales, and the force exerted through the transducer was measured at specific points[25] to ensure that the measures were consistent over the range of forces and measured both low linear forces (e.g. 2 kg) and higher forces (e.g. 10 kg). For the ankle, 7 kg and 10 kg forces were applied to establish end-ankle DF ROM. 10 kg was comparable to the 14 N used by Keating *et al.* (2000). Furthermore, the use of two forces also permitted the stiffness measure to be calculated (Section 4.6.5.3). The inclinometer was set at a relative zero by turning the device on and pressing the ON/ZERO button to set the gauge to 0.0°, which 'calibrated' the device to the reference surface. No manufacturer's instructions were provided for calibration.

*4.4.2.3 Protocol: Peak **Ankle** Dorsiflexion Angle*

Participants were positioned in long sitting with the knee flexed over a 15cm diameter roll to approximately 20°. Dense foam was used under the calf to reduce the impact of posterior compartment soft tissue shortening (Keating *et al.*, 2000) and to keep the leg parallel to the floor. Participants' positions were stabilised using three Velcro® belts placed over the pelvis, thighs and legs to reduce the possibility of movement of the lower leg during testing. The rig was secured to the foot using Velcro® straps across the FFT and at the anterior ankle (Figure 4.6). The standardised starting position was ankle plantigrade, with the lateral malleolus as the axis, and head of the fibular and fifth MTH perpendicular to each other. In this position, the inclinometer was set at zero. If it was not possible to achieve plantigrade due to contracture, the joint was moved as close to this as possible and it was documented as the number of degrees from plantigrade, i.e. – degrees. Similar to Keating *et al.* (2000), a 7 kg force was applied perpendicular to the foot plate. The researcher used the force transducer to apply the set standardised force during the measurement. Force was applied over a 30-second period and repeated three times with a one-minute rest period. A second set of readings were taken at 10 kg force.

[25] 2 kg, 7 kg, 10 kg and 15 kg.

*4.4.2.4 Equipment: Peak **Hallux** Dorsiflexion Angle*

The hallux DF rig developed by Paton (2006), was used to measure passive ROM for hallux dorsiflexion. The rig consisted of a hinged wooden board covered with a wipeable PVC cover for hygiene and participant comfort (Figure 4.6). A digital inclinometer was affixed to the hinged part, and a hook attachment on the rig enabled the strain gauge to pull on the hinged part of the board, permitting passive hallux DF motion. Two forces, 2 kg and 4 kg, were selected through pilot testing. These forces were selected to ensure maximal ROM could be achieved. Furthermore, the use of two forces permitted stiffness measure to be calculated also (see Section 4.5.2.6 for more explanation).

*4.4.2.5 Protocol: Peak **Hallux** Dorsiflexion Angle*

Participants were positioned in sitting, on the edge of the plinth, using their upper limbs to support where necessary. The rig was placed under the foot to be tested, and the joint axis of the MTPJ space aligned with the hinge of the rig. Standardised forces of 2 kg and 4 kg were applied using a strain gauge towards the end of passive hallux DF ROM (Figure 4.6).

4.4.2.6 Measures

Feasibility was evaluated by the completeness of data available, and the researcher reported ease of conducting, any equipment issues and time taken to complete the test. The mean of the three values measured in degrees were calculated for peak passive ankle dorsiflexion and hallux dorsiflexion angle, at each force (low and high) and for both limbs, and used for data analysis. Ankle and hallux PF stiffness was calculated using ROM data from both high and low forces, using Equation 4.1, developed by Marsden *et al.* (2013).

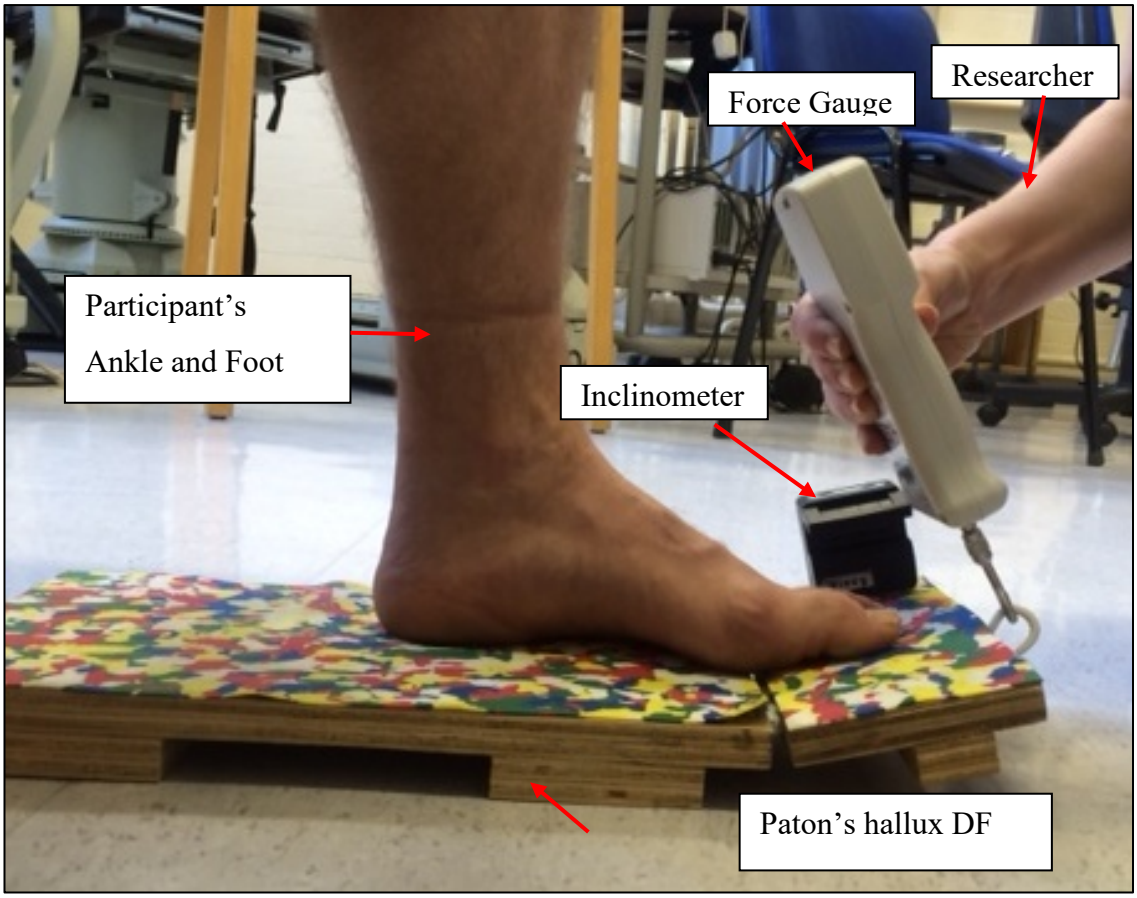


Figure 4.5 Hallux Dorsiflexion Rig

This was defined as change in force over change in passive ROM recorded at the respective force applied.

Equation 4.1 Stiffness Calculation

STIFFNESS = difference in force applied (kg)/change in ROM (°)

Example: Ankle stiffness
= 10kg – 7kg / (average passive ROM at high force (°) − average passive ROM at low force (°))

4.4.3 Ankle Spasticity

The SOPs are found in Appendix 17.

4.4.3.1 Equipment

The Tardieu scale (Morris, 2002; Boyd and Graham, 1999; Tardieu *et al.*, 1954) was used to record the presence of spasticity by ranking the quality of movement during passive ankle dorsiflexion.

4.4.3.2 Procedure

Participants were positioned in long sitting with a 15 cm diameter roll underneath the knee (without the foam support). The researcher (AR) passively moved participants from full available range of ankle plantarflexion to full available range of ankle dorsiflexion at slow and fast velocities[26]. This was achieved by moving the limb either slowly or rapidly through the participants' available range.

4.4.3.3 Measures

Feasibility was evaluated by the completeness of data available and the researcher reported ease of conducting, any equipment issues and time taken to complete the test. Quality of movement (X) was measured on an ordinal scale (0–5)[27] and the angle of the onset of resistance was assessed using visual estimation as per the scale instructions (Appendix 10). Where onset of resistance occurred throughout the range, it was reported as not applicable. Only fast values (V3), that detect movement resistance were analysed for reliability, as spasticity is velocity related and more evident at fast movements (Lance, 1980). Only the most-affected limb was evaluated.

[26]V1: As slow as possible (minimising stretch reflex); V2: Speed of the limb segment falling under gravity; V3: As fast as possible (faster than the rate of the natural drop of the limb segment under gravity).

[27]0 – No resistance throughout the course of the passive movement; 1 – Slight resistance throughout the course of the passive movement, with no clear catch at a precise angle; 2 – Clear catch at a precise angle, interrupting the passive movement, followed by a release; 3 – Fatigable clonus (< 10 seconds when maintaining pressure) occurring at a precise angle; 4 – Unfatigable clonus (> 10 seconds when maintaining pressure) occurring at a precise angle; 5 – Joint is immoveable.

4.5 DATA ANALYSIS

All data for the impairments reported in Sections 4.4.1 to 4.4.3 were input into a Microsoft® Excel spreadsheet for collation, and statistical analysis was conducted using IBM® SPSS® (version 22.0).

4.5.1 Descriptive statistics

Descriptive statistics were applied to all variables as follows:

- categorical data – frequency/counts;
- ordinal data – median and modes, interquartile ranges;
- ratio data – mean, either standard deviation (SD) and/or ranges.

All scalar variables (ratio data) – sway (COF), PPP, regional CA, muscle strength passive ROM – were explored for normal distribution using the Shapiro–Wilk test, which is appropriate for use in sample sizes < 50 (Field, 2013). Any missing data, resulting from being unable to test or from outputs not being sufficient to be read, were noted or reported on. Outliers were removed if they were greater than three SDs from the mean.

4.5.2 Feasibility

Feasibility was evaluated by observing the number of data sets available from the test–retest trials. Additionally, anecdotal notes made by the researcher and/or comments made by participants were reported in relation to ease of testing, practicality, cost and availability of equipment, and time taken to complete. Acceptable time limits are recorded in the SOPs.

4.5.3 Reliability Statistics

For variables with normal distribution, namely passive ROM, muscle strength, pressure variables, the ICC (model 3, *k*) was used to determine reliability of measures. This uses a two-way mixed test where consistency of results is examined (Portney and Watkins,

2009). ICCs were interpreted using conventional guidelines where values < 0.5 were deemed poor; those over 0.5 – 0.7, moderate; and those > 0.7, good (Portney and Watkins, 2009). Furthermore, when ICCs were > 0.8, these were reported as excellent (Sim and Wright, 2000). For absolute reliability, showing magnitude of error, the SEM and mean differences (MD) were reported. SEM is defined as the amount of variance due to the measure, and is calculated by Equation 4.2 (Portney and Watkins, 2009):

Equation 4.1 SEM Calculation

$$SEM = \frac{\text{standard deviation}}{\sqrt{1 - \text{reliability}}}$$

MD is the difference between mean test and rest scores. Limits of agreement and MDs were calculated, and Bland–Altman plots were constructed (Kottner *et al.*, 2011; Bland and Altman, 1986). For agreement using Bland–Altman Plots, the limits of agreement (LOA) were set at 95%, i.e. 2SD away from the mean difference of the data set. No a priori values were set. These could not be established due to lack of, or too little, available data across measures, despite literature stating that *"acceptable limits must be defined a priori, based on clinical necessity, biological considerations or other goals."* (Giavarina, 2015). Therefore, plots were analysed for any bias in agreement.

For non-parametric data, a linear weighted kappa was used to assess reliability. This is an accepted method of evaluating agreement across tests, accounting for the ordering of the data points and level of disagreement in observations (Sim and Wright, 2000). Linear weighted kappa values were evaluated for the Tardieu scale, bilateral and more-affected-side FPI categories, and normal and abnormal classification. Values were interpreted using guidance regarding the strength of agreement where values < 0.4 are unacceptable; those between 0.41–0.6, moderate; 0.61–0.8, good; and 0.81–1, almost perfect (Landis and Koch, 1977). The results were interpreted using standard error of the mean, which is an estimation of population standard deviation (Portney and Watkins, 2009). Confidence intervals (CIs) were used to provide context in which to interpret the results (Sim and Wright, 2000). Evaluation of reliability was conducted in line with GRRAS guidelines.

4.5.4 Clinical Relevance

This was evaluated through analysis of differences between most-affected and least-affected sides for DFL only (see Study 1 aims).

Acceptable findings for inclusion in Study 2 were:

- Feasibility: > 50% of data available, time of testing took no longer than predicted in SOPs and no adverse effects).
- Reliability: moderate or greater reliability with demonstration of agreement in Bland–Altman plots.
- Clinical relevance (applied to DFL only): demonstrated differences between limbs (more- and less-affected) and regions (RFT, MFT, FFT, Toes).

Table 4.6 Data Analysis Plan

Variable	Level of measurement	Descriptive statistics	Figures	Reliability statistics
Foot posture ➢ **Categories** ➢ **Abnormal/normal**	Ordinal/ categorical (dichotomous)	Mode Count Percentages	Bar chart	Kappa (linear weighted)
Toe deformity type	Categorical (fixed or mobile)	Percentages	Nil	N/A
Dynamic foot loading ➢ **Sway velocity** ➢ **Path length** ➢ **Peak plantar pressure** ➢ **Foot contact area**	Ratio	T1 and T2 mean Test mean SD	Tables of values and B–A plots	$ICC_{(3,k)}$ MD Upper and lower LOA SEM B–A plots
Individual/composite Ankle/hallux isometric muscle strength				
Peak ankle/hallux dorsiflexion (low/high force)				
Ankle PF spasticity (quality of reaction, fast velocity)	Categorical (dichotomous) ordinal	Median range	Bar chart	Kappa (linear weighted)

Abbreviations: ICC = intraclass correlation coefficient; LOA = limits of agreement; MD = mean difference; PF = plantarflexor; SD = standard deviation; SEM = standard error of measurement

4.6 RESULTS

This section includes analysis of foot characteristics (static foot posture, toe deformities and DFL characteristics) and neuromuscular impairments (isometric muscle strength measures, peak joint angle, passive stiffness and ankle spasticity). Results are presented according to the research questions being explored.

All testing was conducted on two occasions with approximately two weeks between sessions (15.64 ±11.64 days). This broad range was accounted for by the availability of participants over the summer period when the work took place. Ideally, a gap of two weeks or less to replicate attendance at consecutive physiotherapy appointments would have been preferred. When testing was incomplete, the data was recorded as missing; this is reported for each variable in turn.

4.6.1 Participants

Recruitment response is shown in the flow diagram in Figure 4.7. Participants were recruited through the researcher's attendance at five local stroke groups (Newham, Hackney, Walthamstow, Redbridge and Greenwich) along with advertising through the ARNI website. Numbers who attended the groups varied and information sheets were offered to all participants; however, not all who attended the groups met the selection criteria, e.g. whether participants were able to walk 10 m independently. Two participants were recruited through the ARNI website advert, with most recruited from the most local stroke group (to the researcher AR) in Newham. Eight volunteers expressed an interest but on telephone follow up did not want to attend. In total, 21 participants were recruited. All participants were able to walk a minimum of 10 m with or without an aid and were community dwelling; 17 attended for both test and retest sessions. Four retests were lost as participants did not attend follow up sessions and declined to be reassessed.

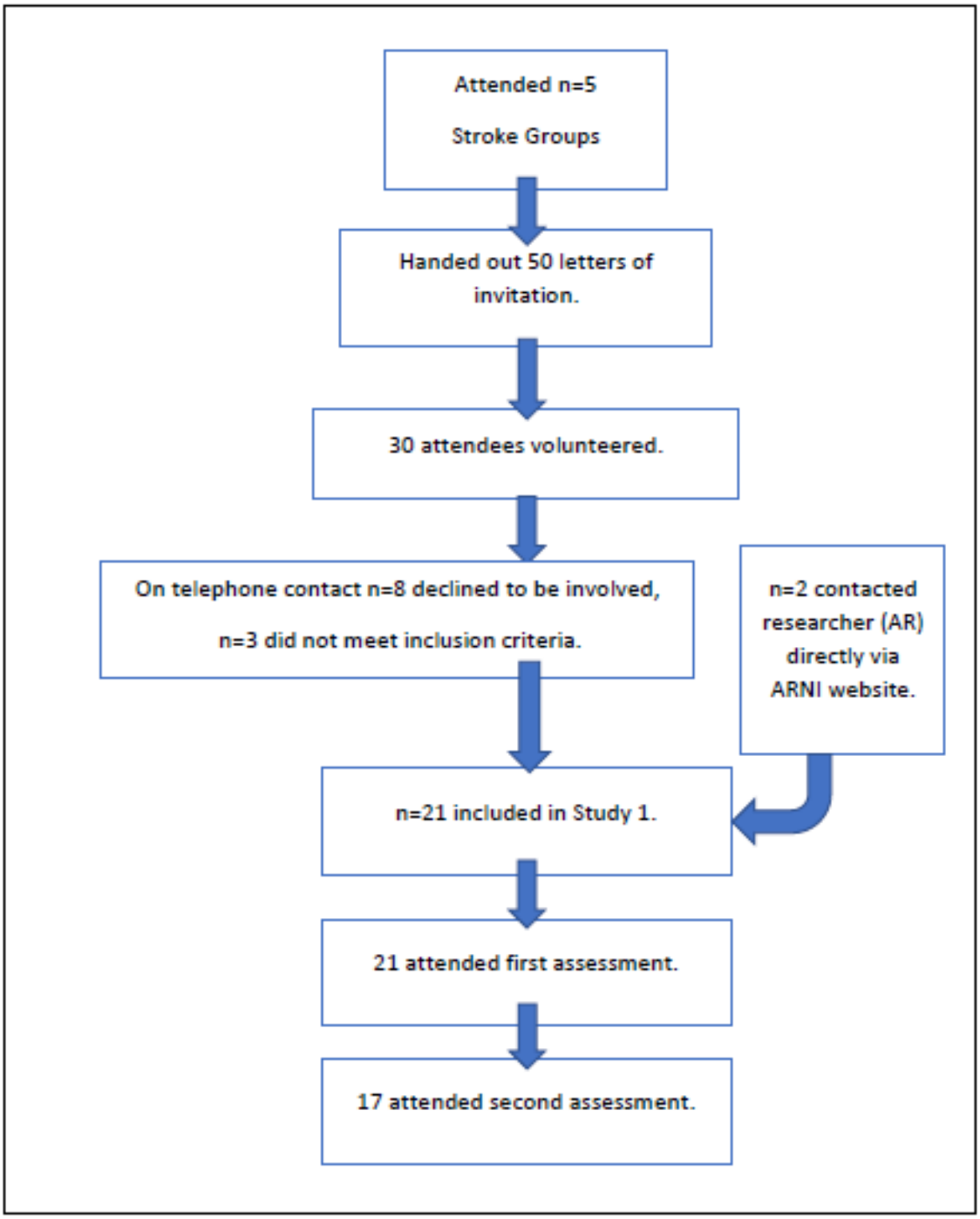


Figure 4.7 Recruitment Flowchart

Of the 17 participants that completed test and retest assessments, eight were male with a mean age of 61.2 ±9.9 years, height 1.67 ±0.12m and weight 76.1 ±13.5 kg (Table 4.7). Nine had a left-sided stroke and the mean time since stroke was 65.2 ±6.83 months, ranging from 9–192 months. Apart from having had a stroke, other self-reported co-morbidities existed: one with sciatica (6%), one with osteoarthritis (6%), two with asthma (12%) and three with hypertension (18%). Of the group, four (21%) were classified as dependent with supervision on the FAC scale and 13 (79%) were independent on level surfaces only[28].

[28] Further information of type of stroke, length of stay and self-care was not available to the researcher as part of this study.

Table 4.7 Participant Demographics

Participant	Gender (M/F)	Age (years)	Weight (kg)	Height (m)	TSS (months)	Affected side	Mobility (over 10 m)	FAC*	Stroke (type/impairments)	Co-morbidities/ other
1	M	59	65	1.55	21	both: R > L	walks with one stick	3	poor comprehension and ability to follow questions	
2	M	45	85	1.73	192	R	independent	4	some mild dysphasia	
3	F	67	75	1.635	18	R	independent	4	some exp dysphasia	
4	M	56	90	1.86	9	L	independent	4		
5	F	70	85	1.62	156	L	w/stick	4	weakness, speech, neglect, temporal lobe	
6	M	54	65	1.745	48	L	w/stick	4		asthma, attends tai chi
7	F	80	64	1.59	48	?L frontal/temporal	independent	4	stroke affected speech, writing, memory, no motor impairment	asthma
8	M	60	100	1.73	96	L	w/stick short dist., wheelchair for longer	4		diabetes type II – well controlled
9	M	59	51	1.68	42	R	w/stick outdoors	4		BP tablets, nil else. Mile end physio (MSK)
10	M	63	91	1.83	66	L	w/stick - short dist., w/chair long dist.	4		

Participant	Gender (M/F)	Age (years)	Weight (kg)	Height (m)	TSS (months)	Affected side	Mobility (over 10 m)	FAC*	Stroke (type/impairments)	Co-morbidities/ other
11	F	72	82	1.44	28	R	Occasionally uses a cane	4		diabetes, high cholesterol, hypertension
12	M	71	95	1.785	17	R	w/stick outdoors	4	ischaemic, affected UL/LL/speech, memory, surgery to remove clot	hypertension, spondylosthesis, diabetes, COPD
13	F	77	65	1.54	38	R	uses a w/stick outdoors	4	Brainstem	ischemic stroke, on simvastatin
14	F	65	NT	NT	90	L	wheelchair long dist., stick inside, AFO	3		heart attack – bypass 2006, high cholesterol, hypertension
15	F	72	60	1.57	192	L	w/stick, scooter long dist.	3		hypertension, arthritis in lumbar spine.
16	F	74	92	1.59	84	L	w/stick (SD)	4		arthritis L knee, high BP, cholesterol
17	F	51	NT	NT	96	L	w/stick, v slow gait, needs wheelchair for distances over 20 m	3	1 H 2I, scattered bleeds throughout	Diabetes – type II, occasional sciatica
18	M	62	73	1.68	72	L	w/stick outdoors, no aid indoors	4	ischaemic stroke	Gout/arthritis

Participant	Gender (M/F)	Age (years)	Weight (kg)	Height (m)	TSS (months)	Affected side	Mobility (over 10 m)	FAC*	Stroke (type/impairments)	Co-morbidities/ other
19	F	59	85	1.57	27	L	w/stick outdoors and indoors	4		Diabetes – type II, hypertension, high cholesterol, falls, arthritis L wrist
20	M	36	82.5	1.73	39	both: R > L	no splint or aid	4		
21	M	46	88.5	1.73	39	R	w/stick indoors and outdoors, wheelchair long dist.	4	haemorrhagic strokes (x2)	Had hydro 1/week, GP ref to physio, botox R calf
Average (*n* = 17)	8 M 9 F	61.2 ±9.9	76.1 ±13.5	1.67 ±0.12	65.2 ±6.83	9 R 8L	-	3: *n* = 4 4: *n* = 17	-	-

(TSS = time since stroke, *FAC, Appendix 11, NT = not tested)

4.6.2 Feasibility in Study 1

Figure 4.8 shows data available for analysis for each measure due to loss of data or missing data. This is complemented by Table 4.8 which shows data availability at test and retest for each measure. Notably, modifications were required to improve attachment to foot and comfort for stroke patients of the ankle passive ROM rig, as identified in initial testing; only nine participants completed both test–retest.

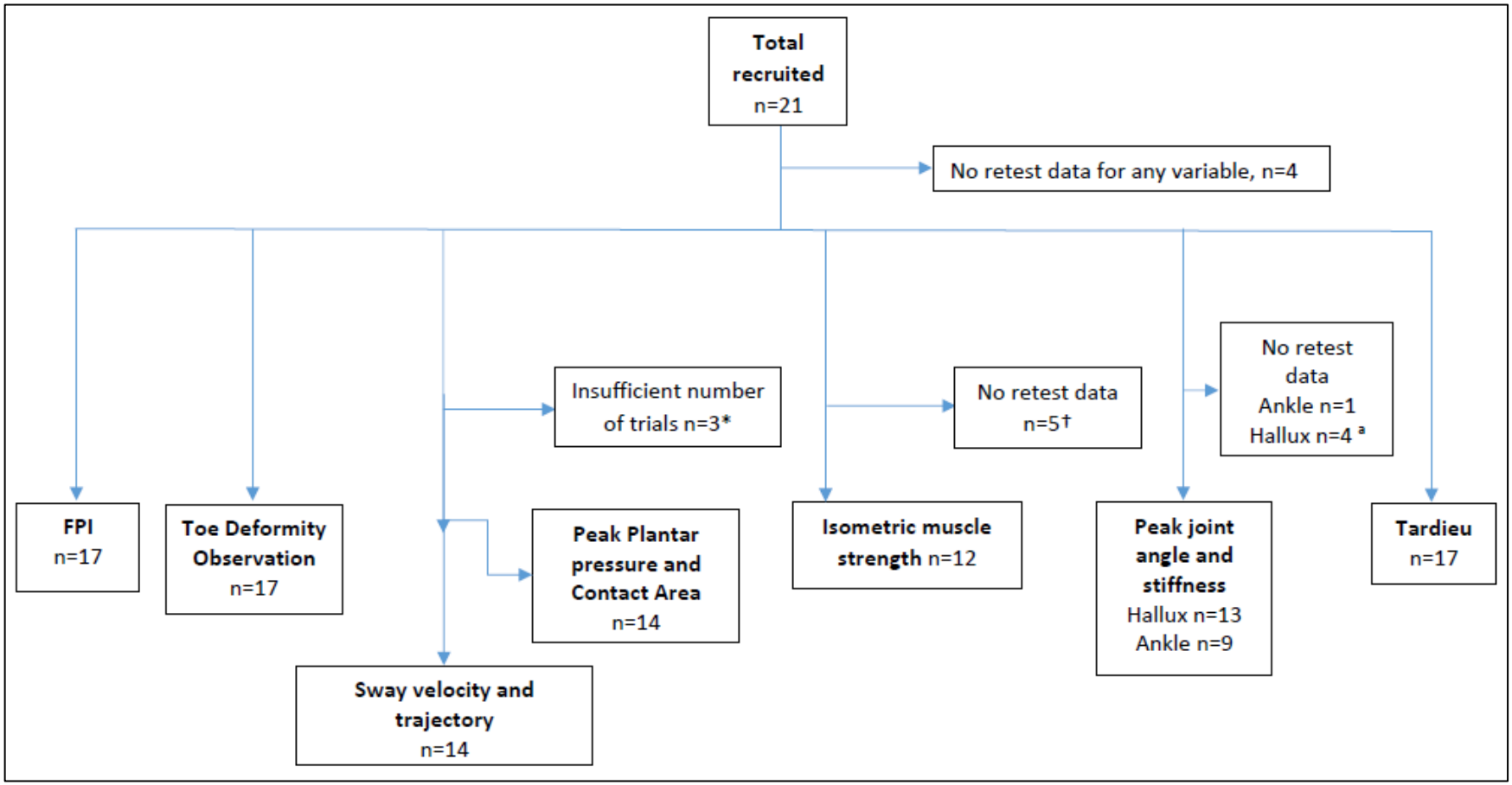


Figure 4.8 Numbers of Participants Included for Analysis of Each Impairment

*Due to variability in gait pattern and incomplete loading of the foot; †Due to equipment set up issues and patient unable to be tested secondary to pain/discomfort; [a]Due to rig modifications, the ankle only tested on n = 10, n = 1 lost at follow up; hallux n = 3 unable to test.

Table 4.8 Data Available for Each Participant at Test (T) and Retest (RT)

	Attendance		Impairment measured															
Participant	Test (T)	Retest (RT)	FPI		Toe deformity		DFL standing		DFL walking		Strength		Angle ADF		Angle HDF		Spasticity	
			T	RT			T	RT	T	RT	T	RT	T	RT	T	RT	T	RT
1	✓	✓	✓	✓	✓		✖	✖	✓	✓	✓	✓	✖	✖	✓	✖	✓	✓
2	✓	✓	✓	✓	✓		✓	✖	✓	✓	✖	✓	✖	✖	✖	✓	✓	✓
3	✓	✓	✓	✓	✓		✓	✓	✓	✓	✖	✓	✖	✖	✖	✓	✓	✓
4	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✖	✖	✓	✓	✓	✓
5	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✖	✖	✓	✓	✓	✓
6	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✖	✖	✓	✓	✓	✓
7	✓	✓	✓	✓	✓		✖	✖	✖	✖	✓	✓	✖	✖	✓	✓	✓	✓
8	✓	✖	✓	✖	✖		✖	✖	✖	✖	✖	✖	✖	✖	✖	✖	✓	✖
9	✓	✓	✓	✓	✓		✖	✖	✓	✓	✖	✖	✖	✖	✓	✓	✓	✓
10	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
11	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
12	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
13	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
14	✓	✖	✖	✓*	✖		✖	✖	✖	✖	✖	✖	✓	✖	✖	✖	✓	✖
15	✓	✓	✓	✓	✓		✖	✖	✖	✖	✖	✖	✓	✓	✓	✓	✓	✓
16	✓	✖	✓	✖	✖		✖	✖	✖	✖	✖	✖	✓	✖	✖	✖	✓	✖
17	✓	✓	✓	✓	✓		✖	✖	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
18	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
19	✓	✖	✓	✖	✖		✓	✓	✖	✖	✖	✖	✓	✖	✖	✖	✓	✖
20	✓	✓	✓	✓	✓		✓	✓	✖	✖	✖	✖	✓	✓	✖	✖	✓	✓
21	✓	✓	✓	✓	✓		✓	✖	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Totals	*21*	*17*	20	18	17	N/A	13	11	14	14	12	14	12	9	14	15	21	17

	Attendance		Impairment measured															
Participant	**Test (T)**	**Retest (RT)**	**FPI**		**Toe deformity**		**DFL standing**		**DFL walking**		**Strength**		**Angle ADF**		**Angle HDF**		**Spasticity**	
			T	**RT**			**T**	**RT**	**T**	**RT**	**T**	**RT**	**T**	**RT**	**T**	**RT**	**T**	**RT**
Total data available for use	***17***		**17**		**17**		**10/11**		**14**		**12**		**9**		**13**		**17**	

*in sitting only. Abbreviations: FPI = foot posture index, DFL = dynamic foot loading, ADF = ankle dorsiflexion, HDF = hallux dorsiflexion.

4.6.3 Key Findings in Study 1

The subsequent section addresses feasibility and reliable for all impairments measured. Table 4.9 summarises these findings.

Table 4.9 Summary of Key Findings Study 1

Impairment	Feasibility	Reliability
Static foot posture	Feasible 17/17 data available 2–5 minutes	Good: κ_w = 0.53–0.60
Toe deformity	Feasible 17/21 data available 5 minutes	
Sway	Feasible 14/17 data available 5 minutes	Moderate to good: ICCs 0.54–0.78
Peak plantar pressure and contact area	Feasible 14/17 data available 15 minutes	4 region: Good to excellent: PPP ICC 0.76–0.96, CA 0.58–98; 8 region: Moderate to excellent PPP ICC 0.36–0.98, CA ICC 0.61–0.97*
Isometric ankle and hallux muscle strength (single measures)	Feasible 12/17 data available 15 minutes	Moderate to excellent: Most-affected side ICC 0.62–0.95 Less-affected side ICC 0.42–0.95
Isometric ankle and hallux muscle strength (composite measures)	Feasible 12/17 data available 15 minutes	Good to excellent: Most-affected side ICC 0.67–0.93 Less-affected side ICC 0.71–0.95
Peak ankle dorsiflexion	Feasible 9/17 data available 10 minutes	Moderate to excellent: ICC 0.53–0.82
Peak hallux dorsiflexion	Feasible 13/17 data available 10 minutes	Good to excellent: ICC 0.70–0.82
Passive ankle and hallux PF stiffness**	Feasible 9–13/17 data available	Poor/absent: ICC 0.00–0.11
Ankle PF spasticity	Feasible 17/17 available 5 minutes	Good: κ_w = 0.78

*PP = peak pressure, CA = contact area. **no additional time required as stiffness was measured concurrently with peak ROM data.
ICC = intraclass correlation coefficient; DF = dorsiflexor; PF = plantarflexor.

4.6.4 Foot Characteristics

4.6.4.1 Static Foot Posture

Research question 1 explored the reliability of using the FPI as a measure of static foot posture[29]; 17 out of 21 (81%) participants had data available, due to the four lost at follow up. The FPI was easy to apply with participants able to stand in bilateral stance for two to five minutes.

Figure 4.9 shows original FPI categories on test and retest for the more-affected side. Median values were similar between test and retest; three (range 0–9) for test compared to four (range –1 to 11) for retest, which was classified as neutral. Neutral foot posture was most commonly reported, with 14 participants demonstrating this on test (82%) and 12 on retest (71%). Reliability was found to be moderate using the original FPI categories (K_w = 0.53, 95% CI 0.06–0.99).

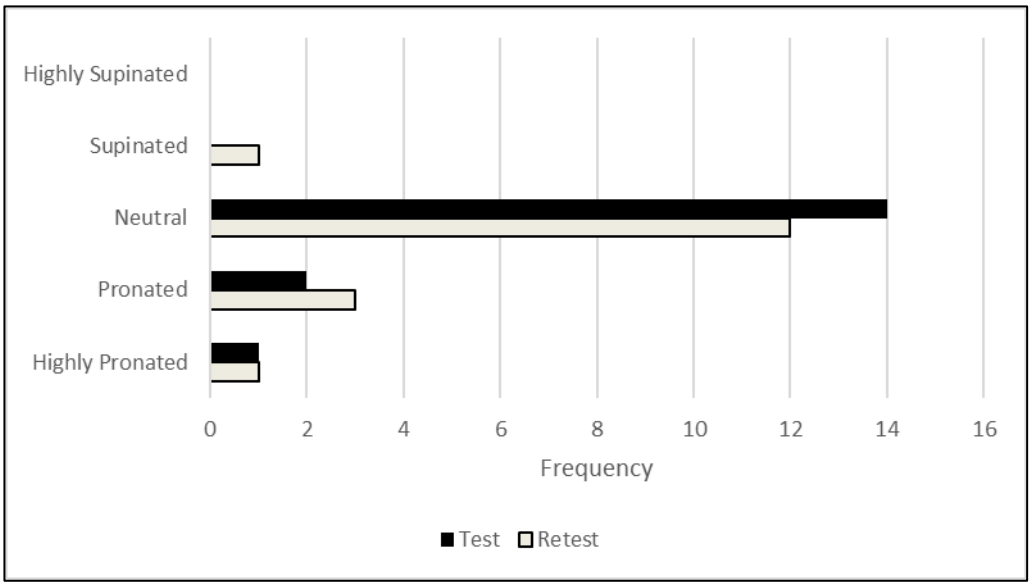


Figure 4.6 Original FPI Frequency for Test and Retest

[29]FPI categories are as follows: Highly supinated = −12 to −5; Supinated = −4 to −1, Normal = 0 to +5; Pronated = +6 to +9; Highly pronated 10+.

Using age-adjusted FPI categories, foot posture ranged from neutral to supinated across test and retest. Neutral foot posture was most commonly reported, with 14 on test (82%) and 11 retest (65%), and only two participants changing categories. Reliability improved using the age-adjusted FPI categories with $\kappa_w = 0.59$, 95% CI 0-0.71. Age-adjusted FPI category frequency is shown in Figure 4.10.

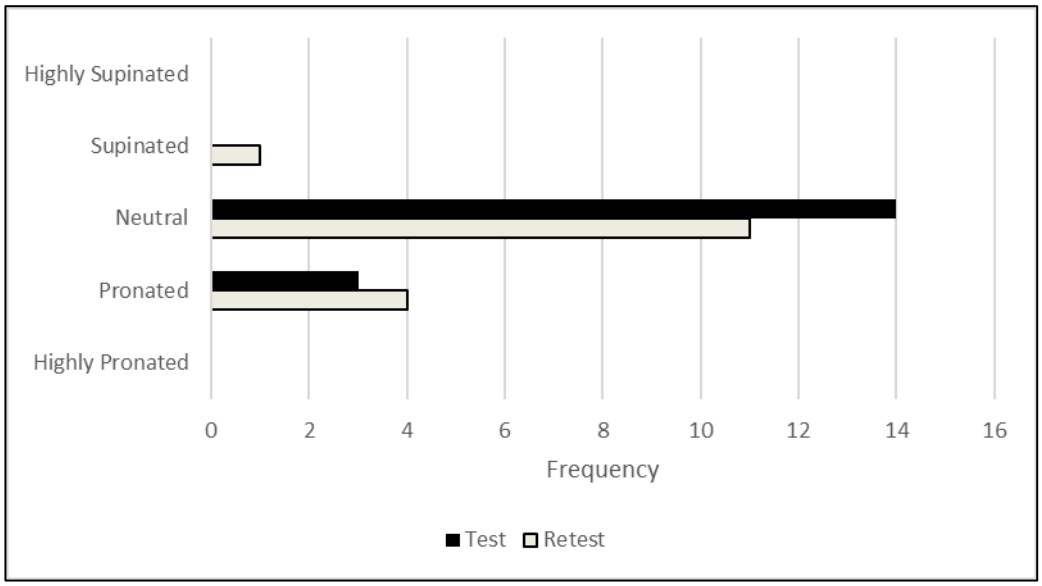


Figure 4.10 Age-adjusted FPI Frequency for Test and Retest on the More Affected Side

Using normal/abnormal classification the mode/median category report was normal on both test and retest, with the two participants that changed categories moving from normal to abnormal (one to pronation and one to supination). Reliability using normal/abnormal classification improved again with $\kappa_w = 0.60$, 95% CI 0.09–1. Notably broad 95% CIs were found for both original and age-adjusted categories.

4.6.4.2 Toe Deformity

Research question 2 set out to explore toe deformity feasibility and presentation by identifying three types of toe deformity, which were documented during sitting, standing and walking. The visual observation and palpation were feasible to conduct, taking no longer than 5 minutes. Data was available for all 21 participants. Observations found that claw toe was present in nine (52%) participants with five (30%) mobile and four (24%) fixed; HHT was found in one (6%) participant only and one (6%) reported hammer toe. In addition, two (12%) participants had HV. Between positions of sitting, standing and

walking, one participant changed from HHT to neutral position. No retest was analysed as video analysis was not evaluated as part of this thesis, see Sections 4.7.2.2 and 4.7.4 for further details.

4.6.4.3 Dynamic Foot Loading

Feasibility and reliability of plantar pressure variables was evaluated. This section includes results for feasibility of use of plantar pressure assessment; reliability of static measure of sway in quiet standing; and dynamic measures of PPP and CA during stance phase of gait. It concludes with comparisons between the more- and less-affected sides as evaluation of clinical relevance of the variables.

4.6.4.4 Feasibility and Reliability of Dynamic Foot Loading During Standing: Sway Velocity and Path Length

Data was available for 10 participants for standing trials. Trials took five minutes to complete. Data was lost at retest from three participants, and a further participant's values were deemed extreme outliers (> 3SD from the mean) and were removed (participant code: P13). Table 4.10 shows that the ICCs were good to excellent, with overall variables being good (ICC = 0.78), *x*-axis (A–P) element being excellent (ICC = 0.85), and *y*-axis (M–L) being moderate (ICC = 0.54). Notably, the same ICC values exist whether COF velocity or path length values were extracted, although test mean values and SD were higher and demonstrated more variance for path length. SEM is indicative of response stability (Portney and Watkins, 2009); stability seemed lower, with higher SEM values for path length than COF velocity.

Table 4.10 Reliability of COF Velocity (cm·s^{-1}) and Path Length (cm)*

Variable		ICC** (95% Confidence Intervals)	Mean Difference (SD)[a]	Test Mean (SD)	Limits of Agreement[†]		SEM
					Lower	Upper	
Velocity	Vector	0.78 (0.34, 0.94)	-2.41 (3.62)	13.26 (5.46)	-9.66	4.84	2.56
	X	0.85 (0.50, 0.96)	-1.62 (2.52)	10.79 (4.54)	-6.67	3.43	1.77
	Y	0.54 (-0.09, 0.86)	-1.51 (2.46)	5.87 (2.62)	-6.44	3.41	1.77
Path Length	Vector	0.78 (0.34, 0.94)	-19.25 (29.00)	106.06 (43.70)	-77.24	38.75	20.50
	X	0.85 (0.50, 0.96)	-12.97 (20.19)	86.32 (36.34)	-40.38	27.41	14.12
	Y	0.54 (-0.09, 0.86)	-12.11 (19.71)	46.93 (20.99)	-51.53	27.30	14.20

**n = 10.*

**Intra class correlation coefficient ($ICC_{(3,1)}$ agreement).

[a]MD = T1–T2, where T1 = test 1 and T2 = retest.

[†]Limits of agreement = MD ± 2 x SD.

NB: Values for vector = the overall vector including *x* and *y*; *x* is in the anterior–posterior direction and *y* is in the medial–lateral direction.

Bland–Altman plots were the same for both COF velocity and path length so only graphs for velocity are shown in Figure 4.11. These show clearly that retest values tended to be higher, with values appearing below the test mean, which also reflected in the retest mean and SD.

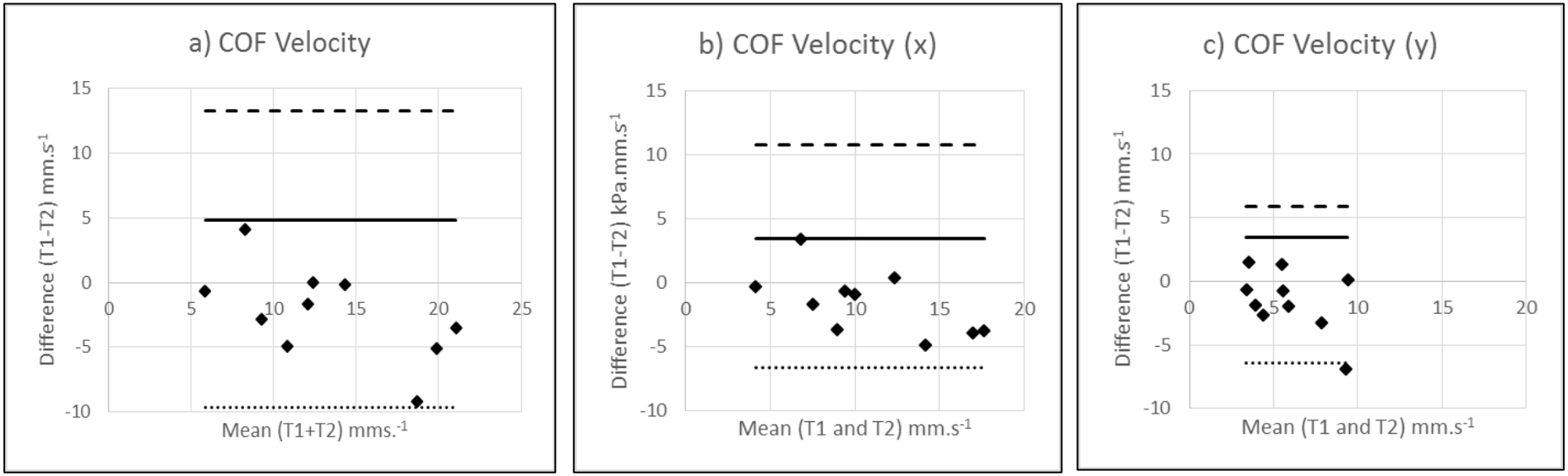


Figure 4.7a, b and c Bland–Altman Plots: Reliability of COF Velocity (kPa·cm·s^{-1})*

*Dashed line = upper limit of agreement; solid line = mean; dotted line = lower limit of agreement; diamonds = difference between test and retest mean.

4.6.4.5 Feasibility of Dynamic Foot Loading Analysis during Walking

DFL data was available for analysis for 14 participants out of the 21 recruited (67%), four participants were lost at follow up. A further two participants demonstrated overlapping foot loads, due to reduced step length, from which data could not be extracted. Lastly, one participant had challenges with footfall onto the pressure platform, so no data was available. The data collection sessions for stroke participants required up to 15 minutes. To obtain three complete footfalls for analysis, an average of seven walking trials including practice trials was required per participant. This amounted to an average of 15 ±5 (range 7–32) foot contacts on the mat per participant. Incidentally, data was also captured for the less-affected side and has been analysed here.

More detailed, and repeated, verbal instructions about the testing procedure were required for participants. Securing the required three footfalls directly on the pressure platform was an ongoing challenge and one participant struggled to ambulate over the mat without shoes, possibly due to the loss of shoe support around the foot. Fatigue and the requirement to rest between trials was also an important consideration during data collection. Repeat trials were necessary to secure a complete foot fall in 50% of the participants. Participants did not raise any concerns with the length of the data collection session. It was noted that those who required a high number of repetitions became more fatigued, but they reported finding the session easier on the second visit. Table 4.11 includes data recorded from both feet. As can be seen, with an average seven trials and 15 foot contacts, many participants had two clean foot contacts on the foot mat in one walking trial due to their reduced stride length.

Table 4.11 Number of Complete Foot Loads Versus Trials for Both Less-Affected and More-Affected Sides for Test and Retest

Variable	Test	Retest
Number of recordings (i.e. walks across the mat)	6.6 ±1.3	7.64 ±2.7
Number of foot loads	15.3 ±5.9	13.9 ±5.3
Number of foot loads per trial	2.4 ±1	1.9 ±1
Less-affected trials with complete foot falls	2.28 ±3	2.14 ±2.2
Less-affected trials with incomplete foot falls	5 ±2.7	4.21 ±2.3
More-affected trials with complete foot falls	3.6 ±1.9	3.8 ±2.1
More-affected trials with incomplete foot falls	4.4 ±3.2	3.7 ±3

4.6.4.6 Reliability of Dynamic Foot Loading Variables (During Stance Phase of Gait)

Peak Pressure:

As part of the evaluation of reliability, geometric regional analysis of four and eight regions were performed and analysed for feasibility and reliability. This is reported for the more-affected side only to fulfil the research question. Results for the reliability of both four- and eight-region reliability are shown below.

Peak pressure measures for four regions are shown in Table 4.12. Mean difference was small for RFT and MFT regions. Good to excellent reliability was found, with ICCs ranging from 0.76–0.96, and with the RFT demonstrating the highest and the toe region showing the lowest ICC. Of note, there were broad 95% CIs found for the FFT and toe regions (0.26–0.94) as seen in Figure 4.13. Overall, the SEM and SDs were higher in the FFT and toes region for four-region analysis demonstrating increased variability in scores. Selected Bland–Altman plots, demonstrating good levels of agreement for these regions, are shown in Figure 4.12 and Figure 4.13 (Appendix 21 for MFT and FFT regions). Occasional values lay outside of the LOA, however, no proportional bias was

apparent. Therefore, reliability of the four foot regions appears good to excellent, with RFT and MFT possessing the highest reliability.

Table 4.12 Four-Region Reliability for Peak Pressure (kPa) for the More-Affected Side*

Foot region	ICC** (95% CI)	Mean difference* (SD)	Test mean (SD)	Limits of agreement†		SEM
				Lower	Upper	
RFT	0.96 (0.87, 0.99)	−8.00 (49.94)	257.07 (115.07)	−107.88	91.88	23.01
MFT	0.88 (0.62, 0.96)	0.21 (39.07)	111.46 (58.27)	78.35	77.93	19.33
FFT	0.81 (0.42, 0.94)	−27.29 (168.70)	331.86 (209.71)	−364.69	310.11	88.97
Toes	0.76 (0.26, 0.92)	−41.29 (137.48)	302.36 (155.77)	−316.25	233.67	76.31

*n = 14.
**Intra class correlation coefficient ($ICC_{3,1}$ agreement).
[a]MD = T1–T2, where T1 = test 1 and T2 = retest.
†Limits of agreement = MD ± 2 x SD.
Abbreviations: SD = standard deviation; SEM = standard error of measurement; RFT = rearfoot; MFT = mid-foot; FFT = forefoot.

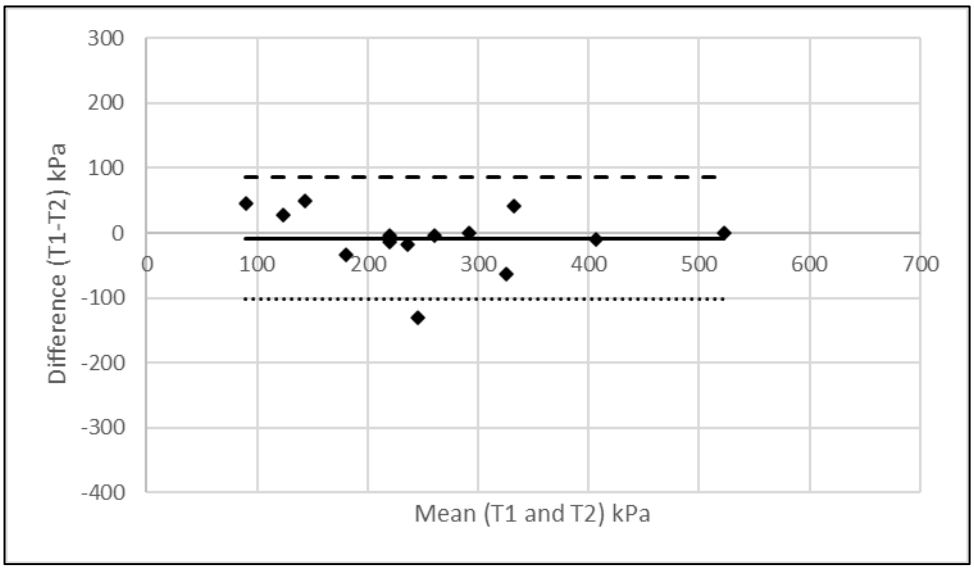


Figure 4.8 Bland–Altman Plot: Rearfoot Region Peak Pressure (kPa)*

*Dashed line = upper limit of agreement; solid line = mean; dotted line = lower limit of agreement; diamonds = difference between test and retest mean.

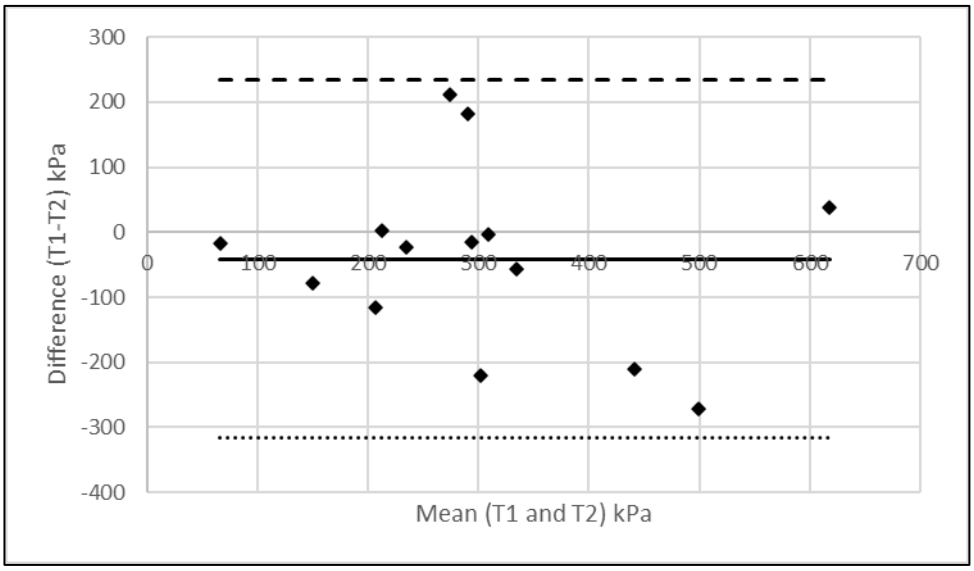


Figure 4.9 Bland–Altman Plot: Toe Region Peak Pressure (kPa)*

*Dashed line = upper limit of agreement; solid line = mean; dotted line = lower limit of agreement; diamonds = difference between test and retest mean.

Reliability for eight regions of peak pressure is shown in Table 4.13. Mean differences were shown through all regions to be small in comparison to the overall test mean, with the largest mean difference found in FFT and toe regions. For eight-region analysis, the ICCs were lower overall (0.36–0.98); however, six of the eight regions exhibited excellent reliability with ICCs of > 0.8 (0.82–0.98). The MToes region demonstrated moderate reliability (ICC = 0.65) and the MMF region showed poor reliability (ICC = 0.36). This was compounded by broad 95% CIs and large SEM. In the case of MFF, the SEM has been inflated due to the low ICC, as the ICC is used in the calculation for SEM. Selected Bland–Altman plots are shown in Figure 4.14 and Figure 4.15 (for the remainder see Appendix 21). These display good agreement across a range of pressures found in the MMF and less agreement in MFF regions; the only bias observed was as mean pressure values increased in regions.

Table 4.13 Reliability for Eight Regions of Peak Pressure (kPa) for the More-Affected Side*

Foot region	ICC (95% CI)	Mean difference (SD)	Test mean ± SD	Limits of agreement		SEM
				Lower	Upper	
MRF	0.87 (0.60, 0.96)	−4.62 (62.39)	244.33 (105.48)	−129.4	120.16	38.03
LRF	0.93 (0.78, 0.98)	−6.23 (60.47)	248.44 (112.34)	−127.17	114.71	29.72
MMF	0.98 (0.92, 0.99)	8.15 (40.36)	61.07 (51.55)	−72.57	88.87	7.29
LMF	0.97 (0.92-0.99)	−2.15 (15.72)	108.96 (51.25)	−33.59	29.29	8.88
MFF	0.36 (−1.19, 0.81)	63.62 (310.36)	272.37 (241.14)	−557.1	684.34	192.91
LFF	0.96 (0.83, 0.99)	−36.54 (54.35)	257.85 (160.37)	−145.24	72.16	32.07
MToes	0.65 (0.22, 0.89)	−20.46 (173.40)	284.26 (166.02)	−367.26	326.34	98.22
LToes	0.82 (0.39, 0.94)	13.31 (96.68)	140.56 (118.89)	−180.05	206.67	5.04

*n = 13. **Intra class correlation coefficient ($ICC_{3,1}$ agreement). [a]MD = T1–T2, where T1 = test 1 and T2 = retest. [†]Limits of agreement = MD ± 2 x SD.

Abbreviations: MRF = medial rearfoot; LRF = lateral rearfoot; MMF = medial mid-foot; LMF = lateral mid-foot; MFF = medial forefoot; LFF = lateral forefoot; MToes = medial toes; LToes = lateral toes; SD = standard deviation; SEM = standard error of measurement.

*Dashed line = upper limit of agreement; solid line = mean; dotted line = lower limit of agreement; diamonds = difference between test and retest mean.

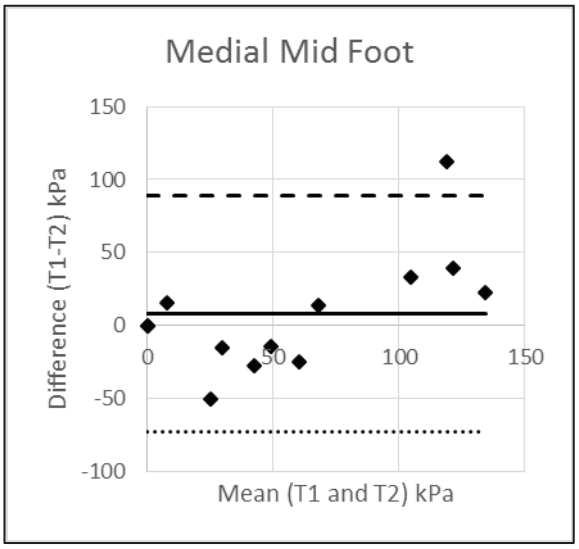


Figure 4.14 Bland–Altman Plot: Medial Mid-Foot Peak Pressure (kPa)*

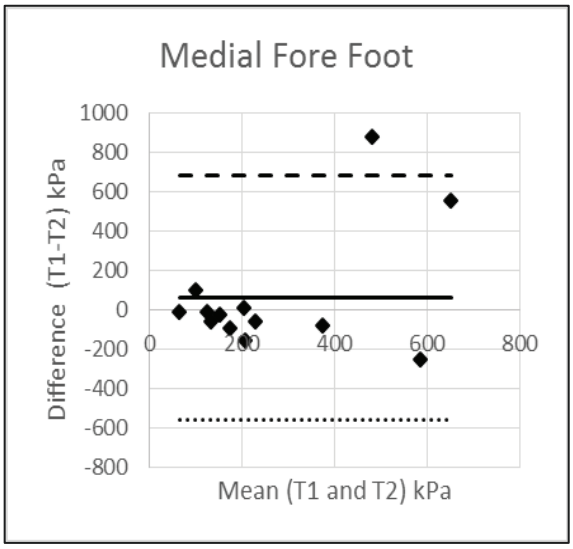


Figure 4.10 Bland–Altman Plot: Medial Forefoot Peak Pressure (kPa)*

Contact Area:

Table 4.14 displays CA for four-region analysis. Mean differences were small for all regions. The reliability for CA (cm^2) follows similar trends as that for PPP. For four-region analysis, the regions again showed excellent reliability (ICC 0.86–0.98) except for the toe region, which was only moderate (ICC 0.58) along with a larger SEM indicating less consistency across participants tested. Notably, the MFT and total foot CA showed best reliability with high ICCs 0.98 and 0.95, respectively, and narrow 95% CIs. Total foot CA displayed excellent reliability of 0.95 for four-region analysis (Table 4.14), although an outlier outside the lower LOA, seen in Figure 4.16, was found due to a large difference between toe regions at test and retest. Overall good agreement without proportional bias was observed in the Bland–Altman plots (Appendix 21).

Table 4.14 Four-Region Reliability for Contact Area (cm^2) of the More-Affected Side*

Foot region	ICC** (95% CI)	Mean difference* (SD)	Test mean (SD)	Limits of agreement†		SEM
				Lower	Upper	
RFT	0.91 (0.72, 0.97)	−0.62 (2.32)	33.51 (3.93)	−5.26	4.02	1.18
MFT	0.98 (0.91, 0.99)	−1.40 (3.37)	28.10 (10.86)	−8.14	5.34	1.54
FFT	0.86 (0.56, 0.96)	1.46 (3.19)*	46.23 (4.43)	−4.92	7.84	1.66
Toes	0.58 (−0.37, 0.87)	0.79 (5.86)	14.68 (5.23)	−0.79	2.37	3.39
Total	0.95 (0.85, 0.98)	0.27 (7.58)	122.89 (16.72)	−0.27	0.81	3.74

**n* = 14, Removed outlier participant 10. **Intra class correlation coefficient ($ICC_{(3,1)}$ agreement).
[a]MD = T1–T2, where T1 = test 1 and T2 = retest. †Limits of agreement = MD ± 2 x SD.
Total = total foot contact area.
Abbreviations: RFT = rearfoot; MFT = mid-foot; FFT = forefoot; SD = standard deviation; SEM = standard error of measurement.

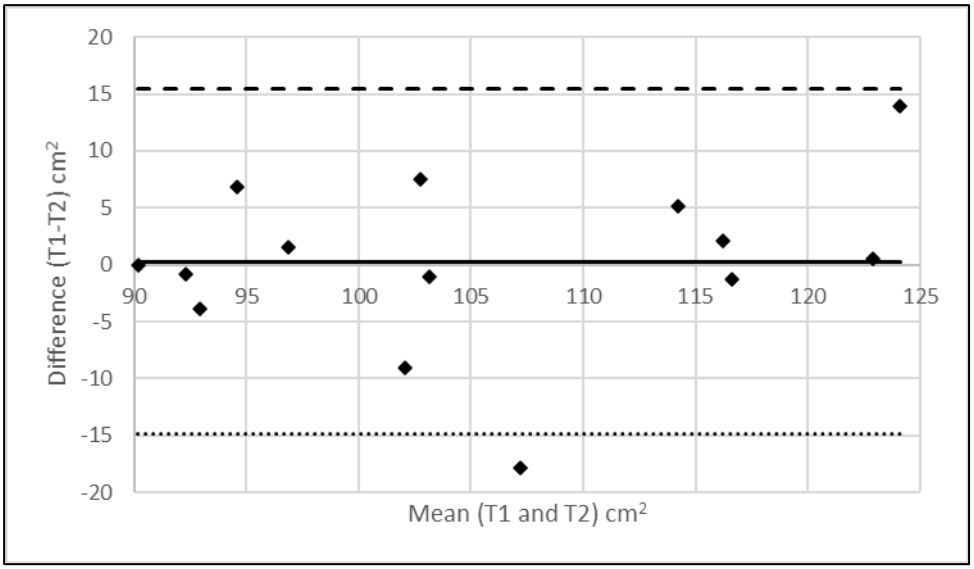


Figure 4.16 Bland–Altman Plot: Total Foot Contact Area for Four Regions*

*Dashed line = upper limit of agreement; solid line = mean; dotted line = lower limit of agreement; diamonds = difference between test and retest mean.

For eight-region analysis (Table 4.15), ICCs were more varied (0.61–0.97) with the MFF and LToes regions being the highest. Again, SEM was highest for the MMF region with this demonstrating the lowest reliability. Removal of two outliers in the MToes region meant this then exhibited good reliability. Total foot CA displayed excellent reliability with an ICC of 0.95 for eight-region analysis, although an outlier outside the lower limit of agreement (Figure 4.17) was found due to a large difference between toe regions at test and retest. Interestingly differences appear in four-region and eight-region Bland–Altman plots. These are thought to arise due to small differences in region mapping prior to data analysis.

Table 4.15 Eight-Region Reliability for Contact Area (cm^2) of the More-Affected Side*

Foot region	ICC (95% CI)	Mean difference (SD)	Test mean (SD)	Limits of agreement		SEM
				Lower	Upper	
MRF	0.71 (0.05, 0.91)	−0.20 (3.30)	12.96 (3.35)	−6.8	6.4	1.80
LRF	0.71 (0.17, 0.91)	−0.86 (2.24)	20.36 (2.42)	−5.34	3.62	1.30
MMF	0.72 (0.07, 0.91)	−0.16 (8.21)	6.04 (8.38)	−16.58	16.26	4.43
LMF	0.61 (−0.25, 0.87)	−0.97 (6.63)	23.03 (6.09)	−14.23	12.29	3.80
MFF	0.92 (0.75, 0.97)	0.96 (2.79)	20.07 (5.04)	−4.62	6.54	1.43
LFF	0.80 (0.42, 0.94)	1.06 (3.49)	26.08 (4.30)	−5.92	8.04	1.92
MToes	0.73* (0.02, 0.92)	0.18 (5.06)	8.81 (3.22)	−9.94	10.3	1.67*
LToes	0.97 (0.91, 0.99)	0.36 (1.05)	5.68 (3.17)	−1.74	2.46	0.55
Total	0.95 (0.85, 0.98)	1.21 (7.51)	123.43 (16.67)	−13.81	16.23	3.73

*n = 14, Outliers removed from T1, participant 2 and 6. Total = total foot contact area. **Intra class correlation coefficient ($ICC_{(3,1)}$ agreement). [a]MD = T1–T2, where T1 = test 1 and T2 = retest. [†]Limits of agreement = MD ± 2 x SD. Total = total foot contact area.
Abbreviations: MRF = medial rearfoot; LRF = lateral rearfoot; MMF = medial mid-foot; LMF = lateral mid-foot; MFF = medial forefoot; LFF = lateral forefoot; MToes = medial toes; LToes = lateral toes; SD = standard deviation; SEM = standard error of measurement.

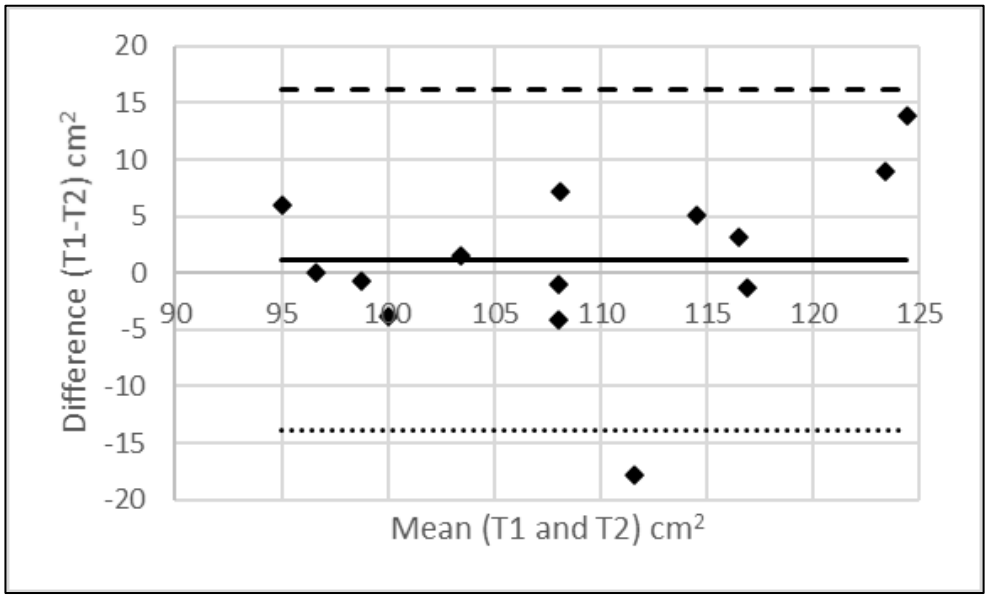


Figure 4.17 Bland–Altman Plot: Total Foot Contact Area for Eight Regions*

*Dashed line = upper limit of agreement; solid line = mean; dotted line = lower limit of agreement; diamonds = difference between test and retest mean.

4.6.4.7 *Clinical Relevance: More-Affected Side Compared to Less-Affected Side*

As part of research question 3, the clinical relevance of the dynamic plantar pressure variables was considered by analysing data from both more- and less-affected sides; however, the number of trials was lower for the less-affected side, thus a subgroup analysis was conducted with a group of 10 to ensure a complete data set was considered and analysis applied. The following tables show these findings. In Table 4.16, these demonstrate, on the whole, larger values for the less-affected sides for both variables. Specifically, peak pressures (kPa) were higher in all regions except for the MFT region on the more-affected side (246.38 ±110.21), with the less-affected side MFT region showing the lowest mean value (129.25 ±51.85); however, statistically significant differences were only found for the RFT and MFT regions (RFT $t = -2.661$; MFT $t = 2.825$; $p < 0.05$). For the CA of all regions, values were lower on the more-affected side. The RFT and toe regions, as well as the total CA, were found to be statistically significant using a paired *t*-test.

Table 4.16 Four-Region Peak Pressure (kPa) and Total Contact Area (cm^2) for More- and Less-Affected Sides*

Foot region	PPP, kPa (SD)			Contact area, cm^2 (SD)		
	Less affected	More affected	*p* value[a]	Less affected	More affected	*p* value[a]
RFT	337.88 (160.41)	185.13 (64.88)	0.03	37.25 (1.76)	32.78 (4.55)	0.01
MFT	129.25 (51.85)	246.38 (110.21)	0.03	30.74 (9.97)	28.56 (11.88)	0.38
FFT	337.38 (131.10)	310.00 (151.07)	0.75	49.29 (10.27)	43.38 (4.03)	0.16
Toes[†]	387.13 (190.01)	333.25 (130.19)	0.40	18.32 (7.21)	13.48 (4.62)	0.05
Total				135.85 (21.67)	118.35 (16.48)	0.02

*n = 10, retest. [†] Toes region demonstrated maximal peak pressure. [a] derived from a paired *t*-test.
Abbreviations: SD = standard deviation; RFT = rearfoot; MFT = mid-foot; FFT = forefoot.

For eight-region analysis (shown in Table 4.17) peak pressure was found to be lower on the more-affected side for all regions except again for both LMF and MMF regions; however, there was no statistical difference found between regions as shown by the non-

significant p values. For total foot CA there was a mixed picture, with no limb showing trends with mean values although the two rearfoot regions show statistically significant differences, $p < 0.05$.

Table 4.17 Eight-Region Peak Pressure (kPa) and Total Contact Area (cm^2) for More- and Less-Affected Sides*

Foot region	PPP, kPa (SD)			Contact area, cm^2 (SD)		
	Less affected	More affected	*p* value[a]	Less affected	More affected	*p* value[a]
MRF	267.38 (80.96)	252.75 (94.23)	0.72	12.15 (2.47)	14.01 (3.22)	0.05
LRF	344.63 (155.83)	263.88 (88.45)	0.27	23.54 (2.63)	20.69 (2.50)	0.02
MMF	41.63 (36.69)	63.87 (50.11)	0.41	4.03 (7.02)	7.38 (9.80)	0.47
LMF	141.00 (58.44)	123.25 (52.44)	0.46	26.29 (5.34)	22.36 (7.11)	0.20
MFF	323.63 (165.18)	306.75 (213.90)	0.83	21.02 (6.47)	21.14 (4.68)	0.97
LFF	294.75 (152.35)	291.50 (128.93)	0.97	27.28 (6.48)	24.64 (4.04)	0.25
MToes†	381.00 (196.62)	300.50 (213.01)	0.57	11.04 (3.85)	8.62 (3.46)	0.22
LToes	177.62 (153.74)	130.12 (111.13)	0.37	7.25 (2.93)	5.35 (4.08)	0.19
Total				134.40 (20.94)	124.08 (17.59)	0.20

*n = 10, retest.† MToes region demonstrated maximal pressure. [a] derived from a paired t-test.
Abbreviations: MRF = medial rearfoot; LRF = lateral rearfoot; MMF = medial mid-foot; LMF = lateral mid-foot; MFF = medial forefoot; LFF = lateral forefoot; MToes = medial toes; LToes = lateral toes; SD = standard deviation; SEM = standard error of measurement.

4.6.5 Neuromuscular Impairments

4.6.5.1 Isometric Ankle and Hallux Muscle Strength

In response to research question 4 and 5, the feasibility and reliability of hand-held dynamometry of ankle and hallux muscle groups was evaluated. The protocols were easy to apply to all muscle groups in both long sitting and sitting; only ankle plantarflexion challenged the researcher's (AR) strength to resist the forces generated by participants (> 20 kg). This occurred in 7/12 participants on the less-affected side and 1/12 on the more-affected side. Testing lasted for 15 minutes in total for all muscle groups, with procedures easy to follow for participants. Retest data was lost for five participants; this was due to pain/discomfort elicited through the technique for four participants and in one instance, the equipment batteries failed.

Isometric muscle strength for the ankle and hallux is shown in Table 4.18 and Table 4.19. More-affected limb strength values were lower than the less-affected limb, with test means < 50% of the corresponding muscle group on the less-affected limb side. All displayed similar variance, as represented by their standard deviations. Table 4.19 displays the ICCs and 95% CIs demonstrating a range of poor to excellent reliability (0.42–0.93). Of note, bilateral ankle DFs demonstrated high ICC, narrow 95% CIs and moderate SEM. For hallux muscle groups, ICCs were lower (0.42–0.70) with greater variance observed in the data, indicating lower agreement between test and retest; however, despite this, overall composite ICCs demonstrated good or excellent reliability with ICCs of 0.78 and 0.93. Bland–Altman plots illustrated some variability in the test–retest data with one value lying outside the limits of agreement for the more-affected side ankle PFs, evertors, hallux PFs and DFs; and the less-affected side ankle PFs, ankle DFs and hallux DFs (Appendix 21). Thus, while reliability was good to excellent, agreement between test and retest was not as convincing.

Table 4.18 Reliability for Isometric Muscle Strength (kg), Single and Composite Groups for the Less-Affected Limb*

Variable		ICC** (95% CI)	Mean difference (SD)[a]	Test mean (SD)	Limits of agreement[†]		SEM
					Lower	Upper	
Composite		0.78 (−0.19–0.95)	17.92 (9.34)	75.21 (21.63)	−0.76	36.60	10.14
Ankle		0.95 (0.84–0.99)	−16.29 (6.81)	58.12 (15.43)	−14.91	12.32	3.45
Hallux		0.71 (−0.02–0.92)	−0.86 (4.27)	7.06 (4.36)	−9.41	7.68	2.35
Single muscle groups	**ADF**	0.95 (0.84–0.99)	1.70 (5.44)	19.31 (5.38)	−9.17	12.58	1.2
	APF	0.87 (0.54–0.96)	0.39 (4.13)	20.27 (5.75)	−7.86	8.64	2.07
	AInv	0.89 (0.44–0.99)	−1.57 (1.94)	9.57 (3.66)	−5.44	2.30	1.21
	AEv	0.92 (0.73–0.98)	−0.55 (1.77)	8.98 (3.17)	−4.10	3.00	0.90
	HDF	0.61 (−0.42–0.89)	−0.38 (2.23)	4.24 (2.03)	−4.83	4.08	1.26
	HPF	0.42 (−1.18–0.84)	−0.40 (2.44)	3.60 (1.96)	−5.28	4.48	1.49

*For n = 12, missing data due to faults in the equipment.
**Intra class correlation coefficient ($ICC_{(3,1)}$ agreement).
[a]MD = T1–T2, where T1 = test 1 and T2 = retest.
[†]Limits of agreement = MD ± 2 x SD.
Abbreviations: ADF = ankle dorsiflexors; APF = ankle plantarflexors, AInv = ankle invertors, AEv = ankle evertors; HDF = hallux dorsiflexors; HPF = hallux plantarflexors; SD = standard deviation; SEM = standard error of the measure.

Table 4.19 Reliability for Isometric Muscle Strength (kg), Single and Composite Groups for the More-Affected Limb*

Variable		ICC** (95% CI)	Mean difference (SD)[a]	Test mean (SD)	Limits of agreement[†]		SEM
					Lower	Upper	
Composite [α]		0.93 (0.73, 0.98)	−6.32 (11.51)	30.48 (23.84)	−29.34	21.68	6.31
Ankle		0.92 (0.65, 0.98)	−6.70 (9.57)	26.48 (20.59)	−25.84	12.44	5.82
Hallux		0.67 (−0.22, 0.91)	0.38 (4.51)	4.00 (4.36)	−8.64	9.41	2.13
Single muscle groups	**ADF**	0.95 (0.68, 0.99)	−2.11 (2.57)	9.16 (6.89)	−7.25	3.03	1.54
	APF	0.83 (0.44, 0.98)	−2.62 (5.78)	9.72 (7.82)	−14.19	8.93	3.22
	AInv	0.90 (0.42, 0.97)	−1.52 (1.76)	3.96 (3.54)	−5.03	1.99	1.11
	AEv	0.80 (0.29, 0.94)	−0.45 (3.37)	3.64 (3.94)	−7.18	6.28	1.76
	HDF	0.62 (−0.44, 0.89)	0.23 (2.39)	2.08 (2.18)	−4.55	4.99	1.34
	HPF	0.70 (−0.12, 0.91)	0.17 (2.29)	1.92 (2.27)	−4.42	4.75	1.24

*For n = 12, missing data due to faults in the equipment.
**Intra class correlation coefficient ($ICC_{(3,1)}$ agreement).
[a]MD = T1−T2, where T1 = test 1 and T2 = retest.
[†]Limits of agreement = MD ± 2 x SD.
Abbreviations: ADF = ankle dorsiflexors; APF = ankle plantarflexors, AInv = ankle invertors, AEv = ankle evertors; HDF = hallux dorsiflexors; HPF = hallux plantarflexors; SD = standard deviation; SEM = standard error of the measure.

4.6.5.2 Peak Ankle and Hallux Dorsiflexion Angle

To address research question 6, the feasibility and reliability of peak passive ankle and hallux dorsiflexion was explored. The bespoke tools were easy to position and use for all participants. The force transducer made the tool more cumbersome but did not preclude use. Testing took no longer than 10 minutes for ankle dorsiflexion, and five minutes for hallux dorsiflexion. Notably, due to the modifications on the ankle passive dorsiflexion rig, only nine participants completed both test–retest. The hallux dorsiflexion rig was used with all 21 participants and produced 13 test–retest data sets. The analysis of the data in Table 4.20 shows all more-affected side mean values (test, retest and test mean) were lower for both peak ankle and peak hallux dorsiflexion. The same trends were found for low and high force values. Standard deviation of test means was lowest for less-affected

side peak hallux dorsiflexion, which also had the lowest SEM. MDs were similar for all peak ankle dorsiflexion and reflected mean values, however the MD for the less-affected side peak hallux dorsiflexion was almost zero for both less-affected high force measures. All measures had higher mean retest values except for the more-affected side peak hallux dorsiflexion (low force) and less-affected peak hallux dorsiflexion (high force). Peak hallux dorsiflexion had good to excellent reliability (ICCs 0.70–0.82), although broad 95% CIs were observed, so this reliability needs to be taken with some caution. Peak ankle dorsiflexion on the less-affected side had moderate to excellent reliability (ICCs 0.53–0.83). Notably CIs were broad for all ICCs although the SEM varied little.

Table 4.20 Reliability of Peak Ankle and Hallux Angle (°) at Low and High Forces*

Variable	ICC** CI (95%)	Mean difference (SD)[a]	Test mean (SD)	Limits of agreement[†]		SEM
				Lower	Upper	
Less-affected ADF (°)	0.53 (−0.66, 0.89)	−4.69 (12.65)	22.23 (8.77)	−23.93	14.54	6.01
More-affected ADF (°)	0.74 (−0.15, 0.94)	−3.04 (11.01)	12.42 (12.10)	−25.99	19.92	6.17
Less-affected ADF (°)	0.72 (−0.06, 0.93)	−3.63 (10.38)	26.37 (10.29)	−24.40	17.13	5.44
More-affected ADF (°)	0.83 (0.29, 0.96)	−2.06 (8.48)	16.09 (10.81)	−19.56	14.35	4.46
Less-affected HDF (°)	0.70 (−0.44, 0.91)	−0.84 (11.21)	45.29 (10.91)	−23.27	21.60	5.98
More-affected HDF (°)	0.82 (0.38, 0.95)	5.46 (9.21)	36.99 (16.12)	−12.96	23.87	6.84
Less-affected HDF (°)	0.79 (0.29, 0.93)	0.61 (7.01)	53.97 (8.41)	−13.42	14.63	3.85
More-affected HDF (°)	0.76 (0.23, 0.93)	4.11 (10.25)	47.97 (12.30)	−16.38	24.60	6.03

*For hallux n = 13; ankle n = 9.
**Intra class correlation coefficient ($ICC_{(3,1)}$ agreement).
[a]MD = T1–T2, where T1 = test 1 and T2 = retest.
[†]Limits of agreement = MD ± 2 x SD.
Abbreviations: ADF = ankle dorsiflexion and HDF = hallux dorsiflexion; no fill = low force (2 or 7 kg); light grey fill = high force (4 or 10 kg); SD = standard deviation; SEM = standard error of measurement.

4.6.5.3 Ankle and Hallux Plantarflexor Stiffness:

To address research question 7, ankle and hallux PF stiffness was calculated using the change in joint angle at two different forces. As can be seen from Table 4.21, the mean difference for ankle stiffness on the less-affected side was higher than the more-affected side. Reliability was poor with very low ICC values. The more-affected ankle stiffness had a negative ICC (−0.32) as the difference is greater within the subjects than between the subjects (Field, 2013); this has been reset as 0.00 in the table. This demonstrates that the stiffness measurement did not have any reliability for any of the analysed movements; however, as can been seen from Figure 4.18 and Figure 4.19, the reason may be due to an extreme outlier. When this was removed, ICC values improved to 0.38 (95% CI 1.76–0.80) yet still demonstrated poor reliability.

Table 4.21 Reliability of Ankle and Hallux Plantarflexor Stiffness*

Variable	ICC** (95% CI)	Mean difference (SD)[a]	Test mean (SD)	Limits of agreement †		SEM
				Lower	Upper	
Less-affected ankle stiffness	0.02 (−3.35, 0.78)	2.00 (1.41)	1.05 (1.16)	−0.83	4.82	1.14
More-affected ankle stiffness	0.00†† (−4.84, 0.70)	−0.92 (3.88)	1.42 (2.97)	−1.84	6.85	2.89
Less-affected hallux stiffness	0.05 (−2.11, 0.71)	−0.09 (0.40)	0.47 (0.29)	−0.90	0.71	0.33
More-affected hallux stiffness	0.11 (−2.11, 0.74)	0.29 (0.97)	0.53 (0.73)	−1.66	2.24	0.69

*For hallux n = 13; ankle n = 9.
**Intra class correlation coefficient ($ICC_{(3,1)}$ agreement).
[a]MD = T1–T2, where T1 = test 1 and T2 = retest.
†Limits of agreement = MD ± 2 x SD.
††ICC 0.38 (95% CI 1.76–0.80).
No fill = low force (2 or 7 kg), light grey fill = high force (4 or 10 kg).
SD = standard deviation; SEM = standard error of measurement.

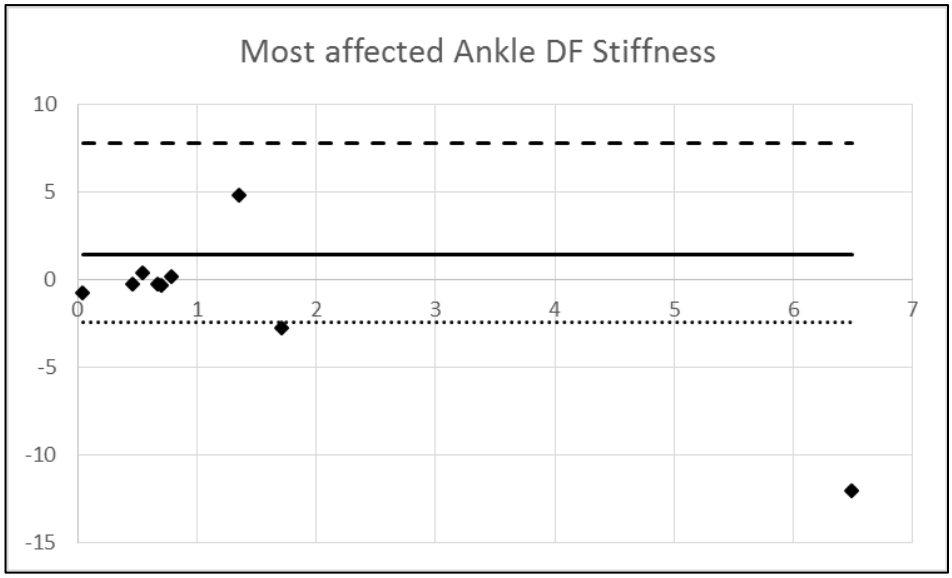


Figure 4.11 Bland–Altman Plot for Ankle and Hallux Stiffness Reliability*

*Dashed line = upper limit of agreement; solid line = mean; dotted line = lower limit of agreement; diamonds = difference between test and retest mean.

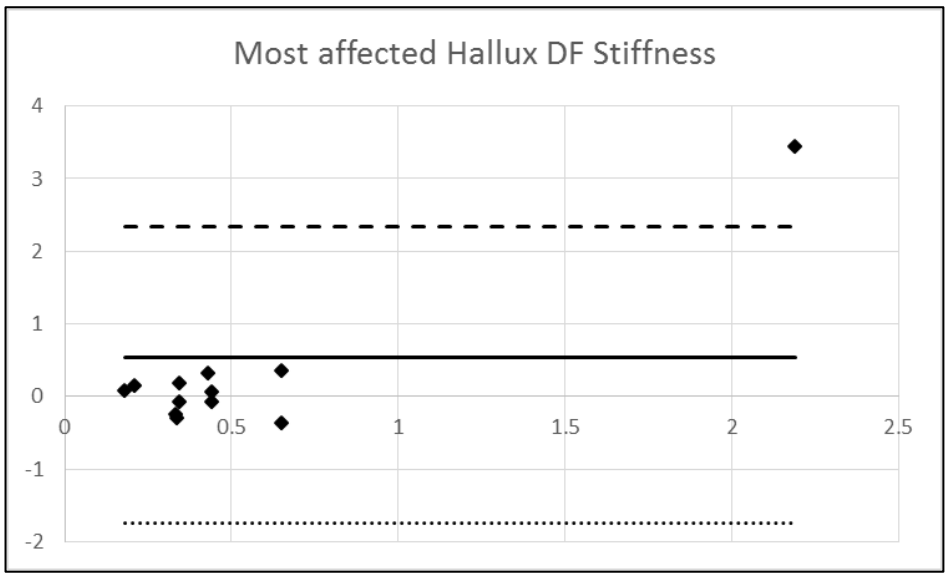


Figure 4.12 Bland–Altman Plot for Hallux Stiffness Reliability*

*Dashed line = upper limit of agreement; solid line = mean; dotted line = lower limit of agreement; diamonds = difference between test and retest mean.

4.6.5.4 Ankle Plantarflexor Spasticity

To address research question 8, this study evaluated reliability of ankle PF spasticity, measured using the Tardieu scale on the more-affected side. The Tardieu scale found that there was spasticity (≥ 1) in four (retest) to seven (test) participants. Additionally, clonus and a mild catch was found in two different participants on retest. Median values for test and retest were zero, with a range of 0–4 only; thus, no participant had an immovable joint. Figure 4.20 shows the frequency of the Tardieu scale scores of quality of reaction (X) on test and retest with the most frequent scores being zero at both test and retest. For fast velocity, the linear weighted kappa statistic was reported as $\kappa_w = 0.78$, with a broad 95% CI (0.56, 0.99).

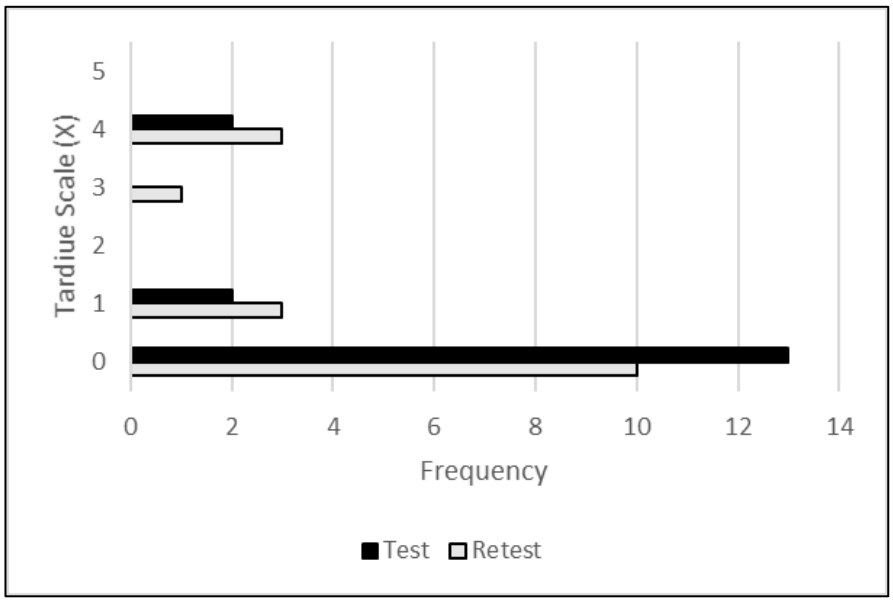


Figure 4.20 Frequency of Tardieu Scale Score on Test and Retest (n = 17)

4.6.6 Key Findings

The key findings from Study 1 are as follows:

- Static foot posture measured by the FPI was feasible (81% data available) and showed moderate reliability ($\kappa_w =$ 0.53–60);
- Toe deformity was feasible to visually observe;
- Dynamic foot loading:
    - COF sway was feasible with moderate to excellent reliability (ICCs 0.54–0.85);
    - Plantar pressure was feasible with good to excellent reliability for four regions (ICCs 0.76–0.96), less so for eight regions (ICCs 0.36–0.98);
    - Contact area was feasible with moderate to excellent reliability, four regions (ICCs 0.58–0.98) and eight regions (ICCs 0.61–0.97);
- Isometric muscle strength ankle and hallux muscle groups using a HHD (single measures) was feasible with moderate to excellent reliability (ICCs 0.42–0.93);
- Isometric muscle strength ankle and hallux muscle groups using a HHD (composite measures) was feasible with excellent reliability (ICCs 0.67-0.95);
- Peak ankle and hallux dorsiflexion was feasible with moderate to excellent reliability (ICCs 0.53–0.83);
- Passive ankle and hallux PF stiffness was feasible but had poor/absent reliability (ICCs 0.00–0.11);
- Ankle PF spasticity measured by the Tardieu scale had good reliability ($\kappa_w =$ 0.78).

4.7 DISCUSSION

4.7.1 Summary of Findings

This work evaluated the feasibility and reliability of multiple measurement tools for foot and ankle impairments after a stroke. Additionally, the clinical relevance of DFL was examined. First, for foot characteristics, good feasibility and reliability was found for measures of static foot posture, as well as DFL components, COF, PPP and CA in four

regions; eight-region PPP and CA had moderate reliability only. Measurement of toe deformity was also found feasible. Second, for all neuromuscular impairments of the foot and ankle, good feasibility was established. Reliability was good to excellent for isometric muscle strength of individual ankle muscles and composite scores, and peak hallux dorsiflexion. Good reliability was found for ankle PF spasticity using the Tardieu scale and for peak ankle DF ROM. Poor to moderate reliability was found for isometric muscle strength of individual hallux muscles. Poor reliability was found for stiffness in both ankle and hallux regions. The results have demonstrated overall that measures of foot characteristics and neuromuscular foot and ankle impairments are feasible, reliable and clinically relevant in the case of DFL. As such, Study 1 has provided a rationale to support their use in Study 2 as potential predictors. The research questions will now be discussed in relation to the results found for specific impairments, with foot and ankle characteristics discussed prior to the neuromuscular impairments.

4.7.2 Foot Characteristics

4.7.2.1 Static Foot Posture

The first research question, '*Is static foot posture using the FPI assessment, feasible and reliable in people with stroke?'* set out to evaluate feasibility and reliability of foot posture analysis in stroke participants using the FPI. The test was feasible for use, being easy to administer, with no data lost. This was, in part, aided by the fact that participants had sufficient standing balance in bilateral stance to stand for the 2–5 minutes it took to carry out the test. Feasibility of the FPI was not reported by Forghany and colleagues (2011); thus, this work enhances understanding of the FPI's applicability in stroke research. Static foot posture assessment using the FPI is therefore recommended for use in people after stroke who can stand unaided for up to 5 minutes. This may be used in a variety of clinical settings, in-patient, outpatient and community.

Reliability of the FPI in this work, with use of age-adjusted categories or normal/abnormal classification, was moderate ($\kappa_w = 0.59$ and $\kappa_w = 0.60$, respectively). Use of the original categories was less convincing with $\kappa_w = 0.53$. Thus, age-adjusted scores are deemed more suitable. Previously, only Lee *et al.* (2015) had tested reliability of the FPI in people with stroke ($n = 22$) and ICCs were found to be 0.81–0.89, showing

excellent reliability. Some reasons for the discrepancy between this work and that reported by Lee *et al*. (2015) may be due to the use of ICCs which can be at risk of overinflating reliability especially where sample sizes are smaller (Field, 2013). Additionally, the kappa coefficients utilised in Study 1 are appropriate and robust as they are designed for use in ordinal data, whereas ICCs are not (Kottner *et al*., 2011). Despite the current work reporting lower reliability than Lee *et al*. (2015), the FPI yielded moderate reliability so it can be incorporated into the Study 2 assessment battery.

4.7.2.2 Toe Deformity

The feasibility of recording toe deformity was explored in order to answer research question 2, '*Is toe deformity classification feasible in people with stroke?'* The visual observation of toe deformity and evaluation of fixed and mobile deformity was feasible, being quick to evaluate and allowing all participants to have data collected. The feasibility of documenting toe deformity after stroke has not been reported previously.

Varying types of toe deformities were found to be present. This study found nine participants (52%) demonstrated claw toe, similar to data from Laurent *et al.* (2010) who found 46% people with stroke to have claw toe. Hammer toe was found in only one participant in the group tested, although this is typically associated with older age (above 65 years) (Menz, 2015). HHT is a rare phenomenon after stroke (2%) (Yelnik *et al.,* 2003), however this work found two participants (12%) to have HHT. Changes across static and dynamic positions were noted with an overall increase in deformity presence; thus, examination in different positions seems to be important.

Study 1 has not examined reliability of visual observation as no retest data was collected for this measurement tool. Reliability testing was originally planned as part of the FAiMiS project using instrumentation which included 3D motion analysis, EMG data and video data; however, due to time constraints, this data was not analysed to confirm findings at both test and retest. Therefore, future work should explore a specific scale to quantify toe deformity after stroke, perhaps similar to the Manchester scale (Garrow *et al*., 2001) adopted by Kunkel and colleagues (2017).

4.7.2.3 Dynamic Foot Loading

Research question 3 asked *'Are plantar pressure variables **feasible**, **reliable** and **clinically relevant** to represent DFL characteristics during stance phase of gait in people with stroke? In particular:*

a. *which variables are clinically relevant to represent DFL characteristics (i.e. peak plantar pressure, foot contact area, centre of force?*
b. *what number of regions are feasible and reliable to obtain data from?'*

Feasibility:

The study evaluated the feasibility of plantar pressure assessment in people with stroke. While the protocol was easy to carry out and the equipment easy to use, data was extracted from static trials and dynamic trials for 14/21 (67%) of the cohort. There were challenges with the experimental protocol during data collection. Data from seven participants was lost during the study; four did not return for retest and three were lost due to difficulties with the data collection process. These participants were unable to walk barefoot across the mat, or their stride length was so short that pressure maps of each foot overlapped one another thus precluding analysis. This could have been addressed by selecting frames from a recording to analyse. As Ng *et al*. (2010) has reported in people with stroke, walking barefoot yields slower walking speed, reduced step length and more time in double support and stance phase than when walking shod. These would appear to be contributory factors; however, they were not evaluated as part of Study 1. The standardised two-step protocol used in this study was feasible for people with stroke with varying mobility (with or without aid) and fatigue levels. This method was preferable than a mid-gait protocol, which was not chosen as neurological gait is highly variable (Patterson, 2008). Even with the two-step gait protocol, multiple foot loads were gained, with an average of 15 footfalls across three trials, per participant.

Previous authors have commented that developing participants' confidence with walking across the pressure mat is important (Rosenbaum and Becker, 1997). In doing so, Study 1 found participants required clearer explanation of the testing procedure. This has implications for training of testers and testing time. Up to 15 minutes were needed for data capture; this may be practicable in a research context but may not transfer well to

clinical settings, reducing valuable therapy time. Repeat trials were required which may have exacerbated fatigue, which is commonly experienced in around 50% of people with stroke (Cumming *et al.*, 2016). Rest periods were provided which also increased the length of the test.

While the use of DFL using a pressure mat was feasible, several challenges were experienced: ensuring participants had an ability to walk barefoot; ensuring step protocols were effective, accommodating for fatigue and participant instructions needed consideration. Given these concerns, in-shoe pressure systems may be advantageous for use in people with stroke (Hillier and Lai, 2009), allowing for evaluation while wearing shoes, rather than barefoot walking. Although statistics on barefoot walking after stroke are unknown, in-shoe data may better represent alterations in foot loading after stroke; however, in-shoe systems are less transferable to clinical settings due to cost and time required to fit.

Adaptations to consider for Study 2 are:

- Consider use of in-shoe system.
- Ensure participants can walk barefoot.
- Use frame selection to ensure specific foot falls can be analysed.

Despite these potential adaptions, in research to ascertain how after stroke the more-affected foot contacts the floor and whether this varies from the less-affected foot, DFL is practical to implement. This has potential to elucidate whether the altered foot contact can be optimised by targeted therapeutic input to ensure better loading throughout stance phase of gait and, therefore, improve gait speed, stability and efficiency.

Reliability of DFL in Standing: Sway Velocity and Path Length:

The study evaluated the reliability of sway velocity and path length. Reliability was mixed with overall values (i.e. those representing vectors not just A–P or M–L dimensions) demonstrating good reliability (ICC = 0.78). SEM and absolute reliability were similar across all variables showing good consistency. Interestingly, retest values were all higher, due to lower stability of the participants on retest; however, reasons as to why this may have consistently occurred are not clear as no changes were made to the protocol or testing

order. It is possible that participants may have paid less attention to retest tasks, which may lower performance. The current ICCs compare well with similar instrumentation used by Szturm *et al.* (2015) who conducted test reliability testing using a pressure-sensitive mat and reported ICCs of 0.70; however, testing took place on a sponge surface and adults were otherwise healthy (mean age 64 years). Another study in anterior cruciate ligament reconstruction reported good reliability with ICCs of 0.70–0.91 using a pressure platform (Kouvelioti *et al.*, 2015), to which the current work demonstrates comparable reliability.

This work only analysed eyes open conditions. Exploration of whether removing visual information has an influence on the neuromuscular control of the foot and ankle is of interest as visual perception is known to influence paretic standing balance (Mansfield *et al.,* 2013). Future work comparing eyes open and eyes closed standing sway velocity using a plantar pressure mat may determine their impact on mobility deficits.

Adaptation to consider for Study 2 is:

- Eyes open and eyes closed conditions

Reliability – Four Regions Compared to Eight Regions:

Study 1 examined whether four- or eight-region analysis would be feasible, reliable and clinically relevant. Given the discrepancy in the number of regions used in current plantar pressure trials (Giacomozzi, 2011) and the number available in software algorithms (TekScan, 2012, p. 260), the number of regions that demonstrated best reliability across PPP and CA were analysed. Analysis of four regions demonstrated that the reliability of RFT, MFT and FFT was excellent, with ICCs of > 0.8; SEM was less than MD and Bland–Altman plots demonstrated good agreement across all regions. These findings are consistent with similar work in older adult populations (Mickle *et al.*, 2010; Menz and Morris, 2006). Lower reliability was found for the toe region; this aligns with findings in healthy child and adult populations (Cousins *et al.*, 2012; Zammit *et al.*, 2010). Four-region CA reliability demonstrated the same outcomes. No comparative research exists that specifically addresses reliability for peak pressure or CA in neurological conditions.

Eight-region analysis demonstrated similar reliability (ICCs of > 0.7), although some regions were less reliable: MMF and MToes peak pressure, and LMF CA, reported poor to moderate reliability (ICC = 0.36–0.65). Great variability, indicated by larger SEM and 95% CIs, along with poor agreement in Bland–Altman plots was found, reducing confidence in these results. To date, no research has published intra-rater reliability for different regions in stroke, thus comparisons are precluded. The results of this study indicate that a greater number of regions (eight versus four) reduces reliability of regional plantar pressure data.

These findings are similar to other studies with different populations. For example, Zammit *et al.* (2010) found some medial foot regions were less reliable in healthy adults, with ICC = 0.69. The MFT region was highlighted by Pataky *et al.* (2008) as being less discerning. Whether this is due to variability in arch formation during dynamic activity or altered loading of the foot to the lateral aspect, as reported by Hessert *et al.* (2005), is unclear. Additionally, altered loading, such as more lateral displacement of COF during stance phase seen in older adults (Spink *et al.*, 2011), may influence plantar pressure values of the medial foot regions. Whether changes in COF displacement during initial contact, loading phases of gait or foot progression influence the medial region in this work was not evaluated.

Controversially, Pataky *et al.* (2008) questioned regionalisation in quantifying pressure analyses; their work found that regional peak pressures in 80% of cases lay outside of geometrically defined regions of interest with the MFT region sensitive to this. This may limit sensitivity of the geometric regionalisation. Analysis of the number of regions required has not been fully explored in healthy individuals, or those with neurological conditions (Giacomozzi, 2011). Interestingly, Zammit *et al.* (2010) explored reliability of foot region application and found this to be excellent (ICC = 0.96–1.00). This was not explored in this study.

Clinical Relevance of Plantar Pressure Variables:

To illustrate clinical relevance, plantar pressure measures of the more- and less-affected sides were compared. The more-affected side demonstrated lower values for both CA and peak pressure, demonstrating altered DFL during stance phase of gait after stroke.

For four-region analysis, lower peak pressure was observed in RFT, FFT and Toes regions on the more-affected side, with the RFT and MFT regions being statistically significant. Eight-region analysis found all regions except the MMT region had lower peak pressure on the more-affected side; none of the eight regions demonstrated statistically significant differences. Lower RFT pressures on the more-affected side may be attributed to reduced loading of the RFT at initial foot contact, synonymous with gait disturbances reported after stroke (Beyaert *et al*., 2015). Similar to this work, Meyring *et al.* (1997) also found lower loading in most of the plantar regions on the affected sides. They also found the MFT region demonstrated higher pressures, which they attributed to the presence of spasticity; however, the association of peak pressure with spasticity was not explored in this work. Alternatively, the more-affected side MFT region may have shown higher pressure due to increased loading from pronation, as over 80% of the group had a pronated foot posture; yet, values for CA do not support this hypothesis, with the less-affected side MFT region having a marginally higher CA.

Contact area using a four-region mask exhibited lower values for all more-affected side regions, with statistically significant differences for RFT, FFT and total foot CA ($p < 0.05$). For eight-region analysis, five of the eight regions demonstrated lower values on the more-affected side, with two regions showing statistically significantly differences: MRF and LRF. This was consistent with the four-region analysis for peak pressure and CA variables suggesting that the RFT is a key region to evaluate in Study 2. Eight-region analysis did not demonstrate a consistent picture across the foot regions, perhaps suggesting the regions were too small or too variable to discern differences. Therefore, the four-region mask for CA is considered superior in detecting differences between more- and less-affected limbs.

While the more-affected side was recorded as neutral for pronated foot types, dynamic foot CA did not increase; in fact, the opposite occurred. This may be due to altered foot

contact, which is frequently reported in people with stroke (Feys *et al.*, 2000), with loss of RFT contact where initial contact is replaced by MFT or FFT region contact. Thus, measurement of CA and evaluation of differences between sides may help show dynamic changes.

For peak pressure and CA, four-region analysis clearly demonstrated differences between limbs with excellent reliability. It is possible that using maximal pressure and total foot contact may be useful predictors in Study 2.

4.7.3 Neuromuscular Impairments

4.7.3.1 Ankle and Hallux Isometric Muscle Strength

Research question 4 evaluated the feasibility and reliability of using a HHD for isometric measurement of ankle and foot muscle strength: *'Are clinical measurements of foot and ankle isometric muscle weakness using a HHD feasible and reliable in people with stroke?'* Study 1 found that a HHD was feasible to use to measure isometric muscle strength in people with stroke at both the ankle and hallux. Protocols were easy to implement, clinically viable, with little data lost on follow up. One challenging aspect was ensuring that adequate opposing strength was offered by the researcher during the 'make' technique. This issue was previously highlighted by Kelln *et al*. (2008) but not previously reported in people with stroke. Despite this, no adaptation was necessary to the protocol as this rarely (once only) affected the more-affected limb.

Overall, muscle strength demonstrated very good to excellent reliability in this work. Excellent ICCs were reported, especially for ankle DF, PF, invertor and evertor muscle groups. These were supported by Bland–Altman plots which showed good agreement. These findings compared well with other studies evaluating muscle strength using a HHD in groups of healthy people and older people (Moraux *et al.*, 2013; Kelln *et al.*, 2008; Spink *et al.*, 2010) as well as those with multiple impairments, including stroke (Bohannon, 1986; Riddle *et al.*, 1989; Yen *et al*., 2017). No systematic errors, as indicated by the low SEM, were apparent for both more- and less-affected sides, showing the protocol to be reliable. While high ICCs were reported in this work for most measures at

the ankle, values for hallux muscle strength are accepted with some caution due to the broad ICC confidence intervals (0.02–0.91). Limits of agreement were larger for ankle PFs than other muscle groups on both more- and less-affected sides, this may have been due to difficulties found by the researcher in resisting the higher forces in ankle PFs (Kelln *et al*., 2008). Despite this, hand-held dynamometry of isometric foot and ankle muscle group strength is deemed acceptable.

Research question 5 was '*Are single or composite measures of ankle and hallux muscle weakness appropriate for use as predictive measures of balance and mobility outcomes in people with stroke?'* Therefore, Study 1 explored whether composite scores or single muscle group scores enhanced feasibility and reliability for use in Study 2 as a predictor of mobility and balance outcomes. This work has shown that composite measures, in comparison to single muscle measures, had higher overall reliability. Recent work by Dorsch *et al.* (2016) reported single ankle muscle group strength to compare limbs of people with stroke and those of controls. Moriello *et al.* (2011) also used composite muscle groupings based on hand-held dynamometry of a gravity respective grading scale. By employing principal component analysis, Moriello *et al*. (2011) found that HHD values for multiple muscles were highly correlated to each other and thus can together summarise strength impairment. Neither study evaluated reliability of composite measures. As reliability was consistently higher for composite data, composite measures were favoured for use in Study 2, although some caution is necessary regarding the hallux grouping due to the poorer ICCs found. Study 2 can use either ankle group or composite values for the predictor models.

4.7.3.2 Peak Ankle and Hallux Passive Dorsiflexion

Study 1 focused on developing foot and ankle passive ROM measures including evaluating the feasibility and reliability of an ankle and hallux ROM rig in evaluating peak ankle and hallux dorsiflexion. This is outlined in research question 6: '*Is it feasible and reliable to measure peak ankle dorsiflexion, ankle inversion and eversion, and hallux dorsiflexion through application of two standardised forces in people with stroke?'* Therefore, this study demonstrated the successful development of a bespoke tool to measure peak ankle dorsiflexion in stroke participants. The use of the bespoke ankle rig and protocol was easily applied in this cohort, with data gained from 9 of the 10

participants tested, demonstrating good feasibility. In addition, mean peak ankle dorsiflexion of 12.42 ±12.10° was similar to other reports of 12.78 ±2.13° (Schindler-Ivens *et al.*, 2008) showing some face validity. The hallux DF rig was feasible for use in people with stroke, yielding data for 13 of the participants. Both rigs enabled assessment of ankle and hallux dorsiflexion peak angle in less than 15 minutes, demonstrating potential clinical applicability. If time to assess could be reduced further this would make application into clinical environment more feasible.

Peak ankle dorsiflexion demonstrated moderate to excellent reliability (ICCs of 0.53–0.83) in this group of stroke participants. Some variability was apparent, which is characteristic of ROM measures (Keating *et al.*, 2000). Although Keating *et al.* (2000) found reliability was excellent with $r = 0.92$, different statistical tests were used and therefore comparisons are precluded. Differences may also be attributed to the systematic error of the tool, variance of values in the sample and the protocol application. Thus, some caution in accepting these results is required. Interestingly, the more-affected side had higher ICCs for both low and high force. Despite this, the results are lower than previous studies in stroke that used the Lidcombe plate, where the ICC observed was 0.97 (Moseley and Adams, 1991), and when standardised force in combination with an inclinometer was used, where the ICC was 0.95 (Harvey *et al.*, 2003). Notably, this has not improved in the current work, perhaps demonstrating how difficult an impairment peak ankle dorsiflexion angle is to measure. This current study extends previous research by demonstrating that both lower and higher forces achieve good reliability. Thus, the bespoke rig showed moderate reliability and will be adopted in Study 2.

Measurement of peak hallux dorsiflexion was feasible using the rig designed by Paton (2006). It had good to excellent reliability for both high and low force. Excellent repeatability has been found by Menadue *et al.* (2006) using goniometry, but no research has been conducted using the rig devised by Paton (2006) at different forces in a neurological population. The hallux DF range achieved using the rig was 47.97 ±12.30° to 53.97 ±8.41° on the less-affected side, almost 20° less than the expected 70° (Palastanga, 1989; Hopson *et al*., 1995). Based on the results of this study at both low and high forces, the rig had good feasibility and reliability in people with stroke, hence the rig will be adopted into Study 2.

4.7.3.3 Ankle and Hallux Stiffness

To address research question 7, '*Is ankle PF muscle stiffness, through application of two standardised forces, reliable to measure in people with stroke?',* the stiffness of the structures limiting ankle dorsiflexion were explored using the application of two forces during ROM measurement. This has enabled evaluation of passive stiffness in line with other papers (Zhang *et al.*, 2015; Marsden *et al.*, 2013; Schindler-Ivens *et al*., 2008); however, the results showed this measure was not reliable, with poor or moderate reliability reported. Given the reliability shown for some measures of passive ROM, this was surprising, but may be explained by a small sample size in which there was a large between-subject difference. Furthermore, the calculation (Marsden *et al.*, 2013) may have been affected by the small change in average ROM meaning that stiffness values were large. Despite this, it demonstrates both the complex nature of quantifying stiffness and that other measures, such as surface EMG and electro-goniometry, may be more suitable (Burridge *et al.*, 2005). Study 2 will therefore not use ankle and hallux stiffness as a predictor.

4.7.3.4 Ankle PF Spasticity

Research question 8 was: *'Is the Tardieu scale a reliable measure of ankle PF spasticity in people with stroke?'* Study 1 set out to evaluate the use of this measure of ankle muscle spasticity. When using the Tardieu scale, the study data showed very good reliability, thus providing confirmation of its reliability. The results agree with Haugh *et al.* (2006) who found both the Tardieu scale and modified Tardieu scale had good reliability in a stroke population. Gracies *et al.* (2010) demonstrated excellent reliability using the Tardieu scale, although this was in a group of patients with cerebral palsy. Beside this, the values obtained also indicated a low occurrence of clonus post-stroke and predominance in mild to moderate spasticity. This aligns with pathophysiological responses after stroke (Sheean, 2002) and prevalence of mild to moderate altered muscle activity (Jang *et al.*, 2015; Watkins *et al.*, 2002). Whether this limits ankle passive ROM, contributes to foot posture abnormalities and alters DFL characteristics is still to be explored.

4.7.4 Limitations

The design of Study 1 was relevant for exploring test–retest analysis; however, there was data loss due to a reduced number of participants available at follow up (non-attendance). No specific concerns were raised by participants, but this may have been attributed to the long assessment battery (2 hours) and logistics with attendance over the summer months. This was compounded for some measures with missing values and thus there were reduced numbers for retest analysis. Whether reducing the number of measures utilised in the assessment battery would improve attendance at retest is not clear. Given the novel and developmental nature of the work, the results are still valuable.

It is suggested that some variables, such as peak ankle dorsiflexion, should be evaluated further. Further evaluation of toe deformity using EMG and video analysis, while attempted, was precluded as insufficient data was captured to allow analysis. Use of 3D motion analysis would have enabled toe deformity and peak ankle/hallux DF ROM to be evaluated, although this would not have been cognisant with the clinical focus of the work. Use of EMG alongside the bespoke rigs would also have increased the robustness of evaluation of muscle stiffness and spasticity as the use of EMG and change in joint motion can differentiate neural and non-neural elements of muscle stiffness (Pandyan *et al*., 2005). Importantly, ankle inversion and eversion were not able to be evaluated because of challenges in the development of a suitable rig and measurement protocol for use. Therefore, it was not possible to fully answer research question 6. Other work has found interesting reductions in inversion/eversion motion using 3D motion analysis in a small group of people after stroke (Forghany *et al*., 2014). Therefore, ankle motion in the frontal plane still requires further evaluation and clinically applicable instruments to quantify it.

Some procedural events occurred which have limited the work. There was no available data for the reliability of toe deformity observation to be evaluated (Section 4.7.2.2), and there was data loss, especially for HHD and DFL; however, researchers using similar protocols would be prudent to ensure careful checking of all equipment prior to testing.

There were multiple questions to addressed in the study, which meant that only focused aspects of feasibility and intra-rater reliability were explored to support selection of

measures to assess foot and ankle impairments after stroke. Clinical relevance was only explored for DFL. It was anticipated that clinical implications would be further explored as part of Study 2. Reliability for eyes closed conditions during sway was not established as previously this had not been considered a measure of interest, despite its role in evaluating balance. Given the dearth of literature around eyes open and eyes closed conditions in evaluating control of neuromuscular function, inclusion of the eyes closed condition during sway was adopted into the assessment battery.

4.8 SUMMARY AND KEY FINDINGS OF STUDY 1

This study has presented data on feasibility, reliability and agreement statistics for a wide range of foot and ankle measures for use after stroke. It has demonstrated suitable feasible and reliable protocols and tools for use in Study 2 and for people with stroke. This is important as the need for measures of foot and ankle impairments after stroke is paramount to understanding their severity and foundational to exploring their impact on functional outcomes. The impact on clinical treatment and service delivery will be considered alongside Study 2 results in Chapter 6. Based on the analysis of the data collected, it has been demonstrated that the protocols for static and dynamic measures of foot function are reliable, along with ankle and hallux single and composite isometric muscle strength. Decision making required a balance of both reliability and agreement data (Kottner *et al*., 2011). Thus, key findings in a small stroke cohort demonstrate (aligned to their Study 1 research question (RQ)):

Foot Characteristics:

- **Foot posture:**
  - ✓ The FPI is feasible and has good reliability (RQ1) for use in people with stroke in a clinical environment for evaluating static foot posture.
- **Toe deformity**
  - ✓ Feasible to visually observe in people with stroke in a clinical environment (RQ2) as a classification.
- **Dynamic Foot Loading:**
  - ✓ **Peak plantar pressure and foot contact area** as a measure of static and dynamic plantar pressure analysis is feasible to evaluate in people with stroke

in a clinical environment (although it comes with some recommendations) (RQ3);

- ✓ **Sway velocity/path length** during quiet standing with eyes open has good reliability for use in people with stroke in a clinical environment (RQ3);
- ✓ Stance phase **peak plantar pressure** and **contact area** variables have good to excellent reliability for evaluating foot loading patterns (RQ3) using a **four-region** mask in people with stroke in a clinical environment;
- ✓ **Plantar pressure variables** may have **clinical relevance,** demonstrating difference in foot loading patterns between feet in people with stroke (RQ3).

Neuromuscular Impairments:

- **Muscle strength:**
  - ✓ HHD to evaluate ankle and foot **isometric strength** is feasible and reliable to use in people with stroke in a clinical environment (RQ4);
  - ✓ Both **single** ankle muscle group *and* **composite** measures of **isometric muscle strength** have moderate to excellent reliability (ankle > hallux) (RQ5).
- **Passive ROM:**
  - ✓ A bespoke ankle DF rig at two forces is feasible and **peak ankle dorsiflexion** has good reliability at two forces mask for use in people with stroke in a clinical environment (RQ6);
  - ✓ A hallux DF rig at two forces is feasible and **peak hallux dorsiflexion** has excellent reliability at two forces for use in people with stroke in a clinical environment (RQ6);
  - ✓ Peak ankle and hallux dorsiflexion can be used as a predictor variable for use in people with stroke in a clinical environment in Study 2 (RQ6);
  - ✓ **Stiffness** of ankle dorsiflexion and hallux dorsiflexion using the methods in this study is not reliable for use in people with stroke in a clinical environment (RQ7);
- **Spasticity:**
  - ✓ The Tardieu scale, quality of muscle reaction in **ankle PF muscle spasticity** has good reliability for use in people with stroke in a clinical environment (RQ8).

Table 4.22 Summary Findings and Evidence Used to Determine Measures Taken Into Study 2

Impairment	Feasibility	Reliability	Evidence and rationale for inclusion in Study 2
Static foot posture	Feasible 17/17 data available 2–5 minutes	Good: κ_W = 0.53–0.60	Study 1 provides **novel data *in English* about the feasibility and reliability of use of FPI after stroke** (Lee *et al*., 2015). ➢ May demonstrate important **foot type changes** with stroke (in addition to age-related ones), which may **predict mobility and balance outcomes** (Forghany *et al*., 2011).
Toe deformity	Feasible 17/21 data available 5 minutes		Study 1 provides **novel *data of the observation and presence of toe deformity in chronic stroke, thus supporting its feasibility.*** ➢ Toe deformity type or presence **may be associated with function** after stroke (Laurent *et al*., 2010).
DFL: sway	Feasible 14/17 data available 5 minutes	Moderate to good: ICCs 0.54–0.78 (4 regions)	Study 1 demonstrates the ***feasibility and reliability for capturing sway velocity in stroke***. This is the first report using a pressure mat to do so. ➢ Sway demonstrates neuromuscular control of foot and ankle, directly impacting on mobility and balance outcomes (Chisholm *et al*., 2011; 2013).
DFL: Peak plantar pressure and contact area	Feasible 14/17 data available 15 minutes	4-region: Good to excellent: PPP ICC 0.76–0.96, CA 0.58–98;	Study 1 reports ***good feasibility and good to excellent reliability (4 regions) in stroke.*** This is the first report using a pressure mat to do so. ➢ Clinical relevance demonstrated by PPP and CA variables appears to distinguish between limbs and may allow for evaluation of stroke v.

Impairment	Feasibility	Reliability	Evidence and rationale for inclusion in Study 2
		8-region: Moderate to excellent PP ICC 0.36–0.98, CA ICC 0.61–0.97*	control groups as found by Meyring *et al.* (1997), Hillier and Lai (2009). ➢ Variables may predict mobility and balance outcome after stroke as in older people (Spink *et al*., 2011).
Isometric ankle and hallux muscle strength (single and composite measures)	Feasible 12/17 data available 15 minutes	SINGLE: Moderate to excellent: Most-affected side ICC 0.62–0.95 Less-affected side ICC 0.42–0.95 COMPOSITE: Good to excellent: Most-affected side ICC 0.67–0.93 Less-affected side ICC 0.71–0.95	Study 1 demonstrated that ***single and composite values of isometric ankle and hallux muscle strength were feasible and reliable*** to measure in people with stroke. ➢ Single and composite values may demonstrate differences between stroke and control groups and between limbs in Study 2 (Dorsch *et al*., 2016). ➢ Composite values may be potential predictors of mobility and balance outcomes (Dorsch *et al*., 2012).

Impairment	Feasibility	Reliability	Evidence and rationale for inclusion in Study 2
Peak ankle dorsiflexion **Peak hallux dorsiflexion**	Feasible 9/17 (ankle); 13/17 (hallux) data available 10 minutes for each joint Feasible data available 10 minutes	ANKLE: Moderate to excellent: ICC 0.53–0.82 HALLUX: Good to excellent: ICC 0.70–0.82	Study 1 found that the bespoke rigs for ***ankle and hallux DF passive ROM using a standardised force were feasible and reliable*** for use in people after stroke. (Although some caution is required due to lack of data available for ankle dorsiflexion.) ➢ Ankle and hallux dorsiflexion angle have evaluated deficits in movement after stroke and may be a potential predictor for mobility and balance in Study 2 (Lamontagne *et al*., 2002).
Passive ankle and hallux PF stiffness	Feasible 9–13/17 data available	Poor/absent: ICC 0.00–0.11	Study 1 demonstrated ***poor or absent reliability despite feasibility appearing good.*** Some evidence exists to support use of stiffness (Schindler-Ivens *et al*., 2008) is evaluating ankle motion after stroke however as reliability was so poor this measure was excluded from Study 2.
Ankle PF spasticity	Feasible 17/17 available 5 minutes	Good: $\kappa_{w=}$ 0.78	Study 1 found using the ***Tardieu feasible and reliable in evaluating ankle plantarflexion spasticity/ quality of movement after stroke.*** ➢ Spasticity has been previously associated with mobility and balance outcomes (Lamontagne *et al*., 2002) and is therefore a potential predictor for Study 2.

Abbreviations: CA = contact area; DF = dorsiflexor; DFL = dynamic foot loading; FPI = foot posture index; ICC = intraclass correlation coefficient; PF = plantarflexor; PP = peak pressure

As a result, the measures to be taken forward into Study 2 are:

- Static foot posture using the FPI;
- Toe deformity type and presence;
- Dynamic foot loading:
    - Sway velocity and path length using COF;
    - PPP using plantar pressure analysis using four foot regions;
    - Foot contact area using plantar pressure analysis using four foot regions;
- Isometric muscle strength using a HHD (single and composite);
- Peak ankle and hallux dorsiflexion using low or high force;
- Ankle PF spasticity using the Tardieu scale.

Adaptations to Take Forward to Study 2 are:

- Refine battery (if possible) to minimise number of measures in order to reduce the amount of missing data.
- For quiet standing trials using plantar pressure analysis, add in an eyes closed condition to enable evaluation of neuromuscular control at the ankle.
- For walking trials, PPP for the whole foot will be extracted.
- Ensure participants can walk barefoot for a distance of 10 m.

Three aspects of Study 1 are still outstanding and are areas for future work to aid reliable clinical assessment:

1. Reliability was not evaluated for toe deformity; this still needs to be established.
2. A tool for ankle inversion/eversion ROM still needs to be established (feasibility and reliability).
3. Joint/muscle stiffness was not reliable, therefore alternative methods of evaluating this quantitively need to be established to aid clinical assessment.

Study 2 seeks to use the measurements above to establish whether these foot characteristics and neuromuscular impairments are predictors of mobility and balance

outcomes. Furthermore, to what extent are foot and ankle impairments present in people after stroke and does this differ from their age- and gender-matched controls.

Chapter 5: STUDY 2: FOOT AND ANKLE IMPAIRMENTS AS PREDICTORS OF MOBILITY, BALANCE AND FALLS OUTCOMES

5.1 INTRODUCTION

Chapter 2 outlined the current limitations in the understanding of the impact of foot characteristics, and foot and ankle neuromuscular impairments, on mobility and balance following stroke. While more is known about muscle strength and joint ROM (Bohannon, 2007; Patten *et al.*, 2004; Lamontagne *et al.*, 2001; 2002; Keating *et al.*, 2000), current research has not examined ankle invertor, ankle evertor and hallux muscle groups, nor indeed foot characteristics such plantar pressure variables or toe deformity (Kunkel *et al*., 2017; Forghany *et al.*, 2011; Laurent *et al.*, 2010). Thus, the severity of deficits at the foot and ankle are not fully explored in the current literature. Some recent work has suggested that asymmetry of foot posture and loss of ankle supination and pronation ROM in people with stroke may be associated with other foot and ankle impairments and with mobility and balance outcomes (Forghany *et al.*, 2015; 2011). The significant deficits in mobility (Langhorne *et al.*, 2009) and balance (Ashburn *et al.*, 2008) after stroke lead to long-term limitations in participation (Langhorne *et al.*, 2009). This provides a clinical incentive to explore further deficits at the foot and ankle after stroke.

Study 1 explored whether foot characteristics and neuromuscular impairments may associate with mobility and balance outcomes. Evaluation of foot and ankle impairments as predictors will culminate in an increased understanding of the influence of foot and ankle characteristics on the mobility and balance of people with stroke. It is expected that this approach will inform clinical decision-making by highlighting influential impairments, thereby contributing to clinical guidelines and guiding assessment and management. This will help to mitigate long-term consequences of impairments at the foot and ankle and their influence on mobility and balance function for people with stroke.

The sole focus of Study 2 was the foot and ankle. Other variables such as knee and hip muscle strength, joint ROM and spasticity were not evaluated as these have already demonstrated an influence on mobility and balance after stroke (Bohannan, 2007;

Lamontagne *et al*., 2002). Thus, specific work at the foot and ankle was required. Inclusion of a wider range of lower limb variables would impact on the sample size required within a regression analysis and therefore challenge the feasibility of conducting this work and diminish attention to the foot and ankle. See Section 5.2.1 for further information on study design.

Study 1 evaluated appropriate reliable and feasible measurement tools for foot and ankle impairment and found that the following measures were feasible and reliable for use with people with stroke in this current work:

- ✓ Static foot posture using the FPI;
- ✓ Toe deformity type and presence using visual observation;
- ✓ Dynamic foot loading using plantar pressure analysis:
    - Sway velocity and path length using COF;
    - Peak plantar pressure (four regions);
    - Foot contact area (four regions);
- ✓ Isometric muscle strength (individual and composite) using a HHD;
- ✓ Peak ankle and hallux dorsiflexion (low and high force) using a bespoke rig;
- ✓ Ankle PF spasticity using the Tardieu scale.

These measures are summarised later in Table 5.3, and accompanied by an explanation of modifications to the protocols or measures for application within Study 2 (Section 5.2.4.1). Additional procedures and equipment were used in this work to assess mobility and balance outcomes. Quantifying walking speed, forward reach, fear of falling and impact of stroke on walking will be described, along with the rationale for their inclusion. The results will be presented in line with the research questions and then discussed in conjunction with relevant literature.

5.1.1 Aims and Hypotheses

The overarching aim of Study 2 was:

> ***To explore whether foot characteristics and neuromuscular foot and ankle impairments identified following stroke differ from normal controls; and whether these are associated with mobility and balance outcomes.***

The following research questions have been addressed:

1) Are there differences between people with stroke and age- and gender-matched controls in the severity of foot characteristics and neuromuscular impairments?
2) Are there differences between the more- and less-affected limb in people with stroke in the severity of foot characteristics and neuromuscular impairments?
3) Are foot characteristics and neuromuscular impairments at the foot and ankle predictors of problems with mobility and balance in people with stroke?

These research questions derived from the literature review presented in Chapter 2 and have been stated as non-directional hypotheses, as shown in Table 5.1.

Table 5.1 Hypotheses in Study 2

Research Question	Hypotheses
1	There will be a difference in *foot posture type* between stroke and control participants.
	There will be a difference in *toe deformity type and presence* between stroke and control participants.
	There will be a difference in *sway velocity and path length* between stroke and control participants.
	There will be a difference in *peak plantar pressure* between stroke and control participants.
	There will be a difference in *foot contact area* between stroke and control participants.
	There will be a difference in *isometric muscle strength (single and composite)* between stroke and control participants.
	There will be a difference in *peak ankle and hallux dorsiflexion* between stroke and control participants.
	There will be a difference in *ankle PF spasticity and presence* between stroke and control participants.
2	There will be a difference in *foot posture type* between more- and less-affected limbs of stroke participants.
	There will be a difference in *toe deformity type and presence* between more- and less- affected limb of stroke participants.
	There will be a difference in *sway velocity and path length* between more- and less-affected limbs of stroke participants.
	There will be a difference in *peak plantar pressure* between more- and less-affected limbs of stroke participants.
	There will be a difference in *foot contact area* between more- and less-affected limbs of stroke participants.
	There will be a difference in *isometric muscle strength (single and composite)* between more- and less-affected limbs of stroke participants.
	There will be a difference in *peak ROM of ankle and hallux dorsiflexion* between more- and less-affected limbs of stroke participants.
	There will be a difference in *ankle PF spasticity and presence* between more- and less-affected limbs of stroke participants.
3	Foot characteristics and neuromuscular impairments will be able to predict in *walking speed* after stroke.
	Foot characteristics and neuromuscular impairments will be able to predict in *timed up and go* (TUAG) after stroke.
	Foot characteristics and neuromuscular impairments will be able to predict in *functional reach* after stroke.
	Foot characteristics and neuromuscular impairments will be able to predict in *falls report* after stroke.

5.2 METHODOLOGY

5.2.1 Study Design

To evaluate relationships between foot and ankle variables and mobility and balance outcomes, Study 2 used a cross-sectional study design. This exploratory type of design allows evaluation of variables and their association with, and between, other variables, enabling the prediction of outcomes (Portney and Watkins, 2009). Data was collected at one time point only. Consistent with a cross-sectional study design, neither dependent nor independent variables were controlled. Two groups were selected: one of people with stroke, and one of age- and gender-matched controls. A control cohort was included to eliminate the confounding effects of age and gender on the outcomes, and to demonstrate differences between those with and those without stroke. This approach is necessary as other work by Spink *et al.* (2011), Mickle *et al.* (2011a) and Menz (2015) suggests that age influences foot and ankle characteristics and balance and mobility outcomes. Likewise, gender may influence some of these factors, such as muscle strength (Menz, 2015; Bohannon, 2007).

5.2.2 Sample Size

To determine the number of participants in the study, an a priori power calculation was completed. As part of the overarching FAiMiS project (Chapter 1, Section 1.2.1), it was anticipated that there were 13 potential predictors of function after stroke to be measured[30]; this represents at least one variable for every 14 participants ($13 \times 14 = 182$). As Section 5.2.5.5 explains, only 10 variables from this current work were selected. A group of control subjects was also recruited for comparison to the stroke group. Previous comparisons of the difference in impairments such as ROM and ankle strength between the more- and less-affected side and/or matched controls have found effect sizes ranging from 0.72–1.8 (Lin *et al.*, 2006; Keating *et al.*, 2000). To detect an effect size of 0.72 with

[30] These are stated in the FAiMiS grant application (dated March 2012) as follows: strength of foot and ankle muscles (predictors 1-3); assessment of joint ROM of the foot and ankle (predictors 4-5); sensory dysfunction and light touch (predictors 6-7) (*not included in this thesis*); static foot posture (predictor 8); dynamic foot loading (predictor 9-10); hypertonia and reflex activity (predictor 11-12); foot pain during walking (predictor 13) (*not included in this thesis*).

a power = 0.9 and alpha = 0.05/15 (to account for multiple comparisons including impairment, balance and walking measures), 45 (= 0.9 × 0.05) matched control participants were required to compare to stroke participants.

5.2.3 Participant Recruitment

In Study 2, 180 stroke participants and 46 control participants were recruited as part of the collaborative multicentre FAiMiS study conducted at two sites: North Devon and East London. Ethical approval was gained from NREC Southwest region Exeter panel in January 2014 (13/SW/0302, Appendix 22). Potential participants were identified by the direct care team who screened patients accessing their services and obtained consent to provide their details to the researchers (AR and TG). In East London, stroke participants were recruited via local hospital NHS Trusts: Barts Health and East London Foundation Trust; stroke consultant follow-up clinics; and from local stroke groups in North, Northeast and Southeast London. In North Devon, stroke participants were recruited via the North Devon NHS Trust and local stroke research networks. Participants were recruited using similar inclusion and exclusion criteria to Study 1, as follows:

Inclusion criteria:

- three or more months after a diagnosed stroke;
- able to walk 10 m independently with or without an aid;
- living in the community;
- over 18 years old;
- able to give informed consent (no significant cognitive/behavioural/language barrier).

Exclusion criteria:

- any significant co-morbidity affecting the foot and ankle (e.g. rheumatoid arthritis);
- any recent surgery or any other neurological condition (e.g. Parkinson's disease).

The 46 healthy control participants were recruited at both sites from social, leisure and community groups such as the University of the Third Age, and relatives of stroke participants. Control participants were recruited using inclusion and exclusion criteria as follows:

Inclusion criteria:

- able to walk 10 m independently with or without an aid;
- living in the community;
- over 18 years old;
- able to give informed consent (no significant cognitive/behavioural/language barrier).

Exclusion criteria:

- any significant co-morbidity affecting the foot and ankle (e.g. rheumatoid arthritis);
- any recent surgery or any neurological condition (e.g. stroke, Parkinson's disease).

Participants that consented to provision of their contact details were followed up by telephone and screened by the researchers. When identified by the direct care giver or researcher, and inclusion criteria were met, they were invited to take part using a formal letter of invitation (Appendix 23) and study information sheet (Appendix 24). At the testing session, understanding of the study implications was checked and written informed consent was gained from participants (Appendix 25). Both researchers that recruited participants had completed Good Clinical Practice training (National Institute for Health Research).

As the recruitment objective was to proportionally match control participants to stroke participants for both age and gender, these characteristics were monitored throughout the recruitment cycle. Stratification of age groups and gender groups with frequent communication between sites was conducted to ensure targets were met. Final distribution across the groups is shown in Table 5.2. Age profiles were well matched for stroke and control groups ($\chi^{2} = 40.72$, $p < 0.84$). Gender matching was also achieved; although there was a higher proportion of females in the control group, no statistically significant difference was found between stroke and control groups ($\chi^{2} = 2.02$, $p < 0.19$).

Table 5.2 Stroke and Control Participants: Gender and Age Profiles Matched

	Stroke (*n* = 180)		**Control (*n* = 46)**	
Gender	**No.**	**%**	**No.**	**%**
Male	107	59%	22	48%
Female	73	41%	24	52%
Age range (years)	**No.**	**%**	**No.**	**%**
20–39	3	2%	1	2%
40–49	13	7%	4	9%
50–59	29	16%	6	13%
60–69	54	30%	15	33%
70–79	54	30%	17	37%
80+	27	15%	3	7%

5.2.4 Protocols

The majority of protocols employed in Study 2, were outlined in Chapter 4. All the variables are shown in Tables 5.3 and 5.4.

5.2.4.1 Adaptations to Procedures or Measures

Few adaptations were implemented between Study 1 and Study 2. For DFL static standing trials with eyes open, both sway velocity and path length were extracted as outlined in Study 1. Additionally, as per the Study 1 recommendation, an eyes closed condition was included in Study 2. This was introduced to remove visual system compensation during the test, thus allowing closer analysis of neuromuscular control of the foot and ankle, albeit not eliminating proprioceptive capabilities. An additional measure, PPP for the whole foot, was extracted from walking pressure recordings and analysed with the view that this may be a useful predictor variable in Study 2. Notably barefoot walking, as proposed in Section 4.7.2, was *not* added as an inclusion criterion due to the short turn around between Phase 2 and 3 of the FAiMiS study. No other modifications to procedures or measures from Study 1 were made.

5.2.4.2 Additional Procedures or Measures

To enable data capture of outcome variables of mobility, balance and falls, several established clinical measures were added. The Fast 10-Metre Walk Test (F10MWT) (Wolf *et al.*, 1999), TUAG (Podsiadlo and Richardson, 1991), FFRT (Duncan *et al*., 1990) and Falls Report were selected as mobility and balance outcome variables[31]. Demographic information was obtained on shoe size, number of falls in the previous three months, and use of walking aids indoors and outdoors. Additional variables were collected for descriptive purposes, including the 12-Item Walking Impact Scale (12-Item WIS), and FES. Measures were chosen due to their established reliability and validity, clinical feasibility and relative short time of application. They were also selected to inform aspects of ICF activity and participation descriptors. These measures are presented in Sections 5.2.4.3 and 5.2.4.4, and SOPs for each measure are also given in Appendices 27–31.

[31] Please note, these were not reviewed in the literature review as these were selected by the FAiMiS project; however, clinimetric properties of the characteristics are included in measure procedures in Section 5.2.4.3.

Table 5.3 Procedures, Equipment and Variables used in Study 2: Demographics and Mobility and Balance Outcomes

	Characteristic/ impairments	Equipment	Variable (units)
Demographics	Age	Weighing scales	Age (years)
	Height	Stadiometer	Height (m)
	Site of stroke	Self-report	Site of stroke
	Type of stroke		Type of stroke
	Time since stroke		Time since stroke
	Shoe size		Shoe size
	Number of falls (in the previous three months)		Number of falls Faller/non-faller
	Use of walking aid		Use of walking aid
	Indoor walking		Indoor walking
	Outdoor walking		Outdoor walking
Mobility and Balance Outcomes	Falls Efficacy Scale	Questionnaire	Fear of falling (out of 64)
	12-Item Walking Impact Scale	Questionnaire	Impact on walking (out of 60)
	Fast 10-Metre Walk Test	10 m walkway and stopwatch	Walking speed ($m \cdot s^{-1}$)
	Timed Up and Go	Chair, 3 m walkway and stopwatch	($m \cdot s^{-1}$)
	Forward Functional Reach Test	Tape measure	Forward reach (cm)
	Falls Report	Number of falls reported in the previous three months	Falls Presence (Yes/No)

Table 5.4 Procedures, Equipment and Variables used in Study 2: Foot Characteristics and Neuromuscular Impairments

	Characteristic/ impairments	Equipment	Variable (units)	Study 1 reference
Foot Characteristics	Static foot posture	Foot posture index	Foot type category (HS, S, N, P, HP*) Abnormal/normal	4.4.1.
	Toe deformity	Observation	HHT, claw toe, hammer toe, Fixed/mobile	4.4.2.
	Dynamic foot loading	HR MatScan™	*Standing:* - Sway velocity ($mm \cdot s^{-1}$) - path length (mm) *Walking:* PPP (kPa) - RFT / MFT / FFT / Toes / Max† Foot contact area (cm^2) - RFT / MFT / FFT / Toes / Total†	4.4.3.
Neuromuscular Impairments	Ankle isometric muscle strength	Hand-held dynamometer	Ankle dorsiflexion (kg) Ankle plantarflexion (kg) Ankle inversion (kg) Ankle eversion (kg)	4.5.1.
	Hallux isometric muscle strength	Hand-held dynamometer	Hallux dorsiflexion (kg) Hallux plantarflexion (kg)	4.5.1.
	Peak ankle dorsiflexion	Bespoke rig	Ankle DF ROM (°) (high and low)	4.5.2.
	Peak hallux dorsiflexion	Bespoke rig	Hallux ROM (°) (high and low)	4.5.2.
	Ankle PF spasticity	Tardieu scale	Presence (Yes/No) Quality of movement (0–5)	4.5.3.

*HS = highly supinated; S = supinated; N = normal; P = pronated; HP = highly pronated. †
RFT = rearfoot, MFT = mid-foot, FFT = forefoot, Max = highest pressure over whole foot, Total = total contact area.
Abbreviations: DF = dorsiflexor; HHT = Hitchhiker's Toe; PP = peak pressure; PPP = plantar peak pressure; ROM = range of movement

5.2.4.3 Mobility and Balance: Outcome Variables

Walking Speed:

Walking speed was measured using the F10MWT. Participants were positioned in standing, wearing their footwear, at the start of a 10 m walkway that was marked out using cones at 0 m, 2 m, 8 m and 10 m (Figure 5.1). A chair was placed at either end in case the participants required a short period of rest. Participants were asked to walk as fast as they could over the 10 m walkway on the 'go' of 'ready, steady, go'. The researcher demonstrated the test first. A stopwatch was used to record timings. Once participants started walking, when the tip of the most anterior part of the leading foot (typically the hallux) of the participant crossed the 2 m mark the researcher started timing. Timing stopped when the toes crossed the 8 m mark. If the participant required a walking aid to safely complete the walk, this was permitted and documented. Time taken was used to calculate average walking speed ($m \cdot s^{-1}$) over the middle 6 m.

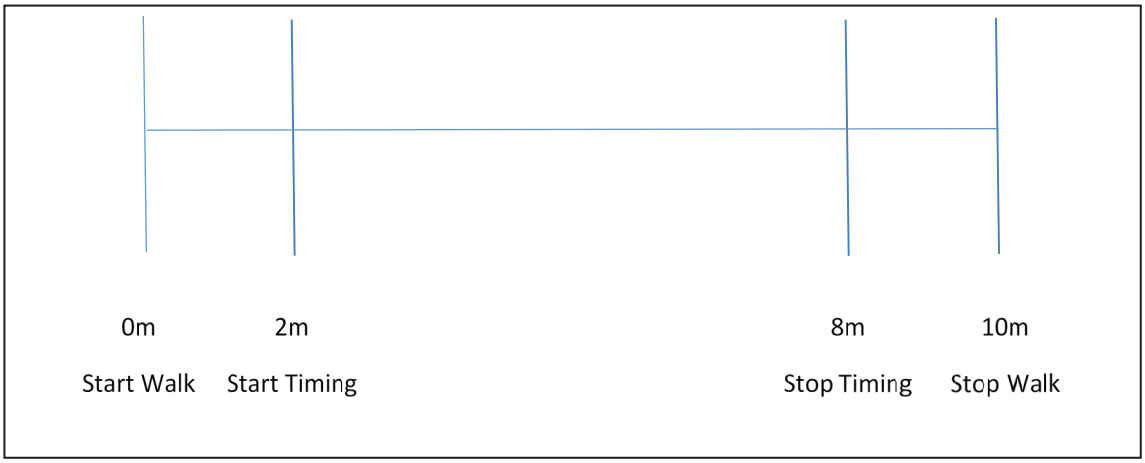


Figure 5.1 F10MWT Walkway

The F10MWT is used extensively in research and clinical practice. It has excellent validity (Lin *et al.*, 2010; Tyson and Connell, 2009; Flansbjer *et al.*, 2005; Wolf *et al.*, 1999) as well as excellent intra-rater reliability ($ICC_{(2,1)}$ 0.97, 95% CI 0.95–0.98, SEM 0.8; Flansbjer *et al.*, 2005) and inter-rater reliability (ICC 0.99; Collen *et al.*, 1990), with responsiveness of 0.05–0.10 $m \cdot s^{-1}$ and a SEM of 0.04 $m \cdot s^{-1}$ (Perera *et al.*, 2006). The mean F10MWT value in chronic stroke is reported as 1.4 ±0.4 $m \cdot s^{-1}$ (Flansbjer *et al.*, 2005). Cut-off scores are correlated with ambulation activity at comfortable walking speed, where a speed of 0–0.04 $m \cdot s^{-1}$ is likely to be household ambulators, 0.4–0.8 $m \cdot s^{-1}$

is limited community ambulators and > 0.8 $m \cdot s^{-1}$ is community ambulators (Bowden, 2008; Schmid and Rittman, 2007).

Timed Up and Go (TUAG):

Participants were seated with their footwear on, in a standard armchair (seat height, 46 cm; arm height, 67 cm). A 3 m distance was marked out by tape or a cone (Figure 5.2). Participants were instructed to walk the distance at a comfortable and safe walking speed, turn 180°, walk back to the chair, and sit down. The researcher demonstrated the test first. The participant then completed the TUAG procedure. Timing using a stopwatch was started on 'go' and stopped when the participant's buttocks touched the seat (measured in seconds). If an aid was utilised, this was recorded.

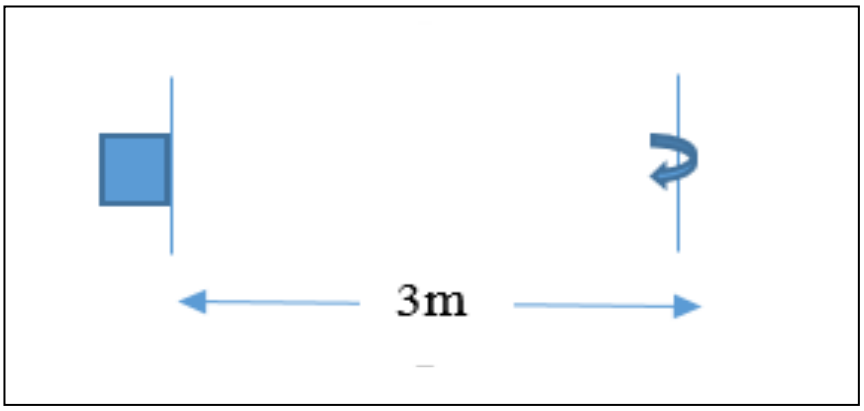


Figure 5.2 TUAG Course

Excellent validity (Knorr *et al.*, 2010) and reliability of the TUAG has been reported in chronic stroke (intra-rater reliability $ICC_{(2,1)}$ 0.96, 95% CI 0.93-0.98, SEM 1.14; Flansbjer *et al.*, 2005), with a minimal detectable change of 2.9 seconds (Flansbjer *et al.*, 2005).

Forward Functional Reach Test (FFRT):

Participants were positioned in standing next to a wall with their footwear on. A tape measure was affixed to the wall, parallel to the floor at the height of the participants' acromion process. Participants were instructed to stand with the less-affected or dominant arm next to the wall (to ensure that any upper limb deficits in people with stroke did not limit the reach test). The arm was held at 90° of gleno-humeral (shoulder) joint flexion, with a closed fist (neutral position at the wrist). Participants were asked to reach as far

forward as they could without taking a step. The researcher demonstrated the test first. The total horizontal translation of the third metacarpal was recorded as Forward Reach distance, which was the distance between the start point and the end point (in centimetres).

Good validity and responsiveness (Katz-Leurer *et al.*, 2009) and excellent intra-rater reliability (ICC 0.89) has been found using the FFRT in people with stroke (Outermans *et al.*, 2010). Normative values for people with stroke range from 25.6 ±7.4 cm (Outermans *et al.*, 2010) to 33.43 ±9.59 cm (Erel *et al*., 2011); SEM is 2.45 cm and minimal detectable change is 3.79 cm (Outermans *et al.*, 2010). No cut-off scores exist for people with stroke, however, falls risk with an odds ratio of 4 has been cited as < 15 cm in elderly men (Duncan *et al*., 1992).

Falls Report:

Participants were asked to report the number of falls they had had in the last three months. Time periods up to 12 months for Falls Report have been found to be specific (> 90%) and sensitive (> 80%) in community-dwelling older adults (Ganz *et al.*, 2005). To ensure that the time since stroke was not a limiting factor to collecting this data, three months was chosen. Falls questioning was undertaken in a sensitive manner to ensure disclosure, as self-reporting of falls is commonly underreported (Hannan *et al*., 2010). A fall was defined as an event where an individual inadvertently comes to rest on a lower surface (World Health Organisation, 2012). This was described to the participant as an unprovoked incident where they have found themselves resting on a low surface such as the floor. The Falls Report was recorded as the number of falls reported by the participant in the last three months. Additionally, Falls Presence was recorded as 'yes', where the number of falls was one or more in the previous three months, and 'no' when there were none.

5.2.4.4 Mobility and Balance: Descriptive Variables

This section includes measures that are not established for use in the stroke population but have been included for descriptive purposes.

12-Item Walking Impact Scale (12-Item WIS):

Participants were asked to complete the 12-Item WIS while seated. It included 12 questions in which participants ranked on a five-point scale how much their stroke had impacted their walking in the past two weeks (1 = not at all; 2 = a little; 3 = moderately; 4 = quite a bit; 5 = extremely), with a maximum score of 60 (Appendix 31). Control participants were asked to report about the impact of their general health on walking using the same measure. Instructions for use were part of the questionnaires and a brief overview was given by the researcher to introduce the questionnaire to the participant. Any questions for clarification were answered by the researcher.

The 12-Item WIS was originally designed for and tested in people with multiple sclerosis and found to be valid and reliable (test–retest: ICCs = 0.78; inter-rater reliability ICC = 0.94) (Goldman *et al.*, 2008; Hobart *et al.*, 2003). Data recorded in people with multiple sclerosis reported a score of 28.2 out of 60 (Goldman *et al.*, 2008). The scale has not been used elsewhere in people with stroke. Yet, as stroke is an upper motor neurone lesion, like multiple sclerosis, the 12-Item WIS has potential face and content validity, although this has not been established.

Indoor/outdoor walking status:

Participants were asked by the researcher to self-report their typical walking ability Indoor walking was classified as 1 = with aids, 2 = independent; outdoor walking was classified as 1 = min/no walking, 2 = walking with aids, 3 = walking no aids. Differences between indoor and outdoor walking were observed. Indoor walking was observed during testing, outdoor walking ability was self-reported. Any differences between the indoor walking score reported by the participants and that observed by the researcher were queried.

Fall Efficacy Scale (FES):

Participants were asked to complete the self-reported FES while seated. The FES included 16 activities, both indoor and outdoor, and required the participant to rank them on a scale of 1–4, from not at all concerned to very concerned (Appendix 32); scores were out of

64. Instructions for use were part of the questionnaire and a brief overview was given by the researcher to introduce the questionnaire to the participant. Any questions for clarification were answered by the researcher.

The FES has been mainly evaluated in older people with little research undertaken in neurological populations. Both validity and reliability are high for those with and without cognitive impairments (Hauer *et al.*, 2011). Cut-off scores have been reported by Delbaere *et al.* (2011) in relation to falls, with scores of 16–19 = low concern; 20–27 = moderate concern; 28–64 = high concern. Data in a chronic stroke population report a mean score of 29.2 ±10.3 (Hauer *et al.*, 2011), although mean ages of these studies are higher than that usually found in a chronic stroke population.

5.2.4.5 Data Collection Environment and Order

As in Study 1, the Human Motor Performance Laboratory at the University of East London was used for data collection; this was named the East London site. At the North Devon site, a large clinical room within the hospital physiotherapy department was used. Participants were required to attend one two-hour testing session; this included the whole assessment battery of the FAiMiS project. Therefore, the tests listed below were preceded by tests for pain (visual analogue scale, VAS, score and descriptors) and lower limb sensation (Nottingham Sensory Assessment scale). Researchers ordered the tests pragmatically to reduce the number of position changes for the participant and to allow for rest breaks between tests. The tests were conducted in the following order:

1. peak ankle dorsiflexion using the bespoke rig at high and low force;
2. ankle dorsiflexion/plantarflexion/inversion/eversion isometric muscle strength using a HHD;
3. ankle PF spasticity using the Tardieu scale;
4. peak hallux dorsiflexion using the bespoke rig at high and low force;
5. hallux DF/PF isometric muscle strength using a HHD;
6. static foot posture using the FPI;
7. DFL variables: sway velocity, PPP, and foot CA using HR MatScan™;
8. visual observation of toe deformity;
9. self-reported questionnaires FES and 12-Item WIS;

10. TUAG;
11. F10MWT;
12. Forward Reach using FFRT.

All physical tests were fully explained to the participants prior to testing. For DFL, isometric muscle strength and peak dorsiflexion angle (ankle and hallux), measures were repeated three times and for both limbs as required. The less-affected side was tested prior to the more-affected side for stroke participants; for control participants, the dominant side was tested before the non-dominant side.

Two researchers carried out the assessments and recorded the data at the two sites: AR in East London and TG in Devon. Consistency and reliability were maintained by following standardised protocols that were jointly set and agreed upon by the two researchers who were experienced Neuro-Physiotherapists (AR and TG)[32]. Accompanying this were SOPs to ensure protocols were carried out in the same way and order (Appendices 13–17 and 27–31). Furthermore, a day of joint training on the devices such as the bespoke rigs and the HHD, as well as the standardised protocols, was conducted and supervised by a third researcher (MC) overseeing the research programme. The credentials for these researchers are found in Appendix 26. No inter-rater reliability testing was conducted due to time constraints and lack of access to participants during the training phase of the FAiMiS project; however, regular contact was maintained between researchers on both sites throughout testing periods to ensure that protocols were adhered to.

5.2.5 Data Extraction and Analysis

Data analysis software IBM® SPSS® (version 24.0) was used for analysis.

5.2.5.1 Demographic Data Analysis

Demographic information was investigated using descriptive measures. Means and SD were determined for age, height and weight, as well as time since stroke and walking

[32] Data is not available.

speed. Frequency counts and percentages were calculated for gender, site and type of stroke, limb dominance/affected limb, indoor/outdoor walking ability and Falls Presence.

Statistical exploration of the data evaluated normal distribution of the scalar/ratio data using the Shapiro–Wilk test for the control group (where sample size is < 50) and the Kolmogorov–Smirnov test for the stroke group (where sample size is > 50), for all variables (Field, 2013), using $p = 0.05$ as the level of significance. Statistical analysis looked for differences between stroke and control group characteristics for age, weight and height. For age, as the data was from independent samples and was not normally distributed, the Mann–Whitney *U* test was used. As weight and height were normally distributed interval level data, the independent student's *t*-test was used. Statistical tests for demographic variables were evaluated for significance using $p = 0.05$ as part of a two-tailed analysis.

5.2.5.2 Foot and Ankle Data Analysis

Differences between the foot and ankle characteristics and neuromuscular impairments were examined between the two cohorts: stroke and age- and gender-matched controls, and between more- and less-affected limbs in the stroke group. To evaluate differences between groups, the less-affected limb (stroke) and dominant limb (control) were compared; and the more-affected limb (stroke) and non-dominant limb (control) were compared. The rationale for this was that the less-affected limb would typically represent a limb with limited effects of the stroke and thus was most similar to the dominant limb of someone without a stroke, e.g. both would be stronger; similarly, the more-affected side and non-dominant limb, e.g. both would be weaker. Therefore, any differences found would not have been inflated. This has been used by Katz-Leurer *et al.* (2009).

First, initial descriptive analysis was undertaken using mean, median and mode, as well as SD and range, to understand the central tendency and spread of the data. Box and whisker diagrams, and/or histograms, were also explored to assist with understanding skew and kurtosis. Second, the data was explored for normal distribution to determine the use of appropriate parametric and non-parametric analysis, using the Shapiro–Wilk test for the control group (where sample size is < 50) and the Kolmogorov–Smirnov test for the stroke group (where sample size is > 50). At this stage, any extreme outliers (> 3SD)

from the mean were removed. Those between 2SD and 3SD from the mean were kept as some data had large ranges and this ensured that data points were not lost; this was pertinent when missing data was high. Outliers, those > 3SD from mean (i.e. 99% of normally distributed data), were excluded as extreme values were at risk of skewing data and breaching normality. Third, analysis of differences between stroke and control groups was conducted using the independent *t*-test and Mann–Whitney *U* test. Analyses of differences between limbs used the paired *t*-test, Wilcoxon Signed-Ranks test and Chi-squared test, as appropriate for the variable. Specific tests are shown in Tables 5.6, 5.7 and 5.8. A Bonferroni correction was applied to the *p* value for two-way comparison of limbs, where $p = 0.05/2 = 0.025$. This was to minimise type 1 errors resulting from multiple comparisons (Portney and Watkins, 2009).

As outlined in Chapter 4, the FPI can be interpreted in a number of ways, including raw scores and age-adjusted scores. A previous work by Forghany *et al.* (2011) has used the approach outlined by Redmond *et al.* (2008) to allow comparability of results and to account for age-related changes across both groups; this was also used in this work and is shown in Section 4.3.1.3, Table 4.3.

5.2.5.3 Mobility, Balance and Falls Data Analysis

Descriptive measures of mobility, balance and falls were analysed using mean and standard deviation for scalar or ratio data, i.e. F10MWT, TUAG, FES, 12-item WIS and Forward Reach. Normal distribution was explored as outlined in Section 5.2.5.1. Differences between groups were analysed by using an independent *t*-test for parametric data or the Kruskal–Wallis test for non-parametric data. Categorical and dichotomous data for indoor and outdoor walking, Falls Report and Falls Presence were described using frequency and counts, with ranges used to indicate the spread of values. Between group comparisons were performed using the Chi-squared test. Statistical significance was determined using $p = 0.05$ as part of a two-tailed analysis.

Table 5.5 Data Analysis by Variable: Foot characteristics

Variable	Level of Measurement	Descriptive Statistics	Type and No. of Comparisons*†	Normal Distribution	Inferential Test
Static foot posture (abnormal and normal)	Categorical	Frequency Percentage	Groups (independent) (2) Limbs (paired) (2)		Chi-squared test
FPI score (-12–12)	Ordinal	Median Mode Range	Groups (independent) (2) Limbs (paired) (2)		Mann–Whitney *U* test Wilcoxon Signed Ranks test
Foot posture (age adjusted) categories (HP/P/N/S/HS)	Ordinal	Median Mode Range	Groups (independent) (2) Limbs (paired) (2)		Mann–Whitney *U* test Wilcoxon Signed Ranks test
Toe deformity type	Categorical (Fixed or mobile)	Mode Frequency Percentages			Chi-squared test
Toe deformity presence	Binary	Frequency Percentage	Presence: Groups (independent) (2) Comparisons within groups across positions (3)		Chi-squared test
Sway velocity	Ratio	Mean SD	Groups (2)	No	Mann Whitney U Test
Path length	Ratio	Mean SD	EO–EC (2)	No	Wilcoxon Signed Ranks test

Peak plantar pressure	Ratio	Mean SD	Groups (2) Limbs (2)	Varied between regions Stroke (LA: RFT, FFT; MA: FFT, toes, foot) Control (Dominant: RFT, toes, MAX; Non-dominant: toes, foot)	Mann–Whitney *U* test Independent *t*-test
Foot contact area	Ratio	Mean SD	Groups (2) Limbs (2)	Varied between regions	Mann–Whitney *U* test Wilcoxon Signed Ranks test

*Group = stroke or control; Limb = most affected, least affected, dominant or non-dominant.
†Bonferroni correction applied ($p = 0.05/2 = 0.025$).

Abbreviations: FPI = foot posture index; HS = highly supinated; S = supinated; N = normal; P = pronated; HP = highly pronated.

Table 5.6 Data Analysis by Variable: Neuromuscular Impairments

Variable	Level of measurement	Descriptive statistics	Type and no. of comparisons*†	Normal distribution	Inferential iest
Individual ankle/hallux isometric muscle strength**	Ratio	Mean SD	Groups (2) Limbs (2) †	Varied between groups	Mann–Whitney *U* test Wilcoxon Signed Ranks test
Composite ankle/hallux isometric muscle strength	Ratio	Mean SD	Groups (2) Limbs (2)	Yes	Independent *t*-test Paired *t*-test
Peak ankle/hallux dorsiflexion (low force)	Ratio	Mean SD	Groups (2) Limbs (2)	Low force – Yes**	Independent and paired *t*-test
Peak ankle/hallux dorsiflexion (high force)	Ratio	Mean SD	Groups (2) Limbs (2)	High force – No	Mann–Whitney *U* test Wilcoxon Signed Ranks test
Ankle PF spasticity (V3 fast speed)	Categorical (≥ 1) (binary) Ordinal	Mode Counts Percentages Median Mode Range	Groups (2) Limbs (2)		Chi-squared test Mann–Whitney *U* test Wilcoxon Signed Ranks test

*Group = stroke or control; Limb = most affected, least affected, dominant or non-dominant. SD = standard deviation.

**Not all data for individual muscle groups had normal distribution. Composite scores for ankle, hallux and all ankle and hallux muscles had normal distribution ($p > 0.20$). ROM normal distribution testing found that all groups had normal distribution at low force, while high force data was not normally distributed. PPP had normal distribution in five of the stroke data sets and five of the control data sets.

†Bonferroni correction applied ($p = 0.05/2 = 0.025$).

Table 5.7 Data Analysis by Variable: Mobility, Balance and Falls Outcomes

Variable	Level of measurement	Descriptive statistics	Type and no. of comparisons*†	Normal distribution	Inferential test
Walking speed (F10MWT)	Ratio	Mean SD	Groups (independent) (2)	Yes	Independent *t*-test
Indoor walking	Ordinal	Frequency Percentages	Groups (independent) (2)		Chi-squared test
Outdoor walking	Ordinal	Frequency Percentages	Between groups (independent) (2)		Chi-squared test
12-item WIS	Ordinal	Median Range	Between groups (independent) (2)		Mann–Whitney *U* test
TUAG	Ratio	Mean SD Median Range	Between groups (independent) (2)	No	Mann–Whitney *U* test
Forward reach (FFRT)	Ratio	Mean SD Range	Between groups (independent) (2)	No	Mann–Whitney *U* test
Fear of falling (FES)	Ordinal	Median Range	Between groups (independent) (2)		Mann–Whitney *U* test
Falls Report	Categorical	Frequency Percentages	Between groups (independent) (2)		Chi-squared test
Falls Presence (in three months)	Ordinal	Median, Range	Between groups (independent) (2)		Chi-squared test

*Group = stroke or control; Limb = most affected, least affected, dominant or non-dominant.
†Bonferroni correction applied ($p = 0.05/2 = 0.025$).

Abbreviations: F10MWT = Fast 10-Metre Walk Test; FES Falls Efficacy Scale; FFRT = Forward Functional Reach Test; TUAG = Timed Up and Go; WIS = Walking Impact Scale.

5.2.5.4 Regression Analysis

Multivariate linear regression analysis explored relationships in the stroke group between foot and ankle impairments as predictors, and mobility and balance as outcome variables. Key criteria and recommendations, which are outlined below, were used to ensure that regression models were acceptable. It is advocated that these are not applied too strictly to ensure regression is still applicable (Field, 2013).

- ✓ **Linearity:** both dependent and outcome variables must be linearly correlated with each other, this is examined using scatter plots (Field, 2013).
- ✓ **Homoscedasticity:** the residuals of predictor variables have similar variance to the outcome, demonstrated by an even scatter plot (Field, 2013).
- ✓ **Multicollinearity:** if correlation between multiple variables has a strong or perfect association (> 0.8), variables should be excluded. Both beta (*b*), the value which indicates strength of contribution to the model, and *R*, the combined association of variables with the outcome variable, will be affected and the impact of an individual variable cannot be seen clearly (Field, 2013). As outlined next, both the variable inflation factor (VIF) and tolerance statistics help determine cut-off values (Field, 2013).
    - **Variable inflation factor:** this gives an indication of multicollinearity between variables. It is a cause for concern when the VIF value of a variable in the model is > 10, (Field (2013); some authors report caution in values > 5 (Nishishiba *et al*., 2014).
    - **Tolerance:** the reciprocal of the VIF (1/VIF) should also be explored (Field, 2013). If this is < 0.2, it indicates a potential problem; if it is < 0.1, it is a serious problem (Field, 2013). To provide a complete picture of the data, this will be provided alongside the findings of the regression analysis.

Multivariate linear regression analysis was completed for combined foot characteristics and neuromuscular impairments to explore how much of the variance in outcome variables was explained by these predictor variables. All variables were simultaneously inputted using the 'enter' method. Dependent variables were the mobility and balance outcomes:

- *Walking speed;*
- *TUAG;*
- *Forward reach.*

Binary logistic regression is similar to multivariate regression analysis but allows for the use of a binary outcome variable (Field, 2013; Portney and Watkins, 2009). This was used to predict membership of variables to only two possible outcomes, such as in the case of Falls Report. *Linearity* is still an assumption, where each predictor was found to have a linear relationship with the log of the outcome variable. Binary logistic regression may be vulnerable to *overdispersion,* where the variance is larger than expected from the model. Analysis of (small) standard errors enabled assessment of this. Binary logistic regression analysis was used to explore predictors for *Falls Report.*

5.2.5.5 Missing Data

Figure 5.3 outlines the missing data reported for each variable with reasons accounting for the data loss and the remaining group numbers (*n*). SPSS® patterns of missing data were explored (using pie charts, pattern grids and histograms) and are reported in the results Section 5.3.5.

Recommendations suggest that for each variable inputted into multivariate regression analysis, there should be at least 10 cases available (Field, 2013). As the power calculation was devised on current reliability of the measures at the start of the FAiMiS project, 13 variables were permitted, equating to 14 cases per variable; however, due to missing data (Section 5.3.5.2), the number of complete cases in Study 2 was $n = 98$ and therefore only a maximum of 10 variables could be selected. These were reviewed using analysis of missing data in SPSS® to help select the number and type of variables that could be used in the regression model. Variables were selected based on reliability from Study 1 and theoretical justification of a potential association with the outcome variable.

In addition, data imputation was conducted. This strategy was employed to ensure that conclusions arrived at were not affected by the missing data values included in analysis (Portney and Watkins, 2009). A total of 50 imputations of complete cases using the ‘fully

conditional specification' technique in SPSS® was performed. This is where each missing value is replaced by several different values and consequently several different completed datasets are generated using 'Multivariate imputation by chained equations (MICE)' (van Buuren and Groothuis-Oudshoorn, 2011). There were 50 imputations selected to protect against the high level of missing data; authors suggest between 10–100 with this based on being more than the percentage of missing data. The results were then pooled from the imputations of all the variables, with residual error accounted for using the Bayesian method (IBM, 2016). As a result, in the final regression analysis both complete cases and imputed or pooled data analysis were explored. Further details are provided in Sections 5.3.5.1 and 5.3.5.2.

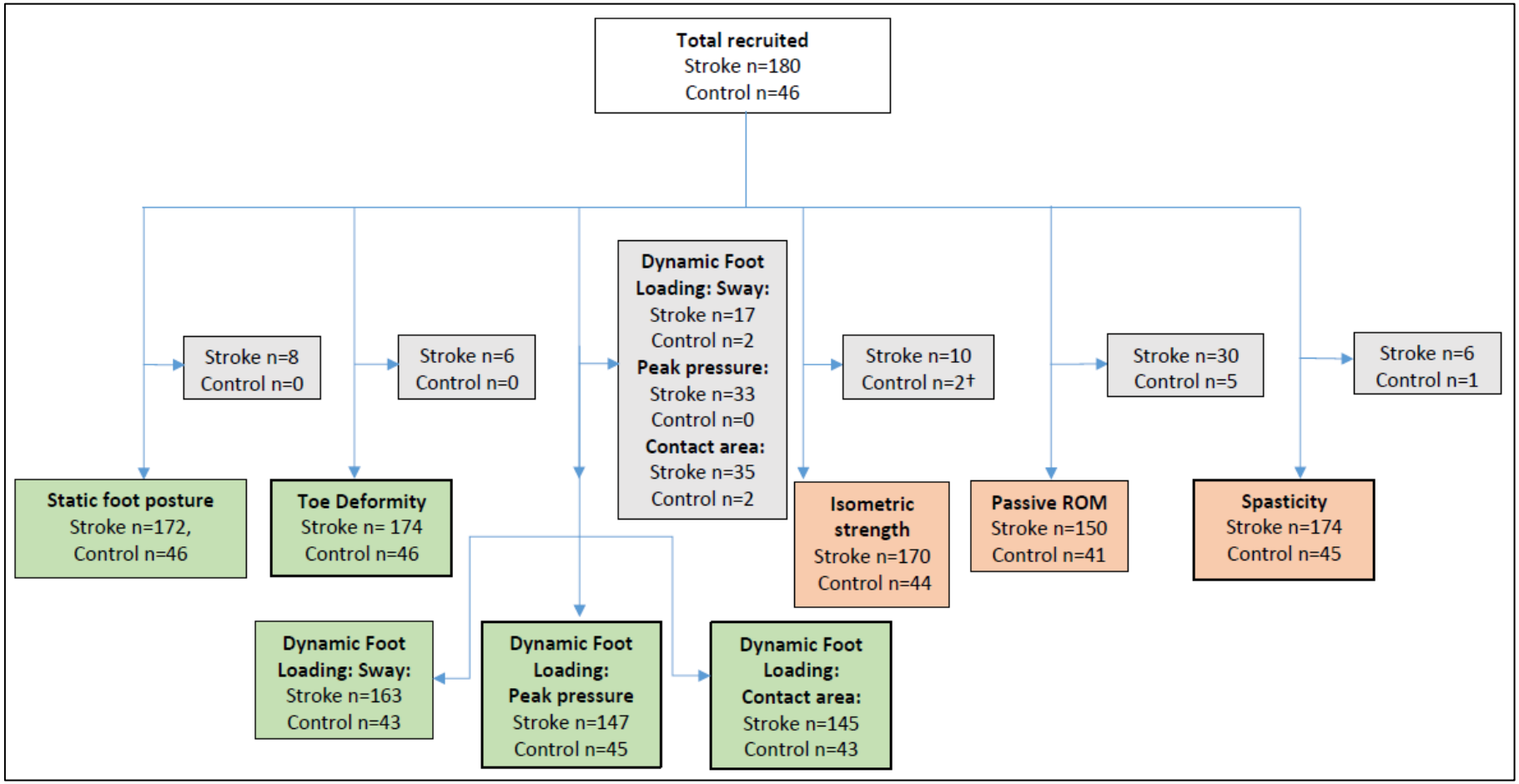


Figure 5.3 Flow Diagram Showing Missing Data for Each Variable

*Due to variability in gait pattern and incomplete loading of the foot, and uncalibrated pressure mat.
†Due to faulty equipment and patient unable to be tested secondary to pain/discomfort.

5.3 RESULTS

5.3.1 Demographics

Table 5.8 shows participant characteristics. There was a greater percentage of males in the stroke group compared to the control group. The average age for the stroke group was 67 ±11 years, compared to 66 ±12 years in the control group. Weight and height were similar between groups with comparable standard deviations. There were no significant differences between the stroke and control participants for age, weight and height. The site and type of stroke reflected a typical stroke group, with the highest proportions in the cerebrum and ischaemic in nature. The average time since stroke was just over three years, ranging from three months to 16 years. Similar proportions of the right- or left-sided being more-affected by stroke were recorded.

Table 5.8 Demographics of All Participants in Study 2*

	Stroke	Control
No.	180	46
Gender	Male 107 (59%) Female 73 (41%)	Male 22 (48%) Female 24 (52%)
Age (years)	67 ±11	66 ±12†
Weight (kg)	78.6 ±17	74.5 ±10.9[a]
Height (m)	1.69 ±0.10	1.69 ±0.11**
Site of stroke	140 (78%) cerebrum 25 (14%) cerebellar and brainstem 14 (8%) other (including unknown)	
Type of stroke	122 (68%) ischaemic 40 (14%) haemorrhagic 18 (10%) unknown	
Time since stroke (months)	Mean = 33 ±49 Median = 12 (222)	
Affected/ dominant Side	81 (45%) right 84 (47%) left 11 (6%) bilateral 4 (2%) unknown	40 (87%) right 6 (13%) left

*Mean ±SD, or median (range), or category: count (%)
†$Z = -0.456$, $p = 0.650$.
[a]$Z = -1.382$, $p = 0.168$.
**$t = -0.334$, $p = -0.401$.

5.3.2 Mobility and Balance Outcomes

Additional information about mobility and balance were collected to provide a fuller description of the groups in conjunction with key outcomes for analytical purposes. All available data, reported as 'n' in Figure 5.3, was analysed. Missing data was due to errors in data recording (e.g. researcher omission) where no value was available.

5.3.2.1 Mobility

Walking speed was used as a final outcome variable. Figure 5.4 shows fast walking speed for stroke and control groups. The mean walking speed of 1.11 (0.8) $m \cdot s^{-1}$ of the stroke group was slower than the 1.81 (0.36) $m \cdot s^{-1}$ of the control group; *t*-test analysis confirmed that there was a statistically significant difference ($t = -10.45$, $p < 0.001$). The stroke group walking speed was 61% of the control group. Table 5.9 shows additional descriptive measures of mobility for both groups: 61 (34%) people with stroke used aids indoors and 99 (55%) used aids outdoors, with 11 (6%) reporting minimal or no outdoor walking. 119 (66%) stroke participants were independent walking indoors, with 70 (39%) being independent outdoors. All 46 (100%) control participants were independent walking indoors; 44 (96%) were independent outdoors, with 4% requiring walking aids outdoors. The 12-Item WIS further emphasised the group differences, with higher scores indicating a greater self-reported impact on walking. The stroke group demonstrated a higher average score of 38 and a larger range of 48 (12–60), compared to 15 and 32 (12–44) in the control group; with the range extending to the maximum score of 60. Statistically significant differences were confirmed between the groups, with $Z = -7.761$, $p < 0.000$.

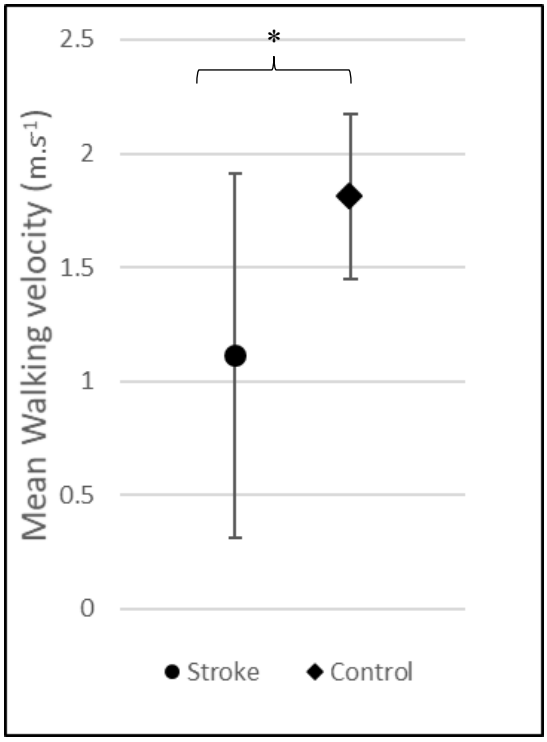


Figure 5.4 Mean Walking Speed of Stroke (*n* = 180) and Control Group (*n* = 44)
*Statistically significant difference independent *t*-test $p < 0.001$.

Table 5.9 Mobility Descriptors for Stroke (*n* = 180) and Control Groups (*n* = 46)

Variable	Stroke	Control
Indoor walking 1 = with aids, 2 = independent	1: 61 (34%) 2: 119 (66%)	1: 0 (0%) 2: 46 (100%)
Outdoor walking 1 = min/no walking, 2 = walking with aids, 3 = walking no aids	1: 11 (6%) 2: 99 (55%) 3: 70 (39%)	1: 0 (0%) 2: 2 (4%) 3: 44 (96%)
12-Item WIS (out of 60)	38 (12–60)[a]	15 (12–44)*

[a]*n* = 178.
**p* < 0.000.

5.3.2.2 Balance

Balance outcomes were reported using the TUAG and FFRT. TUAG results are shown in Figure 5.5. For TUAG, the stroke group took, on average, 10 seconds longer than the control group (18.34 ±13.1 compared to 8.08 ±1.77, respectively), and had a larger dispersion indicating more variance. Statistically significant differences were found between the stroke and control groups ($Z = -7.817$, $p < 0.001$). Forward Reach, measured by the FFRT, is shown in Figure 5.6. This demonstrated that stroke participants on average had a shorter reach by 9 cm; dispersion was similar across both groups. Statistically significant differences were found between the stroke and control groups ($Z = -5.462$, $p < 0.001$).

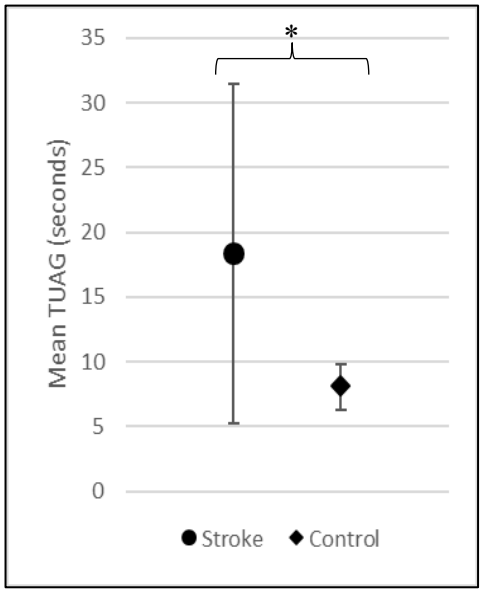


Figure 5.5 Mean TUAG for Stroke (*n* = 179) and Control Groups (*n* = 46)

**p* < 0.001.

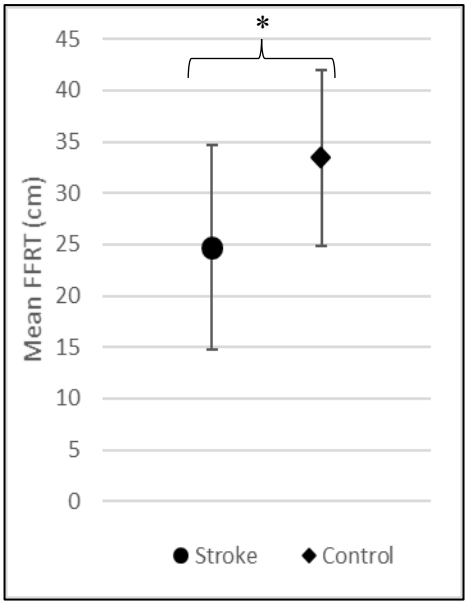


Figure 5.6 Mean Forward Reach for Stroke (*n* = 174) and Control Groups (*n* = 44)
*$p < 0.001$.

5.3.2.3 Falls

Measures for falls are reported in Table 5.10. Falls Report, i.e. the occurrence of one or more falls, was used as a final outcome variable. Falls Report, shown in Figure 5.7, was higher in the stroke group with 72 (40%) stroke participants self-reporting at least one fall in the preceding three months; only three (6.5%) control participants self-reported one fall in the preceding three months. The difference in Falls Report between groups was statistically significant ($\chi^2(1) = 8.344$, $p = 0.004$). Table 5.10 and Figure 5.8 show additional descriptive measures of falls for both groups. The frequency of falls in the stroke group was higher than in the control group with the stroke group reporting up to seven falls in the previous three months, and 49 (27%) control participants reporting one fall only in the previous three months. Notably, both groups most commonly reported zero falls. Fear of falling was measured by the self-reported FES; scores were 13 points higher for the stroke group than the control group. A statistically significant difference was found between groups ($Z = -7.241$, $p < 0.001$).

Table 5.10 Falls Outcomes for Stroke (*n* = 180) and Control Groups (*n* = 46)

Variable	Stroke	Control
Falls Report (Y/N)	N: 108 (60%)* Y: 72 (40%)	N: 43 (93%)* Y: 3 (7%)
Falls (in three months)	0 (0–7)	0 (0–1)
Falls Efficacy Scale (out of 64)	32 (16–64)[a]	19 (14–31)†

*Statistically significant $\chi^2(1) = 8.344$, $p < 0.004$. [a]$n = 178$.

†Statistically significant Mann–Whitney U test $p < 0.000$.

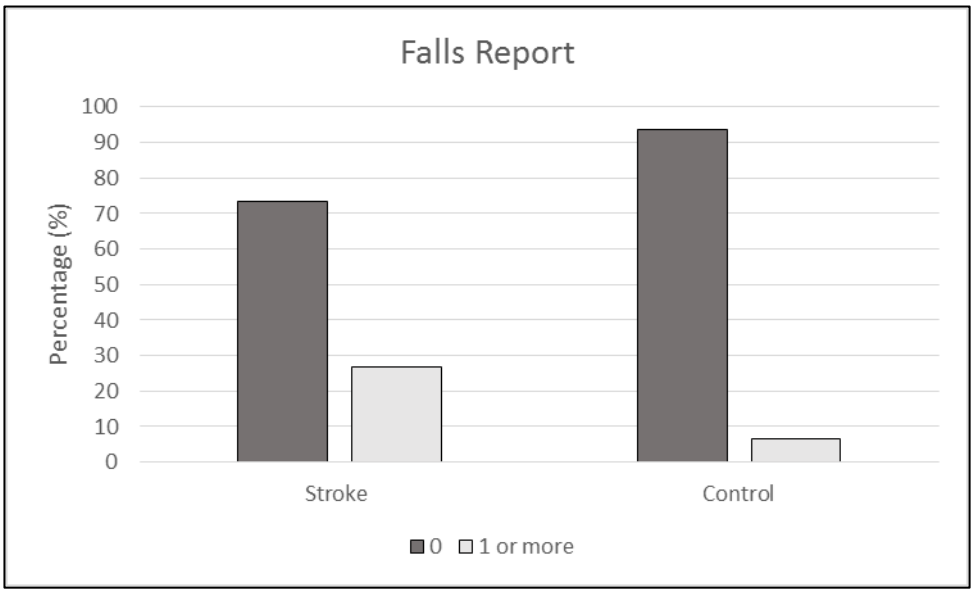


Figure 5.7 Falls Report for Stroke and Control Groups

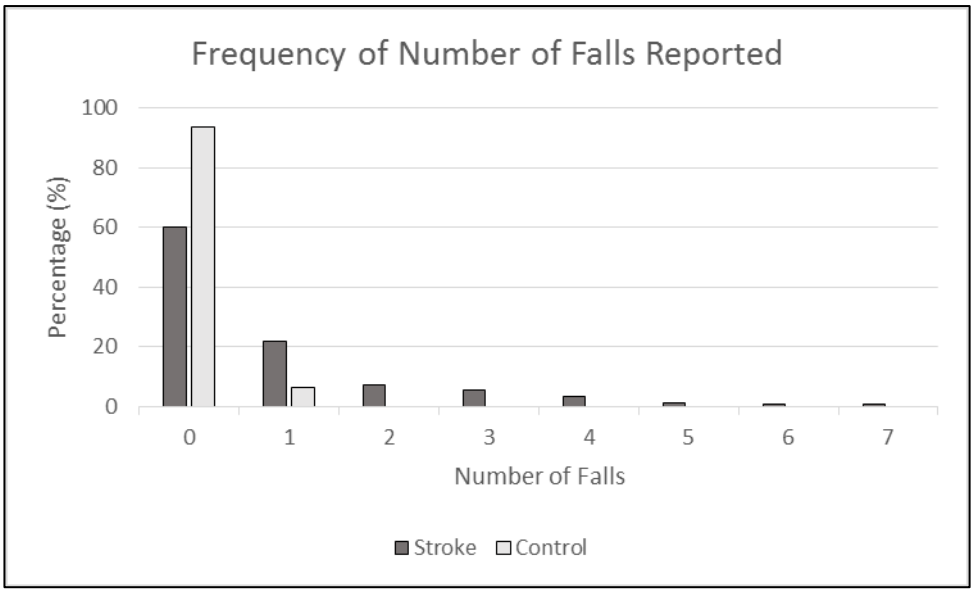


Figure 5.8 Number of Falls Reported for Stroke and Control Groups

5.3.3 Comparison of Stroke and Control Groups for Foot Characteristics

5.3.3.1 Static Foot Posture

The FPI six-item scale was completed for 172 stroke participants and 46 control participants. Missing data was due to incomplete data available for items within the FPI score. FPI scores are shown here using the age-adjusted normal and abnormal classification, FPI score and foot posture category.

Table 5.11 shows normal/abnormal categorisation for FPI. The highest percentage of abnormal foot classification was found in the stroke group on the more-affected limb. Frequencies were similar for the more- and less-affected limb in the stroke group. The control group had greater predominance of normal classification in the non-dominant limb. A significant difference existed between the stroke and control group (more-affected limb compared to non-dominant limb; $\chi^{2} = 3.833$, $p = 0.050$); however, no significant difference was found between the more- and less-affected limbs ($\chi^{2} = 0.308$, $p = 0.579$) in the stroke group.

Table 5.11 Normal and Abnormal FPI Classification

	Stroke		**Control**	
	More-affected	**Less-affected**	**Dominant**	**Non-dominant**
Normal	104 (60%)	109 (63%)	31 (69%)	35 (76%)
Abnormal	68 (40%)	63 (37%)	15 (33%)	11 (24%)

The FPI test scores (not age adjusted) are shown in Table 5.12. Median and mode values were similar in stroke and control groups for both limbs. The stroke group had a larger range in both more- and less-affected limbs. No statistical differences were found between groups ($Z = –0.503$, $p = 0.615$) or between more- and less-affected limbs ($Z = –0.277$, $p = 0.782$).

Table 5.12 FPI Test Scores

	Stroke		**Control**	
	Median	**Range**	**Median**	**Range**
Less-affected/ dominant	2	–3 to 11	1.5	–4 to 9
More-affected/ non-dominant	2	–10 to 12	2	–4 to 9

Figure 5.9 shows age-adjusted FPI categories, which define foot posture type from highly supinated through to highly pronated. The normal foot category (FPI score 1–7 adults 18−59; and 1–8 > 59 years) was the most common foot type, ranging from 60% to 76% across the limbs. In the stroke group, both highly supinated (6%) and highly pronated (2%) postures were found in the more-affected limb, with abnormal supination 30% and abnormal pronation 10%; these were 32% and 4% on the less-affected side, respectively. No significant differences were found between stroke and control groups ($Z = -0.416$, $p = 0.677$) or between the more- and less- affected limb category ($Z = -0.692, p = 0.489$).

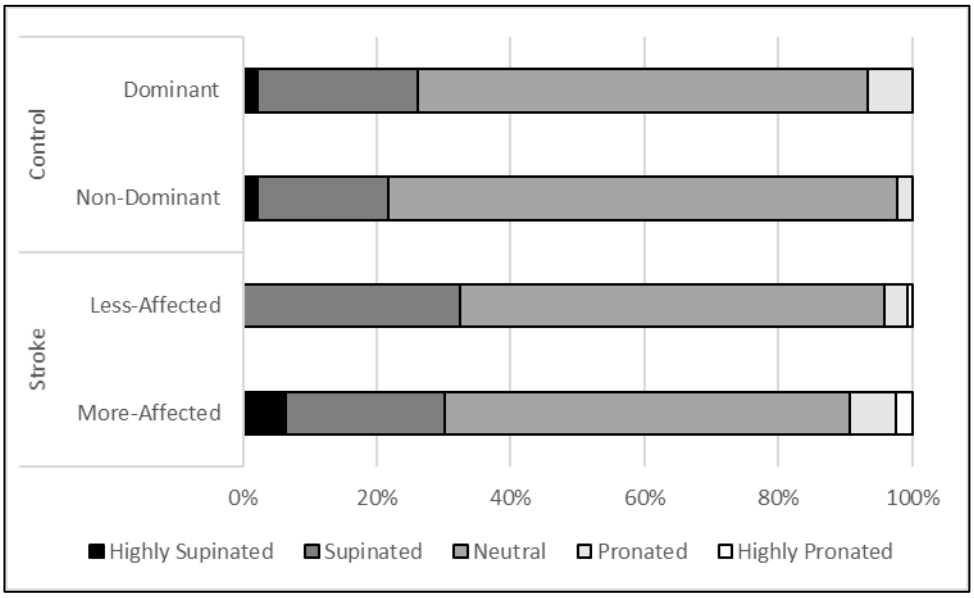


Figure 5.9 FPI Categories for Stroke and Control Participants

5.3.3.2 Toe Deformity

Toe deformity was assessed and identified as present (Yes or No), and if present, as either fixed (F) or mobile (M) across positions of sitting, standing and walking. This was recorded for the more-affected limb in the stroke group and the non-dominant side in the control group. Toe deformity was analysed for 174 stroke and 46 control participants. Missing data was due to the inability to clearly observe toe deformity throughout all position changes.

Figure 5.10 demonstrates that the presence of toe deformity was similar across both control and stroke groups. There was no significant difference in the presence of toe deformity in the two groups ($\chi^2(1) = 0.073$, $p = 0.782$).

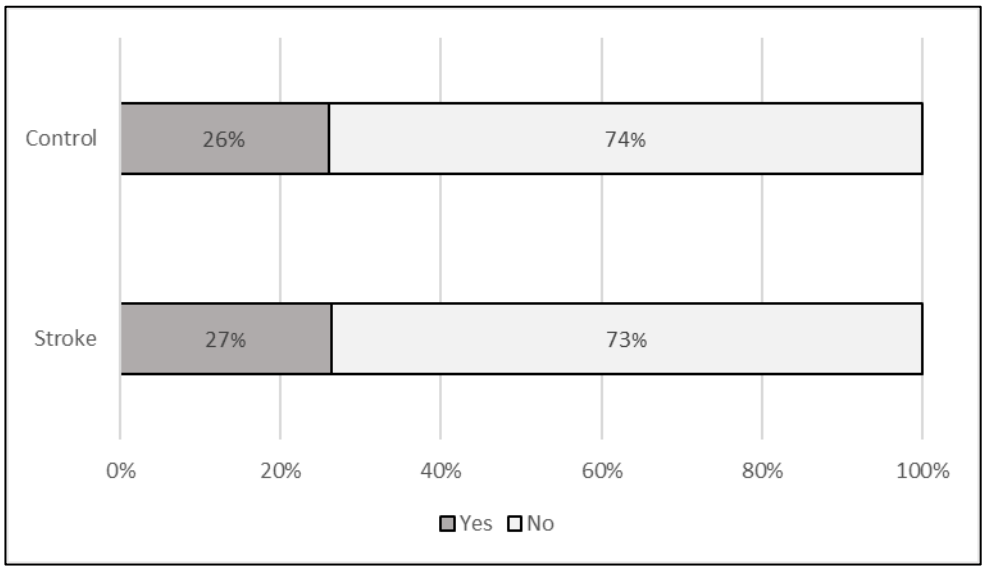


Figure 5.10 Presence of Toe Deformity

Table 5.13 shows the types of toe deformity observed in sitting, standing and walking. Claw toe deformity was the most common type of deformity in both stroke and control groups. HHT was rare (5%) and was only observed in the stroke group. Toe deformity was noted more frequently in standing in the stroke group but no significant difference was found between the groups was found ($\chi^2(1) = 1.428$, $p = 0.232$). No other statistical differences were found between groups in the other positions (sit: $\chi^2(1) = 0.110$, $p = 0.740$; walk: $\chi^2(1) = 3.253$, $p = 0.071$). No statistically significant differences were found within the stroke or control groups for the presence of deformity across each of the positions, although walking toe deformity presence approached significance with $\chi^2(1) = 3.680$, $p = 0.056$. Analysis was conducted on the presence of deformity by looking at differences between positions, with no significant difference found within the stroke group $\chi^2(2) = 2.694$, $p = 0.260$.

Table 5.13 Toe Deformity Presence*

	Claw		Hammer		Hitchhiker's toe	
Position	**Stroke**	**Control**	**Stroke**	**Control**	**Stroke**	**Control**
Sit	17 (10%)	9 (20%)	7 (4%)	4 (9%)	7 (4%)	0 (0%)
	F 7 (4%) M 10 (6%)	F 2 (4%) M 7 (15%)	F 3 (2%) M 4 (2%)	F 2 (4%) M 2 (4%)	F 7 (4%) M 0 (0%)	
Stand	28 (16%)	8 (17%)	8 (5%)	2 (4%)	10 (6%)	0 (0%)
	F 5 (3%) M 23 (13%)	F 2 (4%) M 6 (13%)	F 3 (2%) M 5 (3%)	F 0 (0%) M 2 (4%)	F 1 (1%) M 9 (5%)	
Walk	20 (12%)	4 (9%)	7 (4%)	0 (0%)	9 (5%)	0 (0%)
	F 4 (2%) M 16 (9%)	F 2 (4%) M 2 (4%)	F 3 (2%) M 4 (2%)		F 1 (1%) M 8 (5%)	

*Frequencies (percentages, %); counts (%) for fixed (F) and mobile (M).

5.3.3.3 Dynamic Foot Loading: Sway Velocity in Standing

COF trajectory was extracted as sway velocity and sway path length, with eyes open and eyes closed in standing for 20 seconds. Analysis was conducted for 163 stroke and 43 control participants. Missing data was due to missing trials (n = 11) and removal of six outliers from the stroke group and one from the control group (> 3SD away from the mean).

Table 5.14 shows results for sway velocity and path length. Sway velocity in the stroke group was faster than in the control group with eyes closed, with smaller differences between eyes open. Dispersion was largest in the stroke group with eyes closed. No differences were found between stroke and control participants for sway velocity with eyes open ($Z = -1.177$, $p = 0.239$); however, for sway velocity with eyes closed, a significant difference was found between stroke and control groups ($Z = -3.418$, $p = 0.001$). Differences within groups between eyes open and eyes closed demonstrated statistical differences within stroke ($Z = 9.331$, $p < 0.001$) and control groups ($Z = 3.007$, $p = 0.003$).

Path length in the stroke group was greater than in the control group for both eyes open and eyes closed. Dispersion was very large in the stroke group with eyes closed. For path length with eyes open, differences between the groups revealed no statistical differences ($Z = -1.177$, $p = 0.239$). Path length eyes closed was statistically significant between stroke and control groups ($Z = -3.418$, $p = 0.001$). Differences within groups between eyes open and closed revealed further statistical differences within stroke ($Z = 9.331$, $p < 0.001$) and control groups ($Z = 3.007$, $p = 0.003$).

Table 5.14 Centre of Force During Eyes Open and Eyes Closed*

Variable	Stroke		Control	
	Eyes open	**Eyes closed**	**Eyes open**	**Eyes closed**
Sway velocity ($cm \cdot sec^{-1}$)	12.61 ±6.47††	22.63 ±15.45**††	11.31 ±4.89†	14.28 ±7.41**†
Path length (cm)	100.89 ±51.72††	181.54 ±123.36**††	90.51 ±39.14†	114.20 ±59.24**†

*Mean±SD

**Between stroke and control group, $p < 0.001$.

†Between eyes open and eyes closed within group, $p < 0.003$.

††Between eyes open and eyes closed within cohort, $p < 0.001$.

5.3.3.4 Dynamic Foot Loading: Peak Plantar Pressure

PPP data was available for 147 stroke and 45 control participants. Missing data was accounted for by failed calibration ($n = 3$), data missing for one limb of the participant ($n = 5$), or no walking trials were captured ($n = 22$). Additionally, three outliers were removed from the stroke group. Here peak pressure is reported from values extracted in each of the four foot regions for the three trials on each foot. Whole foot pressure, the maximal pressure recorded from any of the foot regions, was also reported.

Figure 5.11 shows PPP for stroke and control groups for all foot regions. Peak pressures for all foot regions were lower in the stroke group than the control group, except for less-affected side MFT. A wide variance in peak pressure values was indicated by comparatively large standard deviations in all the data collected.

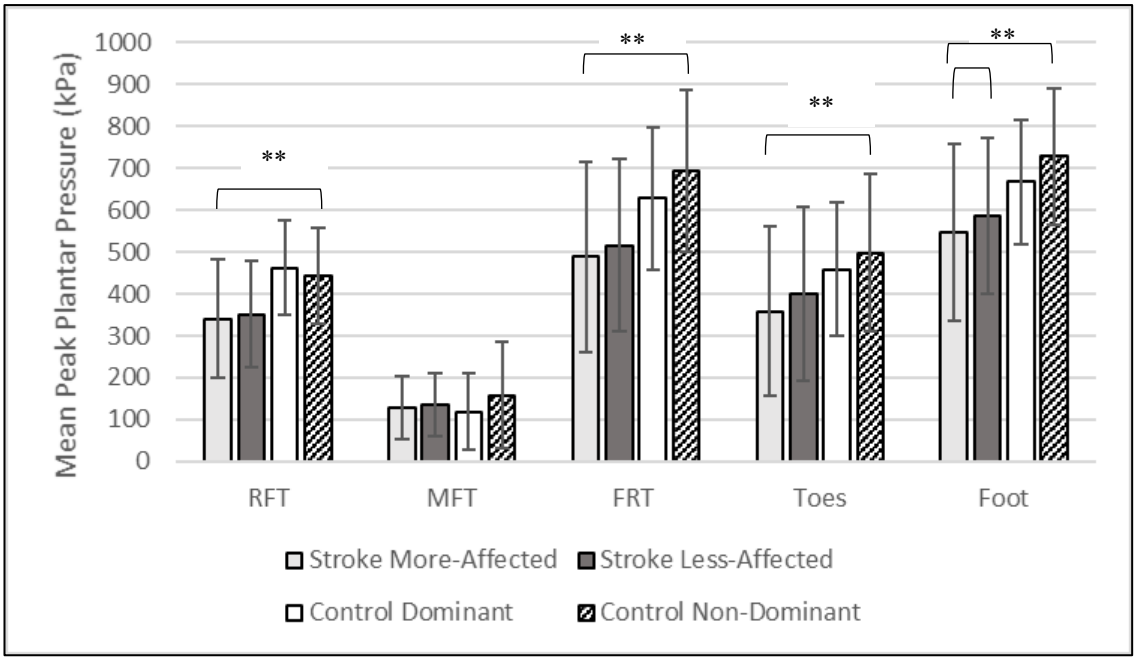


Figure 5.11 Peak Plantar Pressure Across Foot Regions*

* RFT = rearfoot, MFT = mid-foot, FFT = forefoot, Toes = toe region, Foot = maximum pressure from any foot region).
**$p < 0.001$.

Significant differences were found between stroke and control groups for RFT ($Z = -5.399$, $p < 0.001$), FFT ($Z = -3.817$, $p < 0.001$), toe regions ($Z = -3.414$, $p < 0.001$) and foot pressure ($Z = -3.702$, $p < 0.001$); the MFT region showed a non-significant difference ($Z = -1.456$, $p = 0.145$). The values for the more-affected limb were lowest for all regions; limb differences were significant between the more- and less-affected sides for foot pressure only ($Z = -2.612$, $p = 0.009$).

5.3.3.5 Dynamic Foot Loading: Foot Contact Area

Contact area data was extracted for all four regions as well as total foot contact. Analysis of 145 stroke and 43 control participants was conducted. Missing data was accounted for by failed calibration ($n = 3$), missing data for one limb of the participant ($n = 7$), or no walking trials able to be captured ($n = 22$). The slight discrepancy in numbers analysed for peak pressure and CA resulted from different data extraction methods where absence of a region meant that CA could not be extracted, thus resulting a lower amount of available data. Two outliers were removed from the stroke group (> 3SDs from the mean). Descriptive data is shown in Figure 5.12 for stroke and control groups. Between-group

differences were found, with total foot contact being larger by 10 cm^2 in the stroke group than the control group. Small differences between limbs within cohorts were found. Statistical analysis was conducted between groups and showed that the toe region ($Z = 2.99$, $p = 0.022$) and total foot CA ($Z = -4.003$, $p < 0.001$) were statistically different between groups. No statistically significant differences were found between limbs in the stroke group ($p = 0.042$, greater than Bonferroni-corrected $p < 0.025$).

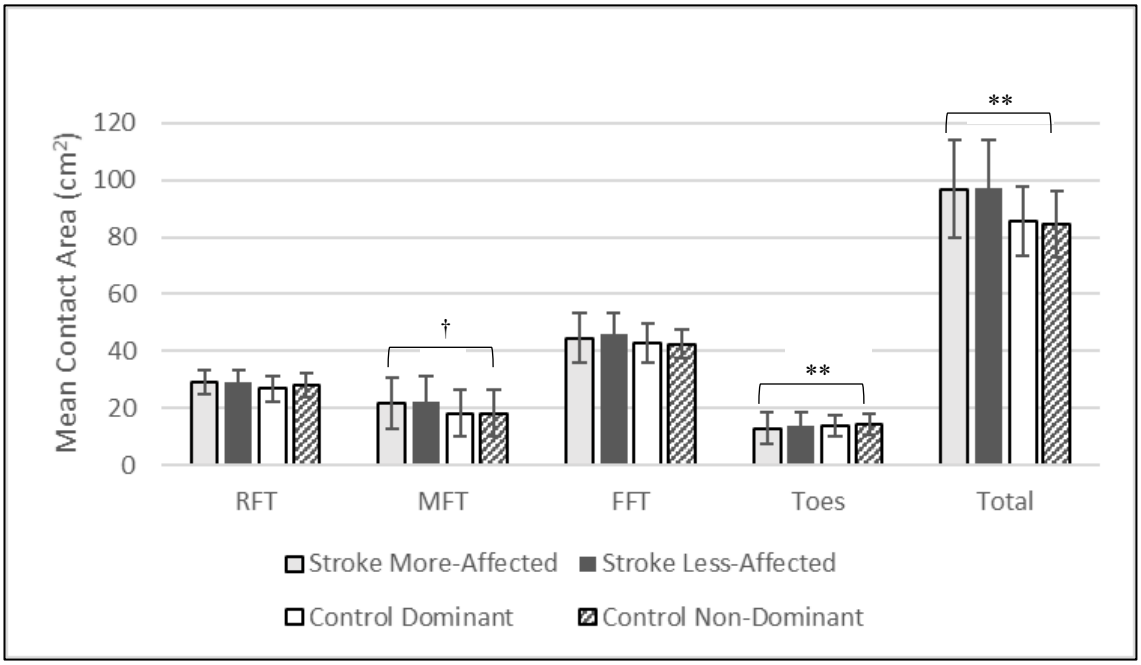


Figure 5.12 Foot Contact Area for all Regions*

*RFT = rearfoot, MFT = mid-foot, FFT = forefoot, Toes = toe region,
**$p < 0.001$ between less-affected and non-dominant limbs.
†$p = 0.042$ between more-affected and dominant limbs.

5.3.4 Comparison of Stroke and Control Groups for Neuromuscular Impairments

5.3.4.1 Isometric Muscle Strength

Isometric muscle strength was measured for six muscle groups at the foot and ankle using a HHD. Data was available for 170 stroke and 44 control participants for all variables. Missing data was accounted for by technological failure (batteries failed) ($n = 1$) or participant unable to cooperate, e.g. tired or unable to select specific muscle activity on the more-affected side ($n = 9$). No values were removed.

Results for individual muscle group strength are shown below in Figure 5.13. Consistently, values in the stroke group for the more-affected side were lower than the less-affected side. Variance was also greater in the stroke group, especially on the affected side. Statistically significant differences were examined between stroke and control groups; muscle strength in all groups had statistically significant differences: ankle DFs ($Z = -6.937$, $p < 0.001$), ankle PFs ($Z = -5.107$, $p < 0.001$), ankle invertors ($Z = -3.536$, $p < 0.001$), ankle evertors ($Z = -5.410$, $p < 0.001$), hallux DFs ($Z = -3.659$, $p < 0.001$) and hallux PFs ($Z = -3.183$, $p < 0.001$). Furthermore, statistically significant differences were also found between muscle strength in the more-affected and less-affected limbs: ankle DFs ($Z = -8.926$, $p < 0.001$), ankle PFs ($Z = -8.532$, $p < 0.001$), ankle invertors ($Z = -8.001$, $p < 0.001$), ankle evertors ($Z = -9.329$, $p < 0.001$) and hallux DFs ($Z = -7.815$, $p < 0.001$); however, the difference between more- and less-affected limbs in the stroke group for hallux PFs was not statistically significant ($Z = -0.075$, $p = 0.940$).

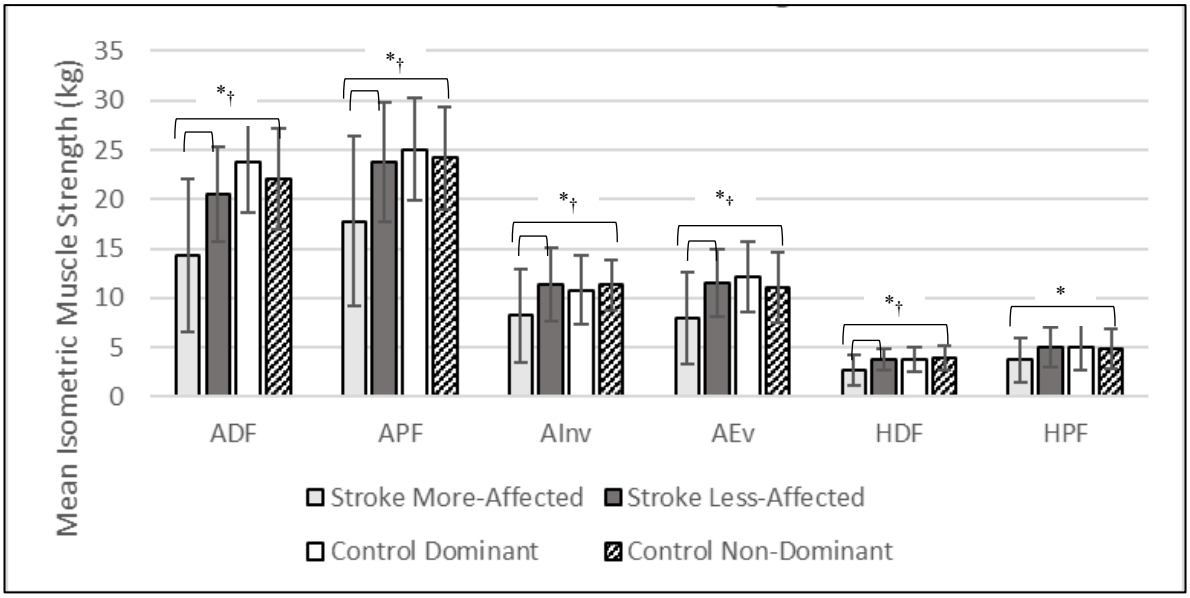


Figure 5.13 Isometric Muscle Strength for Individual Ankle and Foot Muscle Groups (kg)**

**ADF = Ankle dorsiflexors, APF = ankle plantarflexors, AInv = ankle invertors, AEv = ankle evertors, HDF = hallux dorsiflexors, HPF = hallux plantarflexors.
*Between stroke and control groups, $p < 0.001$.
†Between more-affected and less-affected limbs, $p < 0.001$.

Similar patterns were observed when muscles were grouped into ankle, hallux and composite values, as shown in Table 5.15. All ankle and composite values for the stroke group were found to be lower than those of the control group. Hallux values were an

exception where the less-affected side values of the stroke group were similar to the control group values. Dispersion was greatest across all values for the more-affected limb in the stroke group. Statistically significant differences were found between stroke and control groups for all ankle ($Z = -5.870$, $p < 0.001$), hallux ($Z = -3.520$, $p < 0.001$) and composite scores ($Z = -5.650$, $p < 0.001$). Between more- and less-affected sides, statistically significant differences were found for the ankle ($Z = -10.250$, $p < 0.001$), hallux ($Z = -8.093$, $p < 0.001$) and composite values ($Z = -10.230$, $p < 0.001$).

Table 5.15 Composite Muscle Strength Values for Ankle, Hallux and all Muscle Groups

	Stroke (mean ±SD)		**Control** (mean ±SD)	
	More affected	**Less affected**	**Dominant**	**Non-dominant**
All ankle	48.19 ±24.14*†	67.13 ±15.88†	71.72 ±15.07*	68.49 ±14.30
All hallux	6.45 ±3.57*†	8.74 ±2.71†	8.79 ±3.33*	8.73 ±2.97
Composite	54.64 ±27.27*†	75.87 ±17.95†	80.52 ±17.82*	77.21 ± 6.86

*Between stroke and control groups, $p < 0.001$.
†Between more-affected and less-affected limbs, $p < 0.001$.

5.3.4.2 Peak Ankle and Hallux Dorsiflexion Angle

Peak ankle dorsiflexion and hallux dorsiflexion angle were measured by two bespoke rigs using a standardised force for 150 stroke and 41 control participants. Missing data was due to participant discomfort and/or pain ($n = 5$), or insufficient number of trials completed ($n = 25$). No values were removed.

Table 5.16 shows mean peak ankle dorsiflexion for stroke and control groups. Little overall difference was observed in peak ankle dorsiflexion between groups. In the stroke group, peak ankle dorsiflexion was smallest on the more-affected side at the low force, with the largest peak ankle dorsiflexion on the less-affected side at high force. The range of peak ankle dorsiflexion values was slightly smaller in the control group. Statistical analysis demonstrated significant differences between ankle dorsiflexion at both forces between groups (low: $t = 3.526$, $p < 0.001$; high: $Z = -3.711$, $p < 0.001$), and between

more- and less-affected limbs in the stroke group (low: $t = 7.681$, $p < 0.001$; high: $Z = -7.234$, $p < 0.001$).

For the stroke group, peak hallux dorsiflexion was smallest on the more-affected side at low force, with the largest peak hallux dorsiflexion on the less-affected side at high force. The range of peak hallux dorsiflexion values was slightly smaller in the control group and followed the same pattern as that for peak ankle dorsiflexion. For peak hallux dorsiflexion, no statistical differences existed between stroke and control groups at low force ($t = -0.998$, $p = 0.320$) and high force ($Z = -0.171$, $p = 0.865$). Between limbs, statistically significant differences were found in the stroke group (low: $t = 4.634$, $p < 0.001$; high: $Z = -3.791$, $p < 0.001$).

Table 5.16 Peak Ankle and Hallux Dorsiflexion Angle (º) at Low and High Force in Stroke and Control Participants

		Stroke		Control	
		More affected	**Less affected**	**Dominant**	**Non-dominant**
Peak ankle dorsiflexion angle (º)	**7 kg force**	17.19 ±7.11*†	21.69 ±6.03†	21.74 ±4.64*	18.15 ±4.18
	10 kg force	21.45 ±7.77*†	26.30 ±6.52†	25.94 ±4.67*	22.37 ±4.09
Peak hallux dorsiflexion angle (º)	**2 kg force**	37.62 ±9.93†	40.79 ±8.74†	39.32 ±8.91	38.12 ±8.54
	4 kg force	52.42 ±9.87†	55.43 ±9.88†	52.74 ±9.43	51.74 ±9.60

*Between groups, $p < 0.001$.

†Between more-affected and less-affected limbs, $p < 0.001$.

5.3.4.3 Ankle Plantarflexor Spasticity

The Tardieu scale was used to quantify spasticity in ankle PFs, measured at fast and slow speeds; only fast-speed data is reported here, as spasticity is velocity dependent[33]. The presence of spasticity was defined as 1 or more on the Tardieu scale. Quality of movement, i.e. resistance, was reported on a scale 0 = none through to 5 = immobile; scores were then analysed. Data was available for 174 stroke participants and 45 control

[33] Raw data for this can be provided by the author on request.

participants. Missing data was due to discomfort reported on testing (n = 6); no values were removed.

Figure 5.14 shows the proportions of the participants' quality of movement category as measured by the Tardieu scale. The stroke group had higher levels of resistance with 20% demonstrating moderate resistance on the scale, and 6% demonstrating severe restriction/immobility of the ankle joint. For control participants, only two (4%) participants on the non-dominant side and three (6%) participants on the dominant side exhibited resistance to movement. Differences between stroke and control groups were statistically significant ($Z = -5.758$, $p < 0.001$). Between-side comparisons of the more- and less-affected limb also demonstrated a statistically significant difference ($Z = -8.438$, $p < 0.001$).

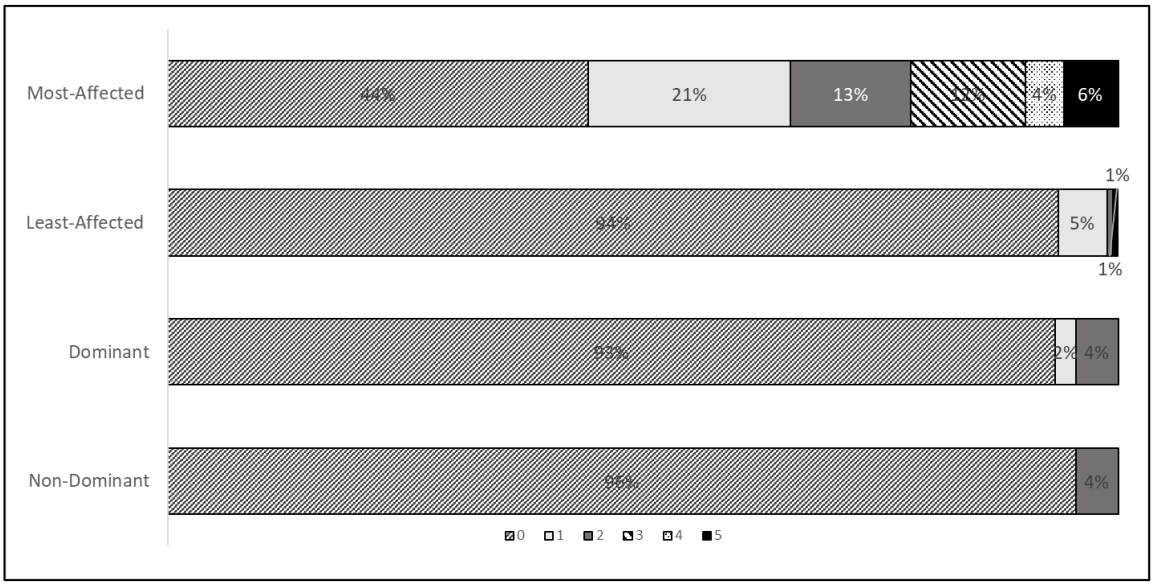


Figure 5.14 Percentages of Stroke and Control Participants' Quality of Movement Score (%)

0 – No resistance throughout the course of the passive movement;
1 – Slight resistance throughout the course of the passive movement, with no clear catch at a precise angle;
2 – Clear catch at a precise angle, interrupting the passive movement, followed by a release;
3 – Fatigable clonus (< 10 seconds when maintaining pressure) occurring at a precise angle;
4 – Unfatigable clonus (> 10 seconds when maintaining pressure) occurring at a precise angle;
5– Joint is immoveable.

The presence of spasticity is shown in Figure 5.15. It shows that 57% demonstrated spasticity in the more-affected limb. In the control group, no more than 9% of the cohort showed resistance to movement. Statistical analysis between the stroke and control group demonstrated that the presence of spasticity was statistically significantly different in the stroke group ($\chi^2 = 28.635$, $p < 0.001$). Further analysis revealed that the more-affected side was statistically significantly different than the less-affected side ($\chi^2 = 5.885$, $p = 0.015$).

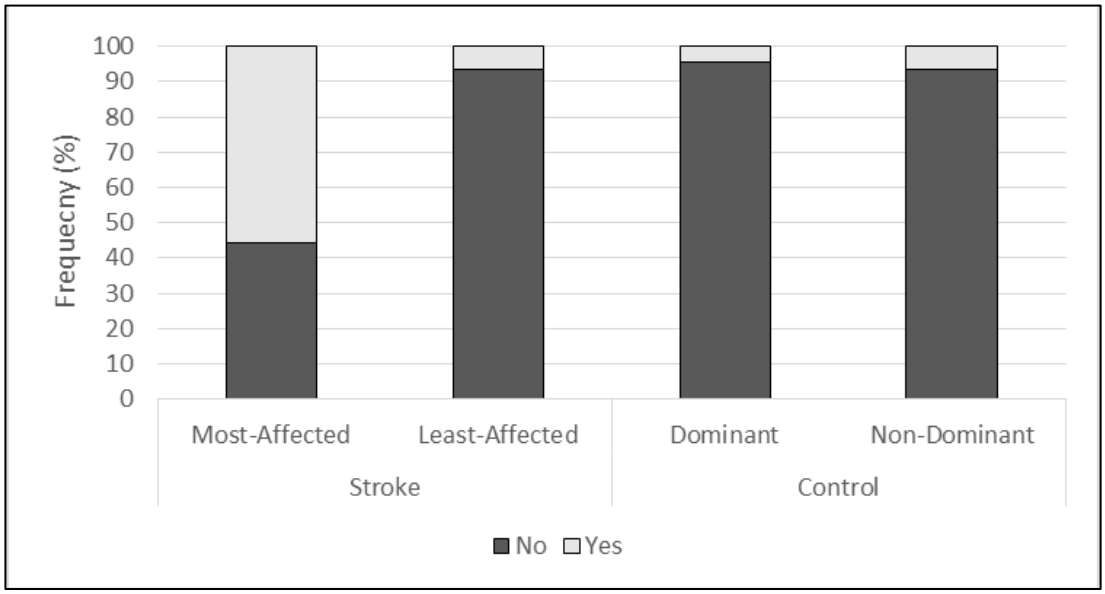


Figure 5.15 Presence of Spasticity

5.3.4.4 Summary of Key Findings

Table 5.17 summarises the differences found between stroke and control participants for foot characteristics and neuromuscular impairments, to address research question 1. Table 5.17 also shows the differences between limbs for foot characteristics and neuromuscular impairments to address research question 2.

Table 5.17 Summary of Statistically Significant Differences Across Impairments for Research Questions 1 and 2

	Research Question 1 Comparison of stroke to control group	**Research Question 2** Comparisons of the more-affected to less-affected limb in the stroke group
Static foot posture – normal/abnormal	✓	×
Static foot posture - category	×	×
Toe deformity presence	× (sit) ✓ (stand)	N/A
DFL: sway velocity	✓*	N/A
DFL: sway path length	✓*	N/A
DFL: peak plantar pressure	✓†	×‡
DFL: foot contact area	✓[a]	×
Individual isometric muscle strength	✓	✓
Ankle and hallux isometric muscle strength	✓	✓
Peak ankle dorsiflexion	✓	✓
Peak hallux dorsiflexion	×	✓
Ankle PF spasticity	✓	✓

*With significant differences between eyes open and eyes closed in both groups.
†Except MFT.
‡Foot pressure only.
[a]Toe region and total foot.
Abbreviations: DFL = dynamic foot loading; PF = plantarflexor.

5.3.5 Impairments as Predictors of Mobility and Balance Outcomes

The third research question of Study 2 was to evaluate whether impairments were predictors of mobility and balance outcomes in stroke participants, using multivariate linear regression and logistic regression analysis.

5.3.5.1 Selection of Variables for the Regression Analysis

Variables for the regression analysis were selected based on multivariate analysis guidelines as reported in Section 5.2.5.4. Outcome variables were selected as part of the FAiMiS study based on review of the literature by the Project Team, thus providing a theoretical underpinning for their use. Predictor variables were selected based on significant differences found from the control cohort and were representative of both foot characteristics and neuromuscular impairments within the stroke group. Due to this, the following variables were not selected at the outset:

- **Static foot posture (categories):** no statistical differences observed. Use of categories would require the use of dummy variables[34] which would increase the number of variables inputted; for example, the FPI would require six variables to be input to reflect just this scale. Therefore, a binary outcome was preferred and abnormal/normal classification was selected. Additionally, reliability found in Study 1 was lower than for normal/abnormal classification.
- **Toe deformity presence:** statistical differences were not consistent between stroke and control groups in deformity type or positions. In addition, recent evidence did not report toe deformity differences as key in functional outcomes (Kunkel *et al.*, 2017). Furthermore, no reliability was explored for this measure in Study 1.
- **Sway path length:** high levels of variance were found despite reliability being good. Furthermore, in comparison to velocity data, this value gave only one dimension (distance), whereas velocity was more highly valued as it demonstrated distance as a value over time.
- **Eyes open sway velocity:** the stroke group did not demonstrate significant differences compared to the control group and was moderately positively correlated with eyes closed ($r = 0.58$, $p = 0.01$).
- **Less-affected side values:** despite significant differences found for isometric muscle strength between sides and peak ankle dorsiflexion angles, these, along

[34] Dummy variables = a type of coding, where codes are assigned to a nominal variable reflecting the presence of certain traits. For more than two categories, more than one dummy variable is required; this is always one less than the number of categories, e.g. in the Tardieu scale, 0–5 would be 4. Therefore, using presence and absence of a variable may be preferable, e.g. abnormal/normal foot posture (Portney and Watkins, 2009).

with CA (which did not have significant differences between limbs), were not included. Values for the more-affected side were prioritised as these were of greater clinical interest.

Therefore, the following variables for the more-affected limb remained:

- Static foot posture (abnormal/normal);
- Sway velocity (EO);
- Peak plantar pressure (all regions, and max foot);
- Foot contact area (all regions and total foot);
- Individual isometric muscle strength;
- Composite (ankle and hallux) isometric muscle strength;
- Peak ankle dorsiflexion;
- Peak hallux dorsiflexion;
- Ankle PF spasticity.

To ensure appropriate predictor variables were used in the final regression analysis, correlation, linearity, multicollinearity and homoscedasticity of predictor variables were evaluated, as outlined in Section 5.2.4.4, this is presented in the following text.

Correlation:

Correlations were evaluated for the remaining variables: PPP, CA, isometric muscle strength, FPI, spasticity and ankle ROM. These yielded some correlations of > 0.8 with significant p values ($p < 0.01$) and therefore had potential to breach guidance for inputting into regression analysis, as outlined in Section 5.2.5.4; however, significant p values in large samples are not necessarily of additional endorsement (Portney and Watkins, 2009), thus strength of correlation was focused on. Where this occurred, both could not be input into the analysis so one predictor variable was selected for each impairment as described below.

Plantar pressure analysis:

Correlation between PPP, regional and whole foot contact area scores was analysed, (Appendix 33, Table A33.1). All foot regions were retained in these correlations to

enhance specificity of results, rather than using values such as total contact area or maximal foot pressure. Both the more-affected RFT and FFT were found to have good correlation, with foot value correlation coefficients $r = 0.89$ and $r = 0.49$ ($p < 0.01$), respectively. Toe region was not selected although correlation was marginally higher than that for the FFT region, this was due to the poorer reliability found for this region in Study 1 (ICC = 0.81, 95% CI 0.42–0.94 versus ICC = 0.76, 95% CI 0.26–0.92). Furthermore, the more-affected side RFT and FFT PPP were well correlated with the less-affected side regions. Therefore, the RFT and FFT were selected for the regression model. On the more-affected side, the MFT and FFT regions were found to be best correlated with total foot contact area.

Isometric Muscle Strength:

Correlation between isometric muscle strength (more-affected side) for individual regions or groups and composite variables was analysed and shown in Appendix 33, Table A33.3. Strong correlations were observed, as has been similarly reported by Moriello *et al*. (2011), with these being strongest for composite ankle and hallux values. Composite ankle and hallux values were chosen as the characteristics of both ankle and hallux muscles were key to retaining some of the specificity of differences observed**.**

After these selection processes, the following more-affected side variables were selected:

- FPI abnormal/normal classification;
- Sway velocity eyes closed;
- Peak pressure RFT and FFT;
- Contact area MFT and FFT;
- Ankle and hallux isometric muscle strength;
- Peak ankle and hallux dorsiflexion (at low force);
- Spasticity presence (> 1).

Further exploration of the variables was conducted prior to running regression analysis, to check that regression analysis assumptions were met. This is explained below.

Linearity:

An assumption for multivariate regression analysis is that predictor variables are linearly correlated with outcome variables. To evaluate this, scatter plots were drawn using SPSS® matrix scatter plots and partial plots within the model. This was conducted for all potential variables listed above. All plots were reviewed and found to be linear in nature (Appendix 34).

Multicollinearity:

This was evaluated to ensure variables did not correlate with each other, equal to or more than a coefficient of $r = 0.70$. From the list of variables above, only ankle and hallux isometric muscle strength breached multicollinearity guidelines, with collinearity diagnostics high between group values: collinearity = 0.92, 0.73; VIF = 4.78, 3.73; tolerance = 0.21, 0.27, respectively. Therefore, these were excluded and *composite* more-affected side isometric muscle strength was selected instead.

Correlations between the final 10 variables selected is presented in Table 5.18. Weak to moderate statistically significant correlations were found between PPP, CA and muscle strength, as well as ankle and hallux DF ROM and spasticity presence.

Table 5.18 Correlations Found Between Variables for Regression Analysis (Spearman's Rho)[a]

	FPI (normal/ abnormal)	Sway velocity	PP RFT	PP FFT	CA MFT	CA FFT	Com-posite	ADF ROM	HDF ROM	Spasticity presence
FPI (normal/abnormal)		−0.012	0.060	−0.029	−0.187	−0.169	−0.041	−0.121	−0.116	0.005
Sway velocity			−0.150	−0.053	0.272**	0.195	−0.158	−0.034	−0.015	0.201*
PP RFT				0.480**	−0.245*	−0.015	0.482**	0.081	−0.006	−0.200*
PP FFT					−0.081	−0.018	0.342**	−0.070	−0.029	−0.124
CA MFT						0.452**	−0.078	−0.057	−0.047	0.046
CA FFT							0.111	0.083	−0.188	0.108
Muscle strength (composite)								0.106	0.064	−0.288**
Peak ankle dorsiflexion									0.254*	−0.332**
Peak hallux dorsiflexion										−0.185
Spasticity presence										

[a]PP = peak pressure, CA = contact area, light grey = moderate correlation, very light grey = weak correlation.
*p = 0.05.
**p = 0.01.
Abbreviations: FPI = foot posture index; PP RFT = peak pressure rearfoot; PP FFT = peak pressure forefoot; CA MFT = contact area mid-foot; CA FFT = contact area forefoot; ADF ROM = ankle dorsiflexor range of motion; HDF ROM = hallux dorsiflexor range of motion

Homoscedasticity:

Using standardised residuals, homoscedasticity was explored for all outcome variables, (F10MWT, TUAG and Forward Reach). An even scatter was found in all plots of standardised predicted values against residual predicted values in relation to the dependent variables (Appendix 35). Good normal distribution was found for all predictor variables with continuous outcomes (Appendix 35) (the F10MWT, TUAG and Forward Reach). For the logistic regression analysis for the Falls Report, observed groups and predicted probability plots were used (Appendix 35). The plots established both normality and that the spread of the residuals was constant. Therefore, this confirmed their homoscedasticity and use as appropriate outcome variables.

Full justification for the selection of variables is summarised in Appendix 36.

The ***final*** list of **more-affected side** variables selected was:

- **FPI abnormal/normal classification;**
- **Sway velocity eyes closed;**
- **Peak pressure RFT and FFT;**
- **Contact area MFT and FFT;**
- **Composite isometric muscle strength;**
- **Peak ankle and hallux dorsiflexion angle (at low force);**
- **Spasticity presence (> 1).**

5.3.5.2 Regression Analysis

Missing Data:

Missing data was explored for the selected variables. Figure 5.16 showed that only 2 variables had complete sets of data, with almost half the cases with incomplete data, although only 10% of total values were incomplete. Appendix 37 demonstrates the pattern of missing values for the individual variables. This showed that peak ankle dorsiflexion angle and peak pressure and CA data possessed the greatest amount of missing data; however, this was still random, despite some signs of a monotone pattern emerging. These were found to be random, with an even distribution of the number of cases and variables lost. Plantar pressure variables and passive ROM data showed the largest proportion of missing data (16% and 19%). The distribution was not consistent across the cases and variables (Figure 5.16 and Appendix 37). Therefore, instead of removing the cases or variables, data was imputed and analysis was conducted on both the original data set and pooled imputed data (Regression Analysis, Section 5.2.5.4).

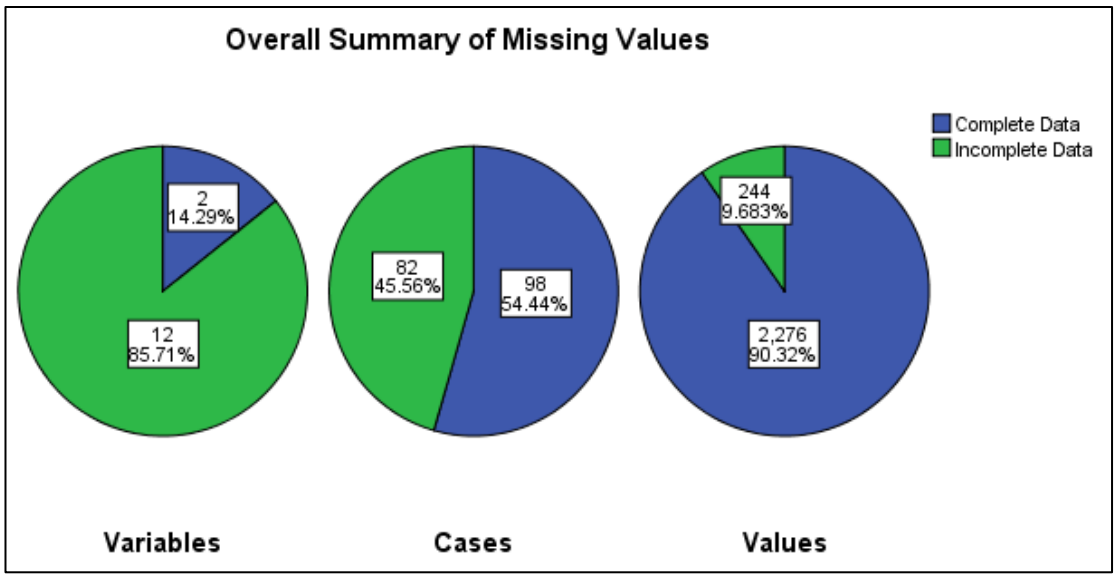


Figure 5.16 Summary of Missing Values Across all Variables, Cases and Values

Once variables were selected and missing data accounted for, multivariate regression analysis was conducted for outcome variables of F10MWT, TUAG and Forward Reach using predictor variables of combined foot characteristics and neuromuscular impairments. Logistic regression analysis was conducted for the outcome variable of Falls

Report using combined foot characteristics and neuromuscular impairments as predictor variables. These are reported below.

Walking Speed:

Multiple regression analysis was applied to predict walking speed (using F10MWT) from all 10 foot characteristics and neuromuscular impairments. These variables statistically significantly predicted walking speed, $F(10,99) = 12.773$, $p < 0.001$, $R^2 = 0.589$, adjusted $R(R2) = 0.543$. All 10 variables combined explained 59% of the variance in walking speed, with four of the variables contributing statistical significance to the prediction, $p < 0.05$, as shown in Table 5.19. Standardised beta coefficients show that the more-affected side muscle strength was the largest contributor, with smaller contributions from sway velocity and peak pressure variables. Faster walking speed was predicted by stronger ankle and hallux muscles on the more-affected side, and higher peak pressures at the RFT and FFT. Slower sway velocity (eyes closed), i.e. more stable participants, had faster walking speed. The narrow confidence intervals reported for these variables demonstrate that the estimates are likely to be good representatives of the true population. Significant variables did not alter with pooled data.

Table 5.19 Complete Case and Imputed Data Regression Analysis for Walking Speed*

	Standardised coefficients	Unstandardised coefficients	95% CI for B lower, upper	*P* value	VIF
	Beta	B			
Complete case analysis (*n* = 98)					
Static foot posture	0.041	0.044	−0.107, 0.196	0.563	1.077
Sway velocity	−0.223	−0.008	−0.014, -0.003	0.003	1.175
Peak pressure RFT	0.195	0.001	0.000, 0.001	0.024	1.556
Peak pressure FFT	0.202	0.000	0.000, 0.001	0.014	1.391
Contact area MFT	−0.069	−0.004	−0.013, 0.006	0.422	1.571
Contact area FFT	0.100	0.006	−0.004, 0.016	0.244	1.574
Muscle strength (composite)	0.425	0.009	0.006, 0.012	0.000	1.478
Peak ankle dorsiflexion	0.122	0.010	−0.002, 0.023	0.111	1.249
Peak hallux dorsiflexion	0.007	0.000	−0.008, 0.009	0.925	1.166
Presence of spasticity	−0.019	−0.020	−0.182, 0.143	0.811	1.308
Imputed data analysis					
Static foot posture		−0.007	−0.144, 0.131	0.926	
Sway velocity Eyes closed		−0.007	−0.011, −0.002	0.002	
Peak pressure RFT		0.001	1.252E-5, 0.001	0.045	
Peak pressure FFT		0.000	7.306E-5, 0.001	0.017	
Contact area MFT		−0.003	−0.012, 0.006	0.507	
Contact area FFT		0.003	−0.007, 0.012	0.606	
Muscle strength (composite)		0.010	0.007, 0.013	0.000	
Peak ankle dorsiflexion		0.011	4.009E-5, 0.023	0.049	
Peak hallux dorsiflexion		0.000	−0.008, 0.007	0.923	
Presence of spasticity		−0.024	−0.159, 0.111	0.725	

*Dark grey shading = variable is a significant contributor to the model.
Abbreviations: CI = confidence interval; FFT = forefoot; MFT = mid-foot; RFT = rearfoot; VIF = variable inflation factor.

TUAG:

Multiple regression analysis was conducted to predict TUAG (seconds) from all 10 foot characteristics and neuromuscular impairments. These variables were statistically significant predictors of TUAG speed, $F(10, 99) = 8.611$, $p < 0.001$, $R^2 = 0.492$, adjusted $R(\text{R2}) = 0.435$. All 10 variables combined explained 49% of the variance in TUAG speed, with four of the variables contributing statistical significance to the prediction ($p < 0.05$), as shown in Table 5.20. Standardised beta coefficients showed that the more-affected side muscle strength was the largest contributor, with CA at the FFT and MFT next, and finally sway velocity. Faster TUAG was predicted by stronger more-affected side ankle and hallux muscles and larger FFT CA; smaller MFT CA and improved standing balance (eyes closed) led to faster TUAG completion. The narrow confidence intervals reported for these variables demonstrated that the estimates are likely to be good representatives of the true population. Only muscle strength was found to be a statistically significant predictor ($p < 0.001$) of TUAG speed using pooled data.

Table 5.20 Complete Case and Imputed Data Regression Analysis for TUAG

	Standardised coefficients	Unstandardised coefficients	95% CI for B lower, upper	P value	VIF
	Beta	B			
Complete Case Analysis (*n* = 98)					
Static foot posture	−0.042	−0.579	−2.745, 1.586	0.596	1.077
Sway velocity	0.181	0.086	0.009, 0.164	0.030	1.175
Peak pressure RFT	−0.182	−0.008	−0.017, 0.000	0.057	1.556
Peak pressure FFT	−0.143	−0.004	−0.009, 0.001	0.113	1.391
Contact area MFT	0.190	0.138	0.002, 0.275	0.047	1.571
Contact area FFT	−0.223	−0.170	−0.313, −0.027	0.021	1.574
Muscle strength (composite)	−0.288	−0.078	−0.127, −0.029	0.002	1.478
Peak ankle dorsiflexion	−0.150	−0.163	−0.344, 0.019	0.079	1.249
Peak hallux dorsiflexion	−0.059	−0.044	−0.164, 0.077	0.472	1.166
Presence of spasticity	0.088	1.191	−1.129, 3.511	0.311	1.308
Imputed data analysis					
Static foot posture		2.302	−1.966, 6.571	0.290	
Sway velocity		0.073	−0.081, 0.228	0.353	
Peak pressure RFT		−0.007	−0.028, 0.014	0.530	
Peak pressure FFT		−0.006	−0.018, 0.006	0.299	
Contact area MFT		0.108	−0.185, 0.401	0.469	
Contact area FFT		−0.098	−0.416, 0.221	0.546	
Muscle strength (compsite)		−0.212	−0.308, −0.116	0.000	
Peak ankle dorsiflexion		−0.330	−0.663, 0.002	0.052	
Peak hallux dorsiflexion		−0.118	−0.340, 0.104	0.298	
Presence of spasticity		1.147	−2.944, 5.237	0.583	

*Dark grey shading = variable is a significant contributor to the model.
Abbreviations: CI = confidence interval; FFT = forefoot; MFT = mid-foot; RFT = rearfoot; VIF = variable inflation factor.

Forward Reach:

Multiple regression analysis was run to predict Forward Reach from all 10 foot characteristics and neuromuscular impairments. These variables were statistically significant predictors of walking speed, $F(10, 99) = 4.865$, $p < 0.001$, $R^2 = 0.359$, adjusted $R(R2) = 0.285$. All 10 variables combined explained 36% of the variance in Forward Reach, with four of the variables contributing statistical significance to the prediction ($p < 0.05$). This is shown in Table 5.21. Standardised beta coefficients demonstrate that sway velocity (eyes closed) was the largest contributor, with the more-affected side muscle strength and CA peak pressure at the FFT also a significant contributor. As sway velocity (eyes closed) reduced, Forward Reach distance increased. The narrow confidence intervals reported for these variables demonstrates that the estimates are likely to be good representatives of the true population. Using pooled data for peak ankle dorsiflexion on the more-affected side replaced CA at the FFT as a statistically significant predictor ($p < 0.001$) of Forward Reach.

Table 5.21 Complete Case and Imputed Data Regression Analysis for Forward Reach

	Standardised coefficients	Unstandardised coefficients	95% CI for B lower, upper	*p* value	VIF
	Beta	B			
Complete case analysis (*n* = 98)					
Static foot posture	0.065	1.392	-2.452, 5.236	0.474	1.091
Sway velocity	-0.301	-0.223	-0.360, -0.086	0.002	1.170
Peak pressure RFT	0.089	0.006	-0.009, 0.022	0.409	1.548
Peak pressure FFT	0.209	0.009	0.000, 0.018	0.040	1.374
Contact area MFT	0.053	0.060	-0.180, 0.300	0.622	1.562
Contact area FFT	0.215	0.256	0.004, 0.509	0.047	1.545
Muscle strength (composite)	0.253	0.107	0.020, 0.194	0.017	1.461
Peak ankle dorsiflexion	0.172	0.289	-0.032, 0.610	0.077	1.249
Peak hallux dorsiflexion	-0.147	-0.169	-0.381, 0.043	0.116	1.158
Presence of spasticity	0.169	3.555	-0.548, 7.658	0.089	1.301
Imputed data analysis					
Static foot posture		0.755	2.118, 3.629	0.606	
Sway velocity		-0.155	-0.247, -0.062	0.001	
Peak pressure RFT		0.005	-0.008, 0.017	0.461	
Peak pressure FFT		0.009	0.001, 0.016	0.026	
Contact area MFT		-0.019	-0.205, 0.168	0.843	
Contact area FFT		0.193	-0.006, 0.392	0.058	
Muscle strength (composite)		0.093	0.030, 0.156	0.004	
Peak ankle dorsiflexion		0.231	0.004, 0.458	0.046	
Peak hallux dorsiflexion		-0.066	-0.223, 0.091	0.411	
Presence of spasticity		2.000	-0.976, 4.975	0.188	

*Dark grey shading = variable is a significant contributor to the model.
Abbreviations: CI = confidence interval; FFT = forefoot; MFT = mid-foot; RFT = rearfoot; VIF = variable inflation factor.

Falls Report:

A logistic regression analysis was performed to ascertain the effects of foot characteristics and neuromuscular impairment after stroke on the likelihood that participants reported one or more falls in the last three months. The logistic regression model was statistically significant, $\chi^2(10) = 21.441$, $p = 0.018$. The model explained 26% (Nagelkerke R^2) of the variance, and correctly classified 75% of cases. Increased sway velocity and reduced peak ankle dorsiflexion was associated with an increased likelihood of falls reported. As shown in Table 5.22, narrow confidence intervals reported for these variables demonstrate that the estimates are likely to be good representatives of the broader stroke population. When data was pooled, only sway velocity remained a significant contributor to the model.

Table 5.22 Logistic Regression Analysis for Complete Cases and Pooled Data Falls Report

	B	Wald	Df	Odds ratio	95% CI for odds ratio lower, upper	*p* value
Complete case analysis (*n* = 98)						
Static foot posture	−0.890	3.378	1	0.411	0.159, 1.061	0.066
Sway velocity	0.048	5.602	1	1.049	1.008, 1.091	0.018
Peak pressure RFT	0.003	2.158	1	1.003	0.999, 1.007	0.142
Peak pressure FFT	−0.001	0.236	1	0.999	0.997, 1.002	0.627
Contact area MFT	−0.008	0.056	1	0.992	0.931, 1.058	0.814
Contact area FFT	−0.037	1.249	1	0.964	0.904, 1.028	0.264
Muscle strength (composite)	−0.008	0.501	1	0.992	0.970, 1.014	0.479
Peak ankle dorsiflexion	−0.112	5.351	1	0.894	0.813, 0.983	0.021
Peak hallux dorsiflexion	0.016	0.304	1	1.016	0.960, 1.075	0.581
Presence of spasticity	0.713	1.636	1	2.040	0.684, 6.080	0.201
Imputed data analysis						
Static foot posture	−0.736			0.479	0.236, 0.973	0.042
Sway velocity	0.027			1.027	1.002, 1.052	0.033
Peak pressure RFT	0.001			1.001	0.998, 1.004	0.376
Peak pressure FFT	0.000			1.000	0.998, 1.002	0.723
Contact area MFT	0.012			1.012	0.964, 1.062	0.627
Contact area FFT	−0.044			0.957	0.909, 1.007	0.093
Muscle strength (compsite)	−0.001			0.999	0.984, 1.015	0.935
Peak ankle dorsiflexion	−0.029			0.971	0.916, 1.030	0.331
Peak hallux dorsiflexion	−0.006			0.994	0.959, 1.031	0.761
Presence of spasticity	−0.363			0.696	0.330, 1.464	0.339

*Dark grey shading = variable is a significant contributor to the model.
Abbreviations: CI = confidence interval; FFT = forefoot; MFT = mid-foot; RFT = rearfoot.

5.3.5.3 Summary of Key Findings

Table 5.23 is a summary of the static and dynamic foot impairments and neuromuscular impairments that were found to be predictors of mobility and balance outcomes, in response to research question 3.

Table 5.23 Statistically Significant Associations for both Original (O) and Imputed (I) Data for the 10 Predictor Variables*

Outcome	**Walking speed** $R^2 = 0.59$		**TUAG** $R^2 = 0.49$		**Forward Reach** $R^2 = 0.36$		**Falls Report** $R^2 = 0.26$	
Variable	O	I	O	I	O	I	O	I
Static foot posture								
Sway velocity	–		+		–	–	+	+
Peak pressure RFT	+							
Peak pressure FFT	+				+	+		
Contact area MFT			+					
Contact area FFT			–		+			
Muscle strength (compsite)	+		–		+	+		
Peak ankle dorsiflexion						+	+	
Peak hallux dorsiflexion								
Presence of spasticity								

*'–' = negative association; '+' = positive association, grey shaded cells = statistically significant contributions

Abbreviations: FFT = forefoot; MFT = mid-foot; RFT = rearfoot; TUAG = Timed Up and Go.

By conducting multivariate regression analysis, the following foot and ankle impairments were found to be moderate to strong predictors of mobility and balance outcomes. These are listed in order, with the strongest contribution to the models first:

- ✓ Sway velocity (eyes closed);
- ✓ More-affected side muscle strength (compsite);
- ✓ More-affected side peak pressure FFT;
- ✓ More-affected side contact area FFT;
- ✓ More-affected side peak pressure RFT;
- ✓ More-affected side contact area MFT;
- ✓ More-affected side peak ankle dorsiflexion (low).

Overall, one predictor variable – sway velocity (eyes closed) – contributed to all four outcome variables; being positively associated with walking speed and Forward Reach and negatively associated with TUAG and Falls Report. Isometric muscle strength contributed to three outcome variables: F10MWT, TUAG and Forward Reach. The remaining variables made smaller contributions to the variance of outcome variables. Only CA made both positive and negative contributions to TUAG.

5.4 DISCUSSION

The aim of this study was to ascertain whether impairments at the foot and ankle of a stroke group differed from an age- and gender-matched group; and how these impairments influenced balance and mobility outcomes. First, this study has shown that for toe deformity, sway velocity, PPP, foot CA, individual isometric muscle strength, compsite ankle and hallux isometric muscle strength, peak ankle and hallux dorsiflexion, and ankle PF spasticity, differences between stroke and age- and gender-matched controls are present and statistically significant. Second, differences between more- and less-affected limbs in the stroke groups were present for static foot posture, individual isometric muscle strength, ankle and hallux isometric muscle strength, peak ankle dorsiflexion, and ankle PF spasticity. Third, multivariate regression analysis revealed sway velocity and isometric ankle and hallux muscle strength as strong contributors to all mobility and balance outcomes after stroke. Additionally, PPP and foot CA also contributed to mobility and balance outcomes; this had not been reported previously in stroke. The following section will explore and explain the findings for individual impairments, with reference to the research programme aims and within the context of previous and current literature. In doing so, the contribution that this work makes to the understanding of the foot and ankle after stroke will be critically evaluated.

5.4.1 Impairments After Stroke: Comparisons to Controls

5.4.1.1 Foot Characteristics

Static Foot Posture:

Static foot posture type measured by the FPI has been reported by previous authors using age-adjusted FPI scales to classify the foot as normal/abnormal. Using this classification, results in the current work found 40% of people with stroke demonstrated abnormal foot posture in the more-affected foot. This result is larger than the third of 73 stroke patients studied by Forghany *et al.* (2011) that had abnormal foot posture; however, no control group was used to determine whether foot posture was different from age- and gender-matched controls. In this work, using the normal/abnormal classification, no statistically significant differences were found between the stroke and the control groups; however, there was a slightly higher percentage of abnormal foot postures in both stroke limbs than control limbs.

Evaluation of foot posture categories in this work demonstrated age-adjusted 30% abnormal supination and 10% abnormal pronation foot type on the more-affected side in people with stroke. These values differ from Forghany *et al.* (2011) who found similar abnormal supination (13%), and abnormal pronation (16%). The current work reported median FPI scores of 2 for people with stroke, demonstrating a neutral foot type that was not statistically different from the control group median score of 2; however, Kunkel *et al.* (2017), in a group of 23 stroke survivors, reported a median FPI score of 8 in the stroke group that was statistically different from the control group's (n = 16) median FPI score of 4.5, p = 0.008. In their work, only two participants (9%) presented with supinated feet, which is a lower proportion than that reported by both Forghany *et al.* (2011) and this current work. Kunkel *et al.* (2017) also reported greater pronation with 75% of the stroke group scoring above 5 for the FPI. Differences between this work and that conducted by Kunkel may lie in the time post-stroke, which was a minimum of three months versus one year respectively. Time since stroke may result in the features of UMNL becoming more apparent over time; that is, negative and non-neural features producing a pronated foot or, conversely, positive and non-neural features forming a supinated foot. The sample recruited was larger in the current work (n = 180 v. n = 23) and may demonstrate a more

characteristic representation of ambulatory stroke population. The use of non-age-adjusted scores, and the older mean age of participants by 10 years (67 ±11 years v. 75.09 ±7.57 years), may explain the high predominance in pronation found in their study as increasing age is known to result in increased pronated foot posture (Menz, 2015). Age-adjusted scores used in this work may have lowered median scores and also explain the discrepancy. Furthermore, greater walking ability may mean that less people with supinated feet were recruited, as supinated feet have been reported to limit mobility (Jang *et al.*, 2015).

Apart from differences between the stroke and control group, significant differences between more- and less-affected limbs in the stroke group were observed. Forghany *et al.* (2011) also reported differences between limbs; however, Kunkel *et al.* (2017) demonstrated a non-significant difference between feet using the FPI, with both feet having a median FPI score of 8. Interestingly, the 'classic' stroke foot posture of plantarflexion and inversion resulting in a supinated foot posture, does not appear as common (18%) as may be thought clinically (Verdie *et al*., 2004; Barnes, 2008). In this cohort, 30% were classified as supinated or highly supinated, being highest on the more-affected side. The shift to the extremes of the scale may indicate that after stroke the range of foot posture seen is greater; this would concur with Kunkel's (2017) findings, although they did not find this specific to the more-affected limb. It is not known at what stage after stroke differences in presentation of pronation and supination between limbs occur, and whether premorbid (and age-related pronation of) foot posture influences foot posture after stroke.

Toe Deformity:

Toe deformity was evaluated to ascertain whether toe deformity presence and type were different from their age- and gender-matched controls. Despite the presence of toe deformity within the stroke group in all positions, no statistically significant differences were found between the stroke and control groups. The most commonly reported deformity type was claw toe at 12–16%. This is lower than the 46% of the 39 people with stroke previously reported by Laurent *et al.* (2010). These discrepancies in prevalence of claw toe may be due to the reduced mobility and acute to sub-acute stage of the participants they recruited. Hammer toe presence was found to be 4–5% in this study and

has not been reported elsewhere after stroke; however, in older adults it is reported to be 13% (Sayli *et al.*, 2018). Reasons for this discrepancy may be due to the self-reported nature of hammer toe presence in work by Sayli *et al.* (2018). HHT was found in 4% of stroke participants, comparable to the 2% reported by Yelnik *et al.* (2003), with the slightly higher presentation possibly due to observation across dynamic positions in this work. Recent work by Kunkel *et al.* (2017) observed HV deformity, finding that it was equally represented in both stroke and control groups. Therefore, it is plausible that the toe deformities may have pre-existed the stroke event, as increasing age is known to precipitate toe deformities such as claw and hammer toe (Menz, 2015). Others have suggested footwear (Menz and Lord, 2001) and heredity genetics (Hannan *et al.*, 2013) may have a part to play. These reasons may account for the absence of between-group differences in this work.

Differences between sitting, standing and walking were also explored, with no statistical differences found. HHT presence increased from 4% to 6% during standing, which may suggest increased muscle activity in the toe extensors due to disordered motor control found following stroke, as proposed by Iwata (2003); however, hammer and claw toe deformities were also present in standing and reduced in the walking position. This finding possibly refutes Iwata's theory as increased overall muscle activity and reduced base of support would normally result in an increase in reflex activity; yet, this was not observed. Other factors that may affect toe deformities are soft tissue and joint stiffness, such as contracture, or muscle weakness, which may hold a joint in a fixed position (Menz, 2015; Iwata, 2003); however, there is no evidence substantiating these mechanisms that can be directly associated with toe deformity observed after stroke.

While these impairments were not statistically different from age- and gender-matched counterparts, attention to these characteristics is still recommended as these may inform clinicians and researchers of impairments that may contribute to altered foot function after stroke. This is because of the implications of altered foot function for footwear prescription, with footwear being a key extrinsic factor in managing balance and mobility (Kunkel *et al.*, 2017). Additionally, this would indicate treatment of altered foot and toe position to enable comfortable and efficient mobility and balance, especially in the presence of increased tone and/or severe stroke.

Sway Velocity:

Dynamic foot loading in standing, measured by sway velocity and path length, was evaluated as an indicator of motor control of the foot and ankle. Statistically significant differences in sway velocity and path length were found for eyes closed conditions between both the stroke and control group. These results show the stroke group was characterised by a greater sway velocity and longer sway path length in standing when eyes were closed; however, no differences between groups were found during eyes open. Similar results have been found by other researchers which may indicate changes in the control process that regulate stability (Nolan *et al.,* 2015). Greater COF[35] displacement in both anterior–posterior/medial–lateral dimensions was found by Chisholm *et al.* (2011) in their research of people with stroke; however, there was no evaluation of eyes open/closed and these findings were from stance phase of gait rather than in standing (bilateral weight bearing). As sway velocity increases in neurologically intact adults when eyes are closed, this work suggests that after stroke there is a greater sway than that of control participants. While better motor control at the foot and ankle appeared to have been retained in the control group in this work, it was not the case for stroke participants, with sway velocity (14.28 ±7.41–22.63 ±15.45 $cm \cdot s^{-1}$) and path length (181.54 ±123.36–114.20 ±59.24 cm) increasing. Potential reasons for this were not found in this work as only weak correlations were found between sway velocity and other variables, although other work may suggest muscle strength influences sway outcomes (Chisholm *et al*., 2013).

Differences between eyes open and eyes closed were analysed between stroke and control groups. Although differences were slight in the control group, changes in both groups were statistically significant. As COF measures were taken in standing, this work did not report inter-limb differences; these have been reported by Hillier and Lai (2009) who found that using the F-scan in-shoe pressure analysis in a group of 15 stroke participants, COF motion (i.e. the centre of all forces on the sensor) during stance was evaluated on both limbs. The COF motion was markedly reduced on the more-affected limb (0.3 cm v. 0.5–0.8 cm). Differences between eyes open and closed were not analysed in their

[35] COF represents the cumulative neuromuscular response that controls centre of mass movement to help maintain forward progression and balance (Chisholm *et al*., 2011).

study. Marigold and Eng (2006) found that medial-lateral postural sway was increased during eyes closed using a force platform; this was explained by more visual dependence. Similarly, Manor *et al*. (2010) explored control of postural sway after right hemisphere middle cerebral artery stroke, also finding increased dependence on vision. Other work post-stroke has found sensory information to reduce postural sway (Cunha *et al.,* 2012; Baldan *et al*., 2014). Additionally, Cunha *et al*. (2012) found that an eyes closed condition in comparison to eyes open showed greater COP trajectory, COP area and path length for people with stroke; however, these researchers all used force platforms. To date, no similar work exists using pressure mats.

The use of the pressure mat for assessing sway velocity and path length provides high quality ratio data, which can characterise whole-body stability or COF excursion as velocity and path length variables. This provides greater insight into neuromuscular functions at the foot and ankle than traditional balance assessments, such as the FFRT, offer. The mat system is considerably cheaper than other instrumented pressure measures (purchased at £11,241 plus VAT in November 2012), such as force plates (upwards of £20,000), and have been found to be valid when compared to these systems (Dyer and Bamberg, 2011; Bickley *et al*., 2019). Given the findings of this work, the use of a pressure mat as a quick clinical tool to quickly quantify neuromuscular function at the foot and ankle after stroke is promising. Evaluation of sway velocity should be used to help monitor changes in balance with reductions on velocity and path length demonstrating improvement. Graphical representations of sway could be presented to patients before and after blocks of treatment to illustrate progress. Therefore, clinicians should consider this tool as a useful addition to their routine practice. In addition, strategies using postural tasks under reduced visual conditions may enhance functional recovery in these individuals.

Peak Plantar Pressure:

DFL was measured using PPP during stance phase of gait. All foot regions in the stroke group, except the MFT, displayed lower peak pressures in foot regions compared to controls, suggesting reduced dynamic loading of the foot after stroke. RFT, FFT, toe regions and whole foot demonstrated statistical differences between stroke and control

groups, suggesting these regions are more susceptible to foot pressure changes. In the current work, MFT regions had smaller changes in peak pressure in the stroke group than those in the control group, which may be expected with the reduced ground reaction forces found during mid stance when the pressure is over the mid regions of the foot (Perry and Burnfield, 2010). Similarly, Garvia *et al.* (1996) found loading and propulsion phases to have significantly lower forces exerted during plantar pressure analysis in stroke participants, with comparable findings reported by Meyring *et al*. (1997) and this work (Study 1). Additionally, Chen *et al*. (2007) conducted a study with 43 stroke participants in which they evaluated plantar pressure in all foot regions. Stroke participants had lower peak pressure than the 20 heathy controls. In people more impaired by stroke (categorised by ground reaction force patterns), they found statistically significant reductions in peak pressures ($p = 0.01$). Their findings parallel the current work; however, statistical evaluation was not undertaken between stroke and control groups.

Some literature differs with the current findings. Hillier and Lai (2009) evaluated CP during tasks in stance in 15 people with stroke and reported increased pressures on the less-affected side; however, unexpected high pressures were also observed in the more-affected foot, demonstrating inconsistencies in presentation of this variable after stroke (although no specific regions were analysed). More recently, Forghany *et al.* (2015) reported peak pressure analysis during stance in 20 people with stroke and 15 healthy controls. On the more-affected limb greater pressure was measured through the medial heel, and less in the medial and central FFT than healthy controls. Thus, further work is required to establish a consensus on changes in peak pressure after stroke in both more- and less-affected limbs.

In the current work, RFT, FFT and toe regions had the lowest mean pressures, lower pressures may have been found in the stroke group in this study due to reduced or redistributed loading. Another reason may have been walking speed across the mat. As the stroke group in the current work was significantly slower, walking speed may have been a possible cause for reduced pressures; however, statistically significant differences were found between more- and less-affected limbs, suggesting deficits in peak pressure were not due solely to walking speed. Additionally, Forghany *et al.* (2015) reported that raised medial heel peak pressures were more likely in household walkers (odds ratio 1.11,

$p < 0.05$), indicating that impaired walking ability may be associated with higher pressures, not lower pressures, in people with stroke.

Deficits in PPP were larger in the more-affected limb, reflected in a statistically significant difference in foot peak pressure. Interestingly, inter-limb differences were not apparent in the control group, demonstrating a more symmetrical foot loading. Chen *et al.* (2007) also found peak pressures in the more-affected limb consistently lower in all regions; however, statistical analysis between limbs was not conducted. Lower plantar pressures were also found throughout the more-affected foot during stance phase, except for medial and mid-foot regions (Meyring *et al.,* 1997). They attributed these lower pressures to reduced foot loading due to the presence of spasticity after stroke; however, in this current work, peak pressure was found to be weakly negatively associated with spasticity when correlation was performed for regression analysis, $r = -0.200$, $p < 0.05$.

Lower pressures in the more-affected limb in stance may be due to compensatory weight bearing on the less-affected side, or reduced muscle strength leading to reduced ground reaction force during stance phase. These inter-limb differences correspond to the findings by Chisholm *et al.* (2011), who found reduced peak pressures on the more-affected side. Whether the medial shift reported by Meyring *et al.* (1997) explains this alerted loading is unclear. The current work did not evaluate medial–lateral differences as Study 1 determined four regions to be a more reliable method of analysing the data. This shows that the alteration of weight-bearing and/or foot-loading pattern in the stroke population is different to control participants, suggesting an underlying pathological mechanism. Mechanisms resulting in these peak pressure changes may include reduced walking speed (Forghany *et al.*, 2015), reduced muscle strength (Chen *et al.*, 2007) and spasticity (Meyring *et al.*, 1997); further research is required as to whether other variables contribute.

Foot Contact Area:

Dynamic foot CA was greater for people with stroke in the RFT, MFT, FFT and total foot regions; toe region CA was smaller. Differences between stroke and control participants were statistically significant in the toe region and total foot CA, with MFT region approaching significance with $p = 0.042$, where $p < 0.025$. Thus toe (and mid-foot)

region(s) may be critical regions in understanding DFL in stance in people with stroke. Increased CA of the foot regions may reflect the lower peak pressure seen and/or the altered foot contact during stance, as explored in the previous section. A larger CA may reflect the higher need of increased base of support (BOS) required to gain stability and altered foot posture to generate propulsive force through ground reaction force, or foot-posture-related changes. Currently, no work has compared foot CA in people with stroke with that of healthy controls without use of an intervention protocol.

No statistical differences were found between more- and less-affected limbs for CA, with values in both limbs very similar. Therefore, CA changes appear to be bilateral rather than specific to the more-affected side. To date, two studies have explored CA in people with stroke. In a group of 15 stroke participants, Hillier and Lai (2009) found that CA increased onto the less-affected side during challenging stance tasks; this was attributed to redistribution onto the lateral border of the foot in most participants. This was not found in the stance phase data evaluated in the current work, and similar data from this work during standing trials with eyes open and eyes closed was not evaluated. Contrary to Hillier's paper, Yang *et al.* (2014) found total foot CA and MFT region CA increased significantly, $p < 0.01$, on the more-affected side when walking robot assisted on a treadmill, despite being de-weighted by 50%. The increase in foot CA reported during robotic assistance was found to improve gait asymmetries suggesting that increased CA is somehow associated with improved gait biomechanics (Yang *et al.*, 2014). Unfortunately, differences in unassisted gait were not evaluated. Hence the differences between this study, Hillier's and the current work are likely due to the robotic intervention. Therefore, changes in foot CA after stroke during stance phase of walking remain unclear and warrant further exploration, especially given the functional consequences of changes in CA as outlined in Section 5.4.2.

5.4.1.2 Neuromuscular Foot and Ankle Impairments

Isometric Muscle Strength:

Composite (ankle and hallux) isometric muscle strength was statistically significantly lower in the stroke group compared to the control group. Similarly, all individual isometric muscle strength was significantly lower in the stroke group than in the control

group. No previous research has reported composite ankle and hallux scores using a HHD after stroke (Section 5.4.2). The findings for individual muscle strength agree with overall deficits reported in previous research for ankle muscle strength (Dorsch *et al.*, 2016; Bohannon, 2007; Patten *et al.*, 2004). Notably, ankle DFs and evertors appeared most affected of all the individual muscle groups in the current work. This differs to Dorsch *et al*. (2016), who found ankle PF and ankle invertor muscle strength were more greatly affected: 57% of controls and 62% of controls, respectively. As the methodologies used were similar (based on Bohannon, 1986), reasons for this difference may lie in the population recruited, which was smaller (by $n = 120$), and TSS, which was 1–6 years compared to 3 months–16 years). Isometric hallux muscle strength, measured by a HHD, has not been reported previously after stroke. The current work is the first report of reductions in isometric hallux muscle strength after stroke; while these were not as large as those seen in the ankle muscle groups, they were statistically different from control participants.

Composite isometric muscle strength was found to be significantly lower in the more-affected limb when compared to the less-affected limb, with the same found for individual muscle groups within the stroke group. Thus, on average, no muscle group at the foot and ankle is spared of weakness following stroke. The largest difference between more- and least-affected limbs was found in ankle eversion and ankle dorsiflexion muscle groups in the more-affected limb. Dorsch *et al.* (2016) also found varying amounts of weakness between more- and less-affected sides. Although more- and less-affected sides were not directly compared, using Dorsch's figures, muscle strength in the more-affected limb was 61–70% of the less-affected limb; however, the values reported by Dorsch *et al*. (2016) cannot be compared to the current work as Dorsch's work used Nm rather than kg to report muscle strength values. In an older work by Morellio and Mayo (2006), using a HHD to measure muscle strength in kg including 63 people with stroke, lower average muscle strength was found than those recorded in this work: on the less-affected ankle DF, 10.5 ±3.3 kg, and the more-affected ankle DF, 9.5 ±3.5 kg, as well as the less-affected ankle PF, 9.2 ±3.4 kg, and the more-affected ankle PF, 7.2 ±3.2 kg. No statistical comparisons were reported, nor were other ankle or hallux muscle groups tested. Reasons for the discrepancy may be the choice of prone and sitting positions in which forces were yielded against gravity, which were different from those chosen in this research. Notably, hallux muscle group strength has not been compared in stroke participants before.

This work presents a clinically feasible assessment of the ankle and hallux isometric muscle strength after stroke using a HHD, as demonstrated in Study 1. Additionally, these findings demonstrate the potential clinical use of testing smaller muscle groups of the foot, including ankle invertors and evertors, hallux DF and PF muscles. Furthermore, isometric foot and ankle muscle strength has been shown to influence functional outcomes after stroke (Dorsch *et al*., 2012). Therefore, assessment may help in directing management of the foot and ankle after stroke by demonstrating the need for specific muscle strengthening and functional training, even for hallux muscles; however, specific training protocols for foot muscles need to be established.

Peak Ankle and Hallux Dorsiflexion Angle:

Peak ankle dorsiflexion and peak hallux dorsiflexion angles were measured using low and high standardised forces, following reported findings that using a known load aided standardisation of the procedure and accounted for the varying muscle resistance found in people with stroke (Gatt and Chockalingam, 2011; Ada and Herbert, 1988). Differences were found between stroke and control groups for peak ankle and hallux dorsiflexion angles. Thus, despite small changes in dorsiflexion range, the peak ankle and hallux dorsiflexion angles for stroke participants were different to that of age- and gender-matched controls. Restricted active ROM is reported by Lamontagne *et al.* (2001, 2002); and passive ROM by Keating *et al.* (2000). Reduced ankle and hallux dorsiflexion peak angle is reported in older populations and related to incidence of falling (Spink *et al.*, 2011); however, alternative tests were used – the lunge test for ankle dorsiflexion and goniometry for first MTPJ ROM – and so direct comparisons are limited.

Despite this, significant differences were found between more- and less-affected limbs for ankle and hallux dorsiflexion, with the more-affected limb showing reduced dorsiflexion range. Currently, very little evidence is available to compare with these results for hallux DF ROM. Kunkel and colleagues (2017) found no significant difference between *active* hallux DF ROM in stroke (36.83º) and control (36.17º) groups in their work. These were similar to the low force scores, 37.62 ±9.93º, but considerably lower than the high force scores, 52.42 ±9.87º; however, in the current work, peak hallux dorsiflexion was > 50º in all limbs recorded, achieving the 50º of ROM required for

efficient gait (Perry and Burnfield, 2010). Although, while passive ROM may have reached > 50º, there is no indication that dynamic ROM, as seen in gait, was maintained above this threshold as gait was not efficient in this group, with slower walking speed reported.

Reasons for the negligible difference in peak ankle dorsiflexion angle may be due to the changes in active ROM, which may be more crucial than those in passive ROM in ambulatory people with stroke. Alternatively, it may be that other ankle movements such as ankle pronation and supination are more clinically relevant (Forghany *et al.*, 2014). These are known to impact the rigidity of the foot as a lever during gait and thus influence walking speed (Forghany *et al.*, 2013). The current complexity of measurement limits this assessment in clinical practice. While the tools used to quantify ankle and hallux dorsiflexion were specifically designed and incorporated highly standardised force limits, the optimal force for use at the ankle or hallux has not been established in the literature. The tools are a potentially clinically feasible way of quantifying DF ROM at both ankle and hallux. Similar tools may be worth developing for ankle inversion and eversion; this was attempted as part of Study 1 but was found to be challenging and not incorporated into Study 2.

Ankle PF Spasticity

Ankle PF spasticity was explored using the Tardieu scale quality of movement score. Two measures were evaluated: presence of spasticity (1 or more on the Tardieu scale) and Tardieu scale score (zero–five). Presence of spasticity was significantly different between stroke and control groups. In comparison to the control group and the less-affected limb, the more-affected side had the highest presence of spasticity, with over 50% having spasticity present. This is greater than in previous works, which reported that ankle PF spasticity in the more-affected limb ranged from 3–36% (Welmer *et al*., 2010; Watkins *et al.,* 2002). Reasons for this are unlikely to lie in the cut-off for presence of spasticity being one or more on the Tardieu scale, as Watkins *et al.* (2002) used the MAS and used one or more as the cut-off for categorising presence of spasticity; however, their work only looked at prevalence of spasticity at 12 months, whereas the current work involved people with a range of three months to 16 years post-stroke. The increased time since

stroke may have allowed secondary non-neural changes due to muscle overactivity to come into effect (O'Dwyer *et al*., 1996); this may have further increased resistance during passive movement. Lamontagne *et al.* (2002) examined spasticity and ankle DF ROM during walking in 30 people with stroke. They found lower ankle dorsiflexion during swing and greater ankle PF spasticity during stance phase when comparing the more-affected to less-affected limb; however, in the current work, a weak negative correlation was found between the peak ankle dorsiflexion angle and ankle PF spasticity ($r = -0.332$, $p < 0.01$). It is not clear if changes in ROM were likely to be caused by stiffness (non-neural) rather than spasticity (disordered sensorimotor control of movement); all three are interlinked.

5.4.1.3 Mobility and Balance Outcomes

Overall, there were significant differences found between stroke and control groups for walking speed, 12-item WIS, TUAG, FFRT, Falls Report and FES.

Walking speed after stroke was reported as 1.1 ±0.8 $m \cdot s^{-1}$ in this work. Despite this being an ambulant, community-dwelling stroke group, this was a significant limitation in walking speed, with the control group reporting 1.81 ±0.36 $m \cdot s^{-1}$; a difference of 0.7 $m \cdot s^{-1}$. However, the values compare well with other groups of people with stroke, being similar to fast walking speeds in stroke reported by Awad *et al*. (2014) at 1.00 ±0.46 $m \cdot s^{-1}$. Furthermore, the values reported in this work are higher than typical 'comfortable' walking speed values found after stroke of 0.8–0.84 $m \cdot s^{-1}$ (Schmid and Rittman, 2007; Severinsen *et al.*, 2011), demonstrating the ability of this stroke cohort to walk faster than commonly reported for habitual or comfortable walking speeds after stroke. Furthermore, the walking speed of the stroke group was 61% of the control group, which is comparable to Severinsen *et al.* (2011) who recruited 48 people with stroke with similar age, height and weight to this work and reported an average walking speed of 59% of normal values. The 1.81 $m \cdot s^{-1}$ reported in this work for the age- and gender-matched control group compared favourably with walking speed reported by Bohannon (1997) in healthy people aged 60–79 years reaching fast walking speeds of more than 1.77 $m \cdot s^{-1}$. Therefore, both groups demonstrate good external validity.

Indoor and outdoor walking demonstrated that the proportion of those requiring aids for walking was statistically higher in the stroke group. Outdoor walking ability in the stroke group showed that almost 55% of people with stroke were not independent without an aid, and 6% were either minimally or not ambulatory outdoors. The findings in the stroke group align with previous reports by Lord *et al.* (2004) who found 41.4% of 130 stroke participants walked outside with an aid. Likewise, Robinson *et al.* (2011) found 44% of 50 people with stroke were mobile with an aid in the community. Considering that the stroke participants were community dwelling, and able to mobilise 10 m, it may be that these individuals may not successfully participate in normal everyday activities such as walking to the local shop. The observed difficulty walking indoors and outdoors was also reflected in the 12-Item WIS (out of 60). A large and statistically significant difference was found between the median value of 38 for the stroke group and 15 the control group; almost four times the minimal clinically important difference of 8 proposed by Mehta *et al*. (2015). Hence, stroke impacts on the self-reported perception of walking after stroke and is likely to contribute to reduced participation observed after stroke. No reports are available reporting the use of 12-item WIS in stroke. Yet the median value found in the current work is 10 points greater than that reported by Goldman *et al.* (2008) for a group of 28 participants with multiple sclerosis, with a mean age of 40 years. Notably, control participants had higher than previously reported values, with 15 in the current work and 2.2 found by Goldman *et al.* (2008). It appears, therefore, that stroke deficits increase the self-reported effects of impact on walking, more than age, gender and people with multiple sclerosis.

The TUAG assessed mobility and balance domains; and statistical differences were found between stroke and control participants. The average TUAG time was characteristic of a chronic stroke population at 18.34 ±13.10 seconds, similar to the 22.6 ±8.6 seconds reported by Ng and Hui-Chan (2005) in their stroke group. The mean TUAG score for the stroke group in this work is associated with a high falls risk category (> 13.48 seconds, Chan *et al.*, 2017), with 49% found to be above this cut-off score. Notably, the time attained by control participants for this research programme of 8.08 ±1.77 seconds was similar to normative data provided by Steffen *et al.* (2002) with a mean of 8 ±2 seconds in a group of 60–69 year olds. These findings illustrate the significant difference in mobility and balance found in the stroke group, particularly highlighting the risk of falls,

a theme that continues in the remaining balance measures. Section 5.4.2 will explore possible contributing factors to falls found at the foot and ankle in detail.

Forward Reach, a measure of dynamic balance and falls risk, demonstrated statistically lower performance in the stroke group. The mean Forward Reach reported in this work at 25 cm, is similar to reports by Outermans *et al*. (2010) in subacute stroke, at 25.6 cm; however, results in other work undertaken in people with stroke range from 25–33 cm, but these groups possessed greater heterogeneity and varying time since stroke (Erel *et al*., 2011; Katz-Laurer *et al*., 2009). The mean Forward Reach reported in this work was 25 cm, with 47% found to be above the cut-off point for risk of falls after stroke which is reported as 21.5cm (Ashburn *et al.*, 2008). The control group mean was statistically higher at 36 cm, lowering the risk of falls, which was reflected in Falls Report in the control group. Therefore, the stroke group had impaired Forward Reach in comparison to their age- and gender-matched counterparts, indicating increased falls risk. The role of the foot and ankle in explaining this deficit will be explored in Section 5.4.2.

Falls Report was found to be significantly different between stroke and control groups. Levels of falls reported were high in the stroke group at 40%, falling within the range of 25–50% found in other reports (Walsh *et al.*, 2017; Ashburn *et al.*, 2008). The findings regarding falls after stroke are reinforced with findings from the FES, which showed a higher fear of falling after stroke. This was found to be significantly different from the control population (32 v. 19) demonstrating 'high concern' (Delbaere *et al.*, 2011). As expected, falls in the control group were low (7%). The frequency of falls was greater in the stroke group (up to seven) than in the control group (up to two only). In older adults over 65 years old, around 30% are reported as experiencing one or more falls a year (Spink *et al.,* 2011). This suggests a possible under-reporting of falls in the control group, which is a widely accepted phenomenon (Hannan *et al*., 2010).

5.4.1.4 Summary

In summary, foot characteristics after stroke are altered in comparison to age- and gender-matched controls for foot posture, sway, PPP and CA. Differences appear more frequently and to a greater extent in dynamic tasks, and were accentuated in the more-affected limb. Neuromuscular impairments show that, after stroke, people have weaker muscles,

especially in ankle DFs and ankle evertors, reduced passive ankle dorsiflexion and hallux DF ROM, and a higher presence of spasticity in ankle PFs than the control group. Differences in mobility and balance outcomes after stroke are considerable, with slower walking velocities and higher self-perceived impact on walking, combined with a higher use of aids, particularly outdoors. The stroke group also had longer TUAG, shorter Forward Reach and higher Falls Report, indicating reduced balance control with inherent falls risk and reduced mobility, compared with their age- and gender-matched counterparts. Together these are important findings, as this is the first research into a community-dwelling group of this size focusing on the foot and ankle after stroke. The new knowledge demonstrating altered foot posture, DFL and lower hallux muscle strength, and smaller passive hallux DF ROM, will help tailor clinical rehabilitation and management, guide treatment approaches and help improve participation levels of people after stroke. This will be explored further in Chapter 6.

The following section will explore whether the selected foot and ankle impairments are predictive of the deficits commonly seen in mobility and balance.

5.4.2 Foot Characteristics and Neuromuscular Impairments as Predictors of Mobility and Balance Outcomes

To determine the impact of foot and ankle impairments on balance and mobility outcomes, selected variables were input into linear and logistic regression analysis. Variables were carefully selected based on theoretical underpinning and their ability to characterise differences from the control cohort as recommended by Nishishiba *et al*. (2014). The rigorous selection process ensured that variables that would not destabilise the regression modelling were included as directed by Field (2013). All less-affected side variables were discounted, and analysis of linearity, correlation and collinearity excluded further variables, thus 10 more-affected side variables remained:

- FPI abnormal/normal classification;
- Sway velocity eyes closed;
- Peak pressure RFT and FFT;
- Contact area MFT and FFT;

- Composite isometric muscle strength;
- Passive ROM, ankle and hallux (at low force);
- Spasticity presence (≥1).

As the results in Section 5.3.5 demonstrated, foot characteristics and neuromuscular impairments at the foot and ankle combined to explain 59% of the variance in walking speed. They also predicted 49% of the variance of TUAG. R^2 values for FFRT and Falls Report, although statistically significant, were not large, with predictor variables contributing to 36% of the variance in Forward Reach distance and 26% of the variance in Falls Report. The two strongest statistically significant contributors across all the mobility and balance outcomes were more-affected side muscle strength and sway velocity (eyes closed). The following section will explore the contribution of foot characteristics and neuromuscular impairments, which were significant predictors of mobility and balance outcomes for each of the regression models.

5.4.2.1 Isometric Muscle Strength

Greater isometric muscle strength on the more-affected side resulted in faster walking speed, a shorter TUAG and a greater Forward Reach distance. Isometric strength contributed with the largest standardised beta coefficients for walking speed and TUAG and the second largest for Forward Reach. Furthermore, it was the only predictor that remained as a contributor in pooled regression modelling for these outcomes. As a key predictor for all outcome variables except Falls Report, foot and ankle muscle strength on the more-affected side after stroke appears vital in predicting mobility and balance outcomes. This finding concurs with other literature that has reported similar findings (Dorsch *et al.*, 2012). Work by Dorsch *et al.* (2012) found that ankle DF and evertor strength measured by a HHD was ranked first and third out of 12 lower limb muscle groups in univariate analysis to positively correlate to comfortable walking speed measured by 10MWT (with $r = 0.50$ and $r = 0.33$, respectively). As part of the selection process for regression analysis, composite isometric muscle strength was found to be strongly associated with ankle and hallux muscle strength, flouting tolerance and superseding VIF. Therefore, analysis of ankle and hallux groups in more detail was precluded in the current work.

Composite muscle strength on the more-affected limb also contributed to TUAG, with greater strength resulting in faster TUAG times. Muscle strength has been found in other research to correlate with function assessed by TUAG after stroke. In 2005, Ng and Hui-Chan reported that ankle PF strength correlated with TUAG scores ($r = -0.860$, $p < 0.003$). Using a HHD in a group of 30 people with stroke, Kligyte *et al.* (2003) also found that TUAG was significantly associated with strength in all four ankle muscle groups ($r = -0.57$ to -0.42, $p < 0.05$), although the negative correlation was not as strong. Whether muscle strength resulted in a difference in the walking sections, or those in turning and sit to stand, is not clear.

Increased ankle and hallux muscle strength on the more-affected side was found to contribute to Forward Reach distance. Therefore, this work demonstrated that ankle and hallux muscle strength combined are influential and predictive of standing balance outcomes. In a group of 30 people with stroke measured using a HHD, Kligyte *et al.* (2003) found that ankle PFs strength significantly associated with FFRT ($r = 0.38$, $p < 0.05$); there were also non-significant associations with other ankle muscle groups, ankle invertors ($r = 0.07$), ankle evertors ($r = 0.10$) and ankle DFs ($r = 0.06$). This current work differs from Kligyte and colleagues' work (2003) in that multivariate analysis of composite values was used and therefore direct comparison is precluded. Kwong *et al.* (2017) reported that ankle DF isometric muscle strength measured using a HHD after stroke was found to contribute to balance score ($\beta = 0.40$, $p < 0.001$); however, balance was assessed using the Berg Balance scale and neither study analysed hallux muscle strength. Thus, this work highlights that greater ankle and hallux strength results in a greater ability to reach forwards, plausibly due to improved foot and ankle motor control in standing balance. This is corroborated by sway velocity also contributing to Forward Reach.

More-affected limb isometric muscle strength did not predict Falls Report. This aligns with work by Ashburn *et al*. (2008) and Hyndman *et al.* (2002). In a group of 110 people with stroke they found that muscle strength and lower limb function measured by the Rivermead (leg and trunk) scale had a non-significant odds ratio 1.16, $p = 0.345$ (Ashburn *et al*., 2008). In fact, upper limb function combined with a history of near falls was a stronger predictor of falls in 12 months after stroke. Similarly, previous work by Hyndman *et al*. (2002) found upper limb function reduced in the 10/22 people with stroke

who had had two or more falls. No comparable work in stroke looking at foot and ankle strength and falls exists for further comparison; however, in older people, Spink *et al.* (2011) found that hallux PFs strength predicted falls risk; yet falls risk was not evaluated in this current work. It is plausible that strength deficits in the stroke group tested were not significant enough to impact on falls.

Overall, isometric strength measurement had strong contribution to both dynamic and static tasks. Thus, foot and ankle isometric muscle strength is associated with mobility and balance outcomes.

5.4.2.2 Sway Velocity

Sway velocity (eyes closed) was also found to be one of the key predictors of all the balance and mobility outcomes evaluated, remaining a predictor in pooled data for Forward Reach and Falls Report. A review by Geurts *et al*. (2005) evaluating a large body of work on sway velocity after stroke reported that force-plate technology capturing COP movements during the 'simple' act of standing can explain 50% (R^2) of the variance of several functional balance and gait measures in patients with stroke. Despite a large body of evidence regarding sway velocity in standing, few papers have used pressure mats. The current findings will be evaluated primarily in relation to these papers only.

Sway velocity (eyes closed) significantly contributed to the variance found in walking speed. Similarly, Mizelle *et al.* (2006) used pressure-sensitive insoles in a group of 33 people with stroke to evaluate the relationship between foot pressure measures and hemiparetic gait. Using a stepwise linear regression model, they reported that 11 COP and symmetry parameters taken over 15 trials of steady state gait cycles were predictive of gait velocity ($R^2_{adj} = 0.9$). Reasons for the high contribution to the regression is most likely due to the measures being taken during gait itself. This appears not as strong when measures are taken in quiet standing as demonstrated in Study 2. Nolan and colleagues (2015) used COP analysis while walking with wireless in-shoe pressure devices, using a drop foot stimulator in 11 people with stroke; they found gait stability and progression improved with increased displacement of COP. Their work demonstrated that improved activation of the ankle DF group resulted in improved stance COP control, thus indicating that improved motor control at the ankle aids gait velocity. Chen *et al*. (2007) evaluated

COF excursion and reported that 'good' ground reaction force (GRF) patterns were highly correlated with walking speed ($r = 0.92$, $p < 0.01$); however, none of this work reports COP in standing as the current work does. Therefore, sway velocity (eyes closed) in standing is associated with walking speed using a pressure mat. In literature using alternative methods, weight-bearing asymmetry has been found to reduce postural sway (Kamphuis *et al*., 2013), with interventions such as increased light touch (Baldan *et al*., 2014) and use of ankle–foot orthoses aiding postural sway (Tyson and Kent, 2013).

TUAG was also partly predicted by sway velocity, with reduced sway velocity resulting in reduced TUAG. TUAG, which includes walking, turning and sit to stand, inherently requires balance and mobility. Reduced sway velocity during standing appears crucial in these TUAG activities. In stroke, similar outcomes to the current work have been reported in standing using force plate analysis with eyes open and eyes closed; sway velocity was found to be strongly associated with TUAG ($r > 0.8$) (Sawacha *et al.*, 2013).

Sway velocity with eyes closed strongly associated with Forward Reach, demonstrating that reduced sway velocity during standing enabled a longer Forward Reach. The strength of contribution that sway velocity had on Forward Reach may be explained by the similarity of the starting position of quiet standing, with Forward Reach additionally requiring an individual to approach their limits of stability (Duncan *et al.*, 1990). Sway velocity – an indirect measure of control of the centre of mass over the foot, or ankle stability – is a multifaceted mechanism that does not rely solely on the foot. Thus, its influence on these functional outcomes does not just reflect changes at the foot after stroke, but multisystem changes throughout the lower limb and trunk. This is borne out in work by Cho *et al*. (2014) where a decrease in postural sway did not reflect improvement of dynamic balance ability. They only found correlations (on foam) between the Berg Balance scale (BBS) score and anterior–posterior postural sway velocity with eyes open, anterior–posterior postural sway velocity with eyes closed, and postural sway velocity moment.

Lastly, sway velocity was a strong contributor to Falls Report both for complete and imputed data analysis, with reduced sway velocity predicting a reduced number of falls reported in the previous three months; however, previous literature has reported that quiet standing sway has previously reported ambiguous results on the relationships between

postural impairments and occurrence of falls (Weerdesteyn *et al*., 2008). Both Forward Reach and Falls Report link closely with identifying people at risk of falls after stroke. Whether measurement of sway velocity using a plantar pressure mat may prove critical for identifying falls or falls risk after stroke has not been established in this work.

5.4.2.3 Peak Plantar Pressure

Peak pressure in both RFT and FFT regions were predictors of walking speed and Forward Reach. As peak pressure increased at the RFT and FFT so did walking speed and Forward Reach. The association between peak pressure and mobility outcomes after stroke is poorly understood. In a group of 20 people with stroke and 15 age- and gender-matched controls, Forghany *et al.* (2015) demonstrated, using a plantar pressure platform, that people with stroke who had greater pressures recorded in the medial heel region were more likely to be household walkers (odds ratio 1.11, $p < 0.05$); however, this differs from the current work, where lower pressures on the more-affected side were reported in all foot regions compared to both control participants and the less-affected side. Additionally, this work did not include those who were solely household walkers. Yang *et al*. (2014) also reported increased MFT and total foot peak pressure during gait which was crucial to improved gait outcomes ($p < 0.05$); however, this was in robotic assisted treadmill walking. Chen *et al.* (2007) conducted a study with 43 stroke participants and examined plantar pressures using in-shoe pressure insoles. Their work attributed the association between GRF patterns and walking speed ($r = 0.92$, $p = <0.01$) to reduced lower limb motor activity, particularly knee flexion and extension (correlation $r = 0.607$, 423, $p < 0.01$). The current work also found muscle weakness was weakly to moderately associated with peak pressure with FFT ($r = 0.342$, $p < 0.01$) and RFT ($r = 0.482$, $p < 0.01$).

Possible reasons for the contribution of peak pressure to walking speed may lie in the role of individual foot regions during stance phase. The RFT, at initial contact, absorbs foot loading and controls the foot as it lowers to the floor, and the FFT region at terminal stance aids with propulsion of swing phase (Perry and Burnfield, 2010; Richards, 2008). Thus, GRFs rise at both RFT and FFT loading resulting in a ‘butterfly effect’ seen throughout stance phase (Perry and Burnfield, 2010). In stroke, limited heel strike is secondary to structural changes such as calf shortening (Lieber and Lieber, 2002; Barnes,

2008) and equinovarus deformity (Verdie *et al*., 2004). This may reduce RFT contact and loading, in turn reducing RFT pressures. Furthermore, reduced gait speed results in reduced vertical GRFs (Perry and Burnfield, 2010) and in turn reduces peak pressures. Reduced walking speed associated with low peak pressures has been reported elsewhere (Burnfield *et al*., 2004) but not consistently (Menz and Morris, 2006) and not after stroke. If muscle strength contributes to walking speed, as shown in this work, it is plausible that reduced RFT and FFT pressure may be due to weakness. Hence plantar pressure platforms may provide a useful tool to evaluate gait improvements after stroke.

FFT region peak pressure significantly contributed to Forward Reach. An increase in more-affected side FFT pressure was associated with a greater Forward Reach distance. It is interesting to note that FFT peak pressures from stance phase of walking were associated with standing balance performance; however, greater loading through the fore foot is required during end of stance phase to allow forward progression in gait, similar to the anterior weight translation required during a Forward Reach in standing (Shumway-Cook and Woolacott, 2011). Therefore, it seems plausible that results for FFT peak pressures on the more-affected side may increase Forward Reach. The current work suggests that people with stroke with reduced pressures in the FFT (during stance phase of walking) may therefore struggle to maintain balance toward the anterior edge of the limits of stability. Postural disturbance in standing balance in all directions are common after stroke, with a disproportionate reduction in postural control to the anterior region (de Haart *et al.*, 2005; Dickstein *et al.*, 1984).

PPPs may be a useful clinical tool to determine whether DFL in people with stroke may be impacting on balance and mobility outcomes. PPPs in RFT and FFT regions have significance in mobility and balance and should form part of clinical intervention after stroke. Therapists may need to focus time within their treatment sessions on these regions to ensure optimal foot loading and weight transference between limbs and towards the edge of the BOS; however, exactly which interventions influence normalised PPP and thus correspond to improved function is not clear. Nolan and colleagues (2015) found that orthotics often equalised peak pressures between the more- and less-affected limbs leading to improved forward progression and stability during walking. It may be that therapist inputs such as mobilisation and tactile stimulation may improve foot contact; however, application of this modality has only recently been evaluated (Aries *et al.*,

2016), and results for plantar pressure analysis are still to be published. Whether these interventions are required for all people with stroke or only those three months after stroke and independently mobile over 10 m still needs to be established.

5.4.2.4 Foot Contact Area

Foot CA in MFT and FFT regions was a significant contributor to balance and mobility in TUAG and Forward Reach regression analysis. Larger CA in MFT and FFT regions had a positive influence, reducing TUAG and lengthening Forward Reach distance. As foot contact is used to indicate plantar loading this is an interesting finding, suggesting that larger CA results in improved mobility and balance; whether this is due to the larger BOS available is yet to be established. This is of note given the relatively small, significant differences found between CA in the foot regions in the stroke and control group. Contact area has rarely been evaluated in research, with no cross-sectional studies reported on in stroke populations. In older adults, recent normative data suggests CAs of 115 cm^2 (female) to 128 cm^2 (male), with the greatest area in the FFT, followed by the RFT and then the MFT (McKay *et al.*, 2017). McKay and colleagues (2017) work found RFT, FFT and whole foot CA was positively, weakly correlated with ankle DF, ankle PF and toe flexor strength ($r = 0.01–0.40$, $p < 0.05$). The association between CA and ankle and hallux muscle strength suggested further variables influencing CA in addition to height, body weight and body circumference (McKay *et al.*, 2017). This work did not find a similar association. Yang *et al.* (2014) found total foot CA and MFT region increased significantly ($p < 0.01$) on the more-affected side when walking robot assisted on a treadmill, with improved gait asymmetries suggesting that increased CA was associated with improved gait biomechanics (Yang *et al.*, 2014). From this current work, loss of stability indicated by increased sway, reduced muscle strength in the ankle and hallux, along with reduced CA, combine to result in reduced balance function as measured by the TUAG and Forward Reach. Therefore, establishing the factors that may influence altered foot CA remains an area for further exploration.

5.4.2.5 Peak Ankle Dorsiflexion

Peak ankle dorsiflexion influenced Forward Reach and Falls Report during original data analysis, with smaller passive ROM on the more-affected side contributing to distance reached forward in standing and falls reporting (i.e. the presence of falls in the previous three months). In view of the small yet significant changes in ankle DF passive ROM after stroke in the stroke cohort, this is an interesting finding, particularly as balance strategies at the ankle require relatively little movement at the ankle. Ankle DF ROM impacts on movement by providing an available range through which to achieve dynamic activity and motion. For example, during gait 12–22° are required for an effective gait (Weir and Chockalingam, 2007). How exactly this translates in influencing falls is less clear, even more so when considering mobility outcomes where greater ankle dorsiflexion is required; however, flexibility at the ankle joint may allow for greater dorsiflexion and may perhaps indicate better muscle synergy resulting in a better response to perturbations which, consequently, mitigates falls. Whether greater passive ROM at the ankle is integral to the prevention of falls has not been extensively explored in the literature, although Kunkel *et al*. (2017) explored first MTPJ ROM and found the reduction in 10° of extension ROM (37–27°) did not impact on the number of falls. No evidence currently exists linking ankle ROM with falls outcomes after stroke. In older people, Spink *et al*. (2011) did not find ankle dorsiflexion a strong contributor to balance, with ankle dorsiflexion only contributing to sit to stand.

5.4.2.6 Non-Significant Predictor Variables

Despite isometric muscle strength and ankle DF ROM predicting mobility outcomes, no other neuromuscular impairments were found to be significant contributors. Notably, static foot posture was the only foot characteristic input into the regression model that did not act as a predictor for any of the mobility or balance outcomes. Yet Forghany *et al.* (2011) found that abnormal foot posture was more frequent in household walkers ($p = 0.01$). As this work included people able to walk 10 m or more independently, household walkers are unlikely to be represented within the Study 2 sample, and therefore may account for why foot posture may not have been found as a contributor to regression analysis. Kunkel *et al*. (2017) reported that stroke fallers had a more pronated foot than non-fallers ($p = 0.027$); however, association between these variables was not evaluated,

and the values reported median scores of 9.5 (faller) and 6 (non-faller) which both fell into the same FPI pronated category. Given these mixed results, establishing consensus on the role of foot posture in mobility after stroke is warranted.

Toe deformity was not a significant variable in the regression modelling. Kunkel and colleagues (2017) found toe deformity was not reported as characteristic of the people with history of falls. Associations with mobility and other balance outcomes were not explored in their work. Peak hallux dorsiflexion and spasticity presence did not significantly predict variance in any mobility and balance outcome, despite hallux dorsiflexion of 50–65° being reported as critical for gait progression (Perry and Burnfield, 2010; Hopson *et al*., 1995). Hallux dorsiflexion was not predictive of falls or balance outcomes, where smaller motions are required at the hallux. Spasticity is inherently challenging to evaluate clinically, although it has previously been found to associate with mobility outcomes after stroke (Lin *et al*., 2006; Lamontagne *et al*., 2002); however, in the current work the presence of spasticity did not associate with mobility and balance outcomes. Reasons for the discrepancy may lie in the use of a different outcome measure, the MAS, and a smaller, less ambulant, sample gait speed of 45.4 $cm \cdot s^{-1}$.

5.4.2.7 Summary

In summary, dynamic foot characteristics, reduced sway velocity, higher peak pressures in rear and forefoot, as well as increased CA of the MFT and FFT, predict mobility and balance outcomes after stroke. Static measures of the foot (foot posture and toe deformity) and effects of disordered motor control, evaluated as spasticity, do not appear to have any influence on mobility and balance outcomes in this study. Further clinical implications are discussed in Chapter 6.

5.4.3 Limitations

The primary limitation in this study was the level of missing data, which meant that the number of complete case analyses was limited. Despite the large sample size recruited, only 54% of the participants in the stroke group were included in the final regression analysis. This highlights some caution over the findings in Study 1 where all measures were deemed feasible. The high level of missing data demonstrated the difficulties in

collecting clinically feasible data from stroke participants, particularly for passive ROM and plantar pressure variables where data loss was greatest. This was compounded by the random distribution of missing data across variables and cases, which meant an even greater number of cases were removed from the final analysis. Missing data concerns were mitigated by data imputation for regression analysis; however, only stronger contributors were consistent between complete cases and pooled analysis. Therefore, the results found only partially represent the group recruited and the findings reported in comparison of stroke and control groups. In response to this limitation, it is recommended to minimise the number of measures taken when undertaking larger trials. Further feasibility/acceptability work or time between studies to reflect on issues and implement adaptations also may have helped to limit missing data.

As part of a large battery for tests for the FAiMiS project, Study 2 may have been vulnerable to data loss due to a long testing protocol which recorded data for 13 predictors. Even though protocols were found to be individually feasible and reliable in Study 1, the ability to obtain complete data sets was challenging. Study 1 as a pilot study was useful but did not demonstrate all possible issues related to feasibility, nor did it evaluate the feasibility of the whole assessment battery including the functional outcomes that were included in Study 2. In response, further piloting of the whole battery may have further minimised data loss. Additionally, plantar pressure protocols may have required more trials, or in-shoe instrumentation could be used, although there are significant financial implications of this.

Prior to the start of the project, data analysis was planned to address the specific aims of the project, with statistical analysis analysing comparisons between stroke and control groups. This meant that the work presented did not stratify results to specific subsets of the stroke population (e.g. age or time since stroke). This may mean there are subgroup features from the cohort recruited that have not been evaluated. This type of stratification, a common feature advocated in current stroke research, was not employed in the current work to ensure that the work was applicable to the widest group of community-dwelling people with stroke.

Finally, retrospective modelling, such as the regression modelling applied in Study 2, yields predictors that are relevant only to the population that has been tested and which

cannot be extrapolated to other populations. In the knowledge of this, Study 2's regression modelling has established the associations only, note the research aims (Section 5.1.1) Furthermore, findings can be extrapolated to similarly to populations of ambulatory, UK based people with stroke (> 3 months). So, this work provides important and valuable understanding of the role of foot and ankle in balance and mobility outcomes.

5.5 SUMMARY AND KEY FINDINGS OF STUDY 2

Study 2 has found that stroke survivors have many deficits in foot and ankle impairments in comparison to their age- and gender-matched counterparts. The foot characteristics after stroke that demonstrated statistical differences were sway velocity and path length, PPP and CA variables. These foot characteristics also had an influence on balance and mobility outcomes. Neuromuscular impairments were also statistically different after stroke in all individual ankle and hallux muscle groups, ankle and hallux DF ROM, and in ankle PF spasticity. Furthermore, muscle strength and ankle DF ROM were found to be predictors of mobility and balance outcomes.

Thus far, this is the first study to explore in detail foot characteristics as well as ankle and hallux neuromuscular impairments and evaluate their effect on functional outcomes. This work makes a significant contribution to the current clinical understanding of how deficits at the foot and ankle impact on function in community-dwelling people with stroke. Predictive ability of the impairments has yielded some novel and interesting results, such as the role of sway velocity (as measured by a pressure mat), PPPs and foot CA, as well as ankle and hallux muscle strength, in predicting mobility and balance outcomes. Knowledge of these associated factors will be useful in shaping clinical assessment and treatment focus for people with stroke. In areas, further work is required to fully explore what impairments may influence for the plantar pressure variables to be significant contributors to functional outcomes. This is explored in Chapter 6.

The next chapter will combine together findings from Chapter 4 (Study 1) and Chapter 5 (Study 2), with a focus on future work and clinical implications of the findings.

Chapter 6: DISCUSSION AND CONCLUSION

This chapter will provide a synthesis and critical evaluation of the findings from Chapters 4 and 5, demonstrating why and in what way the field of stroke rehabilitation is informed by this thesis. Limitations of the overall research programme will be considered alongside future research that may be warranted. As a result, recommendations for clinical practice and future research will be made.

6.1 PURPOSE OF THESIS

In response to a lack of clinically feasible and reliable measures available to assess foot and ankle impairments in people with stroke and the paucity of evidence regarding their impact on functional outcomes, this research programme addressed and fulfilled two key aims:

1. To evaluate the clinimetric properties (feasibility, test–retest reliability, and clinical relevance) of measures of foot characteristics and neuromuscular foot and ankle impairments, for application in people with stroke (**STUDY 1**).

2. To explore whether foot characteristics and neuromuscular foot and ankle impairments identified following stroke differ from normal controls; and whether these are associated with mobility and balance outcomes (**STUDY 2**).

6.2 DISCUSSION OF KEY RESULTS

The key findings of the thesis derived from Study 1 (Chapter 4) and Study 2 (Chapter 5) are summarised and discussed below in the light of current knowledge.

6.2.1 Key Results

Study 1 tested the feasibility and reliability of different foot characteristic measures and neuromuscular impairment measures after stroke. All measures were feasible for use in people with stroke; with this being the first report of the feasibility of static foot posture,

dynamic foot loading, hallux isometric muscle strength and ankle/hallux ROM. Measures that demonstrated reliability included static foot posture (FPI) (κ_w = 0.53–0.60), sway velocity and path length (ICC = 0.54–0.78), peak plantar pressure (ICC = 0.76–0.96) and foot contact area (ICC = 0.58–98) (using a plantar pressure mat), ankle and hallux isometric muscle weakness (using HHD) (ICC = 0.62–0.95), peak dorsiflexion at the ankle and hallux (using bespoke rigs) (ICC = 0.53–0.82, 0.70–0.82, respectively), and ankle spasticity (using Tardieu scale) (κ_w = 0.78); however, it was not possible to develop a robust technique to assess ankle inversion and eversion, and stiffness of ankle dorsiflexion and hallux dorsiflexion was not reliable.

Study 2 demonstrated that there were significant differences for all impairment measures between people with stroke (n = 180) and controls (n = 46), apart from static foot posture (p = 0.615 raw score, and p = 0.677 age-adjusted scores) and toe deformity (p = 0.782). Statistically significant differences were found between stroke and control groups for toe deformity presence, PPP (RFT, FFT, toes, total foot regions), foot contact area (MFT, toes and total foot regions), individual and composite isometric muscle strength, peak ankle dorsiflexion and hallux dorsiflexion, and ankle PF spasticity. Between more- and less-affected sides, statistically significant differences were found for PPP, individual and composite muscle strength, peak ankle dorsiflexion and ankle PF spasticity. Non-significant findings were reported for toe deformity and peak hallux dorsiflexion.

Ten foot characteristics and neuromuscular impairments were selected for multivariate regression analysis, with models showing variable associations (R^2) with the four functional outcomes of interest: R^2 = 0.59 walking speed; R^2 = 0.49 TUAG; R^2 = 0.36 FFRT; and R^2 = 0.26 Falls Presence. The results also demonstrated that the measures of foot and ankle impairment were most correlated with walking speed outcome (explaining 59% of the variance). Reduced sway velocity, greater isometric muscle strength on the more-affected side, and lower PPP (RFT and FFT regions) and CA (MFT and FFT regions) variables were associated with improved mobility and balance outcomes; with peak ankle DF contributing to Falls Report.

6.2.2 Overarching Discussion of Key Results

Assessing people with stroke at the foot and ankle has been challenging due to the lack of feasible and reliable measures. Measurement of foot and ankle impairments is pertinent following stroke given the plethora of symptoms (Carr and Shepherd, 2002) and reported functional limitations (Tyson *et al.*, 2006; Bohannon, 2007; Kwakkel and Kollen, 2013; Dorsch *et al*., 2016). Previously, the foot received little attention after stroke both in the literature and even in stroke management guidelines, with assessment, such as that conducted by podiatrists, rarely mentioned (NICE, 2013b). For therapists and healthcare team workers in the stroke pathway, treatment is focused on the need for early discharge home and lower limb rehabilitation to enable this, e.g. to be mobile with/without an aid (Langhorne *et al*., 2009). Despite this, many people with stroke report not attaining mobility focused goals (20%); furthermore, falls report remains high (28%) (Chen *et al*., 2019). Additionally, clinical assessment of foot function and treatment of foot and ankle impairments is not always prioritised. Previous studies have shown the potential relevance of foot and ankle impairments on functional outcomes and demonstrated a need for robust clinical measures (Forghany *et al*., 2011; Dorsch *et al*., 2012). Foot posture asymmetry after stroke was shown to be associated with walking ability (Forghany *et al*., 2011); reduced isometric ankle muscle strength with slower walking speeds (Dorsch *et al*. 2012). Furthermore, Lamontagne *et al*. (2001; 2002) found ankle PF spasticity and ankle DF ROM associated with aspects of the gait cycle (stride progression). Thus, given their relationship with function, it is important that these foot and ankle deficits have robust clinical measures to assess them.

The results of Study 1 demonstrated that the measures used in this thesis are clinimetrically sound and robust, being both feasible, reliable and, in the case of plantar pressure, clinically relevant. As few reports exist regarding feasibility and reliability of the measures/tools used at the foot and ankle after stroke, this work adds knowledge of measures newly applied in people with stroke (i.e. the FPI, toe deformity observation, plantar pressure analysis). It also advances current use of the measures (e.g. isometric muscle strength of hallux DF/PFs using HHD) in people after stroke. These findings demonstrated that the measures were suitable for use in Study 2 but, more importantly, that these feasible and reliable measures may be used in people with stroke to evaluate

changes at their foot and ankle as part of their stroke management. Hence, they may help inform and enhance current clinical assessment of the foot after stroke (further discussion is found in Section 6.3.1).

The severity of differences in foot and ankle deficits within community-dwelling people with stroke in comparison to an age- and gender-matched control group have been reported in Study 2. As age is known to have an impact on many aspects of foot and ankle function (Menz, 2015), comparing stroke and age- and gender-matched groups was necessary to eliminate confounding factors associated with the ageing process. These results revealed that after stroke people have greater extremes in foot posture, possess more toe deformities, lower PPPs and smaller CA on the more-affected side, weaker ankle and hallux muscles (a third lower than control participants), reduced ankle and hallux DF ROM, and have greater presence of spasticity (often mild only). This enhances existing clinical understanding of the foot after stroke, particularly of foot posture type, toe deformity presence, changes in plantar pressure variables, hallux muscle strength and peak hallux angle, which have been rarely reported after stroke to date. As discussed in Section 5.4.1, this furthers previous work (Meyring *et al*., 1997, Forghany *et al*., 2011, Dorsch *et al*., 2012; 2016; Kunkel *et al*., 2017) by detailing which foot and ankle deficits are present and how severe they may be after stroke. This thesis found primarily neutral foot posture with abnormal pronation and supination similar to Forghany et al (2011). Currently mixed reports of altered PPP and CA values after stroke (Meyring *et al*., 1997; Forghany et al., 2015) was strengthened by this work demonstrating lower PPP and CA across foot regions. Furthermore, for the first-time, hallux muscle strength and DF ROM was demonstrated to be weaker and smaller respectively. Hence, after stroke the foot and ankle on the more-affected side have significant impairments which are not found in people without stroke.

Furthermore, the current work documents the inter-limb differences, demonstrating that the deficits found are not peculiar to the more-affected limb and highlighting the need for bilateral assessment of these foot and ankle characteristics. Between-limb differences in foot characteristics have been found previously in research, such as asymmetry in foot posture (Forghany *et al.*, 2011), and in altered plantar pressure variables (Chen *et al.,* 2007; Meyring *et al.,* 1997). Also, deficits in neuromuscular impairments were found, including reduction in isometric muscle strength bilaterally compared to age- and gender-

matched controls (Bohannon, 2007), ankle DF ROM (Lee *et al*., 2004) and ankle PF spasticity (Lamontagne *et al*., 2002). These previous studies have examined specific foot and ankle impairments and/or a smaller cohort of people with stroke. In this work, statistically significant differences were found for peak plantar pressure, individual and composite muscle strength, peak ankle dorsiflexion and ankle PF spasticity between more- and less-affected sides. Non-significant findings were reported for toe deformity and peak hallux dorsiflexion. On the more-affected side there were more extremes of foot posture and increased spasticity, greater reduction in muscle strength, decreased passive ROM, and lower peak pressures (in all regions). Therefore, this current work advances existing understanding by reporting these between-limb deficits concurrently.

Toe impairments have not been commonly measured or reported after stroke, but this work concurs with previous work by Kunkel *et al*. (2017). No between-limb differences for toe deformity and peak hallux dorsiflexion were observed in Study 2 and similarly, Kunkel *et al*. (2017) have not reported significant inter-limb differences; however, the findings in this work demonstrate agreement that both limbs experience deficits after stroke, which is also reported for isometric muscle strength (Dorsch *et al*., 2012; 2016). So, clinically, while greater deficits may be expected and should be addressed on the more-affected side after stroke, less-affected side impairments should also be assessed and monitored to ensure these can also be treated. Ideally, clinicians should use comparative normal data from age- and gender-matched controls to compare their findings to determine the severity of deficits.

Crucially, this work has also characterised functional sequalae associated with stroke with ICF activity level limitations with a slower walking speed, poorer balance (indicated by a shorter functional reach), and higher frequency and incidence of falls. Study 2 confirmed that 10 foot and ankle impairments were predictive of functional outcomes. While previous studies have shown the extent of functional limitations after stroke, namely reduced walking speed, poor balance control and higher falls report (Bohannon, 2007; Ashworth, 2008; Kwakkel and Kollen, 2013), this is the first of its kind reporting the presence of *multiple* foot and ankle impairments after stroke and their important contribution to mobility balance and falls outcomes in a large group of people with stroke (28–59% of the variance). The contribution demonstrated in this thesis is greater than that

reported in older people where hallux PF strength and ankle inversion/eversion ROM contributed 25% to balance and functional outcomes (Menz, 2015; Spink *et al*., 2011). Critically, after stroke, greater COP sway, reduced ankle and hallux muscle strength, and altered DFL were the key impairments associated with mobility, balance and falls outcomes. Individual isometric ankle muscle strength and sway velocity have been found previously to associate with functional outcomes after stroke with strong positive correlations reported $r = 0.50$ (Dorsch *et al*., 2012) and R^2 of 50% (Geurts *et al*., 2005). This thesis is the first report where combined ankle and hallux muscle strength and plantar pressure analysis has been found to associate with functional outcomes in people with stroke thus advancing current understanding of the role of foot impairments on post stroke function.

Overall, the value of the current work is not only enhancing current knowledge due to the range of impairments evaluated, but also by size of the sample and the range of impairments examined. As it was a large, statistically powered, cross-sectional study including ambulatory people with stroke from two UK sites, the results are highly generalisable to the UK population (associated limitations such as selection bias are dealt with in Section 6.4). Therefore, there is a need for focused assessment and treatment of the foot and ankle (for further discussion see Section 6.3.2). Next, discussion will focus on the explanation and evaluation of the findings and their implementation into clinical practice.

6.3 CLINICAL IMPLICATIONS OF THE FINDINGS

The findings in this work may advance practice by providing tools and protocols to evaluate foot and ankle changes after stroke, outlining the extent of foot and ankle deficits found after stroke and demonstrating the importance of the foot for mobility and balance. This is now critically evaluated and discussed considering current practice and literature.

6.3.1 Clinical Measurement of Foot and Ankle Impairments

Some foot and ankle impairments are already routinely assessed within the stroke pathway and assessments are frequently completed using tools with poor-to-moderate clinimetric properties. This includes isometric muscle strength of the ankle (MRC/Oxford scale) (Cuthbert and Goodheart, 2007), passive ankle ROM (goniometry/visual estimation) (Martin and McPoil, 2005; Gatt and Chockalingam, 2011) and ankle spasticity (MAS) (Bohannon and Smith, 1987). Other impairments are not routinely evaluated, including foot posture, toe deformity, plantar pressure analysis, hallux DF/PF strength and ROM. Therefore, findings reported in Study 1 provide clinicians with a larger range of tools that have potential use in the clinical setting. These tools and measures have established feasibility and reliability to evaluate foot and ankle function in a clinical environment. As such these could be feasibly adopted in the chronic phase after stroke (beyond 3 months), although acceptability of their implementation in hospital, rehabilitation, or community settings was not evaluated in this work. The role of these measures in advancing stroke management and when they could be utilised is summarised in Table 6.1. This is now discussed based on the work in this thesis together with current literature.

- **Foot Posture Type Measured Using the FPI** may suggest structural problems within or influencing foot function (Redmond *et al.,* 2008). This clinically popular assessment tool has been found to be feasible (easy to measure in 2–5 mins) and has good reliability for use in people with stroke, although it is not currently routinely used. Previous work reported the presence of foot posture asymmetry after stroke and extremes of abnormal posture may indicate limitation in functional activity (Forghany *et al*., 2011). Similarly, extremes of abnormal foot posture were reported in this work, although functional associations were not found. Assessment of foot posture within stroke management may help inform clinicians about aspects limiting attainment of functional outcomes and footwear decisions (Forghany *et al.,* 2014). Causes of abnormal foot posture may require interventions for strengthening of the intrinsic muscles and/or longitudinal arches to aid optimal positioning to prevent against pain, degeneration and mal-alignment of other body segments.

- **Toe Deformity** can be clinically observed in sitting, standing or walking and assessed to determine whether deformity is mobile or fixed in nature. Its presence may impair balance and interfere with gait progression as it does in older adults (Mickle *et al.,* 2011b); however, this is still to be evidenced after stroke.
- **Dynamic Foot Loading Using a Plantar Pressure Mat.** In standing, DFL informs clinicians of neuromuscular control at the foot and ankle; deficits in sway velocity may indicate poorer functional outcomes. During stance phase of gait, plantar pressure analysis informs clinicians about regions of the foot with altered loading, with low pressures and reduced CA predicting lower functional outcomes. Deficits in loading in comparison to the less-affected side may indicate treatment is required to improve weight bearing/weight shift during stance phase or contact with the floor. As such, pressure analysis can be used as an outcome measure to monitor treatment efficacy. See Section 6.3.1.1 for more discussion.
- **Ankle and Hallux Isometric Muscle Strength using an HHD.** This can be feasibly and reliably measured in long sitting/sitting depending on the muscles being tested. Assessment demonstrates specific muscle group weakness (including hallux DFs/PFs) which can lead to poor functional outcomes. Deficits found at the hallux in this work demonstrate the importance of strength testing of these muscle groups. Muscle weakness consequently requires strengthening and application within functional movement such as gait (See Section 6.5 for further discussion).
- **Ankle and Hallux DF ROM Using Bespoke Rigs.** This assessment informs clinicians of reduced ankle and hallux DF ROM. Assessment of ankle and hallux ROM may indicate loss of passive ROM in ranges critical for efficient gait/function (Richards *et al*., 2008), which may lead to poorer balance outcomes. This will require treatments to increase ROM and signpost clinicians to explore balance function further.
- **Ankle Spasticity Using the Tardieu Scale**. This feasible and reliable scale informs clinicians about level of muscle resistance which may be impairing movement, such as gait, although ankle PF spasticity was not found to associate/predict mobility and balance outcomes in this work.

Table 6.1 Tools for Use in Clinical Practice

Impairment	Tool and operationalisation	Rationale for inclusion in post stroke management*
Foot posture	Foot posture index Measure in standing	Indicates type of foot posture. Extremes of abnormal posture ***may*** **indicate limitation in functional outcomes.** Helps inform footwear decisions. Causes may require interventions for muscle lengthening/ reduction spasticity.
Toe deformity	Visual observation In supine, sitting and standing	Informs footwear decisions. May impair balance and interfere with gait progression.
Dynamic foot loading	Plantar pressure mat a) in standing and b) during gait (Section 6.3.1)	a) Informs clinicians of neuromuscular control and ankle and foot. **Deficits in sway velocity may indicate poorer functional outcomes**. b) Informs clinicians about regions of the foot with altered loading, with **low pressures and reduced contact area predicting lower functional outcomes.** Deficits in loading in comparison to the less-affected side may indicate specific work to improve weight bearing/weight shift during stance phase or contact with the floor.
Ankle and hallux isometric muscle strength	HHD Measure in supine/sitting	Demonstrates specific **muscle group weakness (including hallux DFs/PFs) which may lead to poor function outcomes**. These will need strengthening by a progressive training programme and application in function.
Ankle and hallux DF ROM	Bespoke rigs	Informs clinicians of **reduced ROM at** ankle and **hallux.** May indicate loss of ROM in ranges critical for efficient gait/function, **which may lead to poorer balance outcomes.** This may require treatments to increase ROM and signpost clinicians to exploring balance function further.
Ankle spasticity	Tardieu scale	Informs clinicians about the extent of muscle resistance which may be impairing movement, such as gait.

*Please note this has not been established by the work in this study.
Grey highlighted rows should be prioritised according to findings from this thesis.
Abbreviations: DF = dorsiflexor; HHD = hand-held dynamometer; ROM = range of movement.

Adoption of such a range of assessment tools requires careful consideration. There is a need to balance clinical need of implementing these tools, which appears crucial given this thesis' findings, with therapy time constraints and ongoing clinical demands. The findings from Study 2 prompt clinicians to consider the potential importance of foot and ankle assessment after stroke and help to guide evaluation of specific foot and ankle impairments, to ensure that deficits impacting on function are not overlooked. Study 2 highlighted key deficits which differ from healthy controls as well as impact on function these were: plantar pressure variables (e.g. sway velocity, peak pressure, contact area and sway velocity); isometric muscle strength of ankle DFs, PFs, invertors, evertors, and hallux DFs and PFs; and peak ankle dorsiflexion ROM (discussed further in Section 6.3.2). However, as previously mentioned, many of these variables are currently not clinically assessed, e.g. hallux muscle strength (MRC/Oxford scale), and DFL is not commonly used in routine stroke assessment. In fact, this work has found that the use of pressure mat analysis and hand-held dynamometry is a feasible and reliable way of appraising whether people with stroke are likely to have deficits in mobility and balance function. Therefore, therapists may need to prioritise plantar pressure and muscle strength assessment measures. This thesis may also support other health professionals such as podiatrists to be increasingly involved and included within the stroke pathway although even podiatrists may not be able to utilise plantar pressure assessment routinely in their practice.

Consequently, it is important for clinicians working within the stroke pathway to be aware of the priority of assessing foot and ankle structure and function after stroke. Additionally, the tools and protocols utilised need to be made accessible to these clinicians and their implementation evaluated in the clinical setting (see Section 6.5).

6.3.1.1 Implementation of Plantar Pressure Analysis After Stroke

A key novel aspect of this work has been the use of plantar pressure analysis to evaluate foot function. Peak pressure analysis is a feasible and reliable measure of dynamic function, able to measure impairments during stance phase of gait, as found in Study 1. Study 2 demonstrated that plantar pressure changes between stroke and control groups, and between more- and less-affected limbs are clinically relevant. Altered foot loading after stroke was reflected by greater COP velocity, lower peak pressures and smaller contact areas and was associated with poorer mobility and balance outcomes. This demonstrates that a technology-enhanced assessment may improve understanding of deficits post stroke, evaluating differences in people with stroke and between limbs.

Typically, therapists in the stroke pathway evaluate gait patterns routinely after stroke (NICE, 2013b). Combining this with a plantar pressure system would serve as a useful tool to enhance assessment and as a guide for stroke management by elucidating specific aspects of foot loading during stance phase. Conducting a plantar pressure assessment could enhance visual gait observations of abnormal /altered loading of the foot through stance in people after stroke, thereby being a useful training tool and useful for providing feedback to patients. It could also provide clinicians working in stroke pathways across the NHS additional useful numerical detail to quantify changes of DFL, enabling treatment to be targeted to specific foot regions or parts of the kinetic chain to improve functional outcomes through discerning evaluation of treatment intervention/s. Plantar pressure analysis has been used in stroke for treatments such as orthotics already (Nolan *et al.,* 2008).

Operationalisation of plantar pressure assessment in clinical practice could take place within most gym/clinic settings provided that there is enough room for the mat to be set up and for the patient to take a few steps before and after walking on the mat. Patients must be able to walk independently and barefooted onto and over the mat. No other patient requirements exist, as time since stroke does not appear to affect evaluation. Once plantar pressure values have been collected, data could be gathered prior to treatment and viewed in real time with the patient to evaluate and discuss foot loading. This could then be reviewed at the end of the session or after a subsequent course of treatment to evaluate changes. Any evaluation of data should consider changes across foot regions; this work

has proposed that four regions (RFT, MFT, FFT and Toes) are feasible, reliable and able to demonstrate stroke specific deficits and inter-limb differences. How treatments influence foot loading is not yet fully known and has already been discussed in Section 5.4.1.1.

6.3.2 Foot and Ankle Impairments After Stroke and their Impact on Functional Outcomes

Foot characteristics reported in Study 2 demonstrated that among people with stroke 40% had abnormal foot posture, with more extremes of foot posture expressed; however, the majority (60%) demonstrated a neutral foot posture. Foot posture identifies key anatomical features of the structure of the foot and categorises these (pronated, neutral, supinated), with abnormality indicated where extremes of posture are observed (Redmond *et al*., 2008). The findings in this work update previous clinical observations which found that the stroke foot is likely to be supinated/inverted, and research reports documenting pronation (Barnes *et al*., 2008). Interestingly, foot posture was not able to predict mobility and balance outcomes in this work, which differs from previous research (Forghany *et al.*, 2011; 2014). So, while foot posture is a feasible and reliable measure, the role of foot posture in function appears limited. As a feasible and reliable measure, assessment can be conducted and findings utilised with confidence to enable clinicians to manage structural foot changes.

Sway velocity was used to characterise foot motor control. Sway was significantly greater after stroke and reflected poor balance demonstrated by reduced Forward Reach distance and a greater number of falls. As previous literature has reported that quiet standing sway has previously reported ambiguous results on the relationships between postural impairments and occurrence of falls (Weerdesteyn *et al*., 2008). This thesis enhances knowledge of the crucial role of the foot in stabilising the body and the negative impact of reduced neuromuscular control after stroke on its function. People with stroke also had lower peak pressure and smaller contact area on the more-affected foot during stance phase of gait, which may have resulted from altered foot loading. This work is a key report documenting the functional impact of plantar pressure variables (PPP and CA in RFT/MFT/FFT regions) after stroke on walking speed, TUAG and Functional Reach, yet not with Falls Presence. This, for the first time, demonstrates following a stroke how vital

foot contact during stance phase is for function. These functional consequences linked to specific DFL (RFT/MFT/FFT) should prompt interventions to improve foot loading, specifically during stance phase, possibly by influencing any underlying causes such as muscle weakness or spasticity (Chen *et al.*, 2007; Meyring *et al.*, 1997). This has been considered historically by Morag and Cavanagh (1998) in healthy individuals. Most previous work attributes the changes in plantar pressures to spasticity (Meyring *et al.*, 1997), mobility (Chen *et al.*, 2007) and strength (Chen *et al.*, 2007). The work conducted in this thesis found isometric muscle strength was moderately associated with peak plantar pressure ($r = 0.482$, $p < 0.01$). This was not found by Forghany *et al*. (2011), thus advancing current understanding of impairments influencing plantar pressure outcomes; however, this thesis did not demonstrate that spasticity or foot posture had an association with peak pressure outcomes, prompting further exploration (Section 6.5).

Notably, the presence of toe deformities was not statistically different from control participants nor associated with functional outcomes. To date, very little is reported about toe deformity after stroke; this work found that people with stroke reported higher frequencies of toe deformity presence across each type and position, significantly increasing clinical knowledge of such impairments. Hence clinicians may find it useful to observe toe deformity presence during assessment and toe deformity presence should be evaluated and managed in relation to footwear choices and attainment of functional outcomes would be prudent.

Neuromuscular impairments in the stroke group displayed a statistically significant loss in *all* individual and composite isometric muscle strength compared to controls, in particular ankle dorsiflexion and eversion, Additionally, the more-affected side muscle strength was approximately two thirds of the least-affected side. These findings mirror similar work in other stroke cohorts (Bohannon, 2007; Dorsch *et al*., 2016) and advance current understanding by demonstrating statistically significant weakness of hallux DF/PF muscles after stroke. Hallux strength deficits on the more-affected side were, on average, 25% lower than the less-affected side. Furthermore, ankle and hallux weakness are associated with multiple functional outcomes. This gives clinicians additional knowledge of the extent of deficits throughout the foot, not just ankle (DF and PF) and as

such enhances current management. Particularly it prompts clinicians to assess and manage *hallux* muscle strength.

Traditionally ankle DF ROM has not always demonstrated the changes expected after stroke due to the complex interplay of muscular and neural factors found (Lamontagne *et al*., 2002; Lin *et al.,* 2006). This work is no different. Slightly reduced peak ankle and hallux DF ROM was found in the stroke group compared to controls, which was statistically significant, with ankle DF ROM found to associate with falls outcome. It may be that the spasticity present may have caused reductions in responses to dynamic balance which if mild may not have influenced ankle DF ROM. Furthermore, greater functional impact may have been found by evaluating active ROM as Forghany *et al*. (2014) found dynamic reductions in ankle ROM in supination and pronation, which were associated with walking ability.

Despite a greater presence of spasticity, with a predominance in Tardieu scale values of 1 or more in the stroke group, interestingly, passive ROM at the ankle and hallux and ankle plantarflexion spasticity had little association with function. This was unexpected as previous work has reported this at the ankle (Lamontagne *et al.*, 2002). Notably, while mechanisms for the changes at the foot and ankle are not fully understood, these deficits are key to understanding mobility and balance deficits in people with stroke.

Therefore, in addition to age, the presence of stroke increases impairments observed at the foot and ankle and their functional impact. Clinically these findings prompt stroke clinicians to prioritise assessment and management of salient foot and ankle characteristics such as evaluation of sway, foot loading and isometric muscle strength. These deficits can be evaluated even in restrictive environments, such as patients' homes where full functional assessment is precluded, first due to clinical applicability (previous section) and second to their established association with functional outcomes. Furthermore, focusing on fewer measures may help therapists use their time efficiently.

6.4 LIMITATIONS

Chapters 4 and 5 have explored their own study-specific limitations. The two studies were both limited by a few factors, namely type of population recruited, study design/analysis, clinical focus and focus on specific deficits at the foot and ankle.

Limitations of recruiting using the inclusion criteria used in Study 1 and 2 were that those people with stroke are likely to demonstrate sampling bias by being well motivated and more independent. They therefore may not present with altered foot characteristics, which may have impacted on mobility and balance performance. Potentially, they may be above the threshold at which the altered foot characteristics influence these outcomes, i.e. by being able to mobilise > 10 m. In addition, a potential selection bias is acknowledged. While inclusion criteria were broad, there are clear subsections of the stroke population who have not been represented in the work; namely acute survivors, those unable to mobilise 10 m independently and those with other co-morbidities affecting mobility and foot structure. Similarly, limitations of recruiting control participants with these inclusion criteria were that it is likely to have gained a convenience sample who were more likely to be active and therefore walk faster and be stronger than other age- and gender-matched counterparts. This may, therefore, have skewed results to show a potential gap between people with stroke and those without.

The study was purposefully designed to include clinically suitable tools; however, this clinically focused approach also presented some challenges, and as a result some areas of interest were not explored, e.g. ankle inversion and eversion and muscle/joint stiffness. The reasons for this are explained in Chapter 4, Section 4.7.4. Thus, these aspects remain an area for further work.

The aim of the current work was focused on the foot and ankle; therefore, effects of knee and hip and other body segments were not accounted for when exploring the variance in mobility and balance outcomes. Other factors not evaluated in this work may also have contributed to walking speed; these include impairments in muscle strength, ROM and spasticity at the hip and knee (Hsu *et al.,* 2003). The lower R^2 values found for Forward Reach and Falls Report may be due to impairments in muscle strength and ROM at the hip and knee (Kligyte *et al*., 2003), and other unexplored factors. Previous research has

found upper limb activity, trunk control, hip and knee strength contribute to standing Forward Reach (Shumway-Cook and Woolacott, 2011; Dickenstein *et al.*, 1984). Falls reporting is multifaceted (Walsh *et al.*, 2017; Ashburn *et al.*, 2008) and therefore cannot be fully evaluated by looking at the foot and ankle only. For this reason, the FES was used to further understand the sample evaluated. Fear of falling was moderate to high in the stroke group, suggesting not just physical elements contributing to falls.

The focus of this thesis has not included changes in foot pain and sensation perception, which is reported to be altered after stroke. Reasons for their exclusion from this thesis are found in Chapter 1. Other work conducted as part of the FAiMiS study now published by Gorst *et al.* (2018) found that sensory perception influenced mobility and balance outcomes after stroke. Other variables, not assessed as part of this thesis, may also influence dynamic plantar loading characteristics. For example, as Nurse and Nigg (2001) demonstrated, sensory perception may also play a role in a group of 10 healthy adults; Nurse and Nigg (2001) altered sensory inputs using ice and found lower peak pressures and pressure time integrals in healthy individuals. Similar findings have been found in diabetics where altered sensory perception is commonplace (Dyck *et al*., 2005). Other symptoms found at the foot after stroke, including pain and swelling (Gorst *et al.*, 2016), may also influence plantar pressure changes. These clinical symptoms found after stroke may further inform understanding of what influence plantar pressure analysis, thus making plantar pressure analysis an even more valuable tool for assessment.

6.5 RECOMMENDATIONS FOR FURTHER WORK

This work has established three key aspects: clinically robust measures of foot and ankle impairments found at least three months after stroke, the extent of these deficits and their functional impact. However, it has left a number of areas unexplored:

- those with severe stroke
- the changes in deficits over time
- effects of treatment of foot and ankle deficits
- whether measures are acceptable for use in the clinical setting
- relationships between impairments and plantar pressure outcomes
- the interrelationship between static and dynamic measures.

Future work has been discussed in both Study 1 and 2 in Chapters 4 and 5, respectively; key areas to be explored further are outlined below.

1. *Further research needs to explore foot and ankle impairments in people with stroke with lower functional or ambulatory status (e.g. FAC 2/3).* This work was representative of an ambulatory community-dwelling group of people with stroke; however, some people after stroke are left with restricted mobility even in their own home (Langhorne *et al*., 2009). Whether the impairments studied in this thesis are present and to a greater severity is not currently known, nor is their impact on function.

2. *Further research needs to conduct longitudinal analysis to better understand functional recovery of foot and ankle impairments after stroke.* As the current work is cross sectional in design, future work should look at the changes to foot and ankle impairments over time in relation to mobility and balance outcomes. This will better determine the influence of these deficits in recovery after stroke.

3. *Further research needs to explore the effects of targeted foot and ankle rehabilitation on improving functional outcomes.* Areas of research must elucidate which treatments targeted at the foot and ankle are most effective in dealing with the deficits that are being reported and researched after stroke. This might include interventions such as mobilisation and tactile stimulation, FES applied to the ankle/foot, or application of orthotics. Alternatively, training programmes for muscle strengthening and ankle and foot flexibility could be developed and applied. These interventions should target the specific foot and ankle deficits highlighted in this work (i.e. plantar pressure, isometric muscle strength and ankle ROM) and evaluate them alongside functional outcomes.

4. *Future research needs to address acceptability of foot and ankle assessment across clinical settings, the multidisciplinary team and its optimal timing in the stroke pathway.* While reliability and feasibility has been established of the measures in this work, acceptability within clinical settings, across multidisciplinary team members and timing within the stroke pathways has not.

As the tools and protocols may be useful in multiple clinical settings where space (and time) is limited for full assessment of mobility, this should be evaluated.

5. *Further research needs to understand the impairments (e.g. muscle strength) and factors (e.g. age, weight, walking speed) associated with altered DFL after stroke.* Plantar pressure variables appear useful clinical outcomes which associate with foot impairments and predict mobility outcomes after stroke. Ascertaining what impairments contribute to these observed changes and the mechanisms of this is crucial for enhanced interpretation of plantar pressure measures. This could be conducted using a hypothesis such as: '*Structural and functional foot characteristics after stroke are predictive of plantar pressure variables*'. This will contribute to the current field of work by enabling clinicians to understand which impairments influence DFL. It would also help researchers to understand what factors need to be controlled for in future studies using plantar pressure analysis.

6. *Further research needs to establish whether static measures can inform dynamic measures of foot function after stroke*. This would include ascertaining the functional significance (if any) of the asymmetrical foot types and toe deformity after stroke. This could be accomplished using a hypothesis such as: '*Static measures of foot function are predictive of dynamic measures of foot function*'. This may aid assessment approaches by enabling clinicians to infer dynamic implications of specific static measures thus increasing the efficiency of assessment processes.

6.6 CONCLUSION: THE FOOT AND ANKLE AFTER STROKE IS CLINICALLY MEASURABLE AND FUNCTIONALLY RELEVANT

This thesis has demonstrated that selected *foot and ankle impairments after stroke are clinically measurable and functionally relevant.* Empirical evidence has been provided about measures that are clinically feasible and reliable for use after stroke and include measures of static foot posture, toe deformity and DFL. Also, isometric muscle strength

testing and bespoke tools for assessing peak DF range applied at the ankle and hallux have been established as feasible and reliable. The use of these tools to evaluate foot and ankle impairments has contributed to the understanding of stroke differences as distinct from age-related changes. After stroke people have greater extremes in foot posture, greater COP velocity (sway), lower peak pressures and smaller contact area on the more-affected side, weaker ankle and hallux muscles (a third lower than control participants), reduced ankle and hallux DF ROM and have greater presence of spasticity (often mild only) compared to age- and gender-matched controls. This is the first report of findings that have shown altered foot loading and weaker hallux muscles after stroke. Deficits in all impairments measured after stroke were greatest in the more-affected limb. Furthermore, stroke participants were also slower walkers, had poorer static balance and had higher falls frequency. Out of the 10 foot and ankle impairments included in regression analysis, isometric muscle strength, sway velocity and, uniquely, altered plantar pressure, predicted mobility, balance and falls outcomes after stroke. These findings demonstrated the functional relevance of the foot and ankle impairments after stroke.

This work may advance practice in three ways. First, it may encourage adoption of clinically feasible and reliable tools into clinical practice. Second, it demonstrates the extent of foot and ankle deficits after stroke and their functional relevance. These two aspects enhance current stroke management by demonstrating that if specific foot and ankle impairments after stroke are evaluated and managed, functional outcomes may improve. Lastly, the current work may inform future work in evaluating plantar pressure changes and improving functional outcomes after stroke by treatment of altered or abnormal ankle and foot characteristics found after stroke.

APPENDICES

APPENDIX 1: FOOT AND ANKLE ANATOMY AND FUNCTION

The Foot and Ankle

The foot complex consists of 26 bones and 33 joints and more than 100 muscles, tendons and ligaments (Palastanga *et al*., 2002). It is clear why the human foot has been described by Leonardo da Vinci as "*a masterpiece of engineering and a work of art"*. Three bones, the tibia, fibular and talus combine to form the ankle joint: the inferior fibiotalar, the tibiotalar joint and the subtalar joint (Perry and Burnfield, 2010). The inferior fibiotalar joint is formed by the rough, convex surface of the medial side of the distal end of the fibular, and a rough concave surface on the lateral side of the tibia. The head of the talus, as the superior aspect of the foot, articulates with the distal tibia bone in the calf forming the saddle-shaped, synovial hinge, the tibiotalar joint (Palastanga *et al.*, 1989), which allows for ankle dorsiflexion and plantarflexion. Finally, the subtalar joint, comprised of the articulation between the calcaneus and the talus, which is cylindrically shaped, allows for supination and pronation, abduction and adduction. These joints are shown in Figure A1.1.

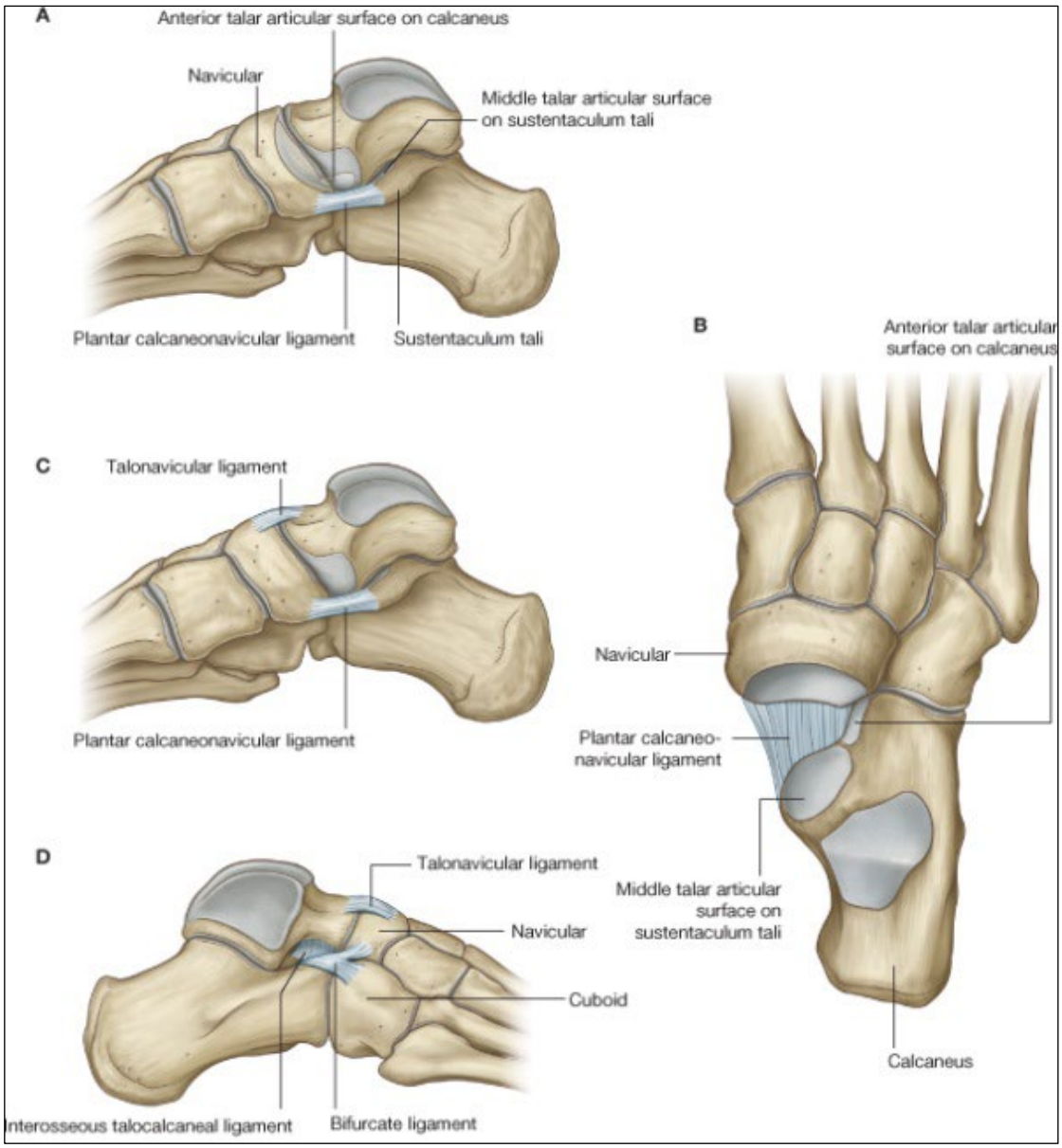


Figure A1.1 Anatomy of the Ankle Joint (*Grey's anatomy for students,* used with permission, www.studentconsult.com)

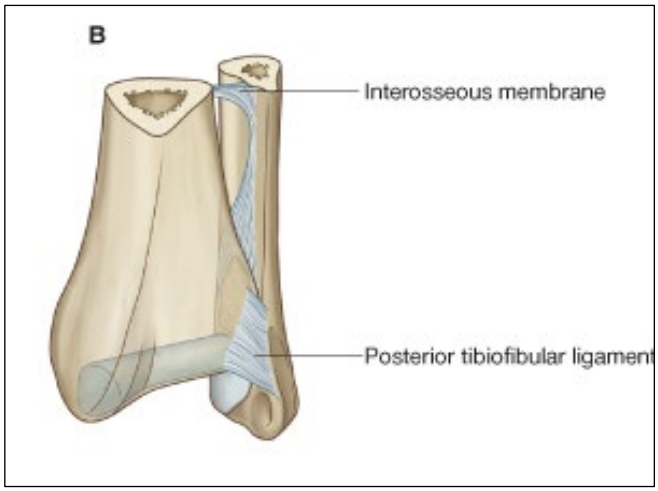


Figure A1.2 Inferior Tibiotalar Joint (Grey's anatomy for students, used with permission, www.studentconsult.com

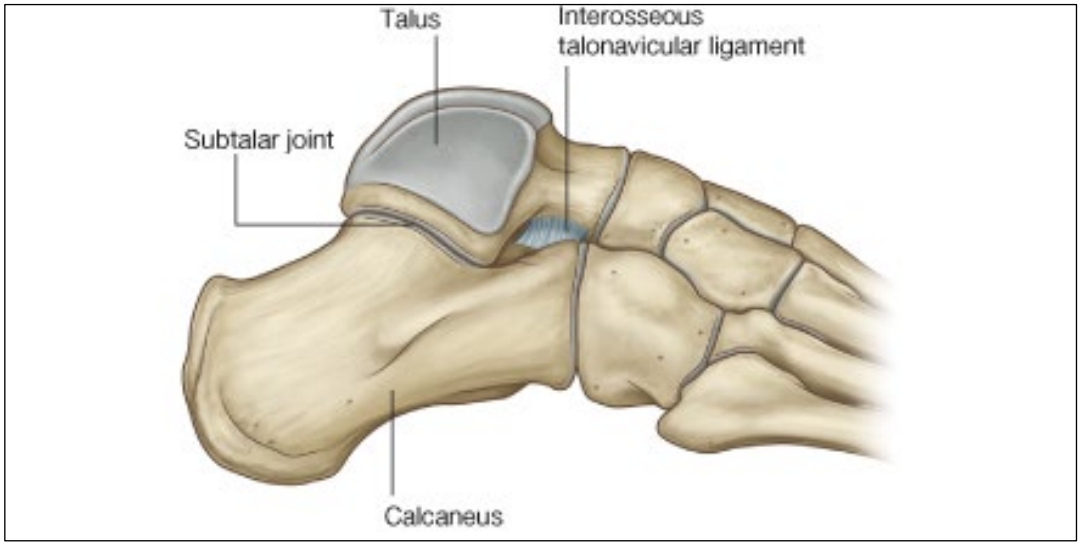


Figure A1.3 Subtalar Joint (*Grey's anatomy for students,* used with permission, www.studentconsult.com**)**

The axis of the tibiotalar joint, which has the largest ROM, is oblique by 10° in the coronal plane and 20° in the transverse plane, with the long axis of the foot in 17° from the midline (Perry and Burnfield, 2010). Thus, the ankle joint (TT) has biplanar movement resulting in plantarflexion with inversion and dorsiflexion with eversion. Overall, the ankle complex allows for multiplanar motion. ROM at each joint is shown in Table A1.1.

Table A1.1 Movements, Joints and Key Muscles of the Ankle and Foot (Palastanga *et al*., 1989)

Movement	Joints	Range of Motion	Muscles
Ankle dorsiflexion	Tibiotalar Subtalar	30° dorsiflexion, 20° eversion at the hallux metatarsophalangeal joint (MTPJ) 70° extension and 45° flexion	Tibialis anterior Extensor digitorum longus Extensor hallucis longus Peroneus tertius
Ankle plantarflexion	Tibiotalar Subtalar	50° plantarflexion	Gastrocnemius Soleus Plantaris Peroneus longus Tibialis posterior Flexor digitorum longus Flexor hallucis longus
Ankle inversion	Subtalar, Transverse (mid) tarsal	30° inversion	Tibialis posterior Tibialis anterior
Ankle eversion	Subtalar Transverse (mid) tarsal	20° eversion	Peroneus longus Peroneus brevis Peroneus tertius
Hallux dorsiflexion	Hallux MTPJ Hallux IPJ	70° extension	Extensor hallucis longus
Hallux plantarflexion	Hallux MTPJ Hallux IPJ.	45° flexion	Flexor hallucis longus Flexor hallucis brevis

Movements at the ankle and foot are controlled by muscles which work over the subtalar, and transverse (mid) tarsal joints. Other muscles cross the ankle and foot to distal insertions on the toes where they contribute to toe flexion/extension as well as

contributing to ankle movements. These muscles are shown in Figure A1.4 and Figure A.1.1. and their actions are outlined in Table A1.1. It is this talocrural articulation on an oblique axis that provides movement in the sagittal plane, dorsiflexion/plantarflexion; frontal plane, inversion and eversion; and transverse plane adduction and abduction. Furthermore, combined movements occur producing triplanar motion called pronation and supination. In addition to the talocrural joint, multiple articulations in the forefoot provide even more degrees of freedom (Palastanga *et al.*, 1989).

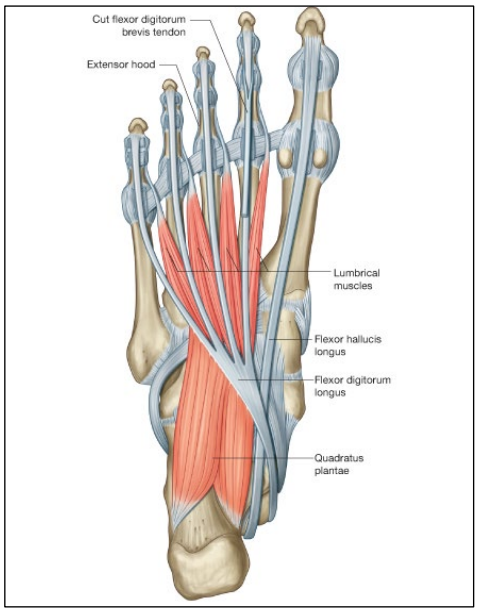


Figure A1.4 Flexor Muscles of the Foot (*Grey's anatomy for students,* sed with permission, www.studentconsult.com)

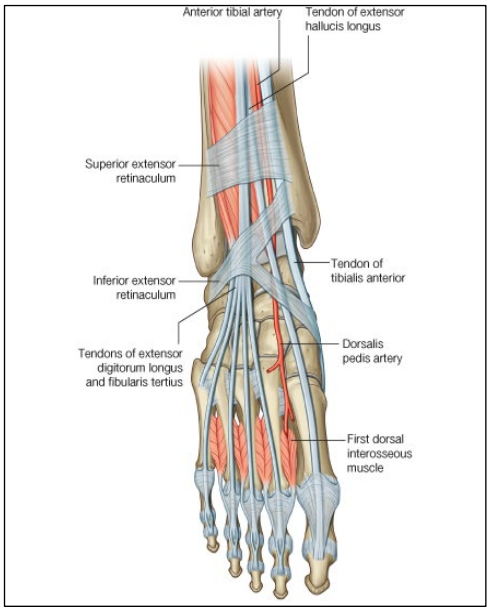


Figure A1.5 Extensor Muscles of the Foot (*Grey's anatomy for students,* used with permission, www.studentconsult.com)

The foot is often described by its posture and regions. Due to the multiple functions the foot performs, it is often divided into three regions known as the rearfoot, mid-foot and forefoot region (Figure A1.6) (Richards, 2008), which are often used to discuss its different functions. The foot is made up of three key arches, the medial longitudinal arch, the lateral longitudinal arch and the transverse arch, which dictate postural features shown in Figure A1.7 and have both passive and dynamic roles during function. Normal foot posture is characterised by the anatomical and structural features of the foot such as medial arch height, navicular height, calcaneal position, toe position or deformity (Redmond *et al.*, 2008). Foot posture is classified broadly as neutral, pronated or supinated depending on foot characteristics present (Redmond, 2005). This is illustrated in detail in the foot posture index (FPI) as shown below in Figure A1.8 using features of both rearfoot and forefoot regions as well as viewing these in multiple planes. The neutral foot is highlighted by the blue circles. characteristics of this index are explored in later Chapters 2 and 3.

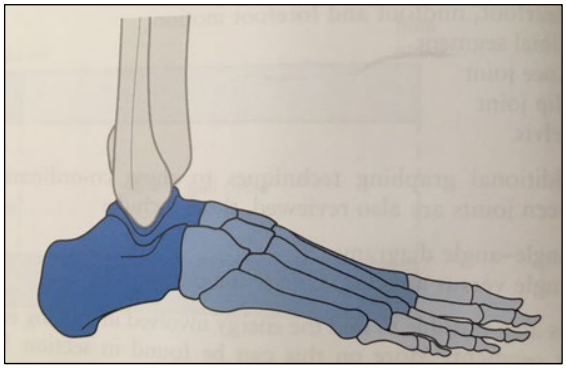


Figure A1.6 Regions of the Foot from Left to Right: Rear Foot, Mid-foot, Forefoot (Richards, 2008)

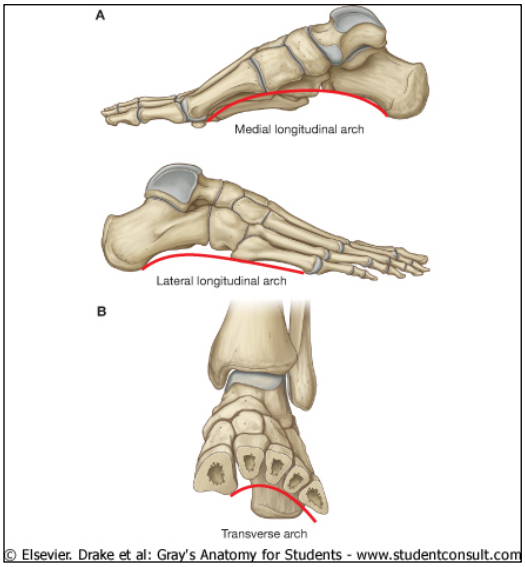
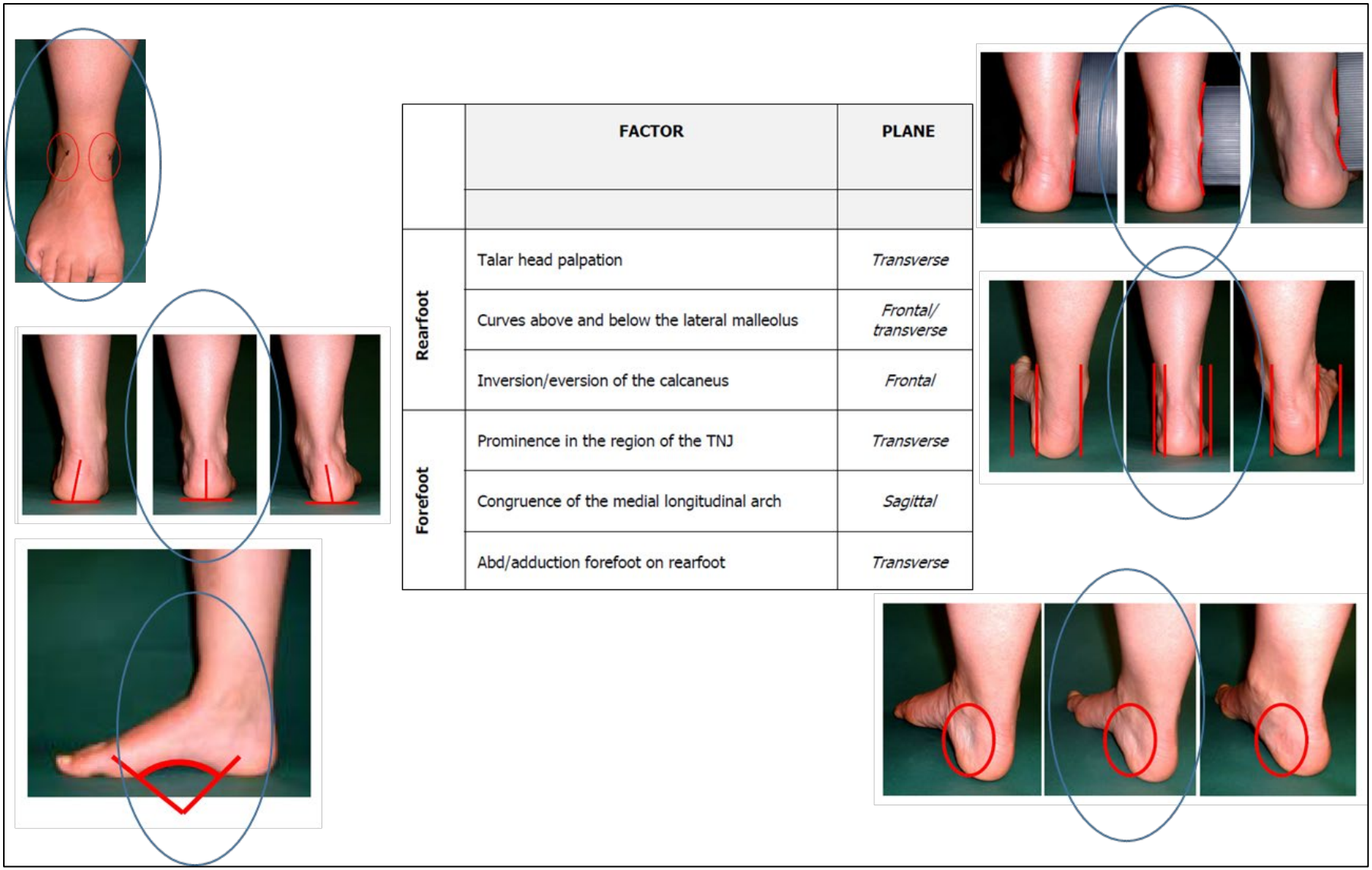


Figure A1.7 Arches of the Foot, a) Medial Longitudinal, b) Transverse



	FACTOR	PLANE
Rearfoot	Talar head palpation	*Transverse*
	Curves above and below the lateral malleolus	*Frontal/ transverse*
	Inversion/eversion of the calcaneus	*Frontal*
Forefoot	Prominence in the region of the TNJ	*Transverse*
	Congruence of the medial longitudinal arch	*Sagittal*
	Abd/adduction forefoot on rearfoot	*Transverse*

Figure A1.8 The Foot Posture Index, Demonstrating Neutral Alignment, Circled in Blue, (Redmond *et al.*, 2008)

The foot and ankle together produce a highly adaptable unit, forming a biomechanical foundation for the lower limb upon which the rest of the body relies. The functions of the foot include: relaying somatosensory and proprioceptive information about foot-floor contact; control of static and dynamic balance or stability; and functional activity such as stepping, turning, walking and running (Shumway-Cook and Woolacott, 2011; Perry and Burnfield, 2010). In bipedal stance, feet provide the primary surface of interaction with the environment during locomotion (Razak *et al.*, 2012). Flexibility and motor control throughout the mid-foot and forefoot regions allow accommodation to a variety of floor surfaces; however, this ability deteriorates with age (Menz, 2015). The ankle is crucial for standing balance performing specialised balance reactions, typified by the ankle strategy, which restores equilibrium after a minor displacement of centre of gravity (Shumway-Cook and Woolacott, 2011; Pollock *et al.*, 2000). Additionally, the hallux has a pivotal role in standing balance in bipedal and single leg stance as Chou *et al*. (2009) demonstrated in a study of 30 females (22.1 ±1.9 years old). Using a constrained versus unconstrained hallux during balance testing resulted in significantly reduced single leg stance balance and poorer directional control during forward and back weight shifting during constrained conditions.

In gait, the foot is the distal anchor about which the lower limb pivots to achieve an efficient cyclical pattern (Perry and Burnfield, 2010) and it is the only contact the body has with the ground during bipedal functional tasks (Forghany *et al.*, 2011). During gait, the foot has four roles as outlined by Perry and Burnfield (2010). First, the foot acts as a rocker, a pivot point, providing heel and forefoot rockers to transfer weight forward during gait controlled by DFs activating eccentrically (Perry and Burnfield, 2010; Richards, 2008). Second, the foot also aids stability during stance as it acts as support through the heel, flat foot and forefoot support phases where the PFs work eccentrically to control the tibia over the foot (Perry and Burnfield, 2010; Richards, 2008). Third, the foot acts as a shock absorber on loading. Fourth, its role is to propel the whole lower limb, and therefore the body, during the gait cycle (Perry and Burnfield, 2010; Richards, 2008). Arcs of motion at the ankle allow for shock absorption, progression and foot clearance (Perry and Burnfield, 2010). This motion totals between 20–40° in the sagittal plane but varies throughout the gait cycle (Richards, 2008). Notably, even the toes form an essential part of the gait cycle acting as the ‘toe break’ as they arc through their ROM at the MTPJ

from 25° at loading through to 55° at push off (Perry and Burnfield, 2010); Hopson *et al*. (1995) reports approximately 65° is required for normal walking. Furthermore, the hallux is essential to triggering the windlass mechanism, which is crucial to providing tension in the longitudinal arch for push off (Richards, 2008).

Therefore, the intricacies of the foot complex and its pivotal role in functional tasks mean that alterations in foot structure may influence mobility and balance, this is seen in Chapters 1 and 2.

APPENDIX 2: LITERATURE SEARCHES

Search 1: Presence of clinically measurable foot characteristics and neuromuscular impairments found after stroke

- Stroke, cerebrovascular accident, hemiplegia, brain injury, neurological condition

AND

- Foot, ankle, subtalar joint, tibiotalar joint, lower limb, leg, calf

AND

- Static foot posture, foot posture, foot position, foot deformity

OR

- Toe deformity, hammer toe, claw toe, Hitchhikers' toe

OR

- Dynamic foot loading, pedobarography, plantar pressure analysis

OR

- Muscle strength, isometric strength, muscle weakness

OR

- Spasticity, hypertonicity, hyper excitability, hyperreflexia, stiffness, high tone

OR

- Range of motion, range of movement, passive range, active range, peak angle, maximum angle

S1	CEREBROVASCULAR ACCIDENT	Alternative searches: older people, older adults, over 65 years.
S2	stroke	
S3	"cerebrovascular accident"	
S4	"CVA"	
S5	"acquired brain injury"	
S6	"traumatic brain injury"	
S7	"head injury"	
S8	"TBI"	
S9	"ABI"	
S10	hemiplegia	
S11	hemiparesis	
S12	"upper motor neuron lesion"	
S13	ACQUIRED BRAIN INJURY	
S14	TRAUMATIC BRAIN INJURY	
S15	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14	

S16	FOOT	
S17	ANKLE	
S18	LEG	
S19	“lower limb”	
S20	“lower extremity”	
S21	S16 OR S17 OR S18 S19 OR S20	
S22	Foot posture	Alternative searches: other impairments
S23	Foot position	
S24	Static foot posture	
S25	Foot posture index	
S26	Foot deformity	
S27	supination	
S28	pronation	
S29	S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR 28	
S30	Prevalence	
S31	Presence	
S32	Severity	
S33	Frequency	
S34	Incidence	
S35	S30 OR S31 OR S32 OR S33 OR S34	

Search 2: Impact of foot and ankle characteristics on mobility, balance and falls after stroke.

Same as above …

AND

- Mobil OR, walk* OR, gait OR step, OR stance OR ambulat OR weight bear*

AND/OR

- Balance, OR postural control OR, postural stability OR, static balance OR, dynamic balance OR, standing balance

AND./OR

- Fall OR, fall risk

S1	CEREBROVASCULAR ACCIDENT	Alternative searches: older people, older adults, over 65 years.
S2	stroke	
S3	“cerebrovascular accident”	
S4	“CVA”	
S5	“acquired brain injury”	
S6	“traumatic brain injury”	
S7	“head injury”	
S8	“TBI”	

S9	"ABI"	
S10	hemiplegia	
S11	hemiparesis	
S12	"upper motor neuron lesion"	
S13	ACQUIRED BRAIN INJURY	
S14	TRAUMATIC BRAIN INJURY	
S15	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14	
S16	FOOT	
S17	ANKLE	
S18	LEG	
S19	"lower limb"	
S20	"lower extremity"	
S21	S16 OR S17 OR S18 S19 OR S20	
S22	Foot posture	Alternative searches: other impairments
S23	Foot position	
S24	Static foot posture	
S25	Foot posture index	
S26	Foot deformity	
S27	supination	
S28	pronation	
S29	S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR 28	
S30	WALKING	Alternative searches: balance and falls
S31	GAIT	
S32	WEIGHT BEARING	
S33	walk*	
S34	gait	
S35	mobil*	
S36	step	
S37	stance	
S39	ambulat*	
S40	"weight bear"	
S41	S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40	

Search 3: Clinimeteric proprieties of assessment tools at the foot and ankle after stroke

Same as Search 1 with the following terms added in place of prevalence etc.

- Assess*, evaluate, measure, quantify
- Feasib*,
- Reliab*, inter* intra*, repeatability,

- Valid*
- Clin* relevan*

S30	Assessment
S31	Feasibility
S32	Reliability,
S33	Validity
S34	Clinical relevance
S35	S30 OR S31 OR S32 OR S33

APPENDIX 3: SEARCH 1 AND 2 PAPERS (TABLE A3.1) AND SUMMARY FINDINGS (TABLE A3.2)

Table A3.1: KEY PAPERS Key papers are highlighted in grey. TSS = Time since stroke

Impairment	Author and Date	Study design and Quality (CASP score)	No. and condition of participants	Relevance (I = Impairment or F = Function)	Key results
Static foot posture	Forghany *et al*. (2011)	Cross-sectional	*n* = 72 stroke Age: 68.3 ±12.6 years TSS: 16.4 ±53 months	I + F	Using age-adjusted FPI scores[36], 30% of participants deviated from normal posture on the more-affected side: • pronated (16%) • supinated (13%) Abnormal foot posture more frequent in people limited to indoor walking, FAC, $p < 0.01$.
	Jang (2015)	Cross-sectional	*n* = 31 stroke Age: 63.4 ±7.5 years TSS: 24.81 ±16.8 months *n* = 32 healthy adults Age: 63 ±8 years	I	FPI total scores (−12 to 12): • Stroke group, paretic side: −0.25 ±2.1, • Stroke group, non-paretic side: 1.74 ±2.3 • Control group, dominant foot: 2.12 ±3.4 Statistically significant differences found between paretic and non-paretic side ($p < 0.05$), and control group ($p < 0.05$). Strong negative correlation between MAS[37] and FPI ($r = 0.78$).

[36] FPI = foot posture index, age-adjusted scores, (Section 4.3.1.1, Table 4.3).
[37] Modified Ashworth scale = 0–3 rating scale for spasticity 0 = none, 1 = mild, 2 = moderate, 3 = severe.

	Kunkel *et al*. (2017)	Cross-sectional	23 stroke, Age: 75.09 ±7.57 years, TSS: 8 years (±6.38) 16 controls, Age: 73.44 ±8.35 years.	I + F	This study explored differences between (eight) foot and ankle characteristics of stroke patients and healthy controls and whether these foot and ankle problems differ between stroke fallers and non-fallers. Foot posture: Greater pronation in stroke (compared to controls) $p = 0.08$ (8 FPI v. 4.5). Greater pronation in fallers (compared to non-fallers), $p = 0.027$.
Toe deformity	Kunkel *et al*. (2017)	Cross-sectional	23 stroke, Age: 75.09 ±7.57 years, TSS: 8 years (±6.38) 16 controls, Age: 73.44 ±8.35 years.	I + F	Toe deformity: HV found in 57% stroke and 81% controls, no differences found between fallers ($n = 12$ and non-fallers, $n = 11$), $p > 0.05$.
	Laurent (2010)	Prospective	39 stroke Age: 58.4 years TSS: 0 months	I + F	46% (18/39) of people with a unilateral stroke, who demonstrated active toe clawing during standing or walking up to three months post-stroke. 15 out of 18 (83%) regained average functional capacities (Barthel[38]: 30–70, PASS[39]: 15–33, FAC[40]: 3–4) and was significantly linked to equinus and/or varus foot, $p < 0.0001$.

[38] Barthel Index used to evaluate motor impairment of the leg and patients' functional abilities.
[39] PASS = postural assessment scale for stroke patients to evaluate balance function
[40] FAC = Functional ambulatory classification to evaluate mobility function.

	Mickle *et al.* (2009)	Cohort study	312 older people Fallers 71.6 ±6.6 years Non-fallers 71.2 ±6.7 years	I + F	Fallers v. non-fallers more likely to have toe deformity: HV (relative risk [RR] = 2.36; 95% CI = 1.03–5.45; $p < 0.01$) and lesser toe deformity (RR = 1.32; 95% CI = 1.04–1.69; $p < 0.01$). Toe deformity was associated with hallux muscle strength: participants who displayed moderate-to-severe HV ($n = 36$) or a lesser toe deformity ($n = 74$) had significantly reduced strength of the hallux and lesser toes, respectively, compared to those without these foot problems ($p < 0.01$; fallers displayed significantly less strength of the hallux (11.6 (SD 6.9) v. 14.8 (SD 7.8)% BW, $p < 0.01$) and lesser toes (8.7 (SD 4.7) v. 10.8 (SD 4.5)% BW, $p < 0.01$).
	Yelnik *et al.* (2003)	Case series	11 with HHT out of 450 stroke Age: 51.7 ±8.8 years ($n = 11$)	I	HHT[41] is seen in approximately 2% (11/450). Of these 11: • 36% had foot pain (4/11), • 100% had shoe difficulties (11/11), • 55% had abnormal posture of the foot (6/11)
	Mickle *et al.* (2011b)	Cross-sectional	312 older people HV Age: 71.9 ±6.7 years HV control Age: 71.9 ±6.6 years	I + F	Older people with HV ($n = 36$) and lesser toe deformities ($n = 71$) The results indicated that, although there were no effects of toe deformities on spatiotemporal gait characteristics or postural sway, the relationship between toe deformities and falls may be mediated by factors other than changes in spatiotemporal gait parameters or impaired postural sway. 1 out of the 12 gait measures taken: variability of gait speed for lesser toe deformity v. controls, 6.2 ±2.6 cm^{-1} compared to 5.1 ±2.0 ($p < 0.05$).

[41] HHT = Hitchhiker's toe

			Lesser Toes deformities Age: 73.2 ±6.9 years Lesser Toes deformity control Age: 73.1 ±6.9 years		
	Spink *et al*. (2011)	Cross-sectional	305 older people, fallers Age: 73.9 ±5.9 years	I + F	Presence of HV (122/305, 40%) assessed by Manchester scale affected performance on the lateral stability and coordinated stability tests ($p < 0.05$). Therefore, toe clawing as a risk factor for impaired balance and walking ability.
Plantar Pressure Analysis	Meyring *et al*. (1997)	Cross-sectional/ cohort study Empirical descriptive study	18 stroke Age: 50.2 ±16.4 years TSS: not specified 111 control Age: 27.2 ±8.4	I	Peak pressures in the stroke group were found to be statistically significantly different from the control group (retrospective cohort of 111) for 3rd and 5th MTHs. (Where 3rd MTH 286 (173) kPa stroke v. 361 (162) kPa control, and 5th MTH 150 (l00) kPa stroke v. 213 (125) kPa control, $p < 0.05$.) Hemiparetic cohort was stratified according to spasticity rating using the AS[42] and found only peak pressures for AS = 2 at the 3rd

[42] AS, Ashworth scale = 0–2 rating sale for severity of spasticity

					MTH were found to be significantly different, $p < 0.05$, (AS 0 395 (163) kPa; AS 1: 275 (144) kPa; AS 2 146 (l00) kPa). Overall, lower peak pressures were found under the lateral forefoot, $p < 0.05$.
	Forghany *et al*. (2015)	Cross-sectional	20 stroke 15 controls *Age and TSS data not available.*	I + F	People with stroke bore greater pressure on the affected side through the lateral heel and lesser toes ($p = 0.01$) and less through the medial and central fore foot ($p = 0.05$) areas than healthy controls. Regression analysis demonstrated that those with higher medial heel pressures were more likely to be household walkers (odds ratio = 1.11, $p < 0.05$).
	Chisholm *et al*. (2011)	Cohort	57 stroke Gait aid group, ($n = 25$) Age: 63.8 ±12.5 years, TSS 28.8 ±28.0 months no gait aid group ($n = 32$) Age: 62.2 ±11.8 years, TSS: 46.1 ±31.5 months	I + F	Evaluated spatiotemporal gait measures and centre of pressure excursion as a measure of stability in people with stroke. Asymmetry in COP excursion was associated with reduced forward progression during gait ($p < 0.05$).

	Mickle *et al*. (2011b)	Cohort	312 older people, fallers Hallux valgus (n = 36) Age: 71.9 ±6.7 years HV control (n = 36) Age: 71.9 ±6.6 years Lesser Toes deformity (n = 71) Age: 73.2 ±6.9 years LTD control (n = 71)		Altered plantar loading profiles in those with a history of falls. (toe deformities contributed to altered plantar pressure distribution with higher pressure found in the location of the deformity, e.g. HV had increased over first and second metatarsals) reported higher peak pressure under 2nd–5th metatarsals in those with lesser toe deformities. PPP: statistically significant differences ($p < 0.05$) were found between HV and controls at 1st MTH, 2nd MTH and between LTD and controls at 2nd MTH, 3rd MTH, Toes 2 and Toes 3–5. Almost all PP were higher in the toe deformity group (excluding HV toes 3–5). PTIs were also explored: statically significant differences ($p < 0.05$) found between HV v. control, at 1st MTH; and between LTD v. control at 2nd MTH, 3rd MTH, toes 2 and toes 3–5.
	Menz and Morris (2006)	Cross-sectional	172 older adults	I	13–53% and 4–40% of variance in maximum force and peak pressures respectively were explained by clinical factors. Body weight was a key contributor to PPP in all regions, except: PPP at MFT region was associated with arch index; 1st MTPJ PPP was associated with MTPJ ROM, PPP at hallux region was explained by hallux PF strength, 1st MTPJ ROM, and HV deformity.

Muscle weakness	Andrews and Bohannon (2000)	Retrospective chart review	48 stroke Age: 63.8 ±11.6 years TSS: 9.6 ± 5.8 (31 completed initial and final evaluation)	I	Evaluated the distribution of static muscle strength impairments in a group of in an inpatient rehabilitation setting, testing eight muscle groups bilaterally, using hand-held dynamometry at two time points (initial and final, gap = 25.9 ±13.5 days). Initial: Ankle DF muscle strength measured 32.2% normal on the more-affected side (74.9 N m compared to 181.1 N m), and 75.8% normal in the less-affected side. Final: 44.3% on the more-affected side and 83% normal in the less-affected side (106.2 N m compared to 198.8 N m respectively).
	Lamontagne *et al*. (2002)	Cross-sectional	30 stroke Age: 57.8 ±10.8 years TSS: 44–153 days 15 healthy controls 59.1 ±9.8 years	I	Muscle weakness during walking using 3D motion analysis, force plate analysis, electromyography and isokinetic dynamometry Reduced peak ankle PF moments during the stance phase of gait, reported on both paretic and non-paretic sides, with paretic sides demonstrating greater deficits Swing phase Dfmax (greatest DF moment) tended to be reduced (not significantly) on the paretic side of the patients compared with control values. This reduction was neither associated with excessive antagonist coactivation nor to PF hyperactive stretch reflexes, but rather to an increased PF passive stiffness.
	Dorsch *et al.* (2012)	Cross-sectional observational	60 stroke Age: 69 ±11 years TSS: 1–6 years	I + F	Muscle strength (N) measured by a HHD. Ankle PFs 93 ±53 (0–239), Ankle DFs 66 ±37 (0–189), Ankle invertors 66 ±41 (0–158), Ankle evertors 55 ±40 (0–136) Positive association with walking speed: ankle DFs (r = 0.50, p = 0.00), Ankle PFs (r = 0.29, p = 0.03),

					Ankle evertors (r = 0.33, p = 0.01) Found that (together with hip flexor strength) ankle dorsiflexion accounted for 31% of the variance found in walking speed (p < 0.01) with poor to moderate associations with ankle dorsiflexion, plantarflexion and eversion and walking speed.
	Bohannon (2007)	Literature review paper	N/A	I + F	Gait comfortable speed Paretic ankle plantarflexion & dorsiflexion; knee extension & flexion; hip flexion, extension, & abduction (isometric force) r_s = 0.73–0.83 (Bohannon, 1989) Non-paretic ankle plantarflexion & dorsiflexion; knee extension & flexion; hip flexion, extension, & abduction (isometric force) r_s = 0.34–0.57 (Bohannon, 1989) Gait distance Paretic ankle plantarflexion & dorsiflexion; knee extension & flexion; hip flexion, extension, & abduction (isometric force) r_s = 0.68–0.79 (Bohannon, 1989) Stair ascent, Paretic hip flexion & extension; knee flexion, & extension; and ankle dorsiflexion (isometric force), r_s = 0.73–0.85 (Bohannon & Walsh, 1991)
	Dorsch *et al*. (2016)	Cross-sectional observational	60 stroke Age: 69 ±11 years TSS: 1–6 years 35 controls Age: 65 ±9 years	I + F	Evaluated maximal isometric strength of 12 muscle groups in lower limbs using HHD. The affected lower limb of the participants with stroke was significantly weaker than that of the control participants for all muscle groups (p < 0.01). Strength (adjusted for age, gender and body weight) was 48% (range, 34%–62%) of that of the control participants. The most severely affected muscle groups were hip extensors (34% of controls), ankle DFs (35%), and hip adductors (38%), and the least severely affected muscle groups were ankle

					invertors (62%), ankle PFs (57%), and hip flexors (55%). The intact lower limb of the participants with stroke was significantly weaker than that of the control participants for all muscle groups ($p < 0.05$) except for ankle invertors ($p = 0.25$). Strength (adjusted for age, gender and body weight) was 66% (range, 44%–91%) of that of the control participants. The most severely affected muscle groups were hip extensors (44% of controls), ankle DFs (52%) and knee flexors (54%).
	Lin *et al*. (2006)	Cross-sectional, descriptive analysis of convenience sample	68 Stroke Age: 61.69 ±13.97 years TSS: 3.91 ±5.87 years	I + F	Evaluated maximal isometric strength APF and ADF using HHD, Spasticity index using EMG, muscle lengthening velocity and ankle DF ROM. PF strength (% of BW) Unaffected 50.04 ±16.63(16.6–91.2) v. affected 37.16 ±19.13(11.8–92.5), $p < 0.000$. DF strength (% of BW) Unaffected 34.57 ±9.84(14.49–67.46) v. affected 22.32 ±13.85(2.2–49.8), $p < 0.000$. Regression analysis: Ankle DF strength was the most important factor determining gait velocity ($R^{2\,=}$ 0.30, $p < 0.01$), with $R^{2\,=}$ 0.36 for temporal asymmetry, ($p = 0.001$).

Reduced ROM	Schindler-Ivens *et al*. (2008)	Cohort	17 chronic hemiparetic stroke Age: 58.7 ±9.0 years TSS: 6.3 ±4.5 years Able bodied participants, n = 15 Age: 51.9 ±14.5 years	I	Evaluated ankle dorsiflexion passive ROM among other lower limb ROM using a biodex dynamometer. Ankle DF ROM was 12.78° in the paretic limb and 15.28° in the non-paretic, although this was not significantly different form controls (11.55°). Stiffness, as a derivative of maximum angle and torque required, was 0.61 in the paretic limb and 0.57 in the non-paretic limb. This was the highest reported stiffness value out of the three muscle groups evaluated, however, no significant differences were found between any ankle variables.
	Lamontagne *et al*. (2000)	Cross-sectional descriptive	14 stroke Age: 54.7 ±10.9 years TSS: 93.7 ±26.4 days 11 healthy controls Age: 50.6 ±11.6 years	F	Paretic side, passive stiffness contributed more (16.8%; range 2.9% to 49.6%) to total PF stiffness during gait compared (p = 0.01) with both the nonparetic side (7.3%) and control values (5.9%). Cause: large muscle tendon passive stiffness, a decreased active muscle contribution, or both. The contribution of passive stiffness was not significantly ($p = 0$.05) related to gait speed in both the patients and the controls.
	Lamontagne *et al*. (2002)	Cross-sectional	30 stroke Age: 57.8 ±10.8 years TSS: 44–153 days	I + F	Ankle PF stiffness was significantly higher, at 66% compared to controls at normal walking speed.

			15 healthy controls Age: 59.1 ±9.8 years		
	Lin *et al.* (2006)	Cross-sectional	68 stroke Age: 61.69 ±13.97 years TSS: 3.91 ±5.87 years	I	Average passive ROM of ankle DF to be 15.39° on the paretic side and 17.56° on the non-paretic side (measured by electronic goniometer). No links to function were explored.
	Forghany *et al*. (2014)	Cross-sectional	20 stroke Age: 65.0 ±10.2 years TSS: 6.9 months[43]	F	Deficits were reported in all three planes of movement rather than the commonly reported sagittal plane deficits in the ankle region, i.e. ankle plantarflexion and dorsiflexion, with a reduction of supination and increase in pronation in comparison to heathy controls.
	Kunkel *et al.* (2017)	Cross-sectional	23 stroke, Age: 75.09 ±7.57 years, TSS: 8 years (±6.38); 16 controls, Age: 73.44 ±8.35 years.	I + F	Evaluated first MTPJ ROM in people with stroke and found this to be significantly reduced ($p < 0.025$) in comparison to age-matched controls; however, this was not found to relate to falls.
	Watkins *et al.* (2002)	Cohort study	106 stroke Age: 69.9 ±11.3 years 12 months after stroke	I + F	Increased muscle tone (spasticity) was present in 29 (27%) and 38 (36%) of the 106 patients when measured using the MAS and TAS, respectively. Combining the results from both scales produced a prevalence of 40 (38%). Those with spasticity had significantly lower Barthel scores at 12 months, $p < 0.0001$.

[43] TSS as median average

Spasticity	Lin *et al*, (2006)	Cross-sectional	68 stroke Age: 61.69 ±13.97 years TSS: 3.91 ±5.87 years	I + F	Spasticity index (%/l·s^{-1}) 8.56 ±6.72 (0.49–35.55). Passive stiffness (deg): Unaffected 4.52 ±4.86 (0.00–15.01) v. affected 5.48 ±4.72 (0.00–17.82), no significant difference between sides, $p = 0.41$. Dynamic ankle spasticity inputted into regression analysis was the most important determinant for gait spatial symmetry $R^{2=}0.53$, $p < 0.001$.
	Hsu *et al.* (2003)	Descriptive analysis of convenience sample	26 stroke Age: 54.2 ±10.9 years TSS: 10.3 ±12.0 months	I + F	Spasticity of the affected PFs was the most important independent determinant of temporal and spatial gait asymmetry during comfortable-speed ($R^{2=}0.76$ for temporal asymmetry; $R^{2=}0.46$ for spatial asymmetry) and fast-speed ($R^{2=}0.75$ for temporal asymmetry; $R^{2=}0.45$ for spatial asymmetry) walking.

Table A3.2: Current Literature and Gaps in Knowledge of Presence of Post Stroke Impairments and their Links to Function

Impairment	Presence	Function
(Abnormal) Static foot posture	30% abnormal - 13% pronated; - 16% supinated (Forghany *et al*., 2011) *No comparison to controls* **GAP:** What is the presence and severity of abnormal foot posture in larger stroke population? Is this significantly different compared to controls?	Abnormal foot posture linked to mobility deficits in stroke (Forghany *et al*., 2011); no association found with falls (Kunkel *et al*., 2017). *Links to spatiotemporal measures of gait and balance not yet explored.* Abnormal foot posture linked to mobility, balance and falls in older people. *(No such links found in stroke to date)* **GAP:** Is foot posture associated with functional outcomes other than ambulation classification? E.g. Gait speed? Balance impairment? Number of Falls?
Toe deformity	• Claw toes: 46% (Laurent *et al*., 2010) *(acute phase only, no comparisons to controls)* • Hammer toes: *(no reports to date).* • HHT: 2% (Yelnik *et al*., 2003) *(no comparison to controls)* • HV: 57% (compared to 85% control) (Kunkel *et al*., 2017) *(no significant difference found, presumed related to age)* **GAP:** What is the presence and severity of toe deformities in larger/chronic stroke population in UK and after acute phase of recovery? Is this significantly different compared to controls? Type: Is it mobile or fixed?	• Claw toes: Despite having claw toes improvements in function are seen in 0-3month phase after stroke (Laurent *et al*., 2010) *(acute phase only, no comparisons to controls)* • Hammer toes: *No functional links explored in stroke* • HHT: *No functional links explored in stroke* • Hallux valgus: No functional links found in stroke (Kunkel *et al*., 2017) *(only explored links with falls)* **GAP:** Do toe deformities after stoke influence functional outcomes such as mobility, balance and falls outcomes?

Dynamic foot loading	In people with stroke: - Reduced PPPs compared to controls (Meyring *et al*., 1997) - Associated with ankle PF spasticity *Few papers, no clear consensus in changes observed.* **GAP:** Do changes in plantar pressure values exist in larger stroke population? Are these significantly different compared to controls? Are altered plantar pressures associated with other body and structure impairments?	In people with stroke: - Reduced plantar pressures in indoor walkers (Forghany *et al*., 2015). *Methodological concerns with work.* In older people: - altered plantar pressure associated with functional outcomes falls (Mickle *et al*., 2011b) **GAP:** Do changes in plantar pressure values influence functional outcomes such as walking speed, impaired balance and falls?
Muscle weakness	Muscle weakness is found after stroke on both most- and least-affected sides in ankle DF/PFs, inverters and evertors. (Dorsch *et al*., 2012; 2016) *No evidence of muscle weakness in hallux or lesser toes after stroke.* In older adults: - evidence of muscle weakness in toes (with history of falls) (Mickle *et al*., 2009) **GAP:** What is the presence and severity muscle weakness in hallux and lesser toes? Does this differ controls?	Muscle weakness at ankle PFs/DFs is associated with multiple functional outcomes: - gait speed (31% variance, Dorsch *et al*., 2012), gait variability (Lamontagne *et al*., 2002), gait asymmetry (Bohannon, 2007), - balance (Kligyte *et al*., 2003), - falls (Hyndman *et al*., 2002). *Little is known about ankle invertors/evertors* *None has been explored for hallux and lesser toes.* In older adults: - ankle invertors/evertor/hallux and lesser toe muscle weakness as has been found to associate with functional outcomes (Spink *et al*., 2011; Mickle *et al*., 2009) **GAP:** Does severity of muscle weakness seen in ankle invertors and evertors influence functional outcomes? Does muscle weakness at the hallux affect functional outcome after stroke?

Reduced ROM	Reduced ankle DF ROM found after stroke – but not consistent and not always significantly different from least-affected side or controls (Kunkel *et al*., 2017 *(only active ROM)*; Schindler-Ivens *et al*., 2008). Reduced hallux/1st MTPJ ROM (Kunkel *et al*., 2017) – significant differences found between most- or least-affected side but not with controls. Ankle PF stiffness present (Lamontagne *et al*., 2002; Lin *et al*., 2006; Schindler-Ivens *et al*., 2008) **GAP:** What is the presence and severity hallux/toe DF ROM after stroke? Is this different from controls? Could ankle and hallux stiffness be a useful measure?	Reduced ankle DF ROM and 1st MTPJ ROM not found to be associated with falls. (Kunkel *et al*., 2017). **GAP:** Is reduced ankle and hallux ROM associated with functional decline after stroke?
Spasticity	Spasticity is found in 38%–66% ankle PFs after stroke. **GAP:** What is the presence and severity of ankle PF spasticity after stroke?	Ankle PF spasticity associated with reduced gait speed and gait asymmetry (Lin *et al*., 2006) **GAP:** Is ankle spasticity associated with poor balance and falls after stroke?

APPENDIX 4: GRRAS Guidelines for Quality of Reliability Studies

Used with permission (Kottner *et al*., 2011)

TITLE AND ABSTRACT	1.	Identify in title or abstract that interrater/intrarater reliability or agreement was investigated.
INTRODUCTION	2.	Name and describe the diagnostic or measurement device of interest explicitly.
	3.	Specify the subject population of interest.
	4.	Specify the rater population of interest (if applicable).
	5.	Describe what is already known about reliability and agreement and provide a rationale for the study (if applicable).
METHODS	6.	Explain how the sample size was chosen. State the determined number of raters, subjects/objects, and replicate observations.
	7.	Describe the sampling method.
	8.	Describe the measurement/rating process (e.g. time interval between repeated measurements, availability of clinical information, blinding).
	9.	State whether measurements/ratings were conducted independently.
	10.	Describe the statistical analysis.
RESULTS	11.	State the actual number of raters and subjects/objects which were included and the number of replicate observations which were conducted.
	12.	Describe the sample characteristics of raters and subjects (e.g. training, experience).
	13.	Report estimates of reliability and agreement including measures of statistical uncertainty.
DISCUSSION	14.	Discuss the practical relevance of results.
AUXILIARY MATERIAL	15.	Provide detailed results if possible (e.g. online)

APPENDIX 5: SEARCH 3 PAPERS AND SUMMARY FINDINGS.

Table A5.1 Papers for Literature Review for Study 1

Impairment	Author and date	Study design	No. and condition of participants	Feasibility/ reliability/ clinical relevance*	Key results
Static foot posture	Redmond *et al.* (2008)	Review (of normal values)	*n* = 619 normal healthy Age: 42.3 ±25.1 years	Relevance	U-shaped relationship found for age; with young and older adults showing higher values, indicating more pronation; a slightly pronated foot posture is the normal position at rest (+4). Systematic differences from the adult normals were confirmed in patients with neurogenic and idiopathic cavus ($F = 216.981$, $p < 0.001$), The results indicated some sensitivity of the instrument to detect a pathological population based on foot posture (defined in the paper as over two standard deviations from the mean, +4), notably neurogenic pes cavus (high medial arch) and a supinated foot posture, was identified.
	Evans *et al*. (2003)	Same-subject, repeated-measures	*n* = 29 healthy children (4–6 years) *n* = 30 adolescent (8–15 years) *n* = 30 adults (20–50 years)	Reliability	The FPI total score showed moderate reliability overall, demonstrating better reliability than most other current measures, although navicular height (normalised for foot length) was the single most reliable measure in adults. $ICC_{(1,1)}$ FPI (adults 20–50): - left: 0.54 (95% CI 0.40–0.70) - right: 0.59 (95% CI 0.45–0.73) - both 0.56 (95% CI 0.46–0.67)

					FPI (adults 20–50) average between 4 raters: $ICC_{(3,1)}$ 0.809, SEM 1.3 (2.5), $ICC_{(2,4)}$ 0.58 (95% CI 0.39–0.72). Item 6 – Congruence of medial longitudinal arch ranked highest reliability: Spearman's p = 0.69 (in adults).
	Menz and Munteanu (2005)	Concurrent validity study	*n* = 95 older adults Age: 78.6 ±6.5 years	Validity and Reliability	Compared three clinical measures of static foot posture. Intra-rater reliability was also explored for FPI and reported as moderate with an ICC of 0.61. 3 clinical measures demonstrated significant associations with each of the radiographic parameters (p = 0.01). The FPI demonstrated weaker correlations with the radiographic parameters (r = 0.42–0.59). FPI was a valid measure of medial arch height when compared with radiographs with navicular height and arch index showing differing aspects.
	Langley *et al*. (2016)		*n* = 30 healthy adults Age: 29 ±6 years	Reliability	Medial longitudinal arch (κ_w = 0.92) and FPI-6 (κ_w = 0.92), moderate for rearfoot angle (κ_w = 0.60) and fair for navicular drop (κ_w = 0.40). Agreement between the measures for foot classification was moderate (κ_f = 0.58).
	Lee *et al*. (2015)		*n* = 22 people with stroke No info available for age and TSS.	Reliability	Evaluated FPI use in a group of and reported high intra- and inter-rater reliability with ICCs of 0.81–0.88. Intra-percentage agreement was high (88.6%). **NB: Abstract only.**
Toe deformity	Garrow *et al.* (2001)		*n* = 13	Reliability	Assessing the severity of HV deformity by means of a set of standardised photographs.

					Six podiatrists were independently asked to grade the level of deformity of 13 subjects (26 feet) on a scale of 1 (no deformity) to 4 (severe deformity). Excellent inter-observer repeatability with a combined kappa-type statistic of 0.86.
	No studies found for clinimetric properties of toe deformity measures in stroke.				
Dynamic Foot Loading	Zammit *et al.* (2010)	Repeated measures	*n* = 30 healthy asymptomatic adults Age: 28.2 ±6.1 years	Reliability	Found moderate to good intra-rater reliability with $ICC_{(3,1)}$ of 0.44–97 (95% CI 0.10, 0.99), with most variability and lower ICCs in MFT and lesser toe regions (second–fifth toe). 0.44 (0.10–0.69). TekScan MatScan™ system demonstrates generally moderate to good reliability.
	Brenton-Rule *et al*. (2012)		*n* = 23 older people with RA Age: 69.74 ±10.1 years	Reliability Feasibility	TekScan® mat system had excellent intra-rater reliability during three stance sway trials with eyes open and eyes closed conditions (anterior–posterior, medial–lateral dimensions), with reported $ICCs_{(2,1)}$ above 0.84 and moderate SEM of 1.27 to 2.35 mm. Feasibility was described as portable and easy to use, suitable for research and clinical settings.
	Hafer *et al*. (2013)		*n* = 22 healthy adults Age: 28.9 ±9.9 years	Reliability	Evaluated intra-mat, intra-manufacturer (two EMED-x plates and two MatScans ™), and inter-manufacturer (Novel and TekScan®) reliability of plantar pressure parameters as well as the number of plantar pressure trials needed to reach a stable estimate of the mean for an individual. 10 walking trials across two devices. All intra-platform $ICC_{(2,1)} > 0.70$. All inter-EMED-x1 reliability correlations were greater than 0.70.

					Inter-MatScan ™ $ICC_{(2,1)}$ > 0.70 in 31 and 52 of 56 parameters when looking at a 10-trial average and a 5-trial average, respectively. Inter-manufacturer reliability including all four devices $ICC_{(2,1)}$ > 0.70 for 52 and 56 of 56 parameters when looking at a 10-trial average and a 5-trial average, respectively. All parameters reached a value within 90% of an unbiased estimate of the mean within five trials.
	Gurney *et al*. (2013)	Test–retest reliability	*n* = 10 people with diabetic peripheral neuropathy Age: 60.9 ±8.6 years	Reliability	Dynamic plantar loading and foot geometry data were collected during barefoot gait with the EMED platform (Novel GmbH, Germany). Two sessions separated by 28 days. For dynamic plantar loading, reliability differed by outcome measure and foot region, with ICCs (one way, random) of > 0.8 and CoVs of < 15% observed in most cases. For dynamic foot geometry, ICCs of > 0.88 and CoVs of < 3% were observed for hallux angle, arch index and coefficient of spreading, while sub-arch angle was less reliable (ICC 0.76, CoV 23%). Reliable in diabetic population.
	Gurney *et al.* (2017)	Feasibility study	*n* = 38 people with diabetes Age: 57 (IQR 51.5–65.5) years	Feasibility	Using a mat and in-shoe-based system (Novel, EMED) to evaluate the feasibility of incorporating pedobarographic testing into the clinical care of diabetic feet in New Zealand. High response rate and positive self-reported experience from

					participants, median time for pedobarographic testing (including study introduction and consenting) was 25 minutes, no adverse events. Recommendations for clinical use: - To inform the design and effectiveness of offloading devices among high-risk diabetic patients; - To increase offloading footwear and/or orthoses compliance among high-risk diabetic patients.
	Hillier and Lai (2009)	Test–retest	*n* = 15 stroke Age: 54–83 years TSS: 0.5–13 years	Reliability Relevance	To evaluate whether F-Scan insole produces reliable data between trial 1 and trial 2 for the parameters of CP and CA. 30 minutes between trials. Four different stance positions (feet together, with eyes open or eyes closed, and feet apart with eyes open or eyes closed. Good to excellent inter-trial reliability: *r* = 0.704–0.986. • CP: Easy task: mean hemiparetic 3.6 kPa v. non-hemiparetic 3.7 kPa; harder task: mean hemiparetic 3.3 kPa v. non-hemiparetic 4 kPa. • CA: redistribution of contact on the lateral border of the more affected foot. • COF: motion was reduced on the more affected lower limb with a mean of 0.3 cm v. 0.5–3.8 cm for the other lower limb.
	Chisholm *et al*. (2011)		*n* = 57 stroke Gait aid group (*n* = 25)	Relevance	Evaluated COF using a pressure-sensitive mat (GAITRite) and measure spatiotemporal measures of gait at comfortable and fast walking speed.

			Age: 63.8 ±12.5 years TSS: 28.8 ±28.0 months No gait aid group (*n* = 32) Age: 62.2 ±11.8 years TSS: 46.1 ±31.5 months		AP-COP displacement and AP-COP velocity were related to the severity of sensorimotor impairment and greater among gait aid users. ML-COP variability was greater under the non-paretic limb, possibly suggesting difficulty with paretic limb swing phase. Reduced or absent forefoot COP time suggests difficulty with forward progression and modified foot function during push-off.
Muscle weakness	Stark *et al*. (2011)	Systematic review	17 papers	Feasibility Validity	Explored correlation between isokinetic and HHD measures of muscle strength in 17 papers. Feasibility: HHD portability, ease of use, cost and compact size. Valid: compared with isokinetic devices yielded minimal differences and therefore considered it a valid tool. Few studies evaluated ankle muscle groups (with only one reporting reliability statistics, Li *et al*., 2006)
	Li *et al.* (2006)	Design description and validation study	*n* = 28 healthy adults	Validity	Evaluated a new HHD able to test at a variety of joint ranges and compared this with an isokinetic device (KinCom) during isometric muscle contractions of lower limbs muscle groups, including ankle PF/DFs. Validity: *r* = 0.97 between HHD and KinCom of pooled muscle strength data; *r* = 0.93 in the ankle PFs, and *r* = 0.60 in ankle DFs.

	Bohannon (1986)	Retrospective study	*n* = 30 neurological patients Age: 51.9 years	Reliability	HHD was reliable for measuring ankle muscle strength in a neurological population, with excellent test–retest reliability for ankle PFs and DFs between 3 raters: $r = 0.97–0.99$, $p < 0.01$.
	Kelln *et al.* (2008)	Repeated measures	*n* = 20 healthy young adults Age: 26 years	Reliability	Performed strength testing using HHD. Good to excellent repeatability (ICCs of 0.8–0.98) for all muscle groups around the ankle and the hallux in a young healthy population. Intra-tester ICC range was 0.77 to 0.97 with SEM range of 0.01 to 0.44 kg. Mean inter-tester ICC range was 0.65 to 0.87 with SEM range of 0.11 to 1.05 kg. Mean intersession ICC range was 0.62 to 0.92 with SEM range of 0.01 to 0.83 kg.)
	Moraux *et al.* (2013)	Repeated measures Exploratory	*n* = 345 healthy subjects Age: 5–80 years *n* = 9 neuromuscular disease patients	Feasibility Reliability	Found ankle dorsiflexion/plantarflexion had excellent reliability, with ICCs of 0.94 and 0.88, respectively, in a cohort of 150 healthy subjects (5–80 years old). This illustrates that good reliability is achievable for ankle dorsiflexion/plantarflexion, ankle inversion/eversion and hallux dorsiflexion/plantarflexion across all age groups in healthy people, and that testing procedures appeared feasible in the neuromuscular disease group.
	Yen *et al*. (2017)	Pilot reliability study Test–retest	*n* = 15 people with stroke Age: 56.6 ±12.9 years No TSS data.	Reliability	Isometric muscle strength using a HHD in a supine position in the acute hospital setting. $ICC_{(3,1)}$ of 0.93 and 0.96 (95% CI 0.815–0.987, SEM 1.23–1.30) were reported for ankle DFs.

					Units of muscle force not stated, no validation of muscle testing between sitting and supine positions.
	Spink *et al.* (2010)	Reliability	*n* = 36 young 23.2 ±4.3 years *n* = 36 older healthy adults Age: 77.1 ±5.7 years	Reliability	Using a HHD with older people, inter-rater reliability $ICC_{(3,1)}$ of 0.77–0.88, intra-rater ICCs were higher, $ICC_{(3,1)}$ 0.78–0.94, for all ankle and foot muscle groups, including the lesser toes.
	Mickle *et al.* (2006)		*n* = 6 young adults	Reliability	Using paper grip test. Showed excellent ICCs of 0.93, 0.92, respectively, for hallux and toes in standing.
Reduced ROM	Martin and McPoil (2005)	Review paper	*n* = 11 studies Neurological Orthopaedic Paediatric	Reliability	Reviewed ankle goniometric measurements, the responsiveness of ankle joint ROM measurement was uncertain. Intra-rater reliability was most widely reported for both ankle plantarflexion and dorsiflexion, with less on inter-rater reliability for ankle dorsiflexion and even less so for ankle plantarflexion (Martin and McPoil, 2005).
	Menz *et al.* (2003)	Test–retest reliability	*n* = 31 older adults	Reliability	Used a modified lunge test, to evaluate ankle DF ROM with the lateral malleolus and head of the fibular, and participants were supported by a wall, test–retest reliability was high with an ICC of 0.87.
	Gatt and Chockalingam (2011)	Review paper	*n* = 755 studies		10 different techniques were identified that included various apparatuses designed specifically for this purpose. Apparatus/equipment: - goniometer - lunge test

					- visual estimation - electrogoniometer - potentiometer - inclinometer/gravity goniometer - lateral radiographs - 2D video - photography - foot attachment - torque ROM device - Lidcombe template/modified Lidcombe template - biplane goniometer - manually controlled instrumented foot plate - equinometer, mechanical equinometer - Iowa ankle device - assess gastrocnemius muscle contracture Recommendations: Validity studies – use patient populations. Standardisation of patient position, foot posture, amount of moment applied and reference landmarks.
	Keating *et al.* (2000)	Test–retest reliability	*n* = 21 stroke Age: 75.4 ±8 years No TSS data.	Reliability	To analyse ankle DF passive ROM in stroke patients while applying a standardised force (14 N). ROM was determined using a goniometer on a photograph of the joint ROM. The Lidcombe plate measured ankle DF ROM and was highly reliable ($r > 0.92$) in both unimpaired and impaired lower limbs.
	Menadue *et al.* (2006)	Test–retest	*n* = 30 adults (11 had a previous ankle injury)	Reliability	Ankle inversion and eversion using goniometry. Reliability in older adults varies with high values for intra-rater reliability and low to moderate for inter-rater testing

			Age: 35.4 years		intra-observer reliability ranged from $ICC_{(2,1)}$ 0.82–0.96 and between session intra-observer reliability ranged from $ICC_{(2,1)}$ 0.42–0.80. Ankle inversion and eversion ROM can be measured with high to very high reliability by the same observer within sessions. Some variability between sitting and prone testing positions.
	Youberg *et al.* (2005)	Cohort	n = 40 healthy adults Age: 23–44 years	Reliability and relevance	Evaluated *passive* ankle inversion and eversion ROM using electromagnetic sensors with the foot positioned with the calcaneus perpendicular to the board and the lower leg positioned with the tibial tuberosity bisecting the long axis of the foot. Readings were taken while in sitting and in a non-weight-bearing position. Passive eversion and inversion ROM was 9.0 ±3.5 and 30.5 ±6.8°, reliability reached $ICC_{(2,k)}$ of 0.98 over five trials; 68.1% of their available passive eversion range of motion, and 13.2% of their available passive inversion range of motion during walking.
	Hopson *et al*. (1995)	Intra-rater reliability study	n = 20 healthy adults Age: 21–43 years	Reliability	Compared four passive measurement techniques of 1st MTPJ ROM. Reported ICCs ranged from 0.91–0.98 across static non-weight-bearing, partial weight-bearing and step weight-bearing conditions with low SEM 0.8–1.38. Significant differences were found between mean MTPJ ROM for all conditions (F = –132.1; df = 4, 76, $p < 0.0001$), with post hoc comparisons significant between all conditions and v.

					dynamic conditions ($p < 0.05$), for which reliability was not reported.
	Paton (2006)	Cohort	n = 24 healthy adults Age: 21–40 years	Feasibility	Has been used successfully to measure passive hallux dorsiflexion in sitting in diabetic participants. No statistics reported
Spasticity	Morris (2002)	Review paper	Number of studies not specified.	Clinical Relevance	Explored the clinical relevance of MAS and Tardieu scale in adults with neurological conditions and recommended that the Tardieu scale is a more useful measure of spasticity, with an ability to distinguish between contracture and spasticity. This was attributed to the standardised speed of movement and inter- and intra-rater reliability and content validity
	Haugh *et al.* (2006)	Systematic review	31 studies	Reliability Validity Clinical Relevance	Explored the use of the Tardieu scale in the measurement of spasticity in their systematic review, 10 studies examined reliability, with few evaluating the use of the Tardieu scale in adults with stroke. Found the Tardieu scale more sensitive and reliable than the Ashworth scale,
	Patrick and Ada (2006)	Cross-sectional study	n = 16 stroke (3 years post) Age: 63±7 years TSS: 1.2–5 years	Validity	Explored whether the Tardieu scale can distinguish contracture. Agreement of 100% was found between the Tardieu scale and EMG of ankle PFs, Agreement between MAS and EMG activity, (r = 0.15), with the Tardieu scale exhibiting clear relationships, r = 0.62. The MAS overestimated the spasticity present in those with contracture.

					However, in the current study, the relationship between the angle of muscle reaction at V3 was only significantly related to the angle at which fast stretch-induced EMG activity occurred in the elbow flexors (r = 0.78, p = 0.04), not in the ankle PFs (r = 0.57, p = 0.14). This suggests that the grade of muscle reaction (X) during the fast velocity stretch (V3) is the most appropriate measure of spasticity from the Tardieu scale.
	Mehrholz *et al*. (2005)	Cross-sectional comparison study	n = 30 severely brain injured patients Age: 63.9 ±12.9 years	Reliability	Evaluated test–retest reliability using MAS at the ankle with knee extended and flexed. Test–retest reliability MAS: - knee extended was κ = 0.47 - knee flexed was κ = 0.62, with low standard error (0.02-0.04). Test–retest reliability Tardieu scale - knee extended κ = 0.72 - knee flexed κ = 0.82, still with low standard error reported. Statistically significant difference (p < 0.001). Inter-rater reliability was only poor to moderate (κ = 0.14–0.47) although significant differences were still found between reliability scores.
	Anasari et al. (2013)	Inter- and intra-rater reliability study	Stroke		To evaluate the reliability of the modified Tardieu scale (MTS) in the measurement of ankle PF spasticity in patients after stroke. Patients were tested by two raters for inter-rater reliability. Patients were retested by one rater at least one week later for intra-rater reliability. The PFs on the hemiparetic side were tested.

					The ICCs of inter and intra-rater reliability across all components of the MTS were moderate and moderately high (range 0.40–0.71). Inter- and intra-rater reliability for the dynamic component of spasticity (R2–R1) were moderate (ICC = 0.57 and 0.40, respectively). The difference between the two raters for R2 was statistically significant (p = 0.001).

*select as many from this list that apply.

Table A5.2 Summary Table of Literature for Clinimetric Features of Measurement Tools of Foot and Ankle Impairments after Stroke

Measurement tool	Feasibility	Reliability	Clinical relevance*
Foot posture using FPI	Not established. Implied by previous studies but not explicitly evidenced.	Not established in stroke. Moderate to excellent in healthy and older people (Menz and Munteanu, 2005; Evans *et al*., 2003)	Established in stroke (Forghany *et al*., 2011; Kunkel *et al*., 2017).
Toe deformity by observation	No. No scales available to measure	No. No scales available to measure	Established HV not functionally relevant in stroke (Kunkel *et al*., 2017). Toe clawing associated with poor functional ability (Laurent *et al.*, 2010).
Foot loading during stance/static standing using plantar pressure	Not established in stroke, although used in multiple papers (Nolan *et al*., 2008; Meyring *et al.*, 1997). Has been explored in RA and older people (Brenton-Rule, 2012 and Gurney *et al.*, 2017).	Not established in stroke. Excellent reliability in older people (Zammit *et al*., 2010).	Partially established; found to associate with spasticity and mobility (Meyring *et al*., 1997; Forghany *et al*., 2015).
Muscle weakness using HHD	Not established. For ankle muscles: implied by previous studies but not explicitly evidenced.	For ankle muscles: good to excellent reliability found (Bohannon, 1986; Andrews and Bohannon, 2000; Yen *et al*., 2017). Not demonstrated for hallux and toes, although research in older adults	Established in stroke, found to correlate with walking speed and balance (Dorsch *et al*., 2012).

	For hallux and toe muscles, or single v. composite values: this has not been established.	demonstrates good to excellent reliability (Spink *et al*., 2010; Kelln *et al*., 2008). Not demonstrated for single v. composite values.	
Reduced ROM using bespoke tools (Lidcombe plate, Paton's rig)	Not established in stroke. Not demonstrated for Lidcombe plate or Paton's rig however both appear feasible.	Not established for ankle dorsiflexion with use of inclinometer or hallux DF rig. Good reliability for Lidcombe plate (Keating *et al.,* 2000), however reliability not demonstrated for Paton's rig.	Yes
Spasticity	Not established in stroke. Implied by previous studies but not explicitly evidenced.	Established in stroke. Good to excellent reliability reported (Singh *et al.*, 2011; Mehrholz *et al*., 2005); however, quality of movement has not been convincingly established despite some reliability work (Haugh *et al*., 2006).	In stroke, found to associate with balance (Kligyte *et al.*, 2003) and mobility outcomes (Lin *et al.*, 2006).

*Please note clinical relevance has been established in Chapter 2.

APPENDIX 6: STUDY 1 ETHICS (UEL)

Study 1 Ethics approval: UEL

Study title: The effects of foot and ankle impairments on mobility and balance in community dwelling adults post stroke: evaluation of psychometric and clinimetric properties of measures of foot and ankle impairment.

THE RESEARCH IN THIS THESIS WAS PART OF A LARGER STUDY, WHICH HAD ETHICAL APPROVAL FROM UEL, AS SUCH THE THESIS TITLE IS SLIGHTLY DIFFERENT FROM THAT OF THE OVERALL RESEARCH PROJECT.

EXTERNAL AND STRATEGIC DEVELOPMENT SERVICES
uel.ac.uk/qa
Quality Assurance and Enhancement

5 March 2013

Dear Mary,

Project Title:	**The Effects of Foot and Ankle Impairments on Mobility and Balance in Community Dwelling Adults Post Stroke: Evaluation of Psychometric and Clinometric Properties of Measures of Foot and Ankle Impairment**
Researcher(s):	**Dr Stewart Morrison and Alison Lyddon (UEL) Professor Jonathan Marsden, Dr Jennifer Freeman and Dr Joanne Paton (University of Plymouth)**
Principal Investigator:	**Dr Mary Cramp**

I am writing to confirm that the application for the aforementioned proposed research study has now received ethical approval following successful amendments requested at the meeting of University Research Ethics Committee (UREC) on **Wednesday 16 January 2013**.

Should any significant adverse events or considerable changes occur in connection with this research project that may consequently alter relevant ethical considerations, this must be reported immediately to UREC. Subsequent to such changes an Ethical Amendment Form should be completed and submitted to UREC.

Approved Research Site

I am pleased to confirm that the approval of the proposed research applies to the following research site.

Research Site	Principal Investigator / Local Collaborator
UEL Campus Laboratory	**Dr Mary Cramp**

Docklands Campus, University Way, London E16 2RD
Tel: +44 (0)20 8223 3322 Fax: +44 (0)20 8223 3394 MINICOM 020 8223 2853
Email: r.carter@uel.ac.uk

EXTERNAL AND STRATEGIC DEVELOPMENT SERVICES
uel.ac.uk/qa
Quality Assurance and Enhancement

Approved Documents

The final list of documents reviewed and approved by the Committee follows:

Document	Version	Date
Participant Information Sheet	1.1	4 March 2013
Written Consent Form	1.0	2 January 2013

Approval is given on the understanding that the UEL Code of Good Practice in Research is adhered to.

With the Committee's best wishes for the success of this project.

Yours sincerely,

Merlin Harries
University Research Ethics Committee (UREC)
Quality Assurance and Enhancement
Telephone: 0208 223 2009
Email: researchethics@uel.ac.uk

31 January 2014

Dear Alison,

Project Title:	**The effects of foot and ankle impairments on mobility and balance in community dwelling adults post-stroke; evaluation of psychometric and clinimetric properties of measures of foot and ankle impairment**.
Researcher(s):	**Alison Lyddon**
Principal Investigator:	**Stewart Morrison**

I am writing to confirm that the application for an amendment to the aforementioned research study has now received ethical approval on behalf of University Research Ethics Committee (UREC).

Should any significant adverse events or considerable changes occur in connection with this research project that may consequently alter relevant ethical considerations, this must be reported immediately to UREC. Subsequent to such changes an Ethical Amendment Form should be completed and submitted to UREC.

Approved Research Site

I am pleased to confirm that the approval of the proposed research applies to the following research site.

Research Site	**Principal Investigator/ Local Collaborator**
University of East London	Stewart Morrison

Summary of Amendments
The project will be extended by three months up until the end of March 2014, to allow the inclusion of more participants in the study, and thereby allow reliability testing on the now developed equipment to inform future work.

Approved Documents

The documents submitted to the UREC meeting on 16 January 2013 have not changed. Ethical approval for the original study was granted on 5 March 2013.

Approval is given on the understanding that the UEL Code of Good Practice in Research is adhered to.

With the Committee's best wishes for the success of this project.

Yours sincerely,

Catherine Fieulleteau
Ethics Integrity Manager
University Research Ethics Committee (UREC)
Email: **researchethics@uel.ac.uk**

APPENDIX 7: STUDY 1: LETTER OF INVITATION

Letter of Invitation to Participate in a Stroke Research Project

Project title: The effects of foot and ankle impairments on mobility and balance in community dwelling adults post-stroke; evaluation of psychometric and clinimetric properties of measures of foot and ankle impairment

Dear Madam/Sir,

People who have had a stroke are being invited to take part in a research study. The research is being undertaken by staff from the University of East London, Stratford.

The research is looking at how foot and ankle problems following stroke affect walking and balance. The aim of this research is to help us understand more about how balance and walking can be improved in people who have had a stroke.

You are being given this letter because you may be suitable to take part in the study. If you are interested in finding out more about the research, we can provide your details to the researchers so that they can contact you about the study. The researchers will be able to tell you more about the research and what's involved.

If you are happy for the researchers to contact you about the study, please tick the statement below and either return this letter to the person who gave it to you or return it in the envelope provided. By agreeing to be contacted by the researchers, you are not agreeing to take part. You are only agreeing to being contacted by the researchers so they may tell you more. If you do not complete and return this letter, you will not be contacted by the researchers and they will not receive your contact details.

Any decision you make about taking part in this study will not affect any future treatment you may receive.

Yours sincerely,

On behalf of *Alison Lyddon*, Researcher on FAiMiS
Tel: 0208 223 4256

□ I am happy for the research team to contact me to tell me more about the study.

My contact details are:

Name: ……

Tel. (inc. code): ……

Email (if you prefer): ……

Date of stroke: ……..

APPENDIX 8: STUDY 1: PARTICIPANT INFORMATION SHEET

Participant Information Letter

Project title: The effects of foot and ankle impairments on mobility and balance in community dwelling adults post-stroke; evaluation of psychometric and clinimetric properties of measures of foot and ankle impairment

Dear ……. [Participant name here]

We would like to invite you to participate in a research study. The study will be conducted at the University of East London, who are the sponsors of the research. To help you know more about the study, please read the question and answer section below. It should help you decide if you would like to be part of the study. Ask us if you would like more information about the study.

What is the purpose of the study?
Problems with the foot and ankle such as muscle weakness or tightness, sensory loss, or loss of range of motion may contribute to limited mobility and poor balance after stroke. These problems and their impact have yet to be fully explored. To be able to study these problems, research is required to establish appropriate clinical measures of foot and ankle problems and test their feasibility and reliability. You are being asked to take part in the research to help us to test the measures for use in a subsequent study.

What will I be asked to do if I decide to take part?
You will be asked to attend the University of East London for testing on two or three occasions so that we can conduct repeat tests. Each session will last between 60 to 90 minutes. During the sessions, measures may be taken of foot and ankle muscle strength, joint range of motion, foot posture and foot motion during gait, sensory function and muscle stiffness/activity during movement. Most of the measures will be physical measures applied to your foot and ankle and will use specialised clinical equipment. Strength of ankle and toes muscles will be tested separately by asking you to push against a small hand held instrument during different motions. Ankle and toe joint range of movement will be measured using devices that control the forces applied as your foot or toes are moved passively. Standard clinical measures will be used to test sensory functions such as light touch, proprioception (joint sense) and vibration perception. To measure foot motion and muscle stiffness/activity, you will be asked to walk along a short walkway. We will place small recording electrodes on the muscles in your lower leg to measure the electrical signals generated by your muscles as they work. We will record

your walking pattern using a pressure mat placed on the walkway, and the position of your toes during walking using a video recording.

Where will this study take place?
The study will take place in University House at the University of East London, Water Lane, Stratford, London. There is a room with the equipment for undertaking this type of research.

How will I travel there and get back home?
We will discuss travel arrangements with you where required. We will help with these arrangements and pay the costs of your travel.

Do I have to take part?
It is entirely up to you whether or not you would like to take part. If you decide to take part but change your mind, you are still free to withdraw at any time.

What are the possible advantages of taking part?
There are no direct benefits to you in taking part in this research. By taking part in the research, you will be provided with information about your foot and ankle function and about your mobility.

What are the possible disadvantages or risks of taking part?
There are minimal risks in taking part in this research. It is possible that you may experience brief and temporary discomfort during assessment of muscle strength and joint range of motion due to muscle stretch. You are not expected to have any after-effects from testing.

What happens if something goes wrong?
We believe that this study is basically safe and do not expect you to suffer any harm or injury because of your participation in it. In the unlikely event that something does go wrong and through our negligence, you are harmed, you will be compensated. However, you may have to pursue your claim through legal action. The University will consider any claim sympathetically. If you are not happy with any proposed compensation, you may have to pursue your claim through legal action. If you would like further information on our insurance cover, please contact: *Martin Longstaff, University of East London, Docklands Campus, Knowledge Dock, London, E16 2RD. Telephone number: 0208 223 7485.*

Who should I contact for further information or if I have any problems/concerns?
If you are interested in taking part in this study but you have further questions, please contact either of the researchers (contact details below) and we will be very happy to help. If at any time, you are concerned about your participation in this study or note any untoward effects, please contact the researchers.

Researcher contact details:
Dr. Mary Cramp, Tel: 0208 223 4544 Email: m.c.cramp@uel.ac.uk
Ms. Alison Lyddon, Tel: 0208 223 4256 Email: a.lyddon@uel.ac.uk
Dr. Stewart Morrison, Tel: 0208 223 2679 Email: s.c.morrison@uel.ac.uk

If you are unhappy about any aspect of your participation in the study and wish to report a complaint, please contact:
Martin Longstaff, University of East London, Docklands Campus, Knowledge Dock, London, E16 2RD. Telephone number: 0208 223 7485.

What will happen to the information collected?
For your participation in the study, you will be assigned a participant code. We will ask you to provide your personal details such as your name, address and phone number. This will be kept in hard copy format together with your assigned participant code in a secure locked cabinet. Only the research team have access to this information. Any measures taken either in hard copy or electronic format will not have your name but will refer to the participant code that has been assigned to you. This information will also be kept securely in a locked cabinet (for the hard copy data) and in secure electronic format. The information will be kept in compliance with the University's Data Protection policy. We will keep your information securely for ten years after the study is completed and then the information will be destroyed.

The information provided will be subject to legal limitations. For example, where there is imminent harm to yourself or others, confidentiality may be broken and passed on to relevant professionals.

It is intended that the information collected from individual participants will be collated and reported for public benefit. Individual participants will not be identified in any report of the study.

University Research Ethics Committee (UREC)
The University Research Ethics Committee has approved this study. If you have any questions about the ethics of the research or about any of the researchers, please contact: researchethics@uel.ac.uk

Thank you for your consideration of the information provided here.

Yours sincerely,

Alison Lyddon
Primary Researcher

Mary Cramp
Principal Investigator

APPENDIX 9: STUDY 1: CONSENT FORM

Written Consent Form

Project title: The effects of foot and ankle impairments on mobility and balance in community dwelling adults post-stroke; evaluation of psychometric and clinimetric properties of measures of foot and ankle impairment

This research project is funded by the Dr William M. Scholl Podiatric Research and Development Fund and will be conducted at the University of East London. Participation in the research is voluntary and you are free to withdraw at any time. The procedures consist of assessment of foot and ankle function including muscle strength, joint range of motion, foot posture and foot motion during gait, sensory function and muscle stiffness/activity during movement. The data collected may be published for public benefit, but your personal information will be anonymous in any report. There are no external contractors involved in the research. Please fill in this form, circling 'yes' or 'no' and then print your name, sign and date the form at the end. Then hand the form to the researcher.

Have been given a copy of the information sheet to keep?	Yes/No
Do you understand the details provided in the information sheet and feel sufficiently informed?	Yes/No
Have you been given the chance to talk about the study and ask questions?	Yes/No
Do you understand the procedures and time involved in this study?	Yes/No
Have you been given the information and do you understand the risks involved in participating?	Yes/No

Have you recently (past month) been involved or are simultaneously involved in another research study?	Yes/No
Have you been informed of the confidentiality procedures and do you accept them to be adequate?	Yes/No
Are you happy for video recordings to be taken for the purposes of assessing your foot function?	Yes/No
Do you consent to taking part in this study?	Yes/No
Are you aware of your right to withdraw from the study at any time without having to give reasons?	Yes/No
Do you know who to contact if there are problems?	Yes/No

Allocated number (to be completed by researcher):	
Participant name (print):	
Participant signature:	
Date and time:	

APPENDIX 10: STUDY 1: DATA COLLECTION FORM

Patient Demographics

Name: **DOB:**

Height: **Weight:**

Date of stroke:

Type of stroke: Haemorrhagic / Ischaemic *

(use prompts of bleed/clot)

Side of stroke: Right / Left *

*(circle as appropriate)

Recruitment centre:

NORTH DEVON: ……..

EAST LONDON: Barts Health / Newham /

Other ……..

Current treatment/Medication:

Walking aids:

Functional Ambulatory Classification scale (FAC):

Last fall:

No. of falls in last three months:

Any other comments, (e.g. Any current treatment specific to stroke, i.e. physiotherapy, changes in medication)

ROM

	Movement	Low force*			High force^			Comments
		1	2	3	1	2	3	
Non-affected	Ankle DF							
	Hallux DF							
Affected	Ankle DF							
	Hallux DF							

*Low force – Ankle 7 kg, Hallux 2 kg.
^High force – Ankle 10 kg, Hallux force to achieve end ROM.
NB: 7 kg = approx. 14 N m depending on length of moment arm (approx. 10cm)

Ankle PF Muscle Spasticity:

Velocity to stretch (V)

V1 As slow as possible
V2 Speed of the limb segment falling
V3 As fast as possible (> natural drop)

V1 is used to measure the passive range of Motion. (PROM). Only V2 and V3 are used to rate spasticity

Quality of muscle reaction (X)

0 No resistance throughout passive movement
1 Slight resistance throughout, with no clear catch at a precise angle
2 Clear catch at a precise angle, followed by release
3 Fatigable clonus (<10secs) occurring at a precise angle
4 Unfatigable clonus (>10secs) occurring at a precise angle
5. Joint Immobile

Angle of muscle reaction (Y)

Measure relative to the position of minimal stretch of the muscle (corresponding at angle)

Spasticity Angle

R1 Angle of catch seen at Velocity V2 or V3

R2 Full range of motion achieved when muscle is at rest and tested at V1 velocity

	Test	V (1/3)	Y (deg)	X (0–5)	R1 (deg)	R2 (deg)
Non-affected	1					
	2					
	3					
	Average					
Affected	1					
	2					
	3					
	Average					

NB: Please note if subject complaining of pain, discomfort, other associated reactions.

Muscle Strength

	Movement	Trial			Comments
		1	2	3	
Non-affected	Ankle DF				
	Ankle PF				
	Ankle Inv				
	Ankle Ev				
	Hallux PF				
	Hallux DF				
Affected	Ankle DF				
	Ankle PF				
	Ankle Inv				
	Ankle Ev				
	Hallux PF				
	Hallux DF				

Static Foot Posture: FPI

Foot Posture Index:

	Right **Affected / Non-affected***	**Left** **Affected / Non-affected***
1. Talar head		
2. Lat malleous		
3. Calcaneus		
4. Med arch		
5. Talonavicular joint		
6. Abduction toes		
Total:		
Foot classification:		

*circle as appropriate

Toe Deformity: Observational Analysis

Toe deformity:

Claw toe ☐ Mobile/fixed

Hammer toe ☐ Mobile/fixed

Hitchhiker's toe ☐ Mobile/fixed

(tick box and circle as applicable)

APPENDIX 11: FUNCTIONAL AMBULATORY CLASSIFICATION (FAC)

FAC	Ambulation Description	Definition
0	Nonfunctional ambulation	Subject cannot ambulate, ambulates in parallel bars only, or requires supervision or physical assistance from more than one person to ambulate safely outside of parallel bars
1	Ambulator-Dependent for Physical Assistance Level II	Subject requires manual contacts of no more than one person during ambulation on level surfaces to prevent falling. Manual contacts are continuous and necessary to support body weight as well as maintain balance and/or assist coordination
2	Ambulator-Dependent for Physical Assistance Level I	Subject requires manual contact of no more than one person during ambulation on level surfaces to prevent falling. Manual contact consists of continuous or intermittent light touch to assist balance or coordination
3	Ambulator-Dependent for Supervision	Subject can physically ambulate on level surfaces without manual contact of another person but for safety requires standby guarding on no more than one person because of poor judgment, questionable cardiac status, or the need for verbal cuing to complete the task.
4	Ambulator-Independent Level Surfaces only	Subject can ambulate independently on level surfaces but requires supervision or physical assistance to negotiate any of the following: stairs, inclines, or non-level surfaces.
5	Ambulator-Independent	Subject can ambulate independently on nonlevel and level surfaces, stairs, and inclines.

APPENDIX 12: FOOT POSTURE INDEX-6

	-2	-1	0	+1	+2
Talar head palpation	Talar head palpable on lateral side/but not on medial side	Talar head palpable on lateral/slightly palpable on medial side	Talar head equally palpable on lateral and medial side	Talar head slightly palpable on lateral side/palpable on medial side	Talar head not palpable on lateral side/but palpable on medial side
Supra and infra lateral malleoli curvature (viewed from behind)	Curve below the malleolus either straight or convex	Curve below the malleolus concave, but flatter/more than the curve above the malleolus	Both infra and supra malleolar curves roughly equal	Curve below the malleolus more concave than curve above malleolus	Curve below the malleolus markedly more concave than curve above malleolus
Calcaneal frontal plane position (viewed from behind)	More than an estimated 5° inverted (varus)	Between vertical and an estimated 5° inverted (varus)	Vertical	Between vertical and an estimated 5° everted (valgus)	More than an estimated 5° everted (valgus)
Prominence in region of TNJ (viewed at an angle from inside	Area of TNJ markedly concave	Area of TNJ slightly, but definitely concave	Area of TNJ flat	Area of TNJ bulging slightly	Area of TNJ bulging markedly
Congruence of medial longitudinal arch (viewed from inside)	Arch high and acutely angled towards the posterior end of the medial arch	Arch moderately high and slightly acute posteriorly	Arch height normal and concentrically curved	Arch lowered with some flattening in the central position	Arch very low with severe flattening in the central portion - arch making ground contact
Abduction/adduction of forefoot on rearfoot (view from behind)	No lateral toes visible. Medial toes clearly visible	Medial toes clearly more visible than lateral	Medial and lateral toes equally visible	Lateral toes clearly more visible than medial	No medial toes visible. Lateral toes clearly visible.

APPENDIX 13: STANDARD OPERATING PROCEDURE: FOOT POSTURE

Equipment:

FPI-6 proforma
Pen
Data collection sheet

Protocol:

1. Instruct participant of procedure:
   "This test is used to look at your foot position when you are standing barefooted. You will be asked to march on the spot for 10 seconds and stand still for a couple of minutes while I look at your foot position."
2. Participant in an upright standing position with a chair a step behind them. The participant is instructed to march on the spot a few times and then come to a standstill and maintain this position for 2 minutes. (Allow patient to touch back of chair or plinth to maintain balance if required.) Instruct participant of procedure:
   "Now, please march on the spot for 10 seconds and stand still for a couple of minutes while I look at your foot position. Thank you."
3. Apply the assessment tool as per the proforma, starting with the less-affected foot first. Assessing the following in turn:
   a. Talar head palpation
   b. Supra and intra lateral malleolar curvature
   c. Calcaneal frontal plane position
   d. Prominence of region of TNJ
   e. Congruence of the medial longitudinal arch
   f. Abduction/adduction of the forefoot on the rearfoot
4. Rate each component on a scale from -2 to +2 as outlined by the proforma.
5. Write the score for each component and foot on the data collection sheet.
6. Repeat steps 2-5 for the more-affected side.

APPENDIX 14: STANDARD OPERATING PROCEDURE: PLANTAR PRESSURE DATA

Equipment:

TekScan HR Mat™
Laptop with Tekscan® software installed (Research v.6.70)
Non-alcoholic wipes to clean the mat
Space required: enough for 6–7 m walkway (minimum, although the 10MWT in Study 2 will require 10 m walkway).
Two small cones
Pen
Data collection sheet

Protocol:

Set up and calibration (completed before the participant arrives):

1. Set up 'new patient' file in the TekScan® system (use same ID number as assigned during demographic data collection).
2. Run calibration protocol with the tester if appropriate, (see calibration protocol, TekScan, 2012, pp. 125–128).
3. Set trigger for recording at > 2 kPa and sampling rate 50 Hz.

TekScan© Step Calibration:

4. Instruct participant of procedure:
   "I will now be analysing the pressure that goes through your foot while standing and walking. To do this you will now be asked to step into the mat bare footed to adjust the mat to your weight".
5. Now complete the step calibration protocol as found in HR Mat™ Manual, TekScan, 2012, pp. 129–132).
6. Save the calibration file using participant code (to ensure ease of analysis), i.e. 01cali.

Standing Trials:

7. Set up 'new movie' and set to record.
8. Instruct participant of procedure:
   "When I say 'go' please step onto the mat and stand still, looking forwards, for 20 seconds, when I say 'stop' please step back off the mat and take a seat if you need to rest. We will repeat these three times.
9. With the participant in quiet standing on the mat, (relaxed, looking straight ahead, eyes open) record three standing trials. No use of an aid was permitted, but participants could sit down between trials if required.

Walkway familiarisation:

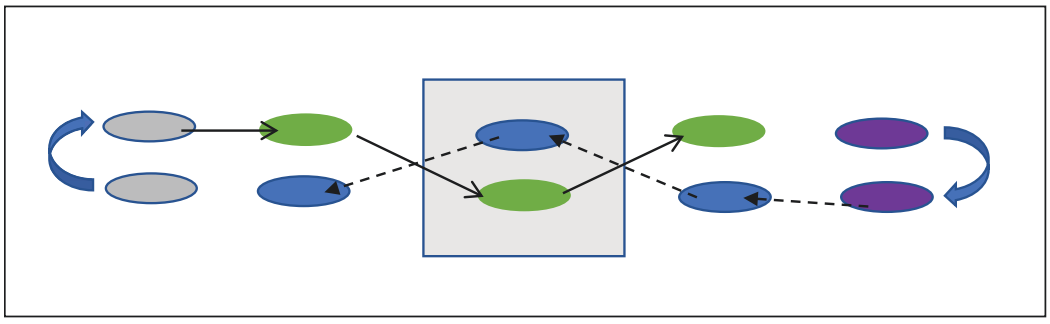
10. Instruct participant of procedure:

"*This test will record how your foot behaves while you are walking. It involves walking barefooted at your own comfortable speed over this pressure-sensitive mat. Firstly, we will practice the protocol and then I will ask you to walk over the mat at least three times in both directions at a comfortable speed. If you want to sit down at either end, then please inform the researcher and use the chair provided".*

11. Position the participant at the start of the walkway, 2 steps away from mat so the second foot, that which is being recorded, falls onto the mat. Find the starting point in both directions so that the recorded foot strikes the mat consistently.
12. Familiarise the participant to the walkway by letting them practise walking over the mat.
13. Use the cones to indicate the start of the walk and instruct the participant which foot to step with first. (Do this for both 'ends' of the walkway.)

Walkway protocol:

14. Open a new movie in TekScan® and set to record.
15. Instruct participant to walk at a comfortable walking speed along the walkway, marked out in step 11. Save recording.
16. Instruct the participant to turn around (those subjects who tire easily can have a seat while they wait).
17. Repeat in the opposite direction and save recording.
18. Rest (in standing or sitting) for 30 seconds.
19. Repeat 2 more times So 3 'good' trials are recorded in both directions (good trial = whole footprint on pressure mat, this can be checked by reviewing recorded movie). See diagram below for illustration.
20. Save all movies for analysis, naming individual files in the medical/diagnosis box (e.g. 01right1).



Square = TekScan® pressure mat
Oval = a single foot
Blue arrows = 180 degree turn
Purple ovals = standing position for start of R foot fall recorded walk
Grey ovals = standing position for start of L foot fall recorded walk
Solid arrows = walk for R foot falls onto mat
Dotted arrows = walk for L foot falls onto mat

APPENDIX 15: STANDARD OPERATING PROCEDURE: MUSCLE STRENGTH TESTING

- ***ANKLE MUSCLES***

Equipment:

Lafayette® hand-held dynamometer (HHD), with medium and large head, set to measure in kg
Plinth (with adjustable height and head)
Pillow/10 cm thick foam
Velcro Straps x3
15 cm diameter (neuro) roll
7 mm foam padding applied to 'head' (to ensure patient comfort)
Pen
Data collection sheet

Protocol:

1. Instruct the participant about the procedure:
   "These tests will look at the strength in your ankle muscles. I will now position your leg flat on the pillow/foam, we will them take some readings of the strength of your ankle muscles in different directions. If you feel any discomfort or pain at any point please let me know."
2. Position the participant in long sitting with lower limb supported by a 15 cm diameter roll underneath their knee. Using head of fibula and lateral malleolus as reference points align them horizontally, parallel to the floor and support this position with a pillow/foam under the calf.
3. Stabilise the limb by using a Velcro strap to fasten the pelvis, thigh and calves in the position, being careful to not move the limb out of position. (This will discourage compensatory movement that may occur due to patient effort.)
4. Position the Lafayette® HHD and Tester as follows:

Movement	Head size*	Participant	Tester
Ankle dorsiflexion	Large curved head, with foam layer (7 mm thick).	On the centre of the dorsum of the foot, just proximal to the metatarsal heads.	Positioned at the end of the bed facing the participant and in a wide step stance position with the plinth approximately hip height to allow good biomechanical advantage for the tester. Upper limbs will be neutral at shoulder region and 90° at the elbow with the wrist flexed, and hands grasping the HHD. Resistance will

			be given in a plantarflexion direction in line with the mid shaft of the tibia using body weight as necessary.
Ankle plantarflexion	Large curved head, additional one layer of foam (7 mm thick).	Place the HHD on the centre of the plantar aspect of the foot over the metatarsal heads.	In the same position as above but with wrists extended. And resistance offered in a dorsiflexion direction.
Ankle inversion	Medium flat circular head, with foam layer (7 mm thick).	Place the HHD on the medial aspect of foot halfway down shaft of the 1st metatarsal.	Positioned still facing the participant and in step stance, upper limbs in a slightly flexed, abducted and internally rotated, wrist extended position. Position should enable force given to oppose inversion movement. For left foot, this will be the right UL. For right foot; the left UL.
Ankle eversion	Medium flat circular head, with foam layer (7 mm thick).	On med aspect of foot, 5th met head (mid-point).	Positioned with the opposite upper limb holding the HHD and opposing eversion.

NB: Alignment of the foot. Hind foot relative to forefoot is partially maintained by the position of the HHD head, tester needs to observe any excessive forefoot movement and note down, also discourage the patient from utilising additional/compensatory muscle activity form pelvis, hip and knee).

5. Ask the participant to pull/push against the direction of resistance.
   "OK, this will be a practice test. When I say pull/push… up/down/in/out, into/away from* my hand, just using the muscles in your foot, keep pulling/pushing until I say relax". (* delete as appropriate.)*
6. Resistance applied by tester will be increased to resist movement of the ankle to hold it in a neutral position and record isometric muscle activity ('make' test).
7. During this, the tester will offer encouragement to ensure maximal recruitment of the muscles by telling the patient to "*keep pulling/pushing*" approximately 3 times (over 5–10 second period timed on the HHD and indicated by bleeps, this will vary the length of time the participant takes to recruit to their maximal strength output) then, "*and now relax*".
8. Allow patient to rest for 15 seconds and notify the participant it is no longer a test.
9. Repeat this procedure 3 more times, recording the peak force output (kg) for each test on the data collection sheet, allowing for a 15-second rest period between each measurement.
10. Repeat stages 6–8 for each movement component in the following order: Less-affected foot: Ankle dorsiflexion → ankle plantarflexion → ankle inversion → ankle

eversion. More-affected foot: ankle dorsiflexion → ankle plantarflexion → ankle inversion → ankle eversion. Record peak force output (kg) on the data collection sheet for each muscle group.

- ***HALLUX MUSCLES***

1. Explain procedure to participant:
   "This will be similar to the previous test but you will be sitting with your foot on a stool and I will be testing the strength in your big toe muscles, again if you feel any discomfort, please let me know."
2. Starting with the less-affected foot first get the participant positioned in sitting on the edge of the plinth, foot on stool, hip and knee at 90 degrees. Positioned with the joint axis on the edge of the stool (closest to the tester).
3. Position the Lafayette © HHD and Tester as follows:

Movement	Head size*	Participant	Tester
Hallux dorsiflexion	Small diameter head, with foam layer (7 mm thick).	On top of nail bed using the head.	Positioned kneeling on the floor. One hand holding the HHD and the other stabilising the foot, with web space round ankle.
Hallux plantarflexion	Small diameter head, with foam layer (7 mm thick).	On centre of toe pad using the head.	Positioned kneeling on the floor. One hand holding the HHD, the other stabilising the foot.

4. Participant is then requested to resist the testers resistance (make technique).
   "OK. When you are ready push up (DF)/down (PF) into my hand, keep pushing until I say relax."
5. Encouragement will be given if required to get the maximal strength, using phrases such as *"keep pulling/pushing".* Once this is reached then the participant will be told *"and relax".*
6. Allow patient to rest for 15 seconds and notify the participant it is no longer a test.
7. Repeat this procedure three more times recording the peak force output (kg) for each test on the data collection sheet, allowing for a 15-second rest period between each measurement.
8. Then repeat stages 3–7 for plantarflexion and then on the more-affected side for dorsiflexion and plantarflexion.

APPENDIX 16: STANDARD OPERATING PROCEDURE: ANKLE AND HALLUX PEAK ANGLE

➢ ANKLE DORSIFLEXION

Equipment:

Specifically made device – thermoplastic foot plate and metal device fitted with inclinometer and force gauge.
15 cm diameter (neuro) roll
Pillows
Plinth
Two long Velcro straps
Pen
Data collection sheet

Protocol:

1. Position participant in long sitting on an adjustable plinth (head at approx. 60 degrees up), pillow behind head, neck, for comfort.
2. Explain the procedure to the participant:
   "You will now be asked to relax while I move your ankles up and down, each one in turn, to measure how much movement there is. Please ask me to stop if it is too uncomfortable."
3. Position the less-affected side limb with the calf in a horizontal position, parallel to floor (lateral malleolus and fibula head aligned, with of aid of long armed set square). Use the 15 cm diameter roll and foam/pillow to support the knee and calf, respectively.
4. Stabilise the limb by using a Velcro strap to fasten the pelvis, thigh and calves in the position being careful to not move the limb out of position. (This will discourage any additional movement; the manoeuvre is passive.)
5. Fix the foot plate onto the participant using Velcro straps. Ensure comfort is maintained.
6. For ankle dorsiflexion: position participant in long sitting, attach force gauge and hand grip at level of metatarsal heads, centred on 2nd metatarsal head.
7. Conduct one familiarisation procedure, researcher to push on hand hold to force of 7 kg directly along the line of the shaft of the tibia. Instruct the participant to:
   "sit back and relax while I move your ankle up. hold it there for 5–10 seconds and then down, let me know if it becomes uncomfortable."
8. When force of 7 kg is reached and the angle position is held stable, press hold on the inclinometer. Then reposition the foot in PF resting position.
9. Allow a 15-second rest and notify the participant there will be three repeated tests.
10. Repeat this procedure (steps 6–8) 3 times. Allow for a 15-second rest between each test. Record the value on inclinometer (degrees) in the data collection sheet each time.
11. Repeat for the procedure (steps 6–10) for force value of 10 kg on the less-affected foot.

12. Then repeat steps 3–11 on the more-affected side.

- **HALLUX DORSIFLEXION:**

Equipment:

Rig developed by Jo Paton
Hook for strain gauge
Strain gauge
Inclinometer
Plinth
Pen
Data collection sheet

Protocol:

1. Participant sitting on edge of plinth, knees and hips at 90 degrees. Thighs supported on plinth. Relaxed posture, eyes looking ahead, hands resting on the plinth to offer stability.
2. Explain the produce to the participant:
   "You will now have your big toe movement measured. Sit here on the plinth, and stay relaxed while I move your big toe up hold it for up to 10 seconds and then back down to the floor."
3. Position the rig underneath the less-affected foot.
4. Position the MTPJ line directly over hinge of the testing jig.
5. Position the Tester's foot posterior to the heel of the participant's foot.
6. Place the inclinometer onto the test rig, on the moveable part, perpendicular to the hinge. Fix into position using double-sided tape to stop movement during testing procedure. Set the inclinometer to zero degrees whilst foot rig is horizontal.
7. Attach the strain gauge via the hook to the end, moveable hinge part of the rig. Using strain gauge pull toe into passive hallux dorsiflexion, until strain applied is 2 kg.
8. Pressing '*hold'* on the inclinometer. Then lower the hinge part of the rig slowly to the floor. This is a familiarisation reading.
9. Repeat 3 more times. Record angle by pressing '*hold* 'on the inclinometer and record the angle (degrees) achieved on the data collection sheet.
10. Repeat 3 more times on the less-affected side at 4 kg force to achieve end of range and record the angle (degrees) achieved on the data collection sheet.
11. Repeat steps 3–10 on the more-affected side.

APPENDIX 17: STANDARD OPERATING PROCEDURE: ANKLE SPASTICITY

Equipment:

Tardieu scale (modified, only fast and slow speeds for testing)
Plinth
Pen
Data collection sheet

Protocol:

1. Position the participant in supine or long sitting, under the less-affected side place a 15 cm diameter roll under knee for comfort, to reduce stretch on gastrocnemius.
2. The test will be explained to the participant:
   "This test aims to find out how active your muscles in your calf are when someone else moves your foot. I will move your foot 4 times towards and away from you slowly and then at a fast speed. Try and stay relaxed throughout the movement. If you feel any pain or discomfort, please let me know."
3. Tester position in stride step alongside participant. The tester's hand will be placed to cup the less-affected side calcaneus with forearm along the plantar surface of the foot. The participant will be taken passively from full available range of ankle plantarflexion to full available range of ankle dorsiflexion.
4. Repeat trials at 2 different speeds. V1 as slow as possible and then V3 as fast as possible with a 15-second rest between each one.
5. Measure the quality of movement (X) on an ordinal scale (0–5) and record this on the data collection sheet.
6. Repeat steps 3–5. twice more on the less-affected limb.
7. Repeat steps 1–6 on the more-affected side.

APPENDIX 18: COF DATA EXTRACTION PROTOCOL

Summary
The TekScan® research mat software is a programme that turns pressure values from a pressure mat into visual, graphical and numerical data. The software itself has a pre-set algorithm, which cannot be utilised for the current FAiMiS study, mainly due to the trial protocol adopted. Thus, a specific region definition and format has had to be developed. The three-phase protocol (A–C), in the step-by-step guide below, outlines the finalised method adopted for the centre of pressure (COP) variable during standing trials.

Technical Objective
To extract data for COP velocity and pathway length (vector of total trajectory) from a static standing trial with eyes open and eyes closed into a .csv file.

Layman's Terms Objective
To be able to pull out balance values when standing on the mat from the TekScan® movie files for normal standing position so that the data can be used in numerical format for further data analysis.

Input
Standing trial data in .fsx format (from .tpm file of participant).

Output
Excel sheet with **COP** when both feet are loaded on the mat.

Secondary Output
Region object boxes saved for future use (i.e. extraction of other variables of interest).

Equipment
- TekScan® foot research v7.0. software installed.
- Data: All .tpm files imported into database in TekScan®.
- MATLAB® software installed.

Time
Estimated time per trial = 3–5 minutes max.

Preparation
- Install TekScan® foot research software.
- Import all participant trials (.tpm) into database. To do this, open TekScan®, click on patient database (see top left of tool bar, group of three faces), click

on import patient/movies and browse for .tpm file, then click import. Please note, this has to be done individually.

- **Read through the whole protocol (A–C) outlined below prior to commencing.**

File Coding/Key

Participants are denoted by participant site/type/number, e.g. ALC05 or ALS53.

Site:	AL = East London; D = North Devon.
Participant type:	C = control; S = stroke.
Participant number:	e.g. 01, 02, … 72 … 110.

Trials are described by type/side/number, e.g. ‘stand eo’, or ‘walk r 3’.

Trial type (located in the diagnosis section):	Sit = sitting; **stand eo = standing eyes open;** **stand ec = standing eyes closed;** walk = walking trial.
Trial side:	L = left; R = right.
Trial number:	1, 2 or 3.

Please note, each movie file has its own frame number, which is preserved from original testing. Therefore, refer only to the participant number and trial type and number for identifying them.

APPENDIX 19: MATLAB® SCRIPT FOR COF DATA EXTRACTION

```
% clear
clear
close all
clear global
clc

participant data
(1) get data in
[files, path] =  uigetfile('.csv','Load COP data first','MultiSelect','off');
ifile =  strcat(path, files);

data(:,:) = dlmread(ifile,',',[ 44 3 443 4]); % changed for old version of fscan was 38 to 1035 (21 1018 = old
version)
datain1 = ifile; % save file name

(2) Filter the data
 [b,a] = butter(6,0.2); %type help butter to discover what this does % this filters 6th order up to 5 Hz SAMPLING
RATE  = 50 Hz
data_filt(:,:) = filtfilt(b,a,data(:,:));% this is the data filtered to 5 Hz 6th order butterworth
s = size(data_filt);

% omit1 = 10; % omit time in secs
% omit = omit1*200; % number of datapoints AFTER INTEROPLATION
 duration  = 8;

% Analyse all
data_diff = diff(data_filt)*10;
data_filtsq = data_diff.^2;
data_filtsq =  data_filtsq(:,1)+data_filtsq(:,2);
pathlength1 = sqrt(data_filtsq);
pathlength = sum(pathlength1);
copvel_all = pathlength/duration;

% analyse y

pathlength_y = sum(abs(data_diff(:,1)));
copvel_y = pathlength_y/duration;

% analyse x

pathlength_x = sum(abs(data_diff(:,2)));
copvel_x = pathlength_x/duration;

meandata = mean(data_filt);
s3 = size(data_filt);
meandata2 = repmat(meandata,s3(1),1);

data_remove = data_filt-meandata2;

figure(1)
plot(data_filt(:,1),data_filt(:,2));
title(copvel_all)

figure(2)
plot(data_remove(:,1),data_remove(:,2));
title(copvel_all)
axis([-20 20 -20 20])

Save the data
save workspace to disk
[name, path] = uiputfile('*.mat','save workspace');
outfile  =  [path name];
save('outfile.txt','datain1',
'copvel_all','copvel_y','copvel_x','pathlength_y','pathlength_x','pathlength','data','data_filt','-ascii', '-tabs');

format shortG;
format compact;
files
copvel_all
copvel_x
copvel_y
pathlength
```

APPENDIX 20: PLANTAR PRESSURE AND CONTACT AREA DATA EXTRACTION PROTOCOLS

Summary
The TekScan® research mat software is a programme that turns pressure values from a pressure mat into visual, graphical and numerical data. The software itself has a pre-set algorithm, which cannot be utilised for the current FAiMiS study mainly due to the trial protocol adopted. Thus, a specific region definition and format has had to be developed. The four-phase protocol (D–G), in the step-by-step guide below, outlines the finalised method adopted for the peak contact pressure variable during a walking trial.

Technical Objective
To extract data for peak contact pressure from four regions of a footprint of a single walking (dynamic) trial into a .csv file.

Layman's Terms Objective
To be able to pull out maximum pressure values when walking over the mat from the TekScan® movie files for four foot regions so that the data can be used in numerical format for further data analysis.

Input
Single walking trial data in .fsx format (from .tpm file of participant).

Output
Excel sheet (.csv) with **peak contact pressure/contact area** under **rearfoot, mid-foot, forefoot and toes**.

Secondary Output
Region object boxes saved for future use (i.e. extraction of other variables of interest).

Equipment
- TekScan® foot research v7.0. software installed.
- Data: All .tpm files imported into database in TekScan®.

Time
Estimated time per trial = 3–5 minutes max.

Preparation
- Install TekScan® foot research software.
- Import all participant trials (.tpm) into database. To do this, open TekScan®, click on patient database (see top left of tool bar, group of three faces), click on import patient/movies and browse for .tpm file, then click import. Please note, this has to be done individually.

- **Read through the whole protocol (D–G) outlined below prior to commencing.**

File Coding/Key

Participants are denoted by participant site/type/number, e.g. ALC05 or ALS53.

Site:	AL = East London; D = North Devon.
Participant type:	C = control; S = stroke.
Participant number:	e.g. 01, 02, … 72 … 110.

Trials are described by type/side/number, e.g. ‘stand eo’, or ‘walk r 3’.

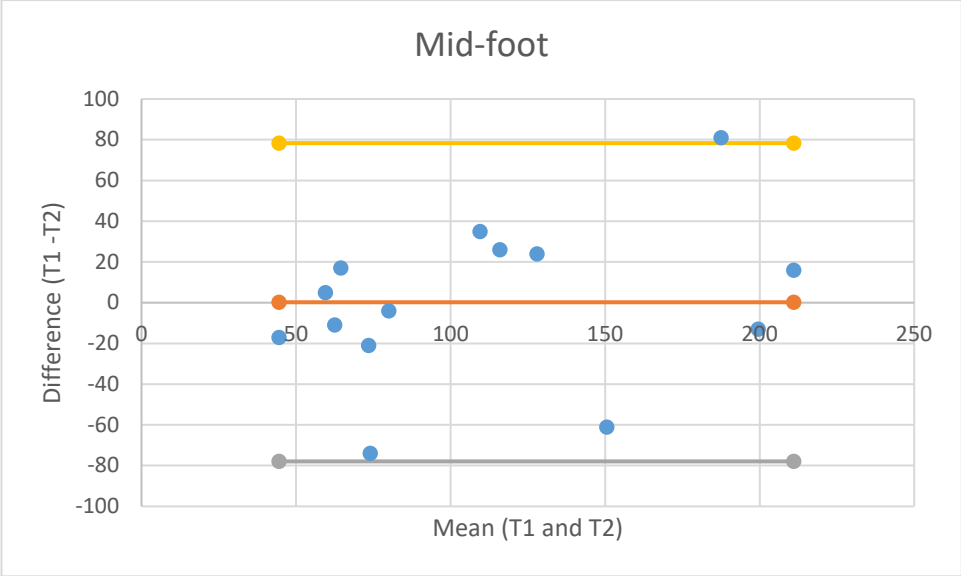
Trial type (located in the diagnosis section):	Sit = sitting;
	stand eo = standing eyes open;
	stand ec = standing eyes closed;
	walk = walking trial.

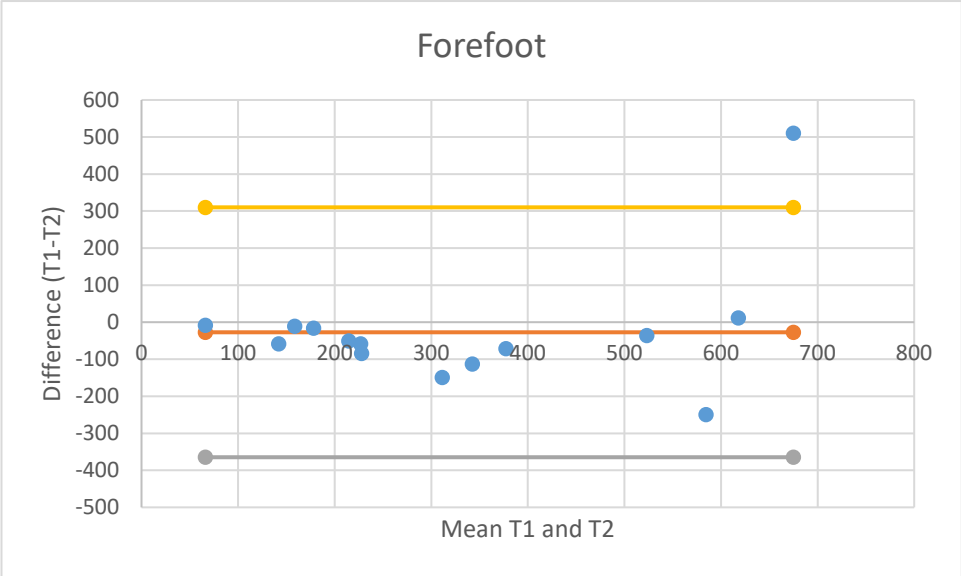
Trial side:	L = left; R = right.
Trial number:	1, 2 or 3.

Please note, each movie file has its own frame number, which is preserved from original testing. Therefore, refer only to the participant number and trial type and number for identifying them.

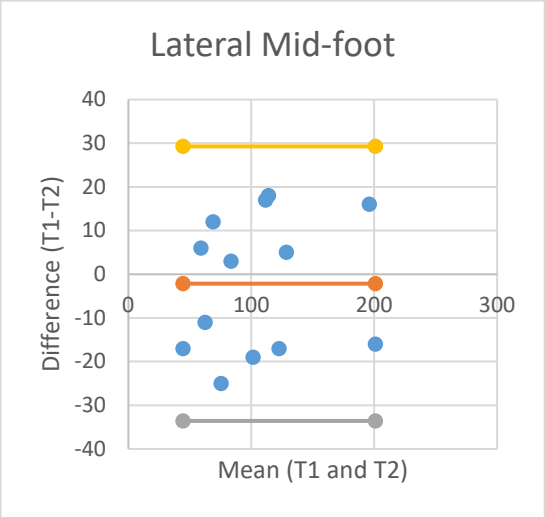
APPENDIX 21: STUDY 1 BLAND–ALTMAN PLOTS

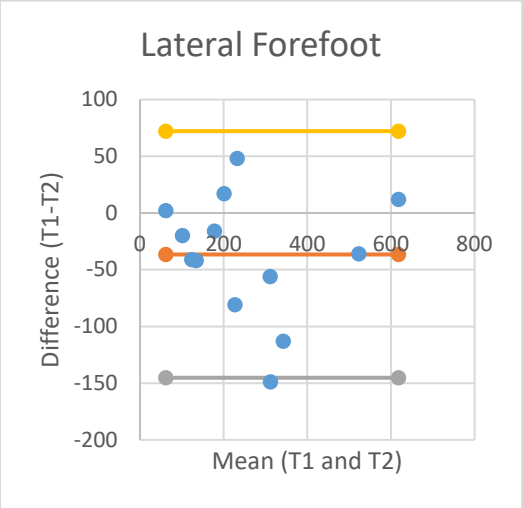
Peak Pressure Four Regions

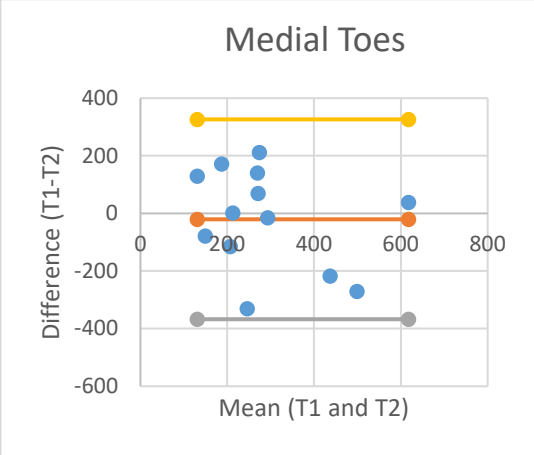


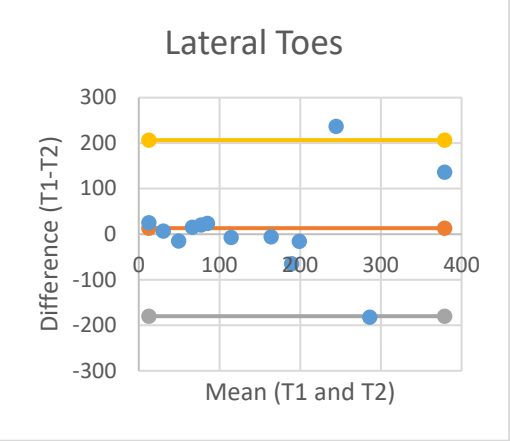


Peak Pressure Eight Regions

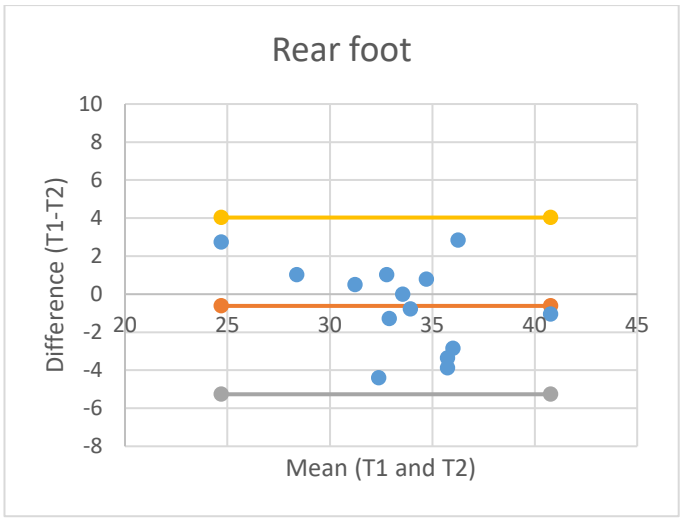


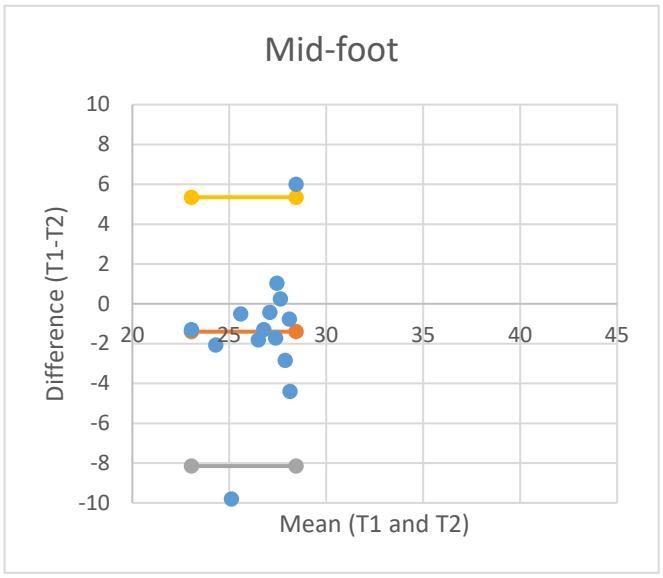


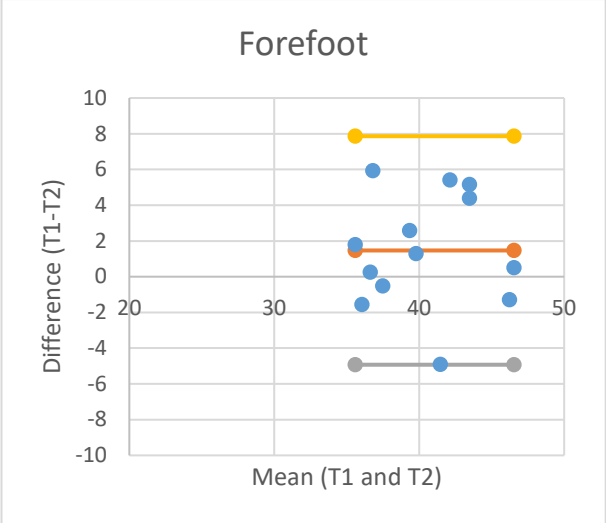


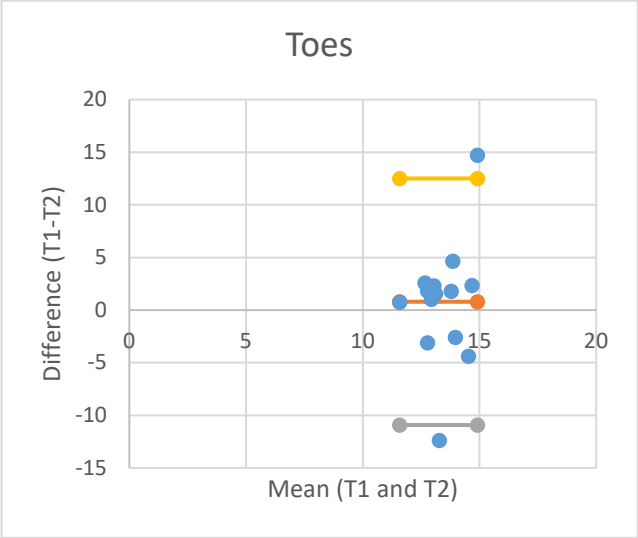


Contact Area Four Regions

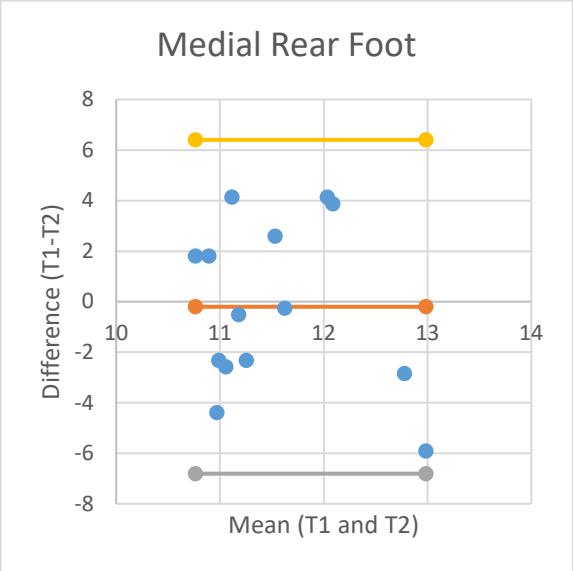


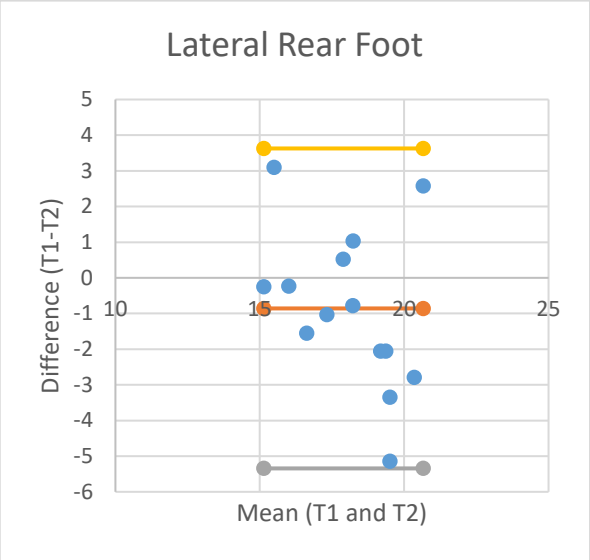


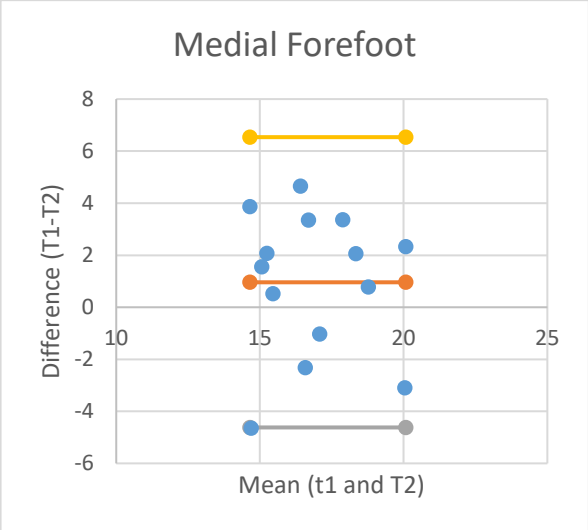

Forefoot
Difference (T1-T2)
10
8
6
4
2
0
-2
-4
-6
-8
-10
20
30
40
50
Mean (T1 and T2)

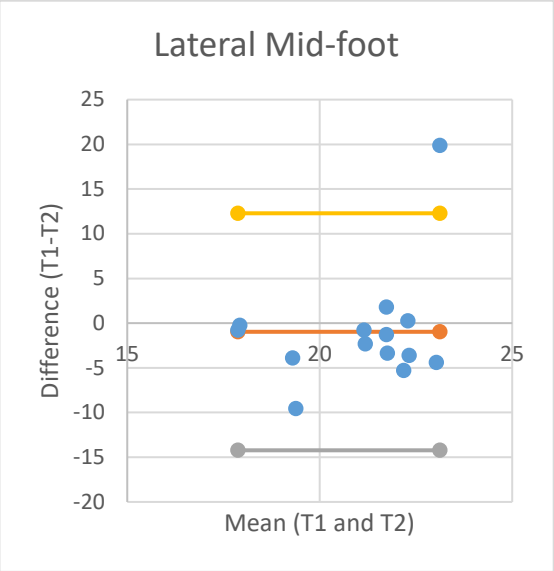

Toes
Difference (T1-T2)
20
15
10
5
0
-5
-10
-15
0
5
10
15
20
Mean (T1 and T2)

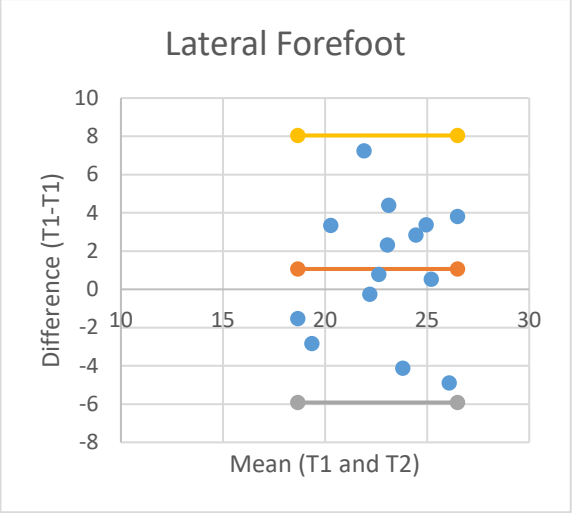
Contact Area Eight Regions

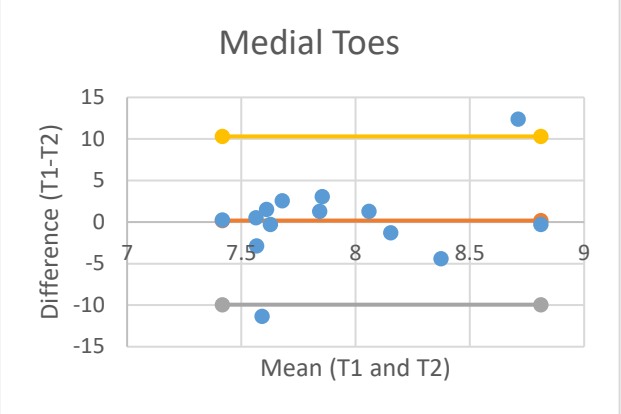


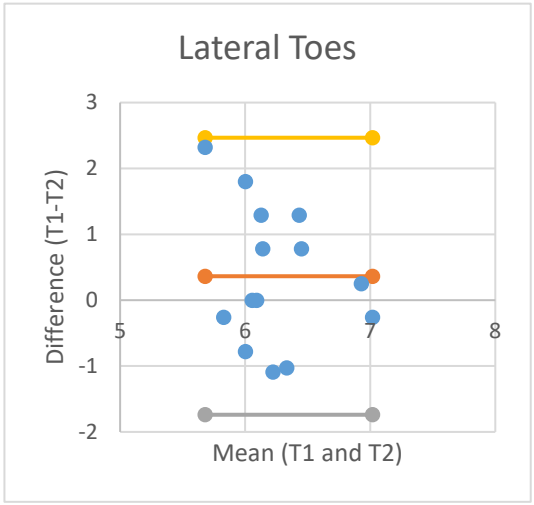


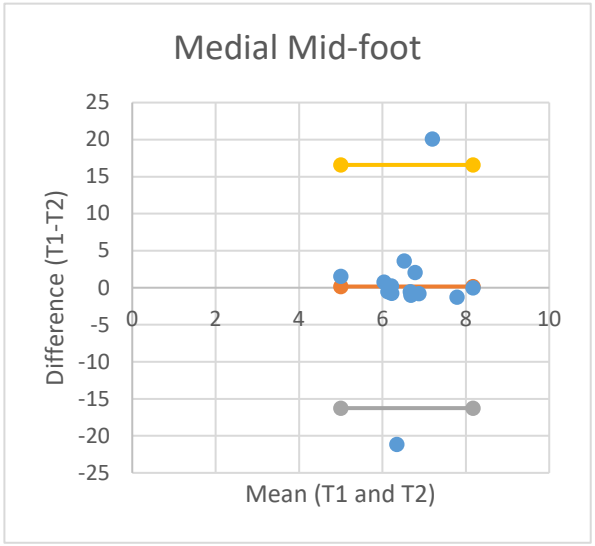




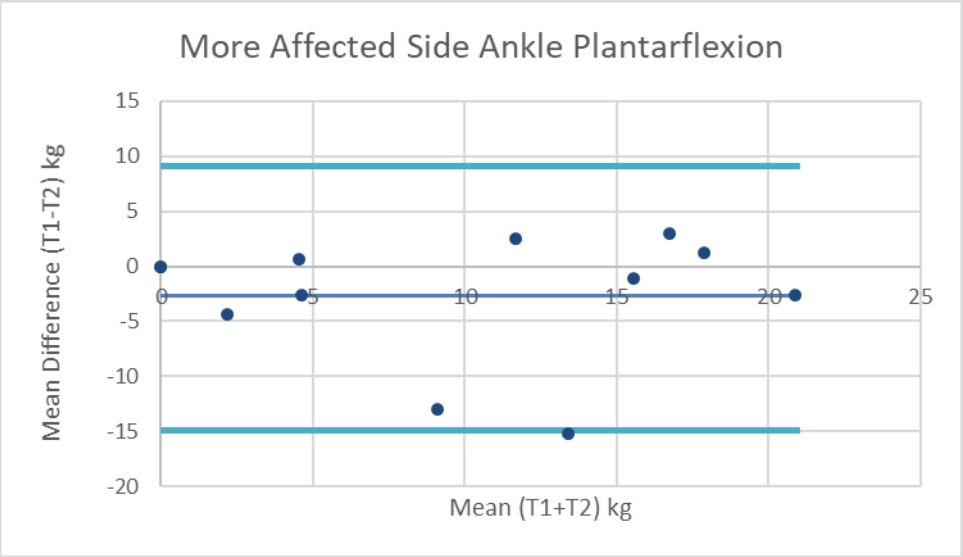


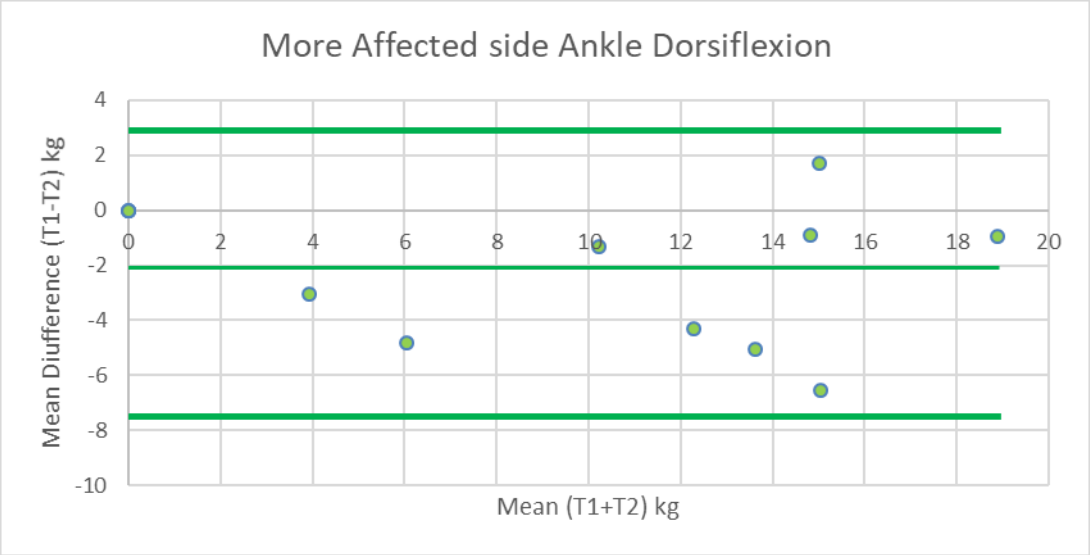


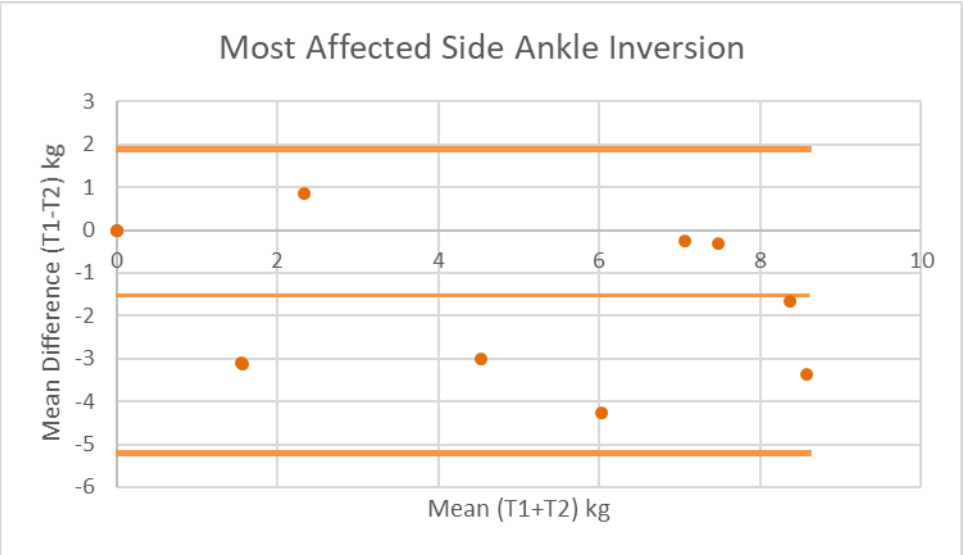

Lateral Toes
Difference (T1-T2)
3
2
1
0
-1
-2
5
6
7
8
Mean (T1 and T2)

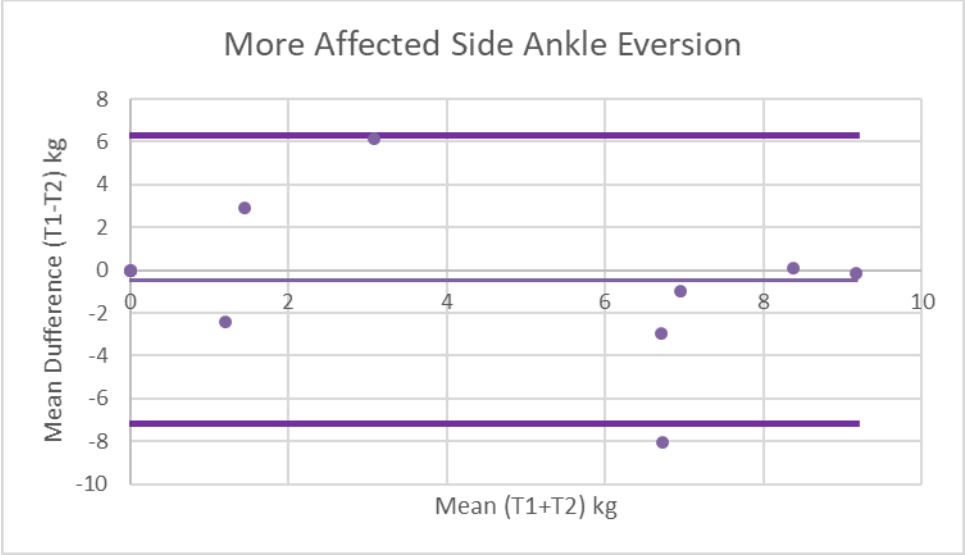

Medial Mid-foot
Difference (T1-T2)
25
20
15
10
5
0
-5
-10
-15
-20
-25
0
2
4
6
8
10
Mean (T1 and T2)

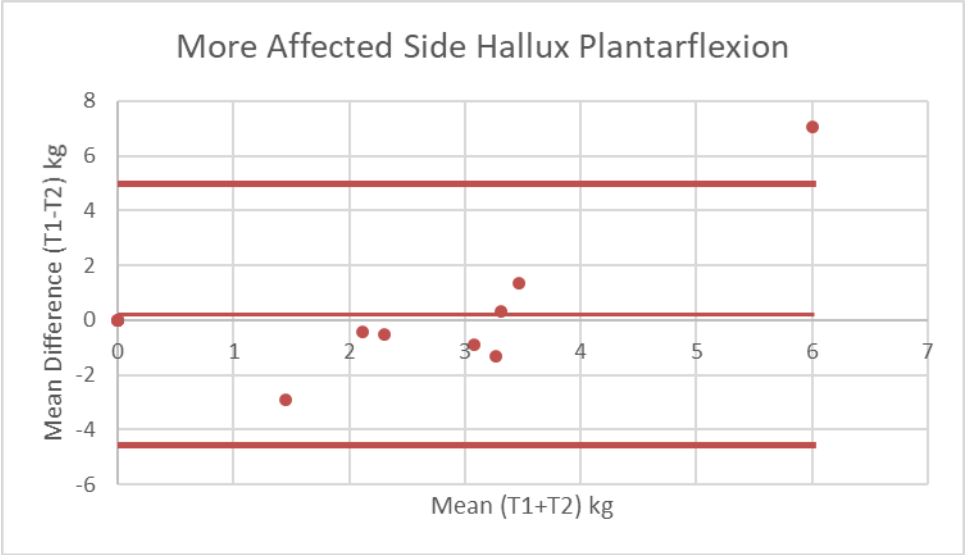
Isometric Muscle Strength (Single muscle groups)

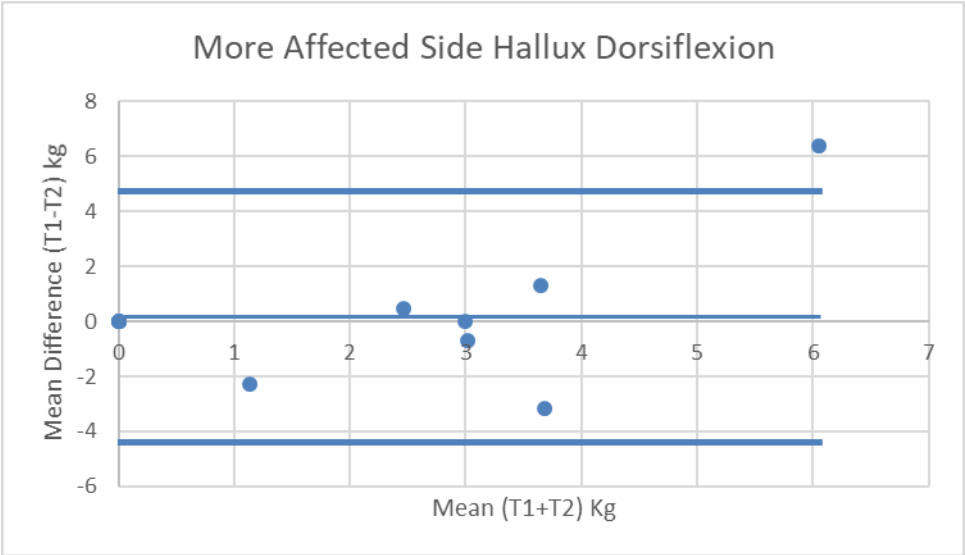




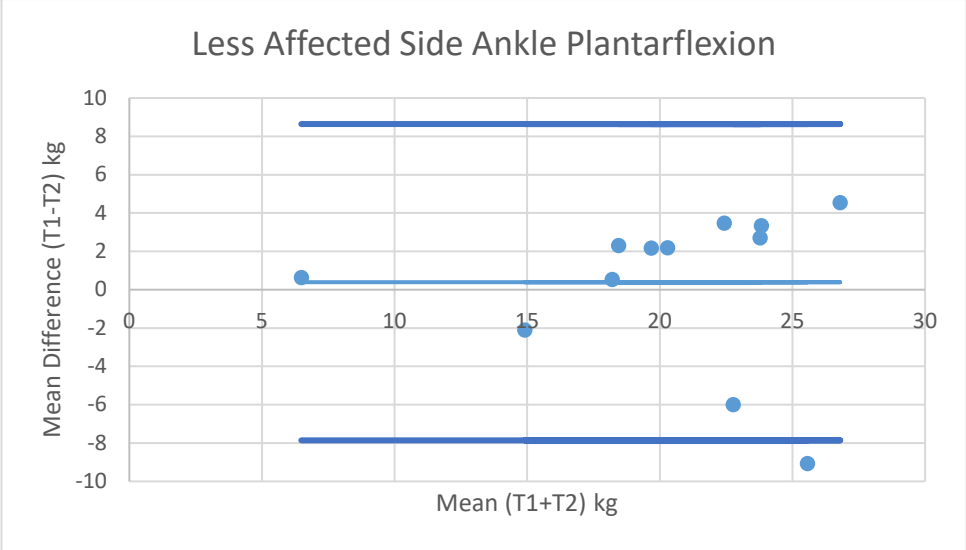


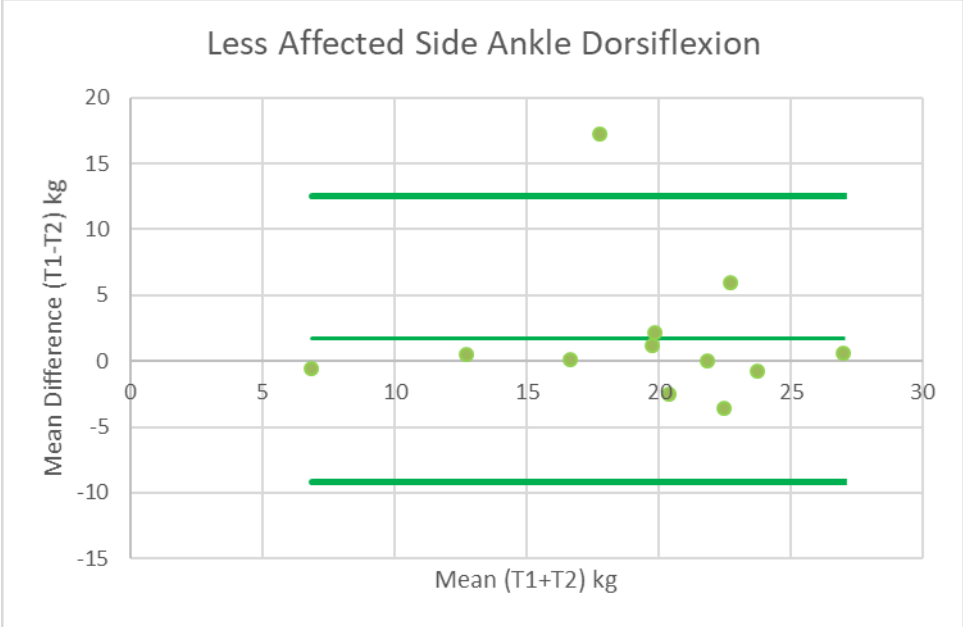


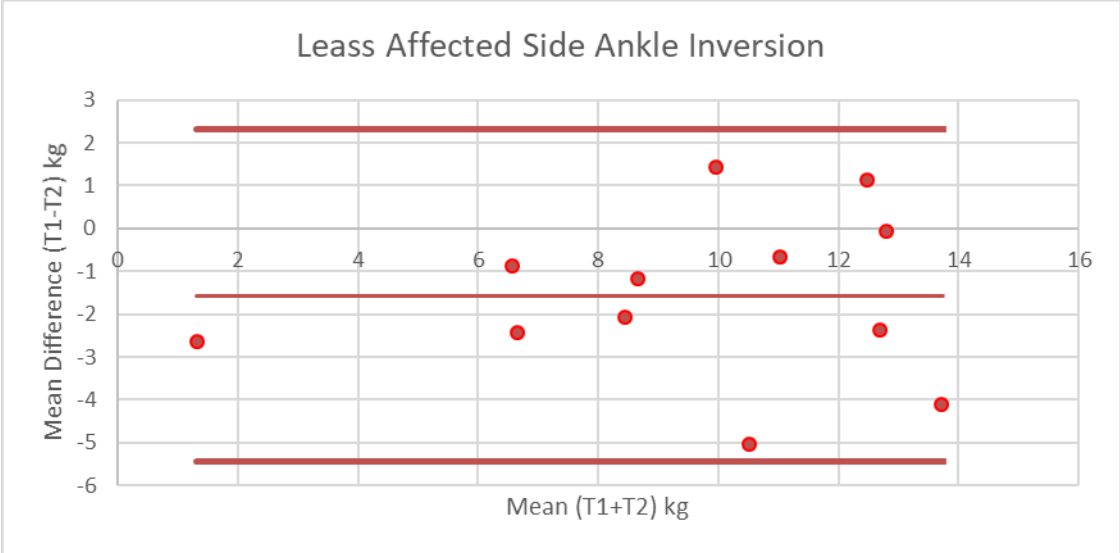


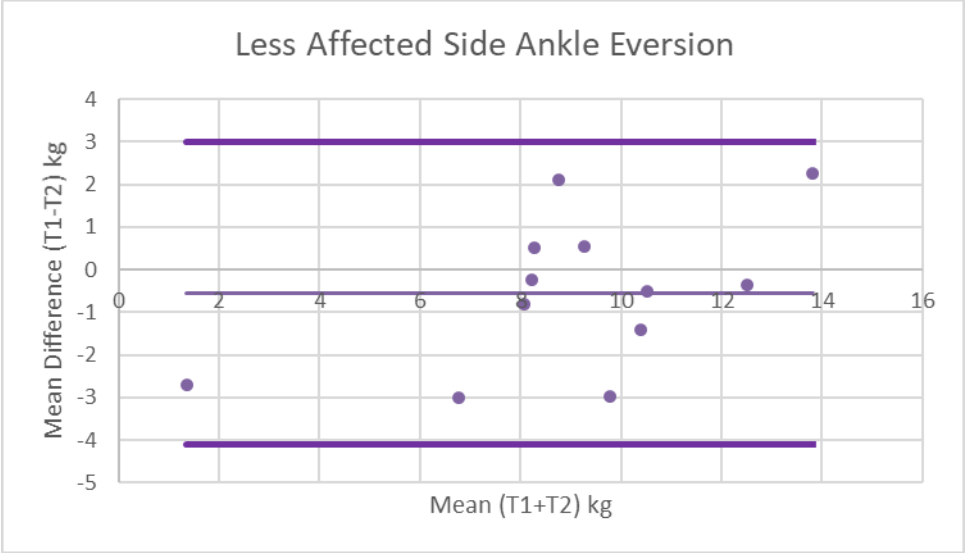


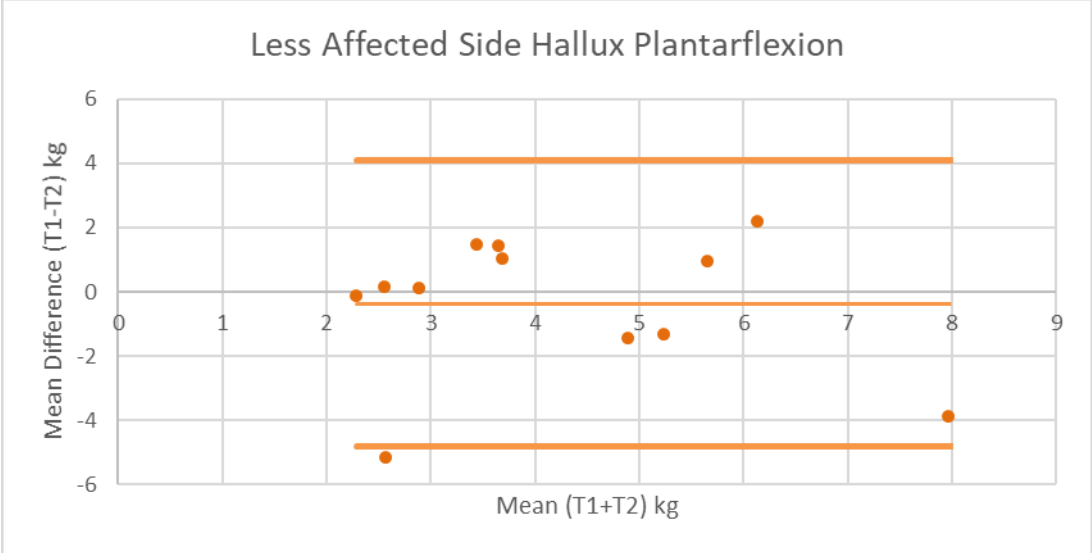
*Graphs with data at $x = 0$, $y = 0$, may represent more than one data point.

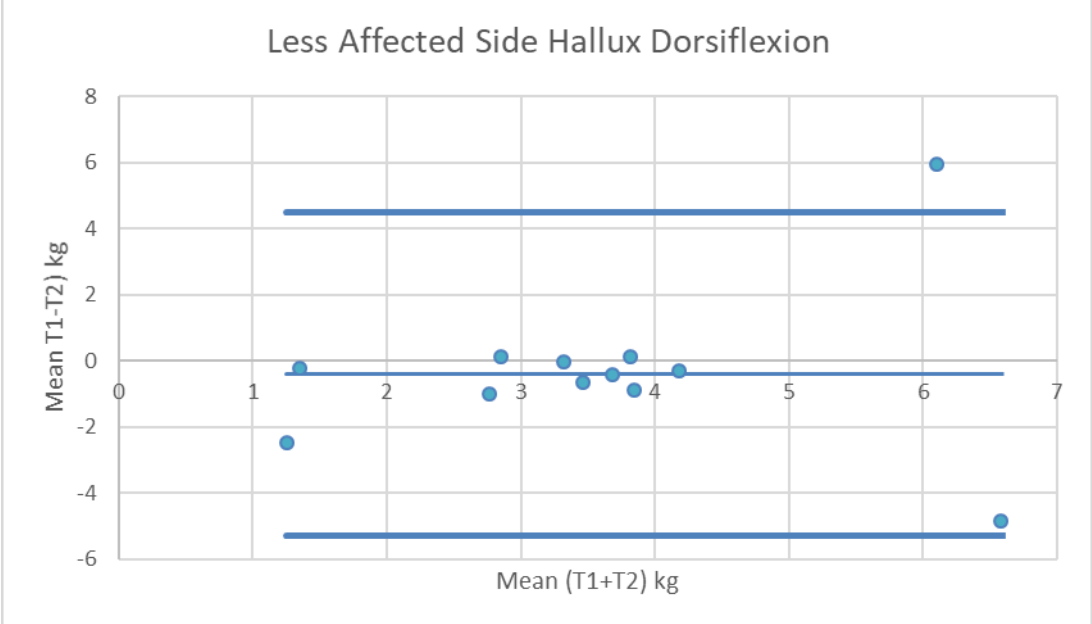

Less Affected Side Ankle Plantarflexion
Mean Difference (T1-T2) kg
10
8
6
4
2
0
-2
-4
-6
-8
-10
0
5
10
15
20
25
30
Mean (T1+T2) kg


Less Affected Side Ankle Dorsiflexion
Mean Difference (T1-T2) kg
20
15
10
5
0
-5
-10
-15
0
5
10
15
20
25
30
Mean (T1+T2) kg

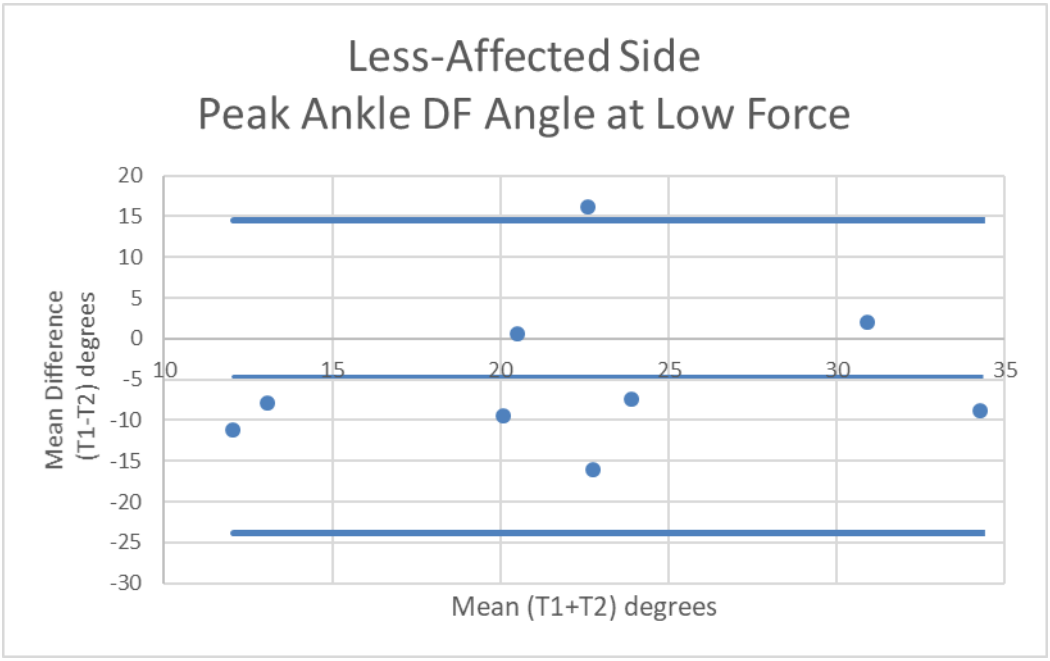

Leass Affected Side Ankle Inversion
Mean Difference (T1-T2) kg
3
2
1
0
-1
-2
-3
-4
-5
-6
0
2
4
6
8
10
12
14
16
Mean (T1+T2) kg

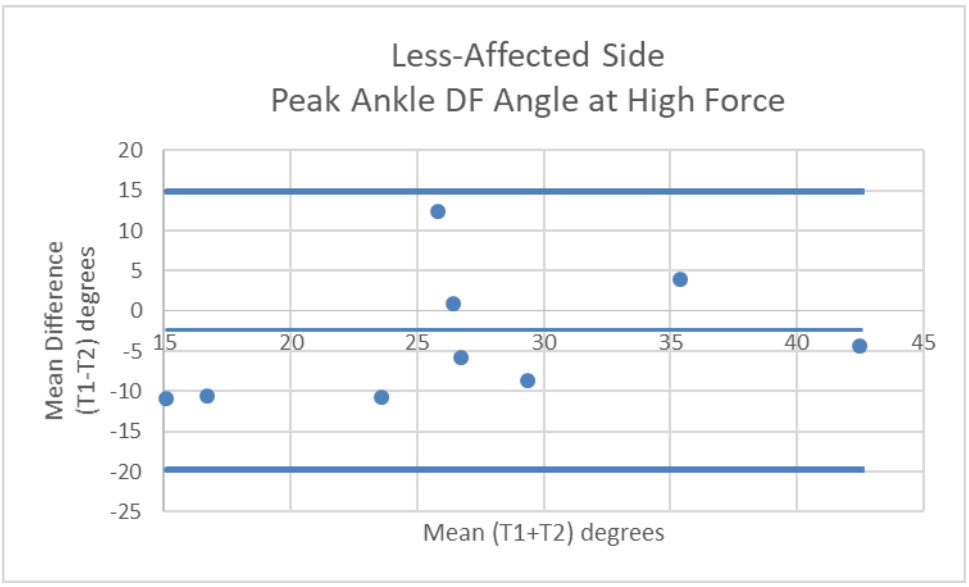

Less Affected Side Ankle Eversion
Mean Difference (T1-T2) kg
Mean (T1+T2) kg
4
3
2
1
0
-1
-2
-3
-4
-5
0
2
4
6
8
10
12
14
16

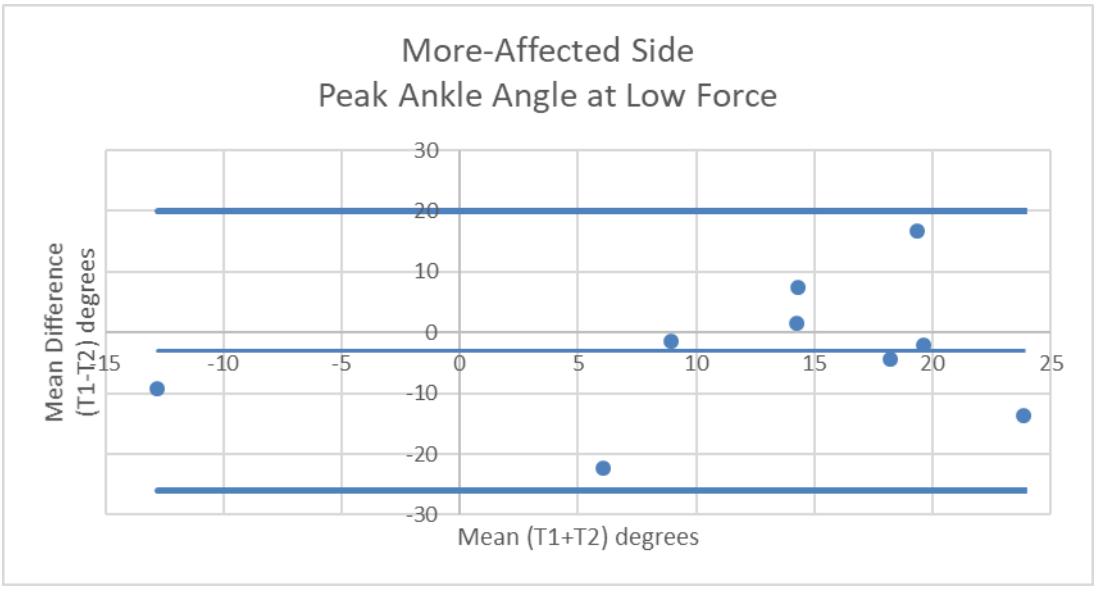

Less Affected Side Hallux Plantarflexion
Mean Difference (T1-T2) kg
Mean (T1+T2) kg
6
4
2
0
-2
-4
-6
0
1
2
3
4
5
6
7
8
9

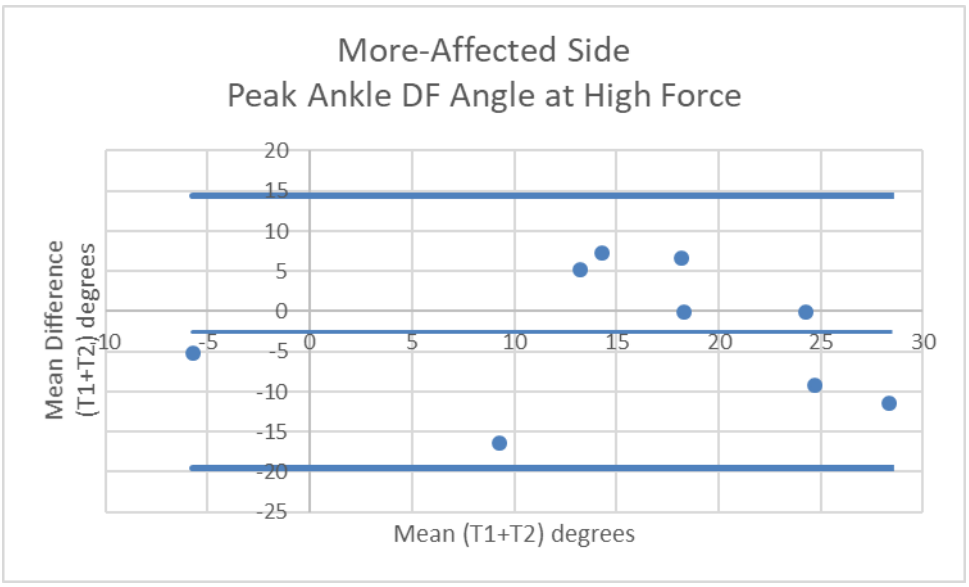

Less Affected Side Hallux Dorsiflexion
Mean T1-T2) kg
Mean (T1+T2) kg
8
6
4
2
0
-2
-4
-6
0
1
2
3
4
5
6
7

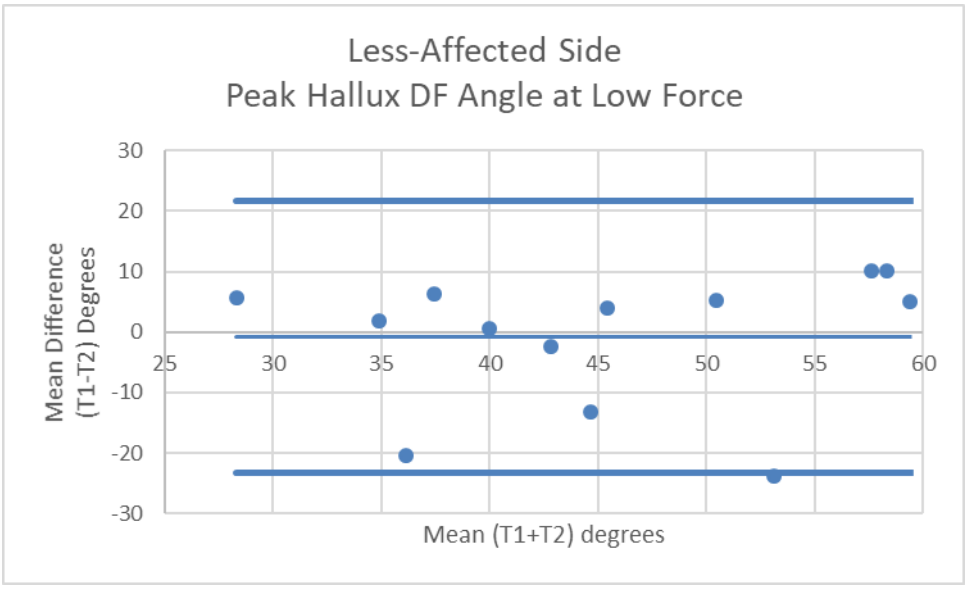
Peak angles at the Ankle and Hallux at Low and High forces

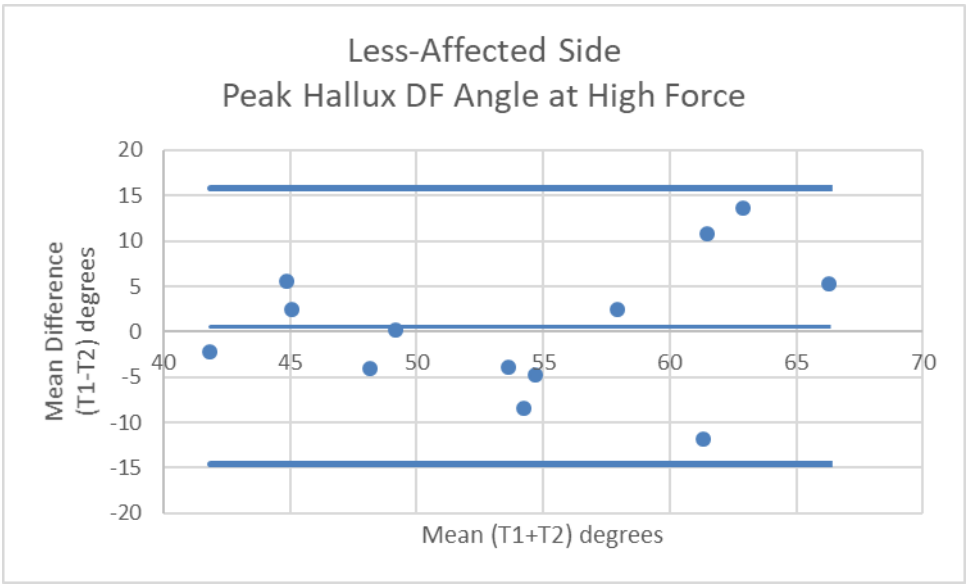


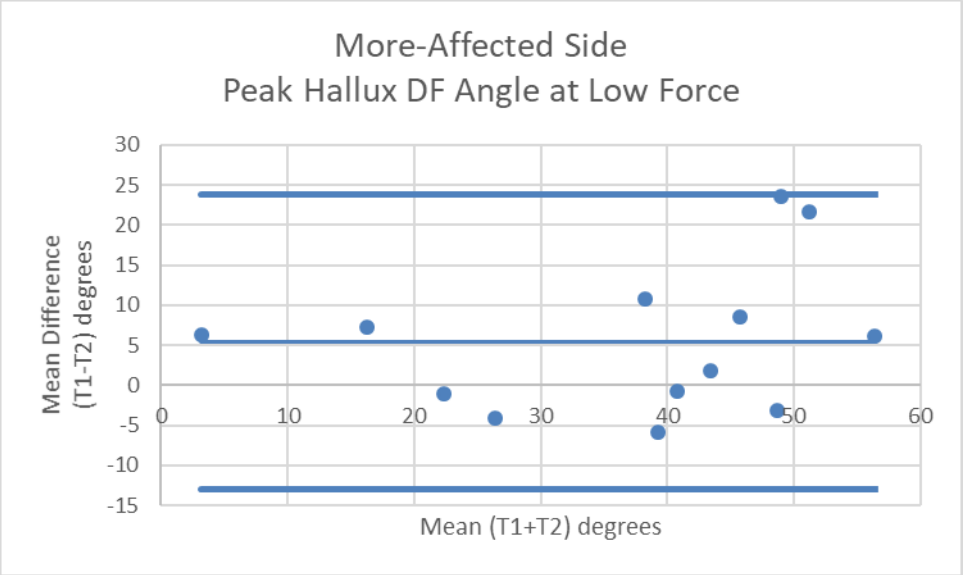


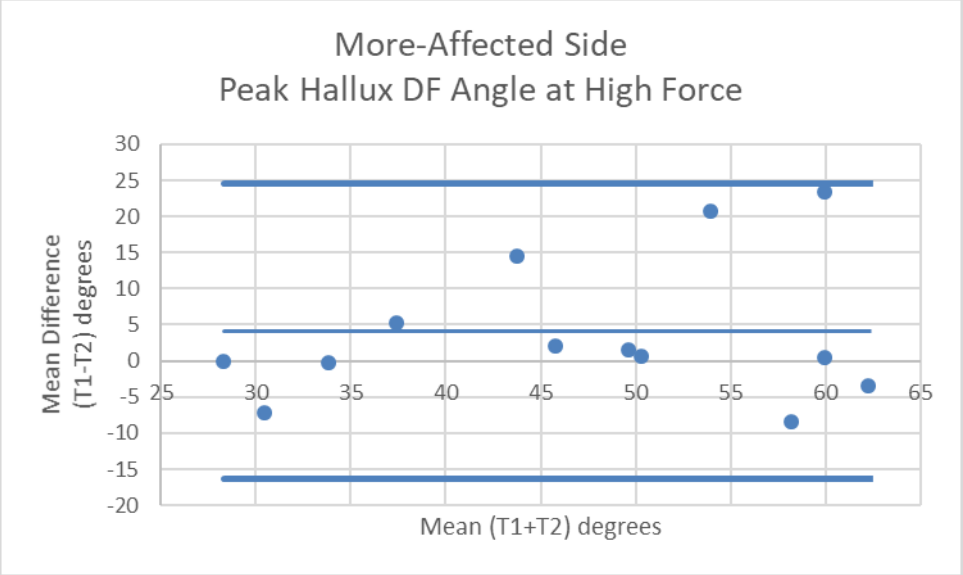

More-Affected Side
Peak Ankle Angle at Low Force
Mean Difference (T1-T2) degrees
30
20
10
0
-10
-20
-30
-15
-10
-5
0
5
10
15
20
25
Mean (T1+T2) degrees


More-Affected Side
Peak Ankle DF Angle at High Force
Mean Difference (T1+T2) degrees
20
15
10
5
0
-5
-10
-15
-20
-25
-10
-5
0
5
10
15
20
25
30
Mean (T1+T2) degrees


Less-Affected Side
Peak Hallux DF Angle at Low Force
Mean Difference (T1-T2) Degrees
30
20
10
0
-10
-20
-30
25
30
35
40
45
50
55
60
Mean (T1+T2) degrees


Less-Affected Side
Peak Hallux DF Angle at High Force
Mean Difference (T1-T2) degrees
20
15
10
5
0
-5
-10
-15
-20
40
45
50
55
60
65
70
Mean (T1+T2) degrees


More-Affected Side
Peak Hallux DF Angle at Low Force
Mean Difference (T1-T2) degrees
30
25
20
15
10
5
0
-5
-10
-15
0
10
20
30
40
50
60
Mean (T1+T2) degrees


More-Affected Side
Peak Hallux DF Angle at High Force
Mean Difference (T1-T2) degrees
30
25
20
15
10
5
0
-5
-10
-15
-20
25
30
35
40
45
50
55
60
65
Mean (T1+T2) degrees

APPENDIX 22: STUDY 2 ETHICS (NHS)

Study 2 Ethical approval: NHS

Study title: The effect of foot and ankle impairments on mobility and balance in community dwelling adults – post stroke a personal and multi-disciplinary approach.

THE RESEARCH IN THIS THESIS WAS PART OF A LARGER STUDY, WHICH HAD ETHICAL APPROVAL FROM THE NHS, AS SUCH THE THESIS TITLE IS SLIGHTLY DIFFERENT FROM THAT OF THE OVERALL RESEARCH PROJECT.

NRES Committee South West – Exeter
Bristol Research Ethics Committee Centre
Whitefriars
Level 3
Block B
Lewins Mead
Bristol
BS1 2NT
Telephone: 0117 342 1390 Fax: 0117 342 0445

21 January 2014

Dr Mary Cramp
Associate Head of Department
University of the West of England
Department of Allied Health Professions
Glenside Campus
Blackberry Hill, Stapleton, Bristol
BS16 1DD

Dear Dr Cramp,

Study title: **The effects of foot and ankle impairments on mobility and balance in community dwelling adults post-stroke – a personal and multi-disciplinary approach**

REC reference: **13/SW/0302**
IRAS project ID: **136674**

Thank you for your letter of 21 January 2014. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 2 January 2014.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant Consent Form: University of Plymouth	3 - Clean & Tracked	20 January 2014
Participant Consent Form: University of East London	3 - Clean & Tracked	20 January 2014
Participant Information Sheet: University of Plymouth	3 - Clean & Tracked	20 January 2014
Participant Information Sheet: University of East London	3 - Clean & Tracked	20 January 2014
Participant Information Sheet: University of East London Controls	3 - Clean & Tracked	20 January 2014
Participant Information Sheet: University of Plymouth Controls	3 - Clean & Tracked	20 January 2014

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Advertisement	2	5 December 2013
Covering Letter		18 October 2013
Evidence of Insurance or Indemnity	UEL, UOP, UWE	
GP/Consultant Information Sheets	V1.0	4 October 2013
Investigator CV	M Cramp	
Letter of Invitation to Participant	V1.0	4 October 2013
Other: Summary CV for Supervisor (Student Research)	J Marsden, J Freeman, S Morrison	
Other: Summary CV for Student	2 students: A Lyddon and T Gorst	
Other: Letter from Funder	Notification of award	1 June 2012
Other: Summary CV	Dr J Paton	

Other: Poster	2	5 December 2013
Participant Consent Form: University of Plymouth	3 - Clean & Tracked	20 January 2014
Participant Consent Form: University of East London	3 - Clean & Tracked	20 January 2014
Participant Information Sheet: University of Plymouth	3 - Clean & Tracked	20 January 2014
Participant Information Sheet: University of East London	3 - Clean & Tracked	20 January 2014
Participant Information Sheet: University of East London Controls	3 - Clean & Tracked	20 January 2014
Participant Information Sheet: University of Plymouth Controls	3 - Clean & Tracked	20 January 2014
Protocol		
REC Application		18 October 2013
Referees or Other Scientific Critique Report	Dr W.M. Scholl	
Response to Request for Further Information		9 December 2013

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

13/SW/0302 **Please quote this number on all correspondence**

Yours sincerely,

Miss Georgina Castledine
REC Assistant
Email: nrescommittee.southwest-exeter@nhs.net

Copy to: Jennifer Ames, University of West of England
Sally Tettersell, Research and Development Office, North Devon Healthcare Trust

APPENDIX 23: STUDY 2: LETTER OF INVITATION

(Appropriate NHS Trust Letterhead)

04.10.2013 Version 1.0 REC Ref: 13/SW/0302

Letter of Invitation to Participate in a Stroke Research Project

Project title: The effects of foot and ankle impairments on mobility and balance in community dwelling adults post-stroke

Dear Madam/Sir,

People who have had a stroke are being invited to take part in a research study. The research is being undertaken by staff from (insert local institution).

The research is looking at how foot and ankle problems following stroke affect walking and balance. The aim of this research is to help us understand more about how balance and walking can be improved in people who have had a stroke.

You are being given this letter because you may be suitable to take part in the study. If you are interested in finding out more about the research, we can provide your details to the researchers so that they can contact you about the study. The researchers will be able to tell you more about the research and what's involved.

If you are happy for the researchers to contact you about the study, please tick the statement below and either return this letter to the person who gave it to you or return it in the envelope provided. By agreeing to be contacted by the researchers, you are not agreeing to take part. You are only agreeing to being contacted by the researchers so they may tell you more. If you do not complete and return this letter, you will not be contacted by the researchers and they will not receive your contact details.

Any decision you make about taking part in this study will not affect any future treatment you may receive.

Yours sincerely,

[Direct care worker]

On behalf of *Alison Lyddon*, Researcher on FAiMiS
Tel: 02082234256

□ I am happy for the research team to contact me to tell me more about the study. My contact details are:

Name: ……

Tel.(inc. code): ……

Email (if you prefer): ……..…….

APPENDIX 24: STUDY 2: PATIENT AND CONTROL INFORMATION SHEET

04.10.2013 Version 1.0 REC Ref: 13/SW/0302
Patient and Control Information Sheet

Project title: The effects of foot and ankle impairments on mobility and balance in community dwelling adults post-stroke

Dear Madam/Sir,

We would like to invite you to participate in a research study because you have had a stroke and it may be affecting your walking and balance. The study will be conducted by a researcher who is a trained physiotherapist. The researcher is employed part-time to conduct the research and is studying for a PhD. To help you know more about the study, please read the question and answer section below. It should help you decide if you would like to take part.

Study background
Problems with the foot and ankle such as muscle weakness or tightness, sensation changes, or movement restrictions may contribute to difficulties with walking and balance after stroke. These problems and their impact have yet to be fully explored and more research is needed to help us to better understand how foot and ankle problems experienced after a stroke affect walking and balance.

What is the purpose of the study?
The aim of this study is to investigate whether foot and ankle problems affect walking and balance so that treatment may be improved. We will also be comparing the feet and ankles of people who have had a stroke with those who have not had a stroke to take account of changes that may occur as a result of age. We plan to recruit up to 180

participants who have had a stroke and up to 45 participants who have not had a stroke to take part in the study.

What will I be asked to do if I decide to take part?
You will be asked to attend one assessment session so that we may assess your foot and ankle, your walking and your balance. The session will last about 90 minutes. Measurements will be taken of your foot in sitting, standing and walking. Some of these will involve special equipment applied to your foot and ankle and some will record how your foot moves when you walk using a video recorder. You will also be asked to complete some questionnaires about your mobility and balance.

Where will this study take place?
The study will take place at the Human Motor Performance Centre, University of East London, Stratford Campus, Water Lane, Stratford.

How will I travel there and get back home?
We are happy to help to arrange travel to attend assessment and there are funds available to pay for the cost of your travel. We have allowed for a return minicab fare of £25. If you require alternative travel arrangements, please discuss this with the research team; we will endeavour to accommodate your requirements and meet your travel costs.

Do I have to take part?
No. It is entirely up to you whether or not you would like to take part. If you decide to take part but change your mind, you are still free to withdraw at any time.

What are the possible advantages of taking part?
There are no direct benefits to you in taking part in this research. By taking part in the research, you may be helping us to improve the way foot and ankle problems are managed after stroke in the future.

What are the possible disadvantages or risks of taking part?
There are minimal risks in taking part in this research. It is possible that you may experience brief and temporary discomfort during some of the tests as they will involve stretching certain muscles. You may also feel tired/stiff after the test and on the next day, similar to that felt after undertaking moderate exercise. There is also a risk to you of falling during the mobility and balance assessment although you will be supervised by a physiotherapist during the assessment. We will not be asking you to do anything you do not feel able to do safely.

What happens if something goes wrong or I am unhappy about my participation in the study?
We believe that this study is basically safe and do not expect you to suffer any harm or injury because of your participation in it. In the unlikely event that something does go wrong and through our negligence, you are harmed, you will be compensated. However,

you may have to pursue your claim through legal action. The University will consider any claim sympathetically. If you are not happy with any proposed compensation, you may have to pursue your claim through legal action. If you would like further information on our insurance cover, please contact: *Professor Neville Punchard, Chair, University Research Ethics Committee, University of East London, Water Lane, London, E15 4LZ. Telephone number: 0208 223 4477*. You may also contact the Patient Advice and Liaison Service for independent advice or in case of complaint on 0800 389 8324 or 0207 566 2325.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by the NRES Committee South West – Exeter, and it has also been considered by the Research Ethics Committees of the Universities of Plymouth, the West of England and East London. If you have any questions about the ethics of the research or about any of the researchers, please contact: researchethics@uel.ac.uk

What will happen to the information collected?
All information collected about you during this research will be kept strictly anonymous. All information will be stored electronically on a computer, which is password protected, in a document file that is also password protected. All information will be handled in compliance with the Data Protection Act (1998).

Your name and address (which we need in order to contact you) will be stored separately from the other information you supply during the project so that you cannot be identified from your study records.

What will happen to the results of the research study?
The information gained will be used to improve future treatment of foot, ankle, mobility and balance problems following stroke. We will aim to talk about the work at meetings and conferences in this country and abroad, and we will aim to publish the findings widely in medical journals. Your data will always remain anonymous and your name will not appear on any of the results.

Your rights
Your participation in this study is entirely voluntary. You may withdraw at any time without giving a reason for withdrawal or without it affecting your current or future health care treatment in any way.

Who should I contact for further information or if I would like to take part in the study?
Please contact:

Alison Lyddon
School of Health, Sport and Bioscience,

University of East London
Water Lane,
London, E15 4LZ
Telephone number: 0208 223 4296
Email: a.lyddon@uel.ac.uk

Thank you for your consideration.

Yours sincerely,

Alison Lyddon

[One copy for the participant; one copy for the researcher; original retained on file.]

APPENDIX 25: STUDY 2: CONSENT FORM

Consent Form – University of East London
Version 3.0, 20/01/2014
REC Ref: 13/SW/0302

FAiMiS
Foot and ankle impairments affecting mobility in stroke

UEL University of East London

Project title: The effects of foot and ankle impairments on mobility and balance in community dwelling adults post-stroke

Name of researcher: **Alison Lyddon**

Please initial box

1. I confirm that I have read and understand the Participant Information Sheet dated 20.01.2014 (Version 3.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
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 agree to have video recordings taken for the purposes of assessing my foot function. ☐
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory bodies or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
5. I agree to take part in the above study. ☐

Optional

6. I agree to my GP being informed about my participation in this study. ☐

Name of GP: .....

Contact address: .....

.....

Signatures:

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

[When completed: one copy for participant; one for researcher site file.]

APPENDIX 26: RESEARCHERS' PROFILES

Please note these are taken from the IRAS application dated August 2013.

Name: Alison Lyddon	
Present appointment: *(Job title, department, and organisation.)*	
Lecturer in Physiotherapy, (0.5 WTE) Research Physiotherapist, (0.5WTE) School of Health, Sports and Biosciences University of East London	
Address: *(Full work address.)*	
School of Health and Bioscience University of East London A.E.5.27, Stratford Campus Water Lane, Stratford, London, E15 4LZ	
Telephone number: 02082234256	**Email address:** a.lyddon@uel.ac.uk
Qualifications:	
B.Sc. (Hons) in Physiotherapy, Cardiff University, 2005 MSc in Advanced Health Professions, 2011	
Professional registration: *(Name of body, registration number and date of registration.)*	

Previous and other appointments: *(Include previous appointments in the last 5 years and other current appointments.)*
Rotational Band 5 Physiotherapist, Tower Hamlets PCT, 2005-2009 Acting Band 6 Specialist Physiotherapist in Neurosciences 2007-2009
Research experience: *(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)*
I have conducted both qualitative research and quantitative research at a pre and post graduate level (for my BSc, MSc and an internally funded project in the Graduate School here at UEL). I have been involved in recruitment, methodological decisions, data collection and analysis. Additionally I have provided 2 written dissertations of over 10,000 words and an informal written report.
Research training: *(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, consent or other training appropriate to non-clinical research. Give the date of the training.)*
I have completed a BSc in Physiotherapy (2005) and an MSc in Advanced health Professions – both included the implementation of a research project. Research training was integral to these degrees including research design and undertaking informed consent, I have undertaken GCP training and attended training sessions on data management.

I am also aware of the researchers development programme having undertaken a project related to this framework.
Relevant publications: *(Give references to all publications in the last two years plus other publications relevant to the current application.)*
Nil publications.

Signature:	**Date: 09/10/2013**

Name: Terry Gorst
Present appointment: *(Job title, department, and organisation.)*
Clinical Specialist Physiotherapist - Neuro and Stroke Rehabilitation (0.5 WTE) Research Physiotherapist , School of Health Profession, Plymouth University (0.5WTE)
Address: *(Full work address.)*
Northern Devon Healthcare Trust Stroke & Neuro-Rehabilitation Unit Bideford Hospital, Abbotsham Road, Bideford, Devon EX39 3AG

<table>
<tr><td colspan="2">And

Plymouth University
Peninsula Allied Health Centre
Derriford Rd
Derriford
Plymouth PL6 8BH</td></tr>
<tr><td>Telephone number: 01752 587 599</td><td>Email address:
terry.gorst@plymouth.ac.uk</td></tr>
<tr><td></td><td>terry.gorst@nhs.net</td></tr>
<tr><td colspan="2">Qualifications:</td></tr>
<tr><td colspan="2">B.Sci. (Hons) in Physiotherapy, Plymouth University, 2008
B.Sc (Hons) in Sports Science and Psychology, 1995</td></tr>
<tr><td colspan="2">Professional registration: (Name of body, registration number and date of registration.)</td></tr>
<tr><td colspan="2">Health & Care Professions Council. Reg no: PH89527
Member of the Chartered Society of Physiotherapy (Membership no: 093380)</td></tr>
<tr><td colspan="2">Previous and other appointments: (Include previous appointments in the last 5 years and other current appointments.)</td></tr>
<tr><td colspan="2"></td></tr>
</table>

Rotational Band 5 Physiotherapist, Northern Devon Healthcare Trust September 2008 – November 2010.

Student Physiotherapist, Plymouth University, 2005 – 2008.

Research experience: *(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)*

I am involved in the day to day clinical management and recruitment of patients to on-going stroke clinical research trials within Northern Devon Healthcare Trust namely TWIST, AVERT and SoS.

I have jointly led and completed several clinical audits to date which have required designing, implementing and ultimately presenting at Trust and departmental level meetings.

I have undertaken two research projects (quantitative and qualitative) at undergraduate level, for the final dissertation project in each of the BSc degrees I have completed.

Research training: *(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, consent or other training appropriate to non-clinical research. Give the date of the training.)*

I have completed a BSc in Physiotherapy (2008) and a BSC in Sports Science and Psychology (1995) – both included the implementation of a research project. Research training, both in research design and undertaking informed consent, was integral to these degrees.

I have completed my GCP training as part of my post graduate study prior to undertaking consent for this research study.
Relevant publications: *(Give references to all publications in the last two years plus other publications relevant to the current application.)*
Nil publications.

Signature:	**Date: 31.08.2013**

Name: Dr. Mary C Cramp
Present appointment:
Research Degrees Leader and Principal Lecturer, School of Health and Bioscience, University of East London
Address:
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Telephone number:	**Email address:**
020 8223 4544	m.c.cramp@uel.ac.uk
Qualifications:	

2004 PGD Teaching & Learning in Higher Education, University of East London 1998 PhD, University of East London 1993 MSc Physiotherapy, University of East London 1989 BSc (Hons) Physiotherapy, Trinity College
Professional registration:
Health Professions Council Physiotherapy Register, PH40964, Registered since 1989 The Chartered Society of Physiotherapy, 049335, Member since 1989
Previous and other appointments:
Honorary Research Fellow, Oxford Brookes University
Research experience:
My research interests and experience are based on the physiological and biomechanical investigation of movement dysfunction and developing effective interventions to improve everyday function, with particular focus on those who have had a stroke and those with lower limb dysfunction. I have been the grant holder and principal investigator for three projects funded by The Stroke Association looking at neuromuscular changes after stroke and the benefits of exercise programmes after stroke (1996 -2001). I am currently involved in three funded research programmes. I have supervised two doctoral students to successful completion of their studies (1 clinical and 1 non-clinical) and I am currently supervising 6 doctoral students (3 clinical and 3 non-clinical). In addition, I have supervised over 17 MSc students to successful completion.
Current and Recent grants:
Cramp, Malloch, Vitkovitch (2011-2012) Pre-registration support and research skills development for post-graduate research students through portfolio development. £4,952: Learning Enhancement Opportunity, University of East London

Morrison, Cramp, Drechsler & Ferrari (2010-2013) Does excessive body mass alter the dynamic function of children's feet? £155,252: Dr William M Scholl Podiatric Research and Development Fund

Morley, Cramp & Mawson (2007-2013) An investigation into muscle architectural change in spastic muscle and its treatment in people suffering from Multiple Sclerosis (MS). £62,309: Multiple Sclerosis Society PhD sponsorship

Relevant publications:

Morley A.S., Tod A., Cramp M.C., Mawson S. J. (2011) The meaning of spasticity to people with Multiple Sclerosis: What can health professionals learn? Submitted for review to Disability and Rehabilitation.

Morris M.G., Dawes H, Howells K., Scott O.M. and Cramp M.C. (2010). Muscle Contractile Characteristics: relationship to high intensity exercise. European Journal of Applied Physiology, 110:2; 295 – 300

Cramp M.C., Greenwood R.J., Gill M., Lehmann A., Rothwell J.C., Scott O.M. (2010). Effectiveness of a community-based low intensity exercise programme for ambulatory stroke survivors. Disability & Rehabilitation, 32:3:239-247

Forth H.L., Cramp M.C., Drechsler W.I. (2009). Does physiotherapy treatment improve the self-reported pain levels and quality of life of women with vulvodynia?: A pilot study. Journal of Obstetrics and Gynaecology, 29:5:423 – 429

Morris M.G., Dawes H., Howells K., Scott O.M. and Cramp M.C. (2008) Muscle Fatigue characteristics: relationship with markers of endurance performance. Journal of Sports Science and Medicine, 4:431-436

Cramp M.C. & Scott O.M. (2008). Sensory and motor nerve activation. Chapter 5 in Watson T. (ed) *Electrotherapy - Evidence Based Practice 12th Ed. Churchill Livingstone, Edinburgh*
Cramp M.C. & Scott O.M. (2008). Neuromuscular electrical stimulation: nerve-muscle interaction. Chapter 14 in Watson T. (ed) *Electrotherapy - Evidence Based Practice 12th Ed. Churchill Livingstone, Edinburgh*

Protopapadaki A., Drechsler W.I., Cramp M.C., Coutts F.J., Scott O.M. (2007) Hip, knee, ankle kinematics and kinetics during stair ascent and descent in healthy young individuals. Clinical Biomechanics. 22:203-210

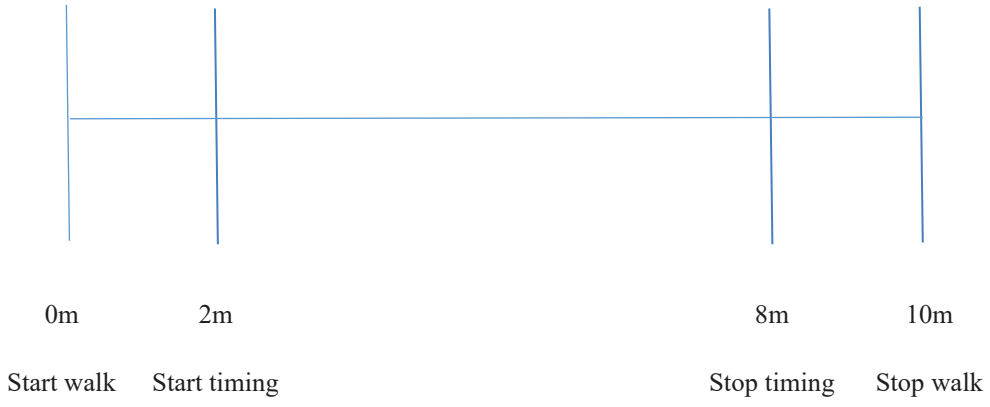
APPENDIX 27: STANDARD OPERATING PROCEDURES: FAST 10MWT

Equipment:
Stopwatch
Measured 10 m walkway (using a metre rule or measuring wheel)
Cones x 4 to make start, 2 m, 6 m and end (10 m) of walkway.
Pen
Data collection sheet

Protocol:

1. Measure and using the cones mark a 10 m walkway, add a mark at 2 m and add a mark at 8 m.
2. Explain the test to the participant:
   "This test will time how long it takes you to walk 10 metres at a comfortable walking speed as I will now demonstrate."
3. Demonstrate the test to the participant.
4. Then ask the participant to walk without assistance along the walkway, only using an assistive device if they would do usually.
5. Instruct the participant as follows:
   "I will say ready, set, go. When I say go, walk as fast as you safely can until I say stop".
6. Start timing when the toes of the leading foot crosses the 2 m mark and stop timing when the toes of the leading foot crosses the 8 m mark. (The time is measured for the middle 6 m (19.7 ft) to allow for acceleration and deceleration.)
7. The test, steps 5–6, should be repeated 3 times and times recoded on the data collection sheet. If assistive devices are used, they should be kept consistent and documented on the data collection sheet.

NB: If physical assistance is required to walk, this test should not be performed



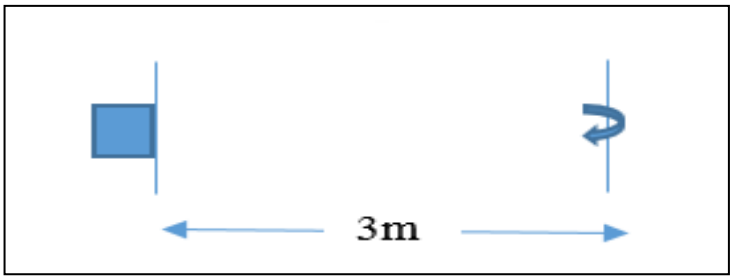
Timed 10-metre walk test (Bohannon, 1997)

APPENDIX 28: STANDARD OPERATING PROCEDURES: TIMED UP AND GO

Equipment:
Chair (46 cm seat height, 67 cm arm height)
Stopwatch
3 m measured walkway
Cone
Pen
Data collection sheet

Protocol:

1. Measure and mark, using a cone, a 3 m (9.8 ft) walkway and place a standard height chair (seat height 46 cm, arm height 67 cm) at the beginning of the walkway.
2. Explain the test to the participant:
   "This test will measure how long it takes you to stand up from the chair, walk 3 metres, turn around, and walk back to the chair and sit back down."
3. The participant should sit on a standard armchair, placing his/her back against the chair and resting his/her arms on the chair's arms. Regular footwear and customary walking aids should be used.
4. Instruct the participant to:
   "*Sit on the chair and place your back against the chair and rest your arms on the chair's arms"*.
   The upper extremities should not be on the assistive device (if used for walking), but it should be nearby.
5. Demonstrate the test to the participant.
6. When the participant is ready, say *"Go"*. The participant should be instructed to use a comfortable and safe walking speed but made aware that they are being timed.
7. The participant should walk to a line that is 3 m (9.8 ft) away, turn around at the line, walk back to the chair, and sit down. The test ends when the patient's buttocks touch the seat.
8. A stopwatch should be used to time the test (in seconds). The stopwatch should start when you say go and should be stopped with the participant's buttocks touch the seat.
9. The test, steps 6–7, should be repeated 3 times and times recoded on the data collection sheet.



Timed up and go (Podsiadlo and Richardson, 1991)

APPENDIX 29: STANDARD OPERATING PROCEDURES: FORWARD FUNCTIONAL REACH TEST

Equipment:
Space to stand, with wall nearby
Tape measure, mounted on wall horizontal to the floor
Chair
Pen
Data collection sheet

Protocol:

1. Explain the test to the participant:
   "*This test will assess your standing balance. You will now be asked to stand with your less-affected arm next to the walk. Without moving your feet you will be asked to reach forward as far as you can."*
2. Participant is positioned in standing, next to, but not touching a wall, positioning the arm that is closer to the wall at 90 degrees of shoulder flexion with a closed fist.
3. The tester records the starting position of the 3rd metacarpal head of the less-affected hand on a metre rule which can be attached to the wall.
4. Instruct the participant to:
   "*Reach as far forward as you can without taking a step.*"
5. The distance of the 3rd metacarpal along the tape measure is recorded.
6. Scores are determined by calculating the difference between the start and end positions, e.g. 52 cm (end distance) − 30 cm (start distance) = 22 cm.
7. Repeat steps 1–5 three times, each time record the reach distance on the data collection sheet.

Functional reach test (Duncan, *et al*., 1990)

APPENDIX 30: STANDARD OPERATING PROCEDURES: FALLS REPORT*

Equipment:
Pen
Data collection sheet

Protocol:

1. Participant in sitting, opposite researcher.
2. Question the participant sensitively:
   "Have you fallen at all in the last 3 months? (By a fall I mean any time where you have inadvertently found yourself resting on a low/er surface such as the floor.) If so, how many times?"
3. Document the response from the participant and record the number of falls on the data collection sheet. Researcher is to ask about causes of falls, to establish a true fall.
4. If no falls are reported researcher is to explore last 3 months with participant to ensure no falls are being missed, e,g. ask about any recent trips.

*Please note this is to be collected during demographic data collection at the start to the assessment battery.

APPENDIX 31: 12-ITEM WALKING IMPACT SCALE (12-ITEM WIS) (HOLLAND *ET AL.*, 2006)

IN THE PAST TWO WEEKS, HOW MUCH HAS YOUR STROKE...	Not at all 1	A little 2	Moderately 3	Quite a bit 4	Extremely 5
…limited your ability to walk?					
…limited your ability to run?					
…limited your ability to climb up and down stairs?					
...made standing when doing things more difficult?					
…limited your balance when standing or walking?					
…limited how far you are able to walk?					
…increased the effort needed for you to walk?					
…made it necessary for you to use support when walking indoors (e.g., holding on to furniture, using a stick, etc.)?					
…made it necessary for you to use support when walking outdoors (e.g., using a stick, a frame, etc.)?					
...slowed down your walking?					
…affected how smoothly you walk?					
…made you concentrate on your walking?					
Sub Total					
				Total	/60

APPENDIX 32: FALLS EFFICACY SCALE (TINETTI *ET AL.*, 1990)

		Not at all concerned 1	Somewhat concerned 2	Fairly concerned 3	Very concerned 4
1	Cleaning the house (eg. sweep, vacuum or dust)				
2	Getting dressed or undressed				
3	Preparing simple meals				
4	Taking a bath or shower				
5	Going to the shop				
6	Getting in or out of a chair				
7	Going up or down stairs				
8	Walking around in the neighbourhood				
9	Reaching for something above your head or on the ground				
10	Going to answer the telephone before it stops ringing				
11	Walking on a slippery surface (e.g. wet or icy)				
12	Visiting a friend or relative				
13	Walking in a place with crowds				
14	Walking on an uneven surface (eg rocky or uneven ground, poorly maintained pavement)				
15	Walking up or down a slope				
16	Going out to a social event (eg religious service, family gathering or club meeting)				
	Sub total				
				Total	/64

APPENDIX 33: STUDY 2: IMPAIRMENT CORRELATIONS

Table A33.1. Peak Plantar Pressure Correlation (Spearman's Rho)[a]

		Less-affected limb					More-affected limb				
	Foot region	**RFT**	**MFT**	**FFT**	**Toes**	**Foot**	**RFT**	**MFT**	**FFT**	**Toes**	**Foot**
Less-affected limb	**RFT**		0.167*	0.349**	0.159	0.304**					
	MFT	0.167*		0.054	0.012	0.081					
	FFT	0.349**	0.054		0.187*	0.792**					
	Toes	0.159	0.012	0.187*		0.524**					
	Foot	0.304**	0.081	0.792**	0.524**						
More-affected limb	**RFT**	0.712**	0.157	0.419**	0.205*	0.365**		0.184*	0.467**	0.320**	0.491**
	MFT	0.187*	0.569**	0.073	0.037	0.134	0.184*		0.114	−0.009	0.106
	FFT	0.403**	0.101	0.699**	0.175*	0.563**	0.467**	0.114		0.312**	0.889**
	Toes	0.249**	0.148	0.124	0.534**	0.312**	0.320**	−0.009	0.312**		0.499**
	Foot	0.424**	0.111	0.607**	0.289**	0.602**	0.491**	0.106	0.889**	0.499**	

[a]light grey highlighted cells = moderate corrleation; dark grey highlighted cells = strong correlation
*p = 0.05
**p = 0.01

Table A33.2 Foot Contact Area Correlation (Spearman's Rho)[a]

		Less-affected limb					More-affected limb				
		RFT	**MFT**	**FFT**	**Toes**	**Total**	**RFT**	**MFT**	**FFT**	**Toes**	**Total**
Less-affected limb	**RFT**		0.383**	0.498**	0.078	0.670**					
	MFT	0.383**		0.359**	0.066	0.785**					
	FFT	0.498**	0.359**		0.106	0.723**					
	Toes	0.078	0.066	0.106		0.162					
	Total	0.670**	0.785**	0.723**	0.162						
More-affected limb	**RFT**	0.687**	0.323**	0.469**	0.162	0.516**		0.343**	0.379**	0.132	0.579**
	MFT	0.379**	0.758**	0.333**	0.013	0.646**	0.343**		0.403**	−0.054	0.786**
	FFT	0.477**	0.371**	0.621**	0.060	0.559**	0.379**	0.403**		0.028	0.704**
	Toes	0.168*	−0.037	0.161	0.386**	0.108	0.132	−0.054	0.028		0.164*
	Total	0.630**	0.644**	0.567**	0.126	0.777**	0.579**	0.786**	0.704**	0.164*	

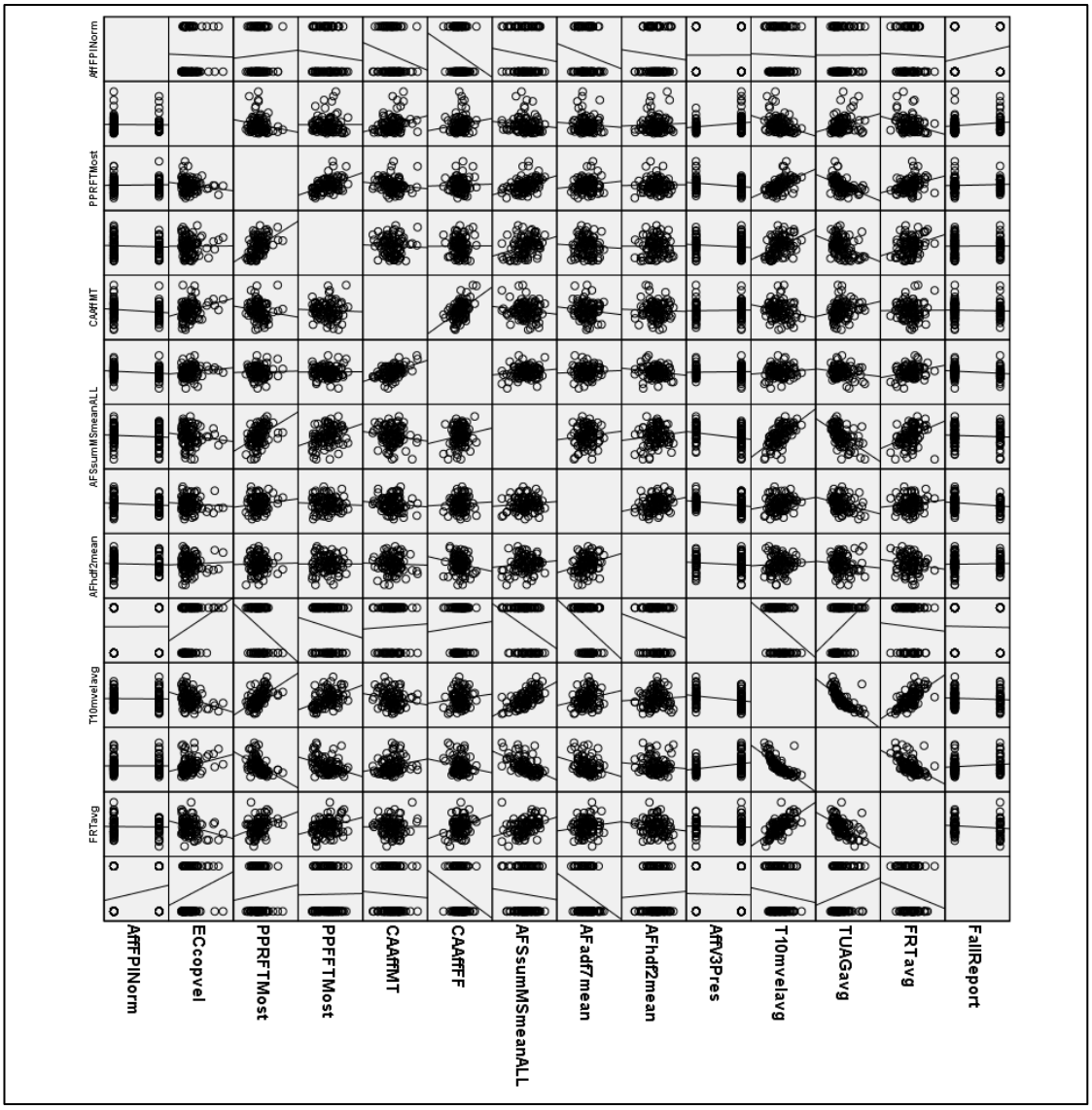
[a]light grey highlighted cells = moderate corrleation; dark grey highlighted cells = strong correlation
*p = 0.05
**p = 0.01

Table A33.3 Correlation of More-Affected Limb Isometric Muscle Strength for Individual Muscles and Composite Muscles[a]

	ADF	APF	AInv	AEv	HDF	HPF	Composite	Ankle	Hallux
ADF		0.872**	0.797**	0.809**	0.729**	0.696**	0.931**	0.943**	0.756**
APF			0.843**	0.867**	0.802**	0.777**	0.963**	0.963**	0.840**
AInv				0.818**	0.778**	0.773**	0.909**	0.903**	0.827**
AEv					0.780**	0.774**	0.921**	0.918**	0.826**
HDF						0.751**	0.845**	0.821**	0.908**
HPF							0.825**	0.796**	0.948**
Composite								0.997**	0.890**
Ankle							0.997**		0.860**
Hallux							0.890**	0.860**	

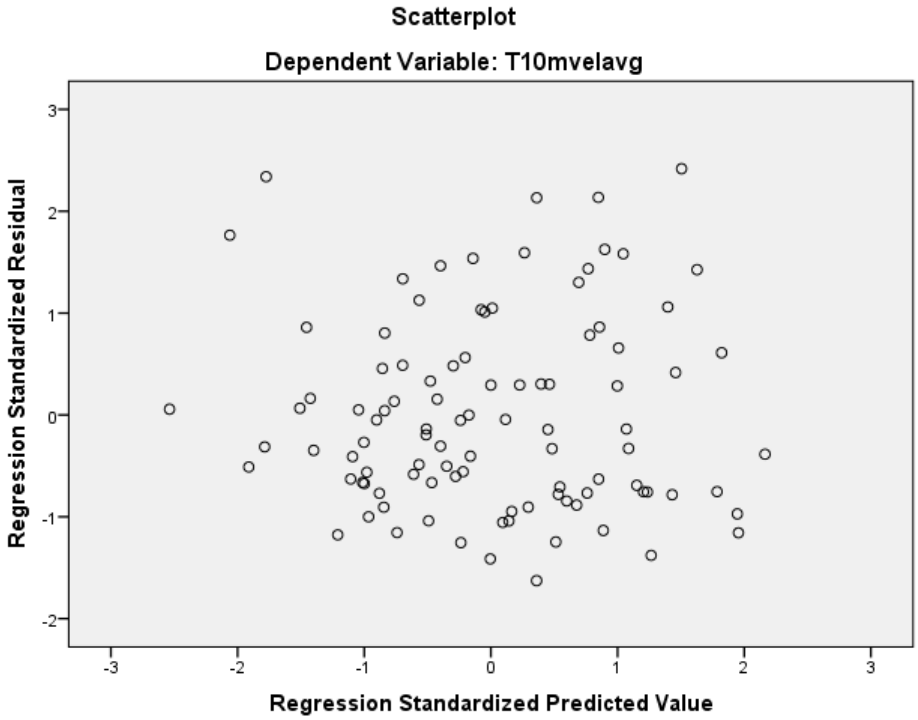
[a]light grey highlighted cells = moderate corrleation; dark grey highlighted cells = strong correlation
*p = 0.05
**p = 0.01

APPENDIX 34: MULTIVARIATE REGRESSION ANALYSIS LINEARITY PLOTS



APPENDIX 35: STUDY 2: NORMAL DISTRIBUTION OF HOMOSCEDASTICITY

F10MWT



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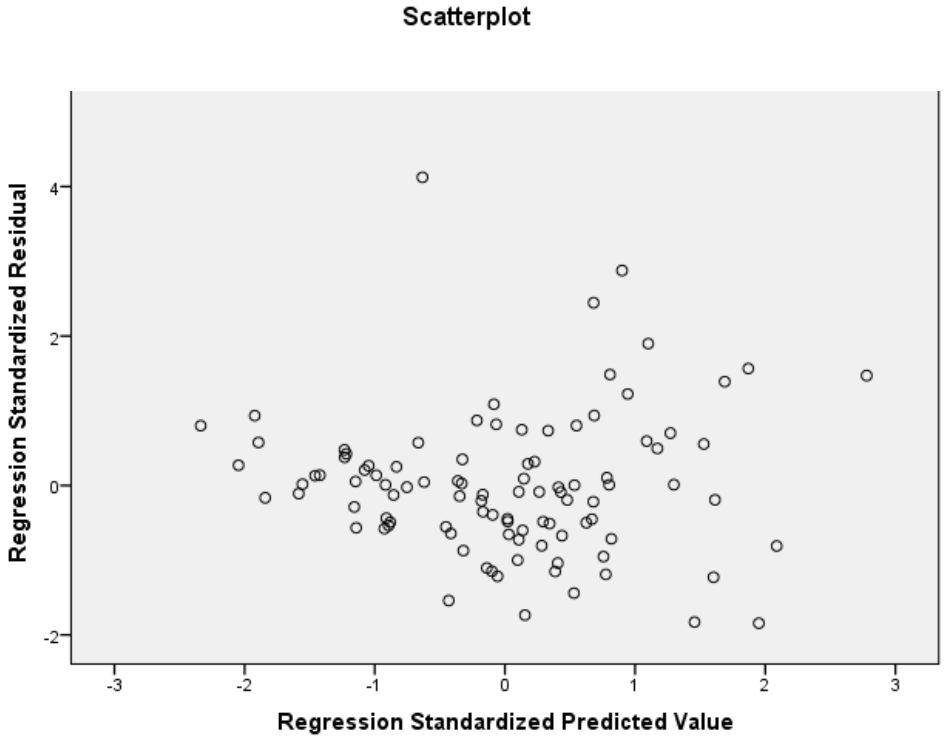
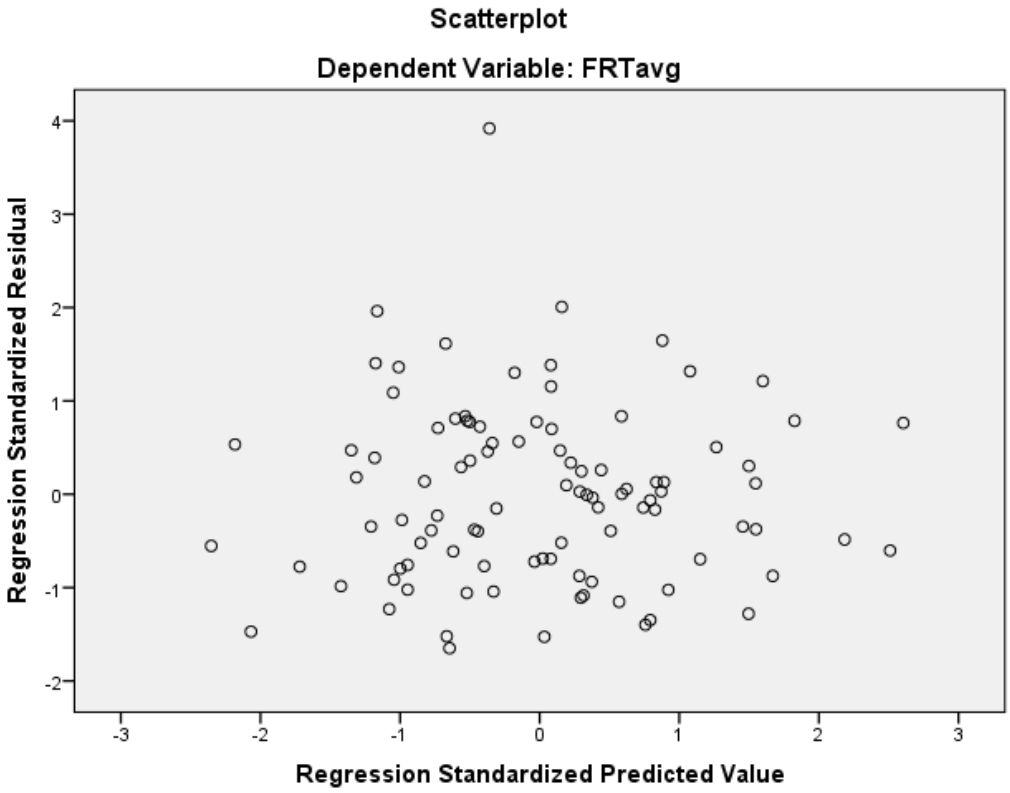


FFRT



Logistic Regression for Falls Report

```
            Step number: 1

            Observed Groups and Predicted Probabilities

       4 +              1      1     0                       1                                          +
         I              1      1     0                       1                                          I
         I              1      1     0                       1                                          I
F        I              1      1     0                       1                                          I
R      3 +          0   0 0  0 1     0   0     0  0  1  1     1    1           1                         +
E        I          0   0 0  0 1     0   0     0  0  1  1     1    1           1                         I
Q        I          0   0 0  0 1     0   0     0  0  1  1     1    1           1                         I
U        I          0   0 0  0 1     0   0     0  0  1  1     1    1           1                         I
E      2 +        110   000  0 001 0 010 0     0  0 01  1    101   11 1        1              1          +
N        I        110   000  0 001 0 010 0     0  0 01  1    101   11 1        1              1          I
C        I        110   000  0 001 0 010 0     0  0 01  1    101   11 1        1              1          I
Y        I        110   000  0 001 0 010 0     0  0 01  1    101   11 1        1              1          I
       1 +  000 0 00100000000 0 00100 00000100 0  00011 0    00011 0010 1   1 1 0            11101      +
         I  000 0 00100000000 0 00100 00000100 0  00011 0    00011 0010 1   1 1 0            11101      I
         I  000 0 00100000000 0 00100 00000100 0  00011 0    00011 0010 1   1 1 0            11101      I
         I  000 0 00100000000 0 00100 00000100 0  00011 0    00011 0010 1   1 1 0            11101      I
Predicted --------+---------+---------+---------+---------+---------+---------+---------+---------+---------
  Prob:   0       .1        .2        .3        .4        .5        .6        .7        .8        .9        1
  Group:  00000000000000000000000000000000000000000000000000000000011111111111111111111111111111111111111111111111111111

          Predicted Probability is of Membership for 1.00
          The Cut Value is .50
          Symbols: 0 - .00
                   1 - 1.00
          Each Symbol Represents .25 Cases.
```

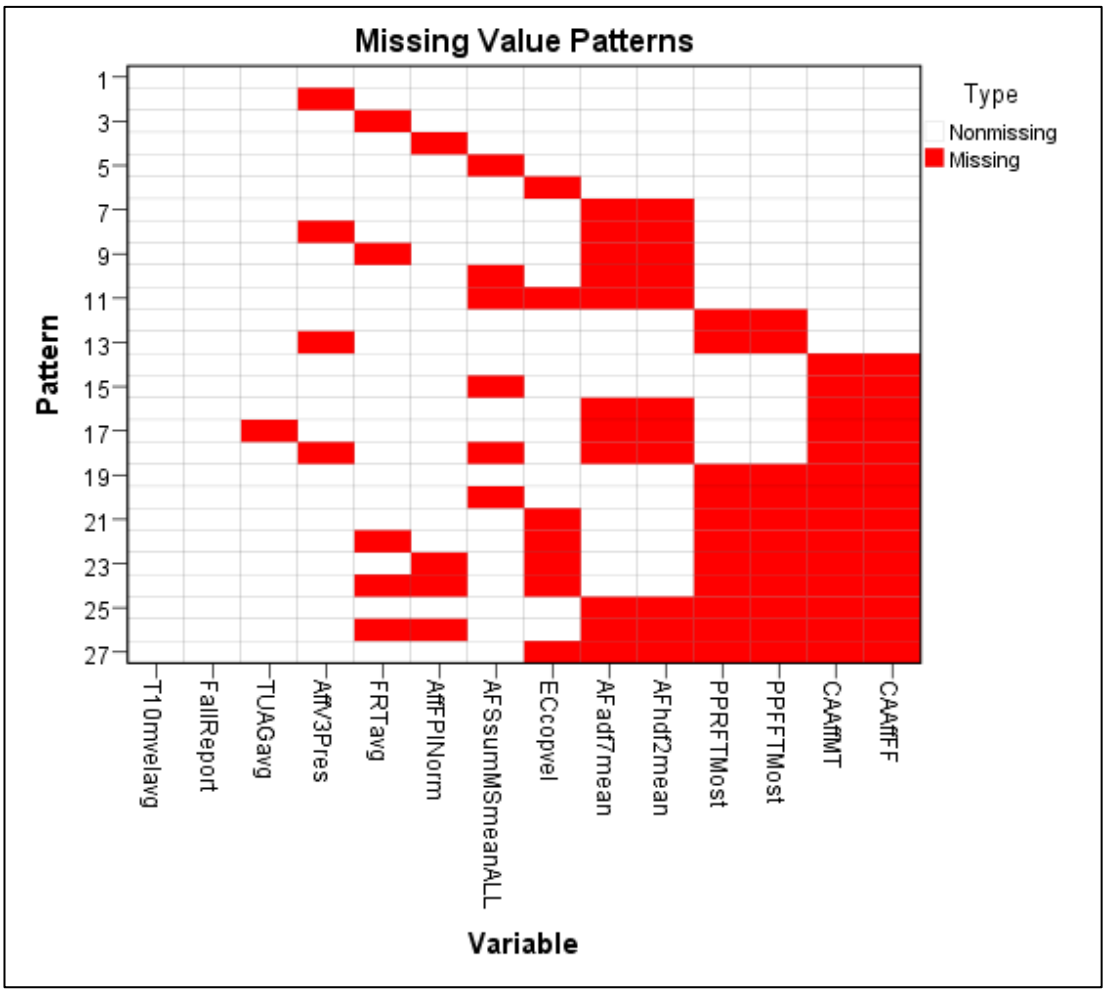
APPENDIX 36: JUSTIFICATION OF VARIABLES INPUTTED TO REGRESSION ANALYSIS

Justification of Variables Inputted to regression Analysis

Characteristics and impairment	Justification – *theoretical underpinning and representative of stroke population*	Variables inputted
FPI Abnormal/normal classification More-affected side	Significant difference between stroke and control group ($p < 0.001$). Due to limitation in number of variables to cases, only binary variables could be considered for the model. Abnormal foot posture has been shown to correlate with walking ability (Forghany *et al*., 2011; Kunkel *et al.*, 2017). ***Therefore FPI (normal/abnormal) on the most-affected side was selected for regression.***	1
Sway velocity Eyes closed	Significant difference between eyes open–eyes closed as well as between stroke and control groups (eyes open–eyes closed), $p < 0.003$. Sway velocity indirectly represents quiet standing balance, with eyes closed compensatory mechanisms that are affected by the stroke are relied on and result in poor control compared to age-matched controls (Spink *et al.,* 2011). ***Therefore, sway velocity with eyes closed was selected for regression analysis.***	1
Peak pressure Rear foot and forefoot More-affected side	Significant difference between stroke and control group ($p < 0.001$). Also, significant differences found between limbs ($p < 0.001$). Rearfoot correlates highly with least-affected side (rho = 0.71). Forefoot correlates highly with maximal foot pressure (rho = 0.89). Yet, it is unknown how this relates to walking speed and balance outcomes in stroke. In older people, foot pressure correlates with walking speed and balance outcomes (Spink *et al.*, 2011). ***Therefore, peak pressure of the more-affected side rear and forefoot region was characteristic of overall foot pressures and selected for regression analysis.***	2
Contact area	Significant differences between stroke and control group ($p < 0.02$).	2

Mid-foot and forefoot More-affected side	Mid-foot and forefoot area correlates highly with maximal foot pressure (rho = 0.77, 0.70, respectively). Contact area may indicate altered loading but, as yet, it is unknown how this relates to walking speed/balance outcomes in stroke. ***Therefore more-affected side mid- and forefoot contact area are representative of overall foot contact area and were selected for regression analysis.***	
Isometric muscle strength ALL (composite) More-affected side	Ankle and hallux composite scores were highly correlated with most-affected side individual muscle strength ($r >$ 0.82); however, they were also co-linear and therefore cannot both be used in the model. Muscle strength has been shown to associate with walking speed and balance (Lamontagne *et al.*, 2001; 2002; Bohannon, 2007); however, no evidence exists when using a HHD to measure muscle strength in stroke. ***Therefore most-affected side of ALL muscles (composite score) was selected for regression analysis.***	1
Passive ROM Ankle, hallux, more-affected side (low force)	Low force data was normally distributed. Significant difference between stroke and control group and both high and low forces ($p < 0.01$). Low and high force values for the ROM were highly correlated ($r > 0.80$). Previously shown that this may relate to walking speed/balance (Lamontagne *et al.*, 2001; 2002). ***Therefore, low force values for ankle dorsiflexion and hallux dorsiflexion selected for regression analysis.***	2
Spasticity presence (>1) More-affected side	Significant difference between stroke and control group and between most- and least-affected sides. Due to the limitation in number of variables to cases, only binary variables could be considered for the model. Previously shown that this may relate to walking speed/balance (Lamontagne *et al.*, 2001; 2002; Forghany *et al.*, 2011). ***Therefore, spasticity presence selected for regression analysis.***	1
	Total variables	10

APPENDIX 37: MISSING VALUE PATTERNS



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