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Dual-task Gait Assessment in Lower Extremity Amputees

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Supervisor: Dr. Susan Hunter, The University of Western Ontario A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Health and Rehabilitation Sciences © Courtney A. Frengopoulos 2017

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Abstract

The purpose of these studies was to develop a reliable dual-task functional mobility protocol and investigate changes in dual-task performance over time in lower extremity amputees. Relative and absolute test-retest reliability of the protocol were evaluated across the population in a study consisting of three groups, with 20 participants per group. A pilot study of 16 participants investigated change in dual-task performance between discharge from rehabilitation and follow-up for both cognitively normal and cognitively impaired individuals. Gait was assessed by the developed protocol as well as an electronic walkway (GaitRITE®). All three groups in Study 1 had excellent relative test-retest reliability and comparable values for absolute test-retest reliability. Study 2 demonstrated that differences in gait and functional mobility exist between cognitively normal and cognitively impaired individuals. These changes are present at discharge from rehabilitation and persist at follow-up. However, improvement in gait and functional mobility is possible for both groups.

Keywords: *lower extremity amputation, gait, mobility, dual-task, older adults, cognitive function*

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List of Abbreviations

ABC: Activities-specific Balance Confidence Scale

AKA: Above knee amputation

AKA/bilat: Complex amputations including above knee and bilateral amputations

BKA: Below knee amputation

BKA-nonvas: Below knee amputations of nonvascular etiology

BKA-vas: Below knee amputations of vascular etiology

CPG: Central Pattern Generators

CRR: Corrected Response Rate

DTC: Dual-task cost

DTCcog: Cognitive dual-task cost

DTCgait: Gait dual-task cost

FSST: Four square step test

ICC: Intraclass correlation coefficient

LEA: Lower extremity amputation

LOA: Limits of agreement

MDC: Minimal detectable change

MDC95: Minimal detectable change with a 95% confidence interval

MoCA: Montreal Cognitive Assessment

PVD: Peripheral vascular disease

SD: Standard deviation

SEM: Standard error of measurement

TMT: Trail Making Test

ΔTMT: Delta Trail Making Test

%CV: Coefficient of variation

Chapter 1: LITERATURE REVIEW

1.1 Introduction

Individuals with lower extremity amputations (LEA) caused by diabetes or vascular complications may face challenges associated with higher-order cognitive processes such as problem-solving, reasoning, concentration and balance (Coffey, O'Keeffe, Gallagher, Desmond, & Lombard-Vance, 2012). These challenges may impact the successful achievement of the endurance, balance or use of higher level cognitive skills necessary for household and community ambulation with a prosthesis (Deathe & Miller, 2005). Despite the best efforts and functional gains in prosthetic-rehabilitation programs, the falls risk for older adults with an LEA exceeds that for frail older adults living in the community (Miller, Speechley, & Deathe, 2001a). The consequences of falling are dire, including not only physical injury, but also a fear of falling that often leads to lack of prosthesis use and social withdrawal (Miller, Deathe, Speechley, & Koval, 2001).

Current amputee literature recognizes the relationship between cognition or cognitive impairment and performance on outcome measures following rehabilitation (Coffey et al., 2012; Frengopoulos, Burley, Viana, Payne, & Hunter, 2017; O'Neill, 2008; O'Neill & Evans, 2009; Sansam, Neumann, O'Connor, & Bhakta, 2009). However, mobility and cognitive tasks have been investigated solely in isolation; the essential role of cognition in mobility has not been studied. To assess the interaction of cognition and mobility, individuals must be observed performing a mobility task while simultaneously performing a distracting cognitive task: the dual-task paradigm (Yogev, Hausdorff, & Giladi, 2008). If the cognitive load of performing the two tasks exceeds the capacity of the individual, performance on one or both tasks will deteriorate, this is known as the dual-task cost (DTC) (Muir, Speechley, et al., 2012). The dual-task paradigm is relevant to most daily activities as these tasks require the multi-tasking of motor and cognitive tasks (Yogev et al., 2008). A reliable dual-task assessment protocol is needed for use in the LEA population, as no such protocol currently exists. The protocol can then be used to

evaluate change in dual-task function of older adults with LEA following discharge from inpatient prosthetic rehabilitation.

1.2 Lower Extremity Amputation

LEA is a reconstructive surgery of the lower limb that may be performed with the goal of maximizing a patient's function and quality of life (Braddom, 2011). The majority of individuals undergoing new LEA in North America are older with multiple comorbidities (Frengopoulos et al., 2017; Helm, Engel, Holm, Kristiansen, & Rosendahl, 1986; Reyes & Leahey, 1977; Stirnemann, Mlinaric, Oesch, Kirchhof, & Althaus, 1987). However the population of individuals living with lower extremity amputations displays a bimodal distribution (Miller, 2000). Younger individuals experience amputations primarily due to traumatic or congenital causes; these people tend to live longer and attain higher levels of mobility when compared to older adults whose amputations are primarily due to vascular or diabetic complications (DeLisa, 2010; Miller, Deathe, et al., 2001; Siriwardena & Bertrand, 1991; van Herk, Arendzen, & Rispens, 1998). The recovery of functional gait is a major focus of rehabilitation for people after an LEA (Braddom, 2011).

1.2.1 Levels of Lower Extremity Amputation

For the purposes of this paper, only major lower extremity amputation will be considered. This includes transtibial or transfemoral amputation, also referred to as below knee amputation (BKA) and above knee amputation (AKA), respectively. Through the knee or knee disarticulation amputations will be considered an AKA, per usual standard, as the functioning knee joint has been lost (Braddom, 2011). Syme's amputations will not be included. The selection of the level of amputation at the time of surgery is based on the need to balance a variety of factors, including preservation of tissue, restoration of function, and cosmetic preference of the patient (Braddom, 2011; DeLisa, 2010). The level of amputation has an inverse relationship with rehabilitation outcomes; the higher the amputation, the lower the rehabilitation potential (Braddom, 2011). Higher amputations are also related to increased morbidity, as are bilateral amputations (Braddom, 2011; DeLisa, 2010).

1.2.2 Rehabilitation Following Lower Extremity Amputation

Rehabilitation following LEA is a complex process because of the differences in expected function of patients based on age, number of comorbidities, etiology of amputation, and amputation level (Deathe, Miller, & Speechley, 2002). The goals of prosthetic rehabilitation are often to improve mobility and activity levels, so measures of functional performance are particularly important (Treweek & Condie, 1998). During prosthetic rehabilitation, individuals need to have the cognitive and physical capacity to don and doff their prosthesis, as well as to learn new techniques for ambulating and adapting to different situations in their environment (Fuhrer & Keith, 1998; Larner, van Ross, & Hale, 2003; O'Neill, Moran, & Gillespie, 2010; Phillips, Mate-Kole, & Kirby, 1993).

Age, time since amputation and number of comorbidities all have a significant impact on an amputee's ability to ambulate with their prosthesis (Johnson, Kondziela, & Gottschalk, 1995; Keagy, Schwartz, Kotb, Burnham, & Johnson, 1986; Kerstein, Zimmer, Dugdale, & Lerner, 1975; Leung, Rush, & Devlin, 1996; Melchiorre, Findley, & Boda, 1996; Moore et al., 1989; Steinberg, Sunwoo, & Roettger, 1985). There is an established trend that ambulatory ability of those with LEA improves between 6 weeks and 4 months following amputation and then plateaus (Czerniecki, Turner, Williams, Hakimi, & Norvell, 2012). One example of this is the observed improvement in 2 Minute Walk Test distance in AKA, BKA and bilateral amputee groups between discharge and 3 month follow-up, after inpatient prosthetic rehabilitation (Brooks, Parsons, Hunter, Devlin, & Walker, 2001). However, many people with LEA present with gait deviations even after completion of intensive rehabilitation, possibly because of the decreased efficiency of ambulation and the increased energy required to be ambulatory (Latlief, Elnitsky, & Kent, 2014; Ward & Meyers, 1995).

The amount of energy required to walk with a prosthetic device varies based on level and etiology of amputation. Individuals with a unilateral, traumatic BKA use approximately 25% more energy to walk compared to non-amputees (Braddom, 2011). For those with BKA of vascular or diabetic etiology, the additional energy expenditure rises to 40% (Braddom, 2011; Latlief et al., 2014). At the above knee level, 63% more

energy is required for traumatic amputees, and increases to 120% for those with diabetic or vascular etiology (Braddom, 2011; DeLisa, 2010; Latlief et al., 2014). For individuals with bilateral BKA, the energy expenditure may range from 40-60% more compared to those without amputations (Latlief et al., 2014).

1.2.2.1 Falls and Lower Extremity Amputation

The presence of ongoing walking problems is a concern due to its relationship to an increased risk of accidental falls among people with LEA. A fall can be defined as "an unexpected event in which the participants come to rest on the ground, floor or lower level" (Lamb, Jorstad-Stein, Hauer, & Becker, 2005). The risk factors for falls in the general population include age, impaired vision, problems with motor control, impaired gait, poor balance, cognitive impairment and polypharmacy (Andersson, Kamwendo, Seiger, & Appelros, 2006; Kulkarni, Toole, Hirons, Wright, & Morris, 1996; Tinetti, Speechley, & Ginter, 1988). Many in the LEA population experience one or more of these risk factors (Kulkarni et al., 1996; MacGilchrist et al., 2010; Miller, Speechley, & Deathe, 2001b). Other falls risk factors have been identified that are unique to individuals with LEA (Hunter et al., 2017). These factors include: a dysvascular etiology of amputation, a reduced sense of vibration, the period following rehabilitation for those with AKAs and the period following surgery for those with BKAs (Hunter et al., 2017).

Despite the best efforts and functional gains in prosthetic-rehabilitation programs, the falls risk for older adults with an LEA exceeds that for frail older adults living in the community (Miller, Speechley, et al., 2001b). Studies have indicated that the annual rate of falls in community-dwelling elderly is approximately 30% (Campbell, Reinken, Allan, & Martinez, 1981; Prudham & Evans, 1981; Tinetti et al., 1988). It has been reported that between 52-58% of community-dwelling amputees sustain at least one fall within a 12 month period (Deathe & Miller, 2005; Kulkarni et al., 1996). This is similar to the prevalence of falls in older adults living in institutions, which has been reported as more than 50% (Tinetti, 1987). Falling may result in a variety of physical and psychological consequences. Aside from physical injuries (Miller, Speechley, et al., 2001b; Tinetti,

1987; Tinetti et al., 1988), a fear of falling (Maki, Holliday, & Topper, 1991; Miller, Speechley, et al., 2001b; Nevitt et al., 1989), decrease in mobility and self-imposed restriction of activity are commonly reported (Miller, Speechley, et al., 2001b; Tinetti, De Leon, Doucette, & Baker, 1994). Restriction of activities may further lead to a worsening of balance (Maki et al., 1991), strength and coordination (Myers & Gonda, 1986).

1.2.3 Cognitive Impairment and Lower Extremity Amputation

Individuals with lower limb amputation are at risk for cognitive impairment due to the increased age at which the majority of amputations are occurring and to the etiology of amputations for these older individuals (Nowygrod et al., 2006). For instance, increasing age is associated with impairments in memory, attention, reasoning and problem solving (Park, 2000). Eighty percent of amputations in Canada (National Diabetes Surveillance System, 2009) and 54% of amputations in the United States (Ziegler-Graham, MacKenzie, Ephraim, Travison, & Brookmeyer, 2008) are caused by peripheral vascular disease (PVD) and diabetes, collectively called dysvascular etiology.

PVD shares pathophysiological mechanisms with cerebrovascular disease (National Limb Loss Information Centre, 2008); these shared characteristics leave individuals with dysvascular amputations susceptible to vascular cognitive impairment (Desmond, 2004; O'Brien et al., 2003). Deficits associated with vascular cognitive impairment have been found in the cognitive domains of attention, executive function and information processing (O'Brien et al., 2003; O'Neill & Evans, 2009). A slowing of motor performance has also been found (O'Brien et al., 2003). Additionally, diabetes is associated with a decline in cognitive functioning and with an increased incidence of dementia (Leibson et al., 1997; Strachan, Deary, Ewing, & Frier, 1997; Verdelho et al., 2007).

The prevalence of cognitive impairment in the amputee population has been reported to be between 8-56% (Coffey et al., 2012; Frengopoulos et al., 2017). This wide range in prevalence may be due in part to differences in age or etiology present in the samples;

older populations and a higher portion of amputations caused by vascular disease and diabetes increase the prevalence of cognitive impairment (Coffey et al., 2012).

1.2.4 Relationship between Cognition and Mobility in Lower Extremity Amputees Certain cognitive domains are thought to be involved with the prosthetic skills necessary for ambulation in people with LEA. Some authors have outlined the domains of memory, attention, concentration, visuospatial abilities and organization to be of particular importance (Hanspal & Fisher, 1991; O'Neill & Evans, 2009). Although, concentration is an ambiguous concept and not a distinct domain, it does have roots in the domains of attention and executive functions. Individuals with impairments in these cognitive domains are likely to face challenges associated with learning how to use their limb and may fail to retain the new information or not be able to initiate the new behaviours (O'Neill, 2008). Impairment in cognition, as measured by the Montreal Cognitive Assessment, is also associated with worse functional mobility at discharge from inpatient prosthetic rehabilitation (Frengopoulos et al., 2017).

Relative to the general population, those with dysvascular amputations are at an increased risk for impairment in the areas of problem-solving, reasoning and concentration (Coffey et al., 2012). Higher levels of cognitive impairment are related to poorer mobility (Hanspal & Fisher, 1991, 1997; Heinemann, Linacre, Wright, Hamilton, & Granger, 1994; O'Neill & Evans, 2009), loss of independence (Taylor et al., 2005, 2007; Weiss, Gorton, Read, & Neal, 1990), and less extensive use of a prosthesis (Bilodeau, Hébert, & Desrosiers, 2000; Pinzur, Graham, & Osterman, 1988; Taylor et al., 2005). Impairment in cognition is also related to falls in the LEA population (Gooday & Hunter, 2004; Pauley, Devlin, & Heslin, 2006; Yu, Lam, Nettel-Aguirre, Donald, & Dukelow, 2010).

Despite the known connection between cognition and mobility, the two concepts have merely been studied in isolation in this population, rather than a direct quantification of the cognition-mobility interaction. There is also a lack of prospective or longitudinal data (Coffey et al., 2012). More research using valid and reliable measures to compare the outcomes of the cognitively normal and cognitively impaired are needed.

1.3 Mobility and Gait

Mobility is the ability to move around in one's environment; it is a crucial component of functional independence (Coppin et al., 2006; Patla, 2001; Patla & Shumway-Cook, 1999). The ability to constantly adapt sensorimotor patterns to safely navigate in one's environments is key for mobility (Hausdorff, 2005; Patla & Shumway-Cook, 1999). This ability to adapt requires interactions between the central nervous system, specifically higher levels of cognitive processing, the musculoskeletal system and the somatosensory system (Woollacott & Shumway-Cook, 2002). One aspect of mobility is gait (Hausdorff, 2005). Gait is a commonly-used term to describe the manner or style of an individual's walking (Whittle, 2007). It can be explained by the functional abilities of locomotion and equilibrium. The ability to activate and maintain rhythmic stepping describes the process of locomotion; equilibrium is one's ability to maintain balance (Nutt, Marsden, & Thompson, 1993).

1.3.1 The Gait Cycle

The gait cycle consists of eight distinct phases that can be used to describe the performance of one limb (Perry & Burnfield, 2010). The same sequence of phases is performed by the contralateral limb, but offset approximately 50% of a cycle (Perry & Burnfield, 2010). The first two phases of gait are the initial contact and loading response phases, these accomplish the task of weight acceptance; the transfer of body weight onto the limb that has just completed swinging (Perry & Burnfield, 2010). The next two phases, mid stance and terminal stance, comprise the single limb support task, where one limb has total responsibility over body weight support (Perry & Burnfield, 2010). The final four phases of the gait cycle are pre-swing, initial swing, mid swing and terminal swing (Perry & Burnfield, 2010). These phases complete the task of swing limb advancement, which allows for the progression of gait (Perry & Burnfield, 2010).

The gait cycle starts with the initial contact of one foot and ends with the next initial contact of that same foot (Kirtley, 2006). One gait cycle is also called a stride, and consists of two steps (Braddom, 2011). Stride length is the distance between consecutive initial contacts of the same foot and is measured in meters (Kirtley, 2006; Whittle, 2007). In normal, symmetrical walking, terminal contact with the floor occurs about 60% of the way through the cycle, following the pre-swing phase (Kirtley, 2006; Perry & Burnfield, 2010; Whittle, 2007). This event divides the gait cycle into two periods: the stance period, when the foot is on the ground, and the swing period (Kirtley, 2006). The stance period contains the initial five phases of the gait cycle, from initial contact through to pre-swing (Perry & Burnfield, 2010). Both feet are in stance phase at the same time approximately 20% of the time, and this is termed double stance time (Kirtley, 2006; Perry & Burnfield, 2010; Whittle, 2007). As walking speed increases, double stance time begins to decrease; it becomes 0% of the cycle when running begins (Kirtley, Whittle, & Jefferson, 1985).

Figure 1.1 The Gait Cycle (adapted from Lim, Huang, Wu, Girardi, & Cammisa, 2007)

1.3.1.1 Factors of Gait

The analysis of the motion and stride measures of gait, also referred to as the kinematics of gait, comprise one method of quantifying gait (Braddom, 2011). The temporal-spatial parameters of gait form the basis of kinematic gait assessment (Braddom, 2011; Kirtley, 2006; Robinson & Smidt, 1981). These parameters can be distributed into five broad domains of gait: rhythm, phase, variability, pace, and base of support (Hollman, Mcdade, & Petersen, 2011).

The first domain, rhythm, is focused on the temporal aspects of gait, the first of which is cadence (Hollman et al., 2011). Cadence is the number of steps taken per minute; natural cadence is a little less than 120 steps per minute, which can be converted to approximately 1 stride per second (Kirtley, 2006). Step time and also fall under this domain, as do swing times, stance time and single limb support time (Hollman et al., 2011). Phase, the second domain, highlights the division of the periods in gait: swing and stance periods, single limb support and double stance periods, and double stance time (Hollman et al., 2011).

The variability domain of gait encompasses all variability parameters of gait, excluding step width variability. These parameters are most commonly measured as the coefficient of variation (%CV) and include the following: stride time and length variability, step time and length variability, swing and stance time variability, and stride speed variability (Hollman et al., 2011). The fourth domain, pace, consists of two spatial parameters (stride length and step length) and the temporal-spatial parameter of gait speed (Hollman et al., 2011). Gait speed is the product of cadence and stride length, and is measured in cm/s or m/s (Kirtley, 2006; Perry & Burnfield, 2010; Whittle, 2007).

Base of support is the fifth and final domain of gait (Hollman et al., 2011). The walking base, also known as the base of support or step width, is a spatial component of gait; measured as the side to side distance between the two feet (Whittle, 2007). Step width and step width variability comprise the base of support domain of gait (Hollman et al., 2011).

1.3.1.2 Lower Extremity Amputee Gait

Amputee gait can differ from non-amputee gait in a variety of ways. Due to the limitations of prosthetic devices, particularly with regards to foot and ankle movement, the non-amputated side may be used to compensate during walking (Braddom, 2011). Among people with a unilateral LEA this compensation may be seen as an increased

stance time on the non-prosthetic side, an earlier terminal stance due to loss of active plantar flexion in the ankle or a vaulting of the normal leg during swing of the prosthesis (Whittle, 2007). Bilateral amputees do not have an uninvolved side and may find balance and recovering from a stumble to be more difficult compared to unilateral amputees (Braddom, 2011).

The level of amputation also has an impact on gait, as above knee prostheses are harder to control than below knee prostheses (Braddom, 2011; DeLisa, 2010; Whittle, 2007). This limitation is related to the musculature of the upper leg that assists with typical walking (DeLisa, 2010). For example, the person needs to have an increased focus during knee flexion, as the quadriceps cannot control this movement while loading (Braddom, 2011; DeLisa, 2010; Whittle, 2007). Also, the hip abductors on the amputated side are not always effective stabilizers of the prosthesis, particularly if the residual limb is short (DeLisa, 2010). Some individuals with an AKA walk with a locked knee, which places a large demand on the musculature of the hip in the swing phase of gait (Whittle, 2007).

Other differences that may be observed in amputee gait include longer cycle times and decreased speed compared to non-amputees (Whittle, 2007). Additionally, a wider stance may also be utilized to improve stability (Braddom, 2011; Whittle, 2007). Comparing right and left-sided kinematic gait data can be used to determine and characterize unilateral impairment in gait (Braddom, 2011).

1.3.2 Gait Analysis

Gait analysis is an evaluation technique used for diagnosing musculoskeletal conditions, observing sport movement, measuring outcomes, and for prescribing or optimizing prosthetic devices (Braddom, 2011). Visual or observational gait analysis can be used in a clinical setting to assess gait. This method of gait analysis is very subjective, and the quality depends on the skill of the observer (Whittle, 2007). These types of analyses could include video-based analysis or the use of stop watches (Whittle, 2007). Only a limited amount of information can be gleaned from these analyses and assessment methods can be quite time consuming (McDonough, Batavia, Chen, Kwon, & Ziai, 2001). Instrumented gait analysis is a more sophisticated method that can provide information on temporal-spatial parameters of gait in clinical and research settings (McDonough et al., 2001; Whittle, 2007). Instrumented walkways in particular are becoming a popular method; these walkways are carpeted mats with pressure-sensitive arrays to record the imprint of each footfall (McDonough et al., 2001). These mats are also easily transportable as they can be rolled up and carted to different locations (Kirtley, 2006). The GAITRite® System is an example of a gait analysis mat with embedded pressuresensitive sensors that are triggered when an individual walks across the mat (McDonough et al., 2001). This provides an accurate and objective alternative to observational gait analysis for analyzing the temporal-spatial parameters of gait.

One limitation of the GAITRite® and other instrumented walkway systems should be noted. When using these systems, only gait information from the feet can be collected and analyzed. Information on alignment of the lower limbs and pelvis as well as changes occurring in the torso or upper limbs are not accounted for. Changes in these other regions of the body are important observational cues that assist with diagnosing changes in walking ability (Braddom, 2011). In particular, alignment of the lower limbs and pelvis is an important consideration in the LEA population as it may indicate that changes need to be made to prosthetic devices to optimize walking potential.

Figure 1.2 Schematic for the GAITRite® Electronic Walkway (adapted from CIR Systems at http://www.gaitrite.com/downloads/WI-02- 15_Technical_Reference_L.pdf)

1.4 Gait Variability

Gait speed at a usual pace is a predictor of adverse outcomes, and may be as sensitive and consistent a predictor of long-term outcomes as composite tools (Abellan van Kan et al., 2009). Cut-off points for gait speeds, unique to different populations, may help to identify those at risk. In the population of community-dwelling older adults, this cut-off is 0.8 m/s (Abellan van Kan et al., 2009). Changes is gait speed could also be used as an outcome measure (Abellan van Kan et al., 2009).

Control of stepping is reflected by both stride time and stride length variability (Gabell & Nayak, 1984). Stride velocity is inversely related to stride variability; a decrease in velocity causes an increase in stride variability (Dubost et al., 2006; Heiderscheit, 2000).

Stride-to-stride variability is defined as the reproducibility of coordinated limb movements between the limbs (Newell & Corcos, 1993). Low stride-to-stride variability points to safe and efficient gait control that requires minimal cognitive demands, in particular in the domain of attention (Hausdorff, 2004; Hausdorff, Rios, & Edelberg, 2001; Hausdorff, Yogev, Springer, Simon, & Giladi, 2005; Maki, 1997).

1.5 Cognition

Cognition is a difficult to define term that can be interpreted in a variety of ways, depending on the perspective of the user. For the purposes of this paper, cognition will be defined as mental processes involved in acquiring, storing, using and manipulating knowledge (Matlin, 1998). Cognition is associated with many other concepts, such as intelligence, comprehension, understanding, awareness and skill; all of these are connected with one or more domains of cognition (Matlin, 1998).

1.5.1 Cognitive Domains

Cognition can be divided into several domains. However these domains are not distinct, and there exists some overlap between them. Three domains will be highlighted here due to their relationship to gait.

1.5.1.1 Executive Function

Executive functions are higher order cognitive processes responsible for the control and regulation of other cognitive processes (Miyake, Friedman, et al., 2000; Yogev et al., 2008). These cognitive skills are necessary for planning, monitoring and carrying out sequences of complex, goal-directed activities (Miyake, Friedman, et al., 2000; Royall et al., 2002). Working memory, the ability to divide attention between tasks and inhibition of information are all components of executive functioning (Hausdorff, 2005; Holtzer, Verghese, Xue, & Lipton, 2006; Sheridan, Solomont, Kowall, & Hausdorff, 2003; Stuss & Knight, 2002). Executive functions are often linked to the frontal lobe (Miyake, Emerson, & Friedman, 2000) as well as the prefrontal lobes, specifically the dorso-lateral prefrontal cortex and the cingulate cortex (Yogev et al., 2008). However, because

executive functions operate by controlling other cognitive processes, other areas of the brain may also be activated (Miyake, Emerson, et al., 2000).

1.5.1.2 Attention

Attention is a term that represents a number of processes related to how an individual becomes receptive to stimuli and how they begin processing this information (Lezak, 1995). However, there is no clear definition of attention. It has been proposed that attention is comprised of anatomical networks whose purpose is to influence other neural networks (Posner, Sheese, Odludaş, & Tang, 2006). Attention can be separated into different functional tasks that include selective, sustained, divided and alternating attention (Hausdorff, Schweiger, Herman, Yogev-Seligmann, & Giladi, 2008). Selective attention enables an individual to filter information (Rogers, 2000) and suppress distractions to concentrate on a specific stimulus (Lezak, 1995). Sustained attention is the ability to maintain focus on a task over a period of time (Lezak, 1995; Rogers, 2000). Divided attention refers to the ability of carrying out multiple tasks at one time; alternating attention is the ability to switch between tasks rapidly (Lezak, 1995; Rogers, 2000; Yogev et al., 2008).

1.5.1.3 Memory

Working memory is a complex concept that refers to a set of short-term information processing systems (Baddeley, Logie, Bressi, Della Sala, & Spinnler, 1986). The dorsolateral and ventro-lateral regions of the prefrontal cortex are said to have a central role in working memory (Stuss & Knight, 2002). When multistep behaviours are being performed, working memory receives the instructions and manipulates them to carry out the tasks (Anderson, 1983; Baddeley, 1992; Fitts & Posner, 1967). A task that utilizes working memory would require holding information in the mind to make it available for processing (Al-Yahya et al., 2011). This is different from a mental tracking task, which requires the holding of information while also performing a mental process (Al-Yahya et al., 2011).

1.6 Cognitive Contributions to Gait and Mobility

Although often thought of as an automatic process, there is much evidence to support that gait requires attention, even for routine walking tasks in healthy people (Beauchet & Berrut, 2006; Beauchet, Dubost, Herrmann, & Kressig, 2005; Woollacott & Shumway-Cook, 2002). In healthy young adults, attentional control is required for the single limb support phase of gait (Gage, Sleik, Polych, McKenzie, & Brown, 2003).

Walking is accomplished through the complex and coordinated patterns of nerve signals from sensory input through to motor output. Control of stepping, including stride time and stride length, mainly depend on communication between the cerebral cortex, cerebellum, basal ganglia and spinal central pattern generators (CPGs) (Newell & Corcos, 1993; Nutt et al., 1993; Whittle, 2007). These CPGs are rhythm generating systems that are controlled by neural input from higher brain centres, and receive feedback from sensors in the muscles and joints of the legs (Dietz, 2003; Duysens & Van De Crommert, 1998). The coordination between the two legs is required for human gait and this is achieved through reciprocal operation of CPGs. Gait speed is associated with performance on executive functions and memory tests as both depend on prefrontal cortex activation, indicating a sharing of neural pathways (Alvarez & Emory, 2006; Holtzer et al., 2006; Suzuki et al., 2004; Suzuki, Miyai, Ono, & Kubota, 2008).

1.6.1 Dual-Task Paradigm

Knowing that cognition and gait are connected through complex neural processes, a method of evaluating the cognitive contribution of gait is necessary. The principle of dual-task gait assessment is to compare the simultaneous performance of mobility and cognitive tasks to performance on each task independently (Abernethy, 1988; Pashler, 1994). Changes in performance may be observed and can be interpreted as the result of competing demands for attentional resources (Pashler, 1994; Woollacott & Shumway-Cook, 2002). The difference in performance of single and dual-tasks depends on an individual's capacity to properly allocate attentional resources when performing the tasks concurrently (Abernethy, 1988; Pashler, 1994). Attention may become overloaded

when two or more activities are performed simultaneously, as both tasks are competing for limited attentional resources (Abernethy, 1988; Pashler, 1994; Treisman, 1969).

1.6.2 Evaluating Cognitive Control of Gait: Dual-Task Interference Theories Several theories have been developed to explain the cognitive-motor interference observed in dual-task testing. Peripheral overload is one theory that may lend explanation for what is observed under dual-task conditions (Beauchet & Berrut, 2006). This theory suggests that similarity between tasks reduces interference, leading to better performance; this is also referred to as a cross-talk model (Beauchet & Berrut, 2006). For example, walking and reverse counting by 1s both have a strong rhythmic component; when concurrently completing these tasks, walking and counting may become synchronized, leading to a positive change in performance (Beauchet et al., 2007).

Another theory of cognitive-motor interference is the bottleneck theory (Yogev et al., 2008). This states that if two tasks need to be processed by the neural network, a bottleneck is created when handling the information (Yogev et al., 2008). In these cases, the second task cannot be properly processed until the first task is complete. During dual-task gait testing, cognitive-motor interference may occur because of higher order cognitive functions that are linked with gait speed control areas, such as executive functions and working memory (Klingberg, 2000).

The capacity sharing model offers a third explanation for what is observed under dualtask conditions (Beauchet & Berrut, 2006; Pashler, 1994; Treisman, 1969). This model postulates that the changes in gait result from capacity interference caused by competing demands for attention (Woollacott & Shumway-Cook, 2002). Attentional resources have a limited capacity, so performing two attention demanding tasks at once overloads these resources (Yogev et al., 2008). Allocation of attentional resources is dependent on the type of cognitive task paired with walking in the combined dual-task (Al-Yahya et al., 2011), as well as the nature and level of difficulty of the walking task (Beauchet et al., 2009; Kressig, Herrmann, Grandjean, Michel, & Beauchet, 2008; Lowry,

Brach, Nebes, Studenski, & VanSwearingen, 2012; Pashler, 1994; Woollacott & Shumway-Cook, 2002). For example, cognitive tasks such as mental tracking or verbal fluency disturb gait more than reaction time tasks because they involve cognitive domains with known associations to gait (Al-Yahya et al., 2011). Complex walking paths, such as ones with turns, challenge resources more than straight path conditions because of the cognitive capacities needed for navigating (Woollacott & Shumway-Cook, 2002). A majority of research is founded within the capacity sharing model.

1.6.2.1 Application of Dual-task gait assessments

Often, mobility requires one to navigate in complicated and unpredictable environments (Patla & Shumway-Cook, 1999); this could include environments that contain crowds, cluttered paths, pets or uneven terrain. Therefore, complex walking tasks reflect one's ability to adapt motor patterns to challenging tasks and forces one to make sensorimotor adaptations to gait (Patla & Shumway-Cook, 1999; Woollacott & Shumway-Cook, 2002). Dual-task gait assessments are promoted as a means to allow researchers to mimic complex walking conditions by pairing motor and cognitive tasks in a safe and controlled setting.

1.6.3 Dual-task Changes in Gait

The rhythmic and automated characteristics of gait are controlled by subcortical brain regions (Nutt et al., 1993), which suggests that control requires minimal to no attention. However, dual-tasking has been shown to affect gait in a variety of populations, including healthy young and older adults and those with neurological diseases such as Parkinson's disease, Alzheimer's disease, brain injuries and stroke (Yogev et al., 2008).

In healthy young adults, stride velocity has been shown to decrease significantly under dual-task conditions compared to when walking alone, this is combined with an increase in stride-time variability (Dubost et al., 2008). In one study, a decrease in stride velocity was related to an increase in stride time, but was not related to stride length (Dubost et al., 2008). These results are consistent with an increase in the double-support phase of gait (Beauchet & Berrut, 2006; Brach, Berthold, Craik, VanSwearingen, & Newman,

2001; Gage et al., 2003), which may serve as a way to reduce the risk of loss of balance by decreasing attentional demands in the swing phase under dual-task conditions (Dubost et al., 2008).

Dual-task related changes in spatial and temporal gait parameters noted across the various populations listed above include: decreased speed, decreased cadence, decreased stride length, increased stride time and increased stride time variability (Al-Yahya et al., 2011; Yogev et al., 2008). Changes in gait related to dual-tasking are sensitive and may distinguish between groups of healthy participants from those with mild cognitive deficits or neurological conditions (Al-Yahya et al., 2011). This is only true of gait speed, and has not been shown for other gait parameters (Al-Yahya et al., 2011). Studies also show that gait in healthy older adults is more affected by concurrent performance of cognitive and motor tasks compared to young adults (Al-Yahya et al., 2011). This may be attributed to age-related changes in cognitive and motor systems (Judge, Ounpuu, & Davis, 1996; Seidler et al., 2010; Snijders, van de Warrenburg, Giladi, & Bloem, 2007).

1.6.3.1 Dual-task Research in the Amputee Population

There is minimal research with regards to dual-task gait testing in the amputee population. One study showed that those with AKAs walked slower, had a wider step width and more asymmetrical gait under dual-task conditions, but these changes were not significant from those of normal controls (Morgan, Hafner, & Kelly, 2016). Another study of those with AKAs found slower gait speeds and longer strides under dual-task conditions (Lamoth, Ainsworth, Polomski, & Houdijk, 2010). There is a need for the development of a reliable dual-task testing protocol that can be used to determine dualtask gait changes in the amputee population as a whole. More research is also needed to assess dual-task gait changes over time in this population.

1.6.4 Dual-task Methodological Concerns

Previous studies of dual-task gait testing related changes during motor-cognitive activities have raised a number of issues regarding methodology (Beauchet et al., 2009). There is variability in the instructions given, which may influence the participants prioritization strategy during dual-tasking (Yogev et al., 2008). Another concern is the lack of standardization of cognitive task type, making comparisons between studies difficult (Beauchet et al., 2009). The use of a well-defined and quantitative mental tracking task (Al-Yahya et al., 2011) may help to improve validity, reliability, consistency and comparability of results (Beauchet et al., 2009). There is also no established method for quantifying the level of attentional load during dual-tasking (Yogev et al., 2008). Determining the amount of attention required to perform tasks may help researchers choose the appropriate combination of tasks for use in testing.

1.7 Rationale

1.7.1 Study 1 – Determining Test-Retest Reliability of a Dual-task Functional Mobility Protocol in Lower Extremity Amputees

Individuals with LEA caused by dysvascular disease face challenges associated with higher-order cognitive processes such as problem-solving, reasoning, concentration and balance (Coffey et al., 2012). These challenges may impact the successful achievement of the endurance, balance or use of higher level cognitive skills necessary for household and community ambulation with a prosthesis (Deathe & Miller, 2005). Despite the best efforts and functional gains in prosthetic-rehabilitation programs, the falls risk for older adults with an LEA exceeds that for frail older adults living in the community (Miller, Speechley, et al., 2001b). The consequences of falling are dire, including not only physical injury, but also a fear of falling that often leads to lack of prosthesis use and social withdrawal (Miller, Deathe, et al., 2001).

Current amputee literature recognizes the relationship between cognition or cognitive impairment and performance in rehabilitation (Coffey et al., 2012; Frengopoulos et al., 2017; O'Neill, 2008; O'Neill & Evans, 2009; Sansam et al., 2009). However, mobility and cognitive tasks have been studied solely in isolation; the essential role of cognition in mobility has not been studied (Williams et al., 2015). To assess the interaction of cognition and mobility, individuals must be observed performing a mobility task while simultaneously performing a distracting cognitive task: the dual-task paradigm (Yogev et al., 2008). If the cognitive load of performing the two tasks exceeds the capacity of the individual, performance on one or both tasks will deteriorate, this is known as the DTC. The dual-task paradigm is relevant to most daily activities as these tasks require the multi-tasking of motor and cognitive tasks.

1.7.1.1 Purpose

The purpose of this study was to determine the relative and absolute test-retest reliability of a dual-task functional mobility protocol to use in the LEA population.

1.7.1.2 Hypotheses

It was hypothesized that: 1) good-excellent relative test-retest reliability would be found across the population of lower extremity amputees and 2) agreement between test and retest assessments would be seen across the population.

1.7.2 Study 2 - Quantifying Change in Cognitive Demand of Ambulating with a Prosthesis

Researchers and clinicians have only recently started to appreciate that cognition plays an essential role in balance and mobility. Increasing evidence from clinical practice and epidemiological studies, as well as a few clinical trials, demonstrates that coordination of motor function and cognitive function is required, even for routine walking (Montero-Odasso, Verghese, Beauchet, & Hausdorff, 2012; Yogev et al., 2008). In fact, the ability to successfully move through one's home and community during the normal activities of daily living requires significant cognitive resources for adapting walking patterns to avoid or negotiate obstacles, change direction and plan a path (Frank & Patla, 2003; Lowry et al., 2012). Subtle changes in executive function are also associated with an increased fall risk (Muir, Speechley, et al., 2012). Until recently, clinicians and researchers have evaluated and treated the cognitive and mobility domains in older adults separately. Approaching these domains as separate entities has obscured common connections and created a gap in our understanding of the cognitive-motor interactions and the potential underlying mechanisms that can affect pathways to disability. This gap may also explain why cognition has received little attention with

regard to intervention strategies for mobility improvement or falls prevention (Montero-Odasso et al., 2012).

Understanding the role of and demands on cognitive resources in the recovery of functional abilities using a prosthesis is essential to change adverse outcomes of falls in older adults with an LEA. Falls in older adults represent an important public-health problem. Older adults with LEA are a subpopulation at particularly high risk of falling. Despite the best efforts and functional gains of prosthetic-rehabilitation programs, the falls risk for older adults with an LEA exceeds that for frail older adults (Dite, Connor, & Curtis, 2007; Parker, Hanada, & Adderson, 2013; Yu et al., 2010). The consequences of falling are dire, including not only physical injury, but also a fear of falling that often leads to lack of prosthesis use and social withdrawal (Miller & Deathe, 2011). Amputeerehabilitation programs need to be able to appropriately target treatment to both physical and cognitive domains of balance to prevent falls, improve functional autonomy and quality of life. The physical demands of using a prosthesis are well understood, yet our understanding of cognition in mobility disability among older adults with an LEA is very limited.

The accepted way to assess the interaction between cognition and mobility is to observe people during a gait or balance task while they simultaneously perform another task (the dual-task paradigm) (Snijders, Verstappen, Munneke, & Bloem, 2007; Woollacott & Shumway-Cook, 2002), If the demands of executing the two tasks exceed the cognitive capacity of the individual, then overall performance will deteriorate (Snijders, Verstappen, et al., 2007). The dual-task paradigm is ecologically relevant as most normal daily activities involve the simultaneous performance of cognitive and motor tasks (multi-tasking) (Woollacott & Shumway-Cook, 2002). Healthy older adults slow down their walking while performing simultaneous tasks (Hausdorff et al., 2008), yet this will be compounded in older adult under complex multitask challenges, such as walking with a prosthesis. Recent studies have shown that a deterioration of walking performance under dual-task testing is associated with an increased fall risk (Muir-Hunter & Wittwer, 2016). Fall-prevention programs for older adults that fail to evaluate the cognitive

demands required for mobility are not successful (Shaw, 2007). There is currently no research on the combined evaluation of cognitive and mobility function in older adults with an LEA undergoing prosthetic rehabilitation. New research is required to inform appropriate fall risk evaluation practices that will lead to novel rehabilitation strategies.

1.7.2.1 Purpose

The purpose of this study was to 1) investigate the changes in gait for older adults with LEA between discharge and four month follow-up and 2) determine the relationship between cognition (sample stratified based on cognitive status) and gait for older adults with LEA.

1.7.2.2 Hypotheses

It was hypothesized that 1) cognitively normal individuals would walk faster and with less variability than cognitively impaired individuals across all time points, 2) gait would be faster with less variability for both groups at follow-up, 3) increased gait variability and slower gait speeds would be observed in both groups when comparing dual-task to single-task performance, 4) the cognitive and gait DTCs would decrease between discharge and four months for both cognitively impaired and cognitively normal individuals with LEA and 5) both cognitive and gait DTCs would be higher in the cognitively impaired group at all assessment time points.

Chapter 2: METHODOLOGY

2.1 Study 1 – Determining Test-Retest Reliability of a Dual-task Functional Mobility Protocol in Lower Extremity Amputees

2.1.1 Study Design

This study was a cross-sectional analysis of test and retest mobility data. Recruitment took place in the Out-patient Amputee Clinic at Parkwood Institute in London, Ontario. Individuals were recruited by their physician following a regularly scheduled appointment and asked to perform single and dual-task functional mobility assessments, cognitive screening and balance confidence screening. Participants were required to return within 14 days for retest assessment under single and dual-task

conditions, as well as updated balance confidence screening. The study took place at Parkwood Institute between March 2016 and January 2017; it was approved by the Health Sciences Research Ethics Board at the University of Western Ontario, and by the Clinical Resources Impact Committee of Lawson Health Research Institute (Appendix A).

2.1.2 Study Population

Three groups were recruited: 1) those with below knee amputations of vascular etiology (BKA-vas), 2) those with BKA of non-vascular etiology (BKA-nonvas), and 3) those with complex amputations (AKA/bilat). For the purpose of this study, complex amputations are defined as those with bilateral BKA and unilateral AKA as these groups require more energy and effort during walking, due to the limitations of their prosthetics (Braddom, 2011; DeLisa, 2010). It has also been shown that these groups have walking scores different than those with unilateral BKA (Linberg et al., 2013).

Individuals were eligible to participate if they were 18 years or older, had a functional use of the English language, had a lower extremity amputation, were using their prostheses for community ambulation and had been using it for at least 6 months. A priori power analysis identified a sample size of 20 people was necessary to identify a desired intra-class correlation coefficient (ICC) of 0.9 with a lower confidence interval of ICC=0.70, α =0.05 and β =0.20 in the reliability analysis (Walter, Eliasziw, & Donner, 1998). Total sample size for this study was 60; 20 from each of the above-mentioned groups.

2.1.3 Outcome Measures

Demographic and medical history information was obtained prior to testing. Individuals were also asked about their 12 month fall history and if they had a fear of falling. At the retest assessment, individuals were asked if they had sustained a fall since their initial assessment.

2.1.3.1 Functional Mobility Assessments

A quiet hallway was used to perform mobility assessments. The primary outcome measure was the L Test; a measure of functional mobility developed for use in the LEA

population (Deathe & Miller, 2005). The L Test was developed as a modified version of the Timed "Up and Go" Test; the longer distance and inclusion of a 90° in the L Test make it a more useful indicator of mobility for the LEA population (Deathe & Miller, 2005).

Gait performance under a straight-path condition is considered a low cognitive challenge activity, while curved or complex-path walking increases cognitive load and can provide meaningful information about daily life walking ability, including adaptation of walking patterns to negotiate obstacles, change directions, or plan a path (Lowry et al., 2012). The greater complexity of the L Test may challenge cognitive and physical resources of the patient more so than a straight path assessment, providing ecological validity to the proposed dual-task assessment protocol.

Testing of the L Test was done through standardized instruction, in which a patient started in sitting and upon the word 'go' rose to standing, walked three metres, performed a 90° turn, walked seven metres, before turning 180°, retracing the L-shape and returning to the seated position (Deathe & Miller, 2005). Individuals were instructed to perform the test at their usual, comfortable, everyday pace. A high level of skill is required to complete the 180° and 90° turns and transfers sitting or standing; these skills are also necessary for mobility in the home (Deathe & Miller, 2005). The original version of this measure has excellent intrarater and interreater reliability, 0.97 (0.93-0.98) and 0.96 (0.94-0.97) respectively (Deathe & Miller, 2005).

Figure 2.1 The L Test of Functional Mobility

Individuals were instructed to complete the original (single-task) version of the L Test, then given a five minute break in sitting before completing the dual-task assessment. Dual-task analysis paired the L Test with the secondary cognitive task of serial subtractions by threes from a number randomly selected between 100 and 150. The same standardized instructions were given for the dual-task version of the assessment as given with the single-task version. Individuals were not given instructions to prioritize the cognitive or mobility task under dual-task conditions. Both single and dual-task L Tests were timed to the nearest 100th of a second in accordance with standard protocol (Deathe & Miller, 2005). To ensure sincerity of effort in performance on the secondary cognitive task, responses were recorded and accuracy of responses was calculated.

2.1.3.2 Cognitive Assessments

A single-task assessment of the distracting cognitive task was performed in sitting. This consisted of the individual performing serial subtractions by threes, starting at 100. Amount of time to complete 18 subtractions was recorded to the nearest hundredth of a second. Accuracy was calculated as follows: (Number of Correct Responses/Number of Given Responses) x 100.

The Montreal Cognitive Assessment (MoCA) was used to quantify cognitive ability. The MoCA is a cognitive screening tool that provides a brief evaluation of 7 cognitive domains (Nasreddine et al., 2005). A total of 30 points are possible, with scores ≥26 considered cognitively normal (Nasreddine et al., 2005). An adjustment for those with 12 or fewer years of education was incorporated, allowing for the addition of one point to the score for these individuals (Nasreddine et al., 2005). This measure was developed to aid in the identification of mild cognitive impairment, and as such is more sensitive to abnormalities compared to other brief assessments (Alagiakrishnan, Zhao, Mereu, Senior, & Senthilselvan, 2013; Montero-Odasso & Muir, 2010; Pendlebury, Cuthbertson, Welch, Mehta, & Rothwell, 2010). The sensitivity of this tool with regards to abnormalities associated with vascular cognitive impairment (Alagiakrishnan et al., 2013) make it suitable for use in the LEA population.

2.1.3.3 Balance Confidence Assessments

The Activities-specific Balance Confidence (ABC) Scale is a self-reported outcome measure that was used to assess the participants' balance confidence on 16 mobilityrelated tasks (Powell & Myers, 1995). The 16-items are rated on a confidence scale ranging from 0% (no confidence) to 100% (complete confidence) in ability to complete the task without losing balance or becoming unsteady (Powell & Myers, 1995). The ABC Scale has demonstrated internal consistency and test-retest reliability in the LEA population, making it a useful measure of balance confidence (Miller, Deathe, & Speechley, 2003).

2.1.4 Statistical Analysis

Participant demographics and scores on cognitive, balance confidence and measures of physical functioning were summarized using means and standard deviations (SDs) or frequencies and percentages, as appropriate.

Relative reliability is the degree to which an individual's position in a sample is maintained upon repeated measurements (Bruton, Conway, & Holgate, 2000). The measure of relative reliability evaluated in this study was the test-retest reliability; the degree to which a result from one test is equivalent to the result on the same test across days when no change is expected to have occurred. Relative test-retest reliability was evaluated using ICC. An ICC value of 0.90 or higher is considered excellent, values between 0.80-0.89 are considered good, values between 0.70-0.79 are considered fair and values less than 0.70 are considered to be of questionable clinical value (Streiner & Norman, 2003).

Two measures of absolute reliability were also calculated. Absolute test-retest reliability is the degree that repeated measurements using the same tool differ for an individual; the smaller the value, the higher the reliability (Streiner & Norman, 2003). The standard error of measurement (SEM) and minimum detectable change (MDC) were used to quantify absolute test-retest reliability. The SEM is an expression of measurement error in the same units as the scale (Stratford, 2004). It is calculated as using the following
formula: SEM= SD √(1-ICC) (Stratford, 2004). The MDC with a 95% confidence interval (MDC_{95}) is an estimate of the smallest change in the score that can be detected beyond measurement error, calculated as follows: MDC $_{95}$ =SEM x $\sqrt{2}$ x 1.96 (Stratford, 2004).

Agreement between test and retest assessments was quantified using Bland-Altman plots (Bland & Altman, 1986). This agreement evaluates the accuracy of comparability between the two testing sessions (Altman & Bland, 1983). These plots are created by graphing the difference in test and retest times against the mean of the two testing times (Bland & Altman, 1986). Bias, estimated by the mean difference and standard deviation of the differences (*s*), was calculated and graphed as a solid horizontal line (Bland & Altman, 2010). The limits of agreement (LOA) lie on either side of the line of bias; 95% of differences are expected to fall within these limits (Bland & Altman, 2010). LOA are calculated as follows: bias ± 2*s* (Bland & Altman, 2010). The LOA appear on graphs as horizontal dashed lines. The MDC $_{95}$ will be used to determine acceptable sizes for the LOA; the LOA should be similar in magnitude to the MDC₉₅.

All statistical analyses were performed using the IBM SPSS Statistics version 24.0 (IBM Corporation, Armonk, NY) and Excel for Windows 10.

2.2 Study 2 – Quantifying Change in Cognitive Demand of Ambulating with a Prosthesis

2.1.1 Study Design

This was a pilot study with a prospective cohort design. Recruitment took place at Parkwood Institute in London, Ontario from the Regional Rehabilitation Program. Individuals undergoing inpatient rehabilitation following a first major LEA were recruited by their physician prior to discharge. Initial assessments were completed within 72 hours of discharge and follow-up assessments were scheduled to coincide with a regularly scheduled follow-up in the Out-patient Amputee Clinic. Recruitment took place at Parkwood Institute between April 2016 and November 2016. This study was approved by the Health Sciences Research Ethics Board at the University of Western Ontario, and

by the Clinical Resources Impact Committee of Lawson Health Research Institute (Appendix A).

2.2.2 Study Population

Individuals with first unilateral LEA were recruited from the inpatient Amputee Clinic at Parkwood Institute. Based on the established cut-off for MoCA scores (Nasreddine et al., 2005), participants were stratified into the following two groups: 1) cognitively normal (MoCA ≥ 26) and 2) cognitively impaired (MoCA <26). Individuals with LEA have regular follow-ups in the Out-patient Amputee clinic; typically patients will return between 4.0- 4.5 months following discharge. To account for variability in clinical practice scheduling, a predetermined follow-up window of 3.5-6.0 months was allowed. During this time it is expected that patients experience ongoing gains in function due to motor learning (Brooks et al., 2001).

Individuals were eligible to participate if they were 50 years or older, had a functional use of the English language, and could walk 10m without the assistance of another person. Certain conditions that would exclude individuals from participating were any physical problem that significantly limited movement or if they were suffering from severe depression. A priori power analysis identified a sample size of 12 per group to allow for 80% power with α error of 5% to detect a 15% difference in DTC.

Due to time constraints, this pilot study only included individuals recruited between April 26, 2016 and November 16, 2016. During this period, 17 individuals discharged from the inpatient rehabilitation program met eligibility criteria and 100% of these individuals consented to participate in the study. One individual withdrew from the study prior to completion of outcome measures during the discharge assessment as they believed the assessment questions did not apply to them. This left a total of 16 individuals for inclusion in the study, eight in each of the above mentioned groups.

2.2.3 Outcome Measures

Demographic and medical history information were obtained prior to testing. The following outcome measures were completed at discharge: single and dual-task

functional mobility assessments, balance and balance confidence assessments, cognitive assessments, and single and dual-task gait assessments. The above measures were also completed at the follow-up assessment, with the exception of cognitive testing. Safety belts were used during all mobility, balance and gait assessments.

2.2.3.1 Functional Mobility Assessments

A quiet hallway was used to perform functional mobility assessments. As previously mentioned, the L Test is a measure of functional mobility that has been developed for use in the LEA population (Deathe & Miller, 2005). Testing was done through standardized instruction, in which a patient started in sitting and upon the word 'go' rose to standing, walked 10 meters in and L-shape, before turning 180° and returning to the seated position (Deathe & Miller, 2005). The original version of this measure has excellent intrarater and interrater reliability, 0.97 (0.93-0.98) and 0.96 (0.94-0.97) respectively (Deathe & Miller, 2005).

Individuals were given a five minute break after completing the original (single-task) version of the L Test. In accordance with the protocol developed in Study 1, dual-task analysis paired the L Test with the secondary cognitive task of serial subtractions by threes starting at 100. Standardized instructions were given for both single and dualtask versions of the assessment. Individuals were not instructed to prioritize either the cognitive or mobility task. Single and dual-task versions of the L Test were timed to the nearest 100th of a second in accordance with standard protocol (Deathe & Miller, 2005). To ensure that a sincere effort was given to performing the secondary cognitive task, responses were recorded and accuracy of responses was calculated.

2.2.3.2 Balance and Balance Confidence Assessments

The Four Square Step Test (FSST) measures coordination, ability to step rapidly and obstacle avoidance (Dite & Temple, 2002). The test is easy to administer and commonly used in the amputee population (Dite et al., 2007; Hart-Hughes, Latlief, Phillips, Groer, & Highsmith, 2014). This study did not use canes, as the original test described (Dite & Temple, 2002), instead tape was placed on the floor in a t-shape (as shown in Figure 2.2) and individuals were asked to avoid stepping on the tape as they performed the test. Standardized instructions were given and individuals were told to remain facing forwards as they stepped forwards, sideways and backwards as quickly as possible, following the designated sequence; both feet must make contact with the floor, prior to stepping into the next square (Dite & Temple, 2002). As indicated in the original article, if it was not possible for the individual to remain facing forwards throughout the sequence, they were allowed to turn before stepping into the next square (Dite & Temple, 2002).

A demonstration was given to participants prior to the commencement of their trials; the assessor stood in square 1, facing square 2 and completed the following sequence: 2, 3, 4, 1, 4, 3, 2, 1. The test was times to the nearest $100th$ of a second and the best of two trials was taken as the score (Dite & Temple, 2002). Participants used their usual gait aid to perform the test.

Figure 2.2 Four Square Step Test

The ABC Scale was used as a measure of balance confidence. This self-reported measure has demonstrated internal consistency and test-retest reliability in the LEA population (Miller et al., 2003).

2.2.3.3 Cognitive Assessments

The MoCA was used to quantify cognitive ability. As previously mentioned, this cognitive screening tool provides a brief evaluation of 7 cognitive domains (Nasreddine et al.,

2005). This tool is suitable for use in the LEA population as it is sensitive to abnormalities associated with vascular cognitive impairment (Alagiakrishnan et al., 2013).

The Trail Making Test (TMT) was also used as a measure of cognitive ability, specifically executive functioning (Yogev et al., 2008). There are two parts to the TMT: Part A requires participants to connect consecutive numbers (1-25); Part B requires the individual to draw a line connecting number and letters in alternating order (Yogev et al., 2008). Part A consists of an attention task while Part B requires cognitive flexibility in order to mentally shift between counting and alphabet tasks (Corrigan & Hinkeldey, 1987; Kortte, Horner, & Windham, 2002). To ensure that individuals understood the instructions for each section of the test an untimed sample of each part was completed prior to completion of the test itself. Parts A and B were timed to the nearest 100th of a second. Scores are reported as a the difference between Parts A and B (ΔTMT) and calculated as follows: ΔTMT = Time to complete Part B – Time to complete Part A (Coppin et al., 2006). The ΔTMT is used to control for the effect of motor speed and visual tracking on performance; this is considered a more accurate measure of executive function than performance on Part B alone (Coppin et al., 2006; Lezak, 1995).

Serial subtractions by 3s from 100 was used as a distracting cognitive task during dualtask conditions. This task was also performed while seated in a quiet room. Different from Study 1, nine consecutive serial subtractions were used as a single-task assessment for the cognitive task, rather than 18. However, the time it took to complete these 9 subtractions was still recorded to the nearest 100th of a second. Accuracy was calculated in the same method as Study 1: (Number of Correct Responses/Number of Given Responses) x 100.

2.2.4 Gait Analysis

Assessments were performed in a quiet, well-lit room under single and dual-task conditions. The GAITRite® System was used in order to analyze the kinematics of gait at discharge and follow-up assessments. This electronic walkway is a 6m by 0.64m mat with pressurized sensors embedded within it. A personal computer is connected to the

mat and runs the GAITRite® System software. As an individual walks across the mat their footfalls activate the embedded sensors and the computer displays these imprints on the screen. This allows the system to capture information on the temporal-spatial gait parameters as the individual completes the test. To ensure that only steady state walking was captured during the assessments one meter acceleration and deceleration zones were provided beyond the ends of the mat. Information from these zones was not picked up by the system and therefore was not included in calculations of gait parameters.

Tape was placed on the floor at the beginning of the acceleration zone and the end of the deceleration zone. Participants were positioned with their feet behind the tape and were instructed to walk across the mat to the piece of tape at the other end. A stopwatch was used to measure time to complete the walk; time was started when first the initial contact was made with the mat and stopped when contact with the mat ended. During single-task performance participants were instructed to walk at their usual, comfortable pace. Dual-task assessment paired this with the secondary cognitive task of serial subtractions by threes from 100, with all other instructions remaining the same. Participants were not given any explicit prioritization instructions prior to dualtask testing. To ensure sincerity of effort on the secondary cognitive task responses were recorded and accuracy of responses was calculated.

The GAITRite® System has demonstrated validity and reliability in the collection of temporal-spatial gait parameters (McDonough et al., 2001; Verghese et al., 2002). The primary variables of interest under single and dual-task conditions were: gait velocity (cm/s), stride time (msec), stride length (cm), step width (cm) and double stance (msec). The variability in four gait parameters was also of interest, these were: stride time variability, stride length variability, double stance time variability and step width variability. These parameters were selected based on the literature, as they have a relationship to gait, stability and falls risk (Hausdorff, 2005; Hausdorff et al., 2001; Montero-Odasso et al., 2012).

Values for the single and dual-task walks on the GAITRite® System will be reported by two methods: gait velocity (cm/s) and time to complete walk (to the nearest $100th$ of a second). This it to allow for calculations of DTCs using the same units both for straight path and complex path walking, while also using gait velocity (cm/s) to evaluate steady state walking in a straight path.

2.2.5 Statistical Analysis

Participant demographics and scores on the above mentioned outcome measures were summarized using medians and SDs or frequencies and percentages, as appropriate. The %CV was used to quantify gait variability in the following four parameters: stride time, stride length, step width and double stance time. The effect of cognition on walking was quantified by the DTC. Two DTCs were calculated for each walking condition: the cognitive DTC (DTCcog) and the gait DTC (DTCgait). The DTCgait was quantified as [(single-task value - dual task value)/single-task value] × 100% for each walking condition (Muir, Speechley, et al., 2012). In order to account for response rate and accuracy of responses when performing the cognitive task, a corrected response rate (CRR) was used (Hall, Echt, Wolf, & Rogers, 2011). The CRR was calculated as: response rate per second x percent correct (Hall et al., 2011). This CRR was then used to quantify the DTCcog using the following formula: [(CRR seated $-$ CRR walking)/CRR seated] \times 100%.

Due to the small sample size of the groups being investigated in this pilot study, nonparametric analyses were used to investigate differences between groups and change over time within groups. Mann-Whitney U Tests, using mean ranks, were performed to compare differences between cognitively normal and cognitively impaired groups at discharge and follow-up. To identify changes within groups between discharge and follow-up, Wilcoxon Signed Rank Test was used.

Statistical significance was set at p < 0.05 for all above mentioned analyses. All statistical analyses were performed using the IBM SPSS Statistics version 24.0 (IBM Corporation, Armonk, NY) and Excel for Windows 10.

Chapter 3: RESULTS

3.1 Study 1 - Determining Test-Retest Reliability of a Dual-task Functional Mobility Protocol in Lower Extremity Amputees

3.1.1 Study Population and Demographics

Sixty-eight individuals with lower extremity amputation were recruited for this study. Eight subjects were unable to return to the clinic within a two week period for retest assessment due to lack of availability of rides (2), illness (2), scheduling issues (1), or other reasons (3). The final sample consisted of 60 participants, 20 individuals in each of the three groups. Demographic characteristics for each of the groups are summarized in Table 3.1. Values are reported as means and standard deviations or percentages where appropriate.

| Variable | Mean ± Standard Deviation | | | | |
|--------------------------------|----------------------------------|-------------------|-------------------|--|--|
| | BKA-vas (n=20) | BKA-nonvas (n=20) | AKA/bilat (n=20) | | |
| Age (years) | 60.36 ± 7.84 | 55.85 ± 14.08 | 58.21 ± 14.88 | | |
| Level of Education (years) | 12.48 ± 2.17 | 14.05 ± 3.38 | 14.85 ± 3.05 | | |
| Gender (%) | | | | | |
| Male | 90.0 | 85.0 | 65.0 | | |
| Female | 10.0 | 15.0 | 35.0 | | |
| Body Mass Index | 33.01 ± 7.40 | 27.41 ± 4.00 | 27.63 ± 5.11 | | |
| Number of Medications | 7.55 ± 3.61 | 3.40 ± 4.12 | 5.25 ± 7.10 | | |
| Number of Comorbidities | 5.95 ± 3.91 | 3.95 ± 3.46 | 5.30 ± 4.88 | | |
| 1 Year Falls History | 0.85 ± 2.68 | 1.05 ± 1.43 | 1.75 ± 2.73 | | |
| MoCA Score | 26.05 ± 2.24 | 26.80 ± 1.99 | 26.75 ± 2.31 | | |
| ABC Score | 74.39 ± 17.65 | 89.70 ± 10.06 | 75.72 ± 21.53 | | |
| L Test time, initial | 31.31 ± 7.30 | 23.49 ± 3.56 | 36.18 ± 19.88 | | |
| L Test time, retest | 29.98 ± 6.81 | 22.56 ± 3.64 | 36.37 ± 19.65 | | |

Table 3.1 Demographic Characteristics of Participants per Group

Notes: MoCA = Montreal Cognitive Assessment, ABC = Activities-specific Balance Confidence Scale, BKA-vas = Below knee amputation of vascular etiology, BKA-nonvas = Below knee amputation of nonvascular etiology, AKA/bilat = Above knee amputation or bilateral amputations of any etiology, n = sample size

3.1.2 Test-Retest Analysis

The relative test-retest reliability was excellent for all three groups. For the BKA-vas group, the relative reliability of the dual-task assessment was ICC=0.98, 95% CI (0.94, 0.99). The BKA-nonvas group had an ICC=0.93, 95% CI (0.80, 0.98) and the AKA/bilat group had a value of ICC=0.998, 95% CI (0.996, 0.999). Absolute test-retest reliability analysis yielded an SEM=1.36 seconds for the BKA-vas group, with MDC₉₅=3.76 seconds. The BKA-nonvas group had similar values, with an SEM=1.34 seconds and an MDC95=3.71 seconds. For the AKA/bilateral group the SEM=1.03 seconds, with an MDC95=2.85 seconds. Results of the relative and absolute test-retest reliability analyses are presented in Table 3.2.

| | Mean ± Standard Deviation | | | | |
|---------------------------|----------------------------------|-------------------|---------------------|--|--|
| Measurement | BKA-vas | BKA-nonvas | AKA/bilat | | |
| Dual-task L Test, initial | 36.75 ± 10.53 | 29.00 ± 5.40 | 41.16 ± 23.03 | | |
| Dual-task L Test, retest | 35.38 ± 9.88 | 27.78 ± 4.83 | 41.27 ± 23.18 | | |
| ICC (95% CI) | 0.98(0.94, 0.99) | 0.93(0.80, 0.98) | 0.998(0.996, 0.999) | | |
| SEM | 1.36 | 1.34 | 1.03 | | |
| MDC_{95} | 3.76 | 3.71 | 2.85 | | |

Table 3.2 Relative and Absolute Test-retest Reliability Results

Notes: ICC = Intraclass correlation coefficient, CI = confidence interval, SEM = Standard error of measurement, MDC $_{95}$ = minimal detectable change with a 95% confidence interval, BKA-vas = Below knee amputation of vascular etiology, BKA-nonvas = Below knee amputation of nonvascular etiology, AKA/bilat = Above knee amputation or bilateral amputations of any etiology

3.1.3 Agreement Analysis

The Bland-Altman plots created for each of the groups indicated that the differences between the protocols did not vary in any systematic way over the range of measurements. These plots also demonstrated that there is adequate agreement between test and retest sessions for all three groups. The LOA for the BKA-vas group were ±4.73. The LOA for the BKA-nonvas group were ±4.71 and the AKA/bilat group had LOA of ±3.69. These LOA values are within the predetermined limits deemed

appropriate for agreement to be present. The Bland-Altman plots for the BKA-vas, BKAnonvas and AKA/bilat groups can be found in Figures 3.1, 3.2 and 3.3 respectively.

Figure 3.1 Bland Altman Plot for BKA-vas Dual-task L Test

Figure 3.2 Bland Altman Plot for BKA-nonvas Dual-task L Test

Figure 3.3 Bland Altman Plot for AKA/bilat Dual-task L Test

3.2 Study 2 – Quantifying Change in Cognitive Demand of Ambulating with a Prosthesis

3.2.1 Study Population and Demographics

Sixteen individuals with lower extremity amputation were recruited for this study; eight individuals in the cognitively normal group and eight in the cognitively impaired group. Thirteen of these 16 individuals were assessed at their follow-up appointment. Reasons for lack of follow-up included: family emergency (1); illness (1); lost to follow-up and unable to contact (1). Of the thirteen individuals that were available for follow-up, six were in the cognitively normal group and seven were in the cognitively impaired group. Demographic characteristics at discharge for the total sample and each of the groups are summarized in Table 3.3. Data are reported as medians and standard deviations or percentages where appropriate. The range of MoCA scores within each group is also provided.

The cognitively normal and cognitively impaired groups are not different based on age, education, body mass index, one year fall history, or ABC scores. These groups also have

similar scores on the TMT, which indicates similar status in executive functioning, even though significant differences in global cognition (assessed using the MoCA) exist (p (0.001) .

| Variables | Total Sample | Cognitively Normal | Cognitively Impaired |
|--------------------------------|---------------------|---------------------------|-----------------------------|
| | $(n=16)$ | $(n=8)$ | $(n=8)$ |
| Age (years) | 61.41 ± 8.10 | 61.72 ± 9.02 | 59.77 ± 7.70 |
| Education (years) | 13.00 ± 2.11 | 13.50 ± 2.10 | 12.50 ± 1.85 |
| Gender (%) | | | |
| Male | 50.0 | 50.0 | 50.0 |
| Female | 50.0 | 50.0 | 50.0 |
| Level of Amputation (% BKA) | 68.8 | 87.5 | 50.0 |
| Primary Etiology of | | | |
| Amputation (% vascular) | 81.3 | 87.5 | 75.0 |
| Mobility Aid (% rollator) | 68.8 | 62.5 | 75.0 |
| Body Mass Index | 30.34 ± 6.93 | 28.62 ± 9.46 | 30.46 ± 3.64 |
| Number of Medications | 11.50 ± 5.52 | 11.50 ± 5.32 | 12.50 ± 6.04 |
| Number of Comorbidities | 6.00 ± 3.14 | 6.00 ± 3.42 | 4.50 ± 2.49 |
| 1 Year Fall History | 2.00 ± 1.18 | 1.50 ± 0.89 | 2.00 ± 2.32 |
| MoCA Score (range) | 25.50 ± 2.50 | 28.00 ± 1.25 (26-30) | 23.50 ± 0.93 (22-25) |
| $\Delta T M T$ | 64.40 ± 30.34 | 52.56 ± 52.56 | 65.48 ± 25.49 |
| ABC Score | 67.33 ± 13.62 | 69.83 ± 10.84 | 65.31 ± 15.36 |
| FSST (sec) | 40.66 ± 40.66 | 25.30 ± 29.42 | 73.38 ± 41.51 |
| Straight Path Walking - | | | |
| single-task (sec) | 14.31 ± 10.96 | 10.48 ± 8.38 | 19.33 ± 11.43 |
| Straight Path Walking - | | | |
| dual-task (sec) | 17.44 ± 11.98 | 12.69 ± 9.19 | 24.96 ± 11.52 |
| L Test - single-task (sec) | 55.69 ± 58.11 | 37.51 ± 46.26 | 107.31 ± 58.67 |
| L Test – dual-task (sec) | 63.52 ± 81.97 | 39.83 ± 53.10 | 116.29 ± 91.22 |

Table 3.3 Demographic Characteristics of Participants at Discharge

Notes: BKA = Below knee amputation, MoCA = Montreal Cognitive Assessment, ΔTMT = Delta trail making test, ABC = Activities-specific balance confidence scale, FSST = Four square step test, n = sample size

Discharge and follow-up data are summarized in Table 3.4 for the 13 individuals who attended their follow-up assessment. The median follow-up time was 4.41 months. Complete follow-up data was only available for 10 of these individuals. Reasons for incomplete follow-up data include: non-ambulatory due to revision of original amputation (1); non-ambulatory due to amputation of the contralateral limb (1); physically unable to complete all of the required testing (1). The two individuals that were non-ambulatory did not have gait data so were excluded from analyses. The individual that was unable to complete testing due to physical fitness is only excluded for the assessment they were unable to complete, the single-task straight path walk. Data are reported as medians or percentages where appropriate.

| | Discharge | | Follow-up | |
|------------------------------|-------------------|--------------------|-------------------|-------------------|
| Variables | Cognitively | Cognitively | Cognitively | Cognitively |
| | Normal $(n=5)$ | Impaired $(n=6)$ | Normal $(n=5)$ | Impaired $(n=6)$ |
| ABC Score | 73.75 ± 10.72 | 62.81 ± 17.90 | 77.19 ± 15.59 | 70.00 ± 14.80 |
| Self-reported Fear of | | | | |
| Falling (% yes) | 20.0 | 16.7 | 60.0 | 33.3 |
| Number of Medications | 6.99 | 6.24 | 6.99 | 7.96 |
| FSST (sec) | 20.94 ± 9.13 | 68.07 ± 48.32 | 15.09 ± 7.75 | 44.70 ± 31.10 |
| Straight Path Walking - | | | | |
| single-task (sec) | 8.79 ± 2.99 | 19.33 ± 8.22 | 6.82 ± 3.19 | $*9.00 \pm 3.04$ |
| Straight Path Walking - | | | | |
| dual-task (sec) | 9.98 ± 2.80 | 24.96 ± 8.54 | 7.36 ± 4.45 | 13.11 ± 10.13 |
| L Test $-$ single-task (sec) | 32.94 ± 13.78 | 107.31 ± 52.17 | 28.59 ± 8.63 | 59.46 ± 50.70 |
| L Test $-$ dual-task (sec) | 34.68 ± 15.16 | 116.29 ± 98.16 | 31.63 ± 10.09 | 72.99 ± 59.10 |

Table 3.4 Assessment Summary Data at Discharge and Follow-up

Notes: ABC = Activities-specific Balance Confidence Scale, FSST = Four Square Step Test, n = sample size, *n=5 for this variable as one individual in the cognitively impaired group was not able to complete this test at follow-up

All participants were using a mobility aid at discharge, the most common being a rollator walker (68.8%). Other mobility aids that were utilized included one cane (2), two canes (2), or standard walker (1). Of the participants that were ambulatory at the time of

follow-up assessment $(n=11)$, 63.6% had a change in mobility aid and were either using a cane (3) or no aid (4). In the cognitively impaired group, 50.0% did not change mobility aids and continued to use rollator walkers at follow-up. Only one participant in the cognitively normal group continued to use a rollator walker at follow-up.

There is an increase in the number of participants reporting a fear of falling at follow-up for both groups. However, scores on the ABC scale indicate that individuals have higher balance confidence at follow-up compared to discharge. Both groups also demonstrated improvement on the FSST, a measure of dynamic balance.

The five individuals that were lost to follow-up were not significantly different from the 11 that remained with regards to age (p=0.282), ABC Score (p=0.692) or MoCA score (p=0.689) upon discharge from inpatient rehabilitation. Times to complete the singletask L Test (p=0.610) and dual-task L Test (p=0.533) were also not significantly different between these two groups. The individuals that were lost to follow-up did not have a higher burden of comorbidity (p=0.583), take more medication (p=0.649) or have a higher body mass index (p=0.126). However they did have significantly higher ΔTMT scores compared to the individuals that completed follow-up testing (p=0.047), suggesting that they may have had more deficits in executive functioning.

3.2.2 Comparison of Discharge and Follow-up Assessments – Between Group Differences in Gait Parameters and Gait Variability

The cognitively normal and cognitively impaired groups demonstrated significant differences across all gait parameters analyzed under single and dual-task conditions at discharge. The cognitively impaired group walked 34.45 cm/s slower when performing single-task walking (p=0.011) and 38.10 cm/s slower under dual-task conditions (p=0.006). Individuals in the cognitively impaired group also spent more time in the double stance period of gait. During single-task conditions they spent 501.42 msec longer in the double stance period than the cognitively normal group (p=0.006). This increased to 773.54 msec during dual-task assessment (p=0.006).

At 4 month follow-up, the cognitively impaired group only differed from the cognitively normal group on two variables under both single and dual-task conditions: gait velocity (cm/s) and stride time (msec). The cognitively impaired group walked 21.50 cm/s slower during single-task testing (p=0.047) and 39.95 cm/s slower during dual-task assessments (p=0.028). Faster stride times for both single-task (p=0.047) and dual-task (0.045) walking conditions were found for the cognitively normal group.

Complete results from the Mann-Whitney U Test comparing gait parameters in cognitively normal and cognitively impaired individuals at discharge and follow-up are summarized in Table 3.5 for single-task conditions and Table 3.6 for dual-task conditions.

Discharge gait variability parameters, calculated as %CV, from cognitively normal and cognitively impaired groups were compared using Mann-Whitney U tests. These groups were not significantly different on any of the four parameters analyzed during singletask assessments: stride time (%CV), stride length (%CV), double stance (%CV) or stride width (%CV). During dual-task testing however, groups were significantly different with regards to stride length variability (%CV). Cognitively impaired individuals had higher levels of stride length variability (%CV) under dual-task conditions (p=0.028).

Analysis of gait data from the four month follow-up revealed that the cognitively impaired group had more stride time variability (%CV) than the cognitively normal group during single-task assessments ($p=0.047$). No differences in gait variability parameters were found for the dual-task testing data.

Table 3.7 displays complete analysis of variability parameters under single-task conditions. See Table 3.8 for complete information on analysis of gait variability parameters during dual-task assessments.

Table 3.5 Comparison of Single-task Gait Parameters in Cognitively Normal and Cognitively Impaired Individuals at Discharge and Follow-up

| Single-task Initial | Gait Velocity (cm/s) | Stride Time (msec) | Stride Length (cm) | Step Width (cm) | Double Stance (msec) |
|---------------------------|----------------------|---------------------------|--------------------|-------------------|----------------------|
| Cognitively Normal | 69.60 ± 20.67 | 700.89 ± 64.53 | 100.97 ± 18.29 | 47.96 ± 6.87 | 490.13 ± 112.41 |
| Cognitively Impaired | 35.15 ± 12.54 | 1058.13 ± 268.60 | 69.80 ± 13.26 | 35.42 ± 4.82 | 991.55 ± 472.66 |
| Mann-Whitney U test | $p = 0.011*$ | $p = 0.006$ * | $p = 0.028$ * | $p = 0.018*$ | $p = 0.006$ * |
| Single-task Follow-up | Gait Velocity (cm/s) | Stride Time (msec) | Stride Length (cm) | Step Width (cm) | Double Stance (msec) |
| Cognitively Normal | 88.70 ± 23.84 | 617.75 ± 70.89 | 113.17 ± 22.14 | 52.22 ± 7.35 | 451.83 ± 101.79 |
| Cognitively Impaired | 67.20 ± 15.56 | 750.00 ± 4148.48 | 98.59 ± 46.69 | 46.54 ± 35.16 | 527.00 ± 7336.64 |
| Mann-Whitney U test | $p = 0.047$ * | $p = 0.047*$ | $p = 0.465$ | $p = 0.465$ | $p = 0.175$ |

Notes: Statistical significant set at p ≤ 0.05, *statistically significant between group difference.

Table 3.6 Comparison of Dual-task Gait Parameters in Cognitively Normal and Cognitively Impaired Individuals at Discharge and Follow-up

| Dual-task Initial | Gait Velocity (cm/s) | Stride Time (msec) | Stride Length (cm) | Step Width (cm) | Double Stance (msec) |
|---------------------------|----------------------|---------------------------|--------------------|------------------|-----------------------|
| Cognitively Normal | 66.50 ± 14.96 | 749.00 ± 72.93 | 100.19 ± 13.13 | 48.45 ± 5.12 | 501.71 ± 121.16 |
| Cognitively Impaired | 28.40 ± 11.32 | 1195.73 ± 485.09 | 67.69 ± 10.40 | 34.95 ± 3.84 | 1275.55 ± 1009.37 |
| Mann-Whitney U test | $p = 0.006$ * | $p = 0.006*$ | $p = 0.011*$ | $p = 0.011*$ | $p = 0.006$ * |
| Dual-task Follow-up | Gait Velocity (cm/s) | Stride Time (msec) | Stride Length (cm) | Step Width (cm) | Double Stance (msec) |
| Cognitively Normal | 88.80 ± 20.12 | 616.71 ± 90.03 | 113.06 ± 16.87 | 51.53 ± 5.94 | 462.17 ± 108.08 |
| Cognitively Impaired | 48.85 ± 24.30 | 973.79 ± 500.93 | 86.38 ± 14.45 | 42.67 ± 5.32 | 798.92 ± 758.66 |
| Mann-Whitney U test | $p = 0.028$ * | $p = 0.045*$ | $p = 0.068$ | $p = 0.068$ | $p = 0.068$ |

Notes: Statistical significant set at p ≤ 0.05, *statistically significant between group difference.

| Single-task Initial | Stride Time (%CV) | Stride Length (%CV) | Double Stance (%CV) | Step Width (%CV) |
|---------------------------|-------------------|---------------------|---------------------|-------------------|
| Cognitively Normal | 5.30 ± 2.26 | 5.62 ± 1.50 | 6.88 ± 1.36 | 38.72 ± 4.65 |
| Cognitively Impaired | 6.69 ± 13.99 | 7.17 ± 2.59 | 7.13 ± 9.39 | 32.69 ± 2.95 |
| Mann-Whitney U test | $p = 0.465$ | $p = 0.273$ | $p = 0.855$ | $p = 0.068$ |
| | | | | |
| Single-task Follow-up | Stride Time (%CV) | Stride Length (%CV) | Double Stance (%CV) | Step Width (%CV) |
| Cognitively Normal | 4.10 ± 2.25 | 3.81 ± 4.18 | 6.14 ± 0.82 | 39.65 ± 3.94 |
| Cognitively Impaired | 12.58 ± 20.29 | 3.82 ± 29.08 | 4.81 ± 8.34 | 37.76 ± 27.52 |

Table 3.7 Comparison of Single-task Gait Variability Parameters in Cognitively Normal and Cognitively Impaired Individuals at Discharge and Follow-up

Notes: %CV = Coefficient of Variation, Statistical significant set at p ≤ 0.05, *statistically significant between group difference.

Table 3.8 Comparison of Dual-task Gait Variability Parameters in Cognitively Normal and Cognitively Impaired Individuals at Discharge and Follow-up

| Dual-task Initial | Stride Time (%CV) | Stride Length (%CV) | Double Stance (%CV) | Step Width (%CV) |
|--------------------------|-------------------|---------------------|---------------------|------------------|
| Cognitively Normal | 6.92 ± 2.59 | 3.13 ± 1.08 | 6.05 ± 2.94 | 37.80 ± 2.58 |
| Cognitively Impaired | 12.21 ± 44.97 | 7.42 ± 4.99 | 14.23 ± 35.87 | 33.49 ± 4.94 |
| Mann-Whitney U test | $p = 0.068$ | $p = 0.028*$ | $p = 0.068$ | $p = 0.144$ |
| | | | | |
| Dual-task Follow-up | Stride Time (%CV) | Stride Length (%CV) | Double Stance (%CV) | Step Width (%CV) |
| Cognitively Normal | 7.03 ± 2.81 | 2.35 ± 2.19 | 4.90 ± 2.29 | 40.90 ± 4.04 |
| Cognitively Impaired | 17.85 ± 47.41 | 4.53 ± 6.65 | 8.04 ± 38.33 | 36.90 ± 4.25 |

Notes: %CV = Coefficient of Variation, Statistical significant set at p ≤ 0.05, *statistically significant between group difference.

3.2.3 Comparison of Discharge and Follow-up Assessments – Within Group Changes of Gait Parameters and Gait Variability

Within group changes to gait parameters between discharge and follow-up were analyzed in cognitively normal and cognitively impaired groups under both single and dual-task conditions. Analysis using Wilcoxon Signed Ranks tests revealed that at followup, the cognitively normal group had faster stride times (msec; p=0.043) and spent less time in double stance (msec; p=0.043) when compared to discharge. This group did not have any significant changes on dual-task parameters between discharge and follow-up.

The cognitively impaired group experienced changes in gait velocity (cm/s), stride length (cm) and step width (cm) between discharge and follow-up for single-task assessment. They walked 32.05 cm/s faster (p=0.043) at follow-up. The group also had longer strides $(p=0.043)$ and a wider step width $(p=0.043)$. The cognitively impaired group also saw changes to dual-task gait parameters during this time. Gait velocity (cm/s) was 20.45 cm/s faster (p=0.046). Stride time was also faster for this group; dual-task assessments at follow-up had stride times that were 221.94 msec faster (p=0.046) when compared to discharge. The stride width (cm) was wider at follow-up compared to discharge for this group as well (p=0.046).

Within group changes to gait parameters are displayed in Table 3.9 for single-task conditions and in Table 3.10 for dual-task assessments.

The within group changes to gait variability parameters between discharge and followup are now presented. The cognitively normal group did not have any significant changes to single-task gait variability parameters during this time. Under dual-task conditions a change in step width (%CV) was observed (p=0.043). The cognitively impaired group had more stride time variability (%CV) at follow-up compared to discharge (p=0.043). This group did not experience any significant changes to dual-task gait variability parameters between discharge and follow-up.

Table 3.11 displays within group changes to gait variability parameters; Table 3.12 displays parameters under dual-task conditions.

| Single-task Gait Variables | Gait Velocity (cm/s) | Stride Time (msec) | Stride Length (cm) | Step Width (cm) | Double Stance (msec) |
|-----------------------------------|----------------------|---------------------------|--------------------|-------------------|--------------------------------|
| Cognitively Normal | | | | | |
| Discharge | 69.60 ± 20.67 | 700.89 ± 64.53 | 100.97 ± 18.29 | 47.96 ± 6.87 | $490.13 + 112.41$ |
| Follow-up | 88.70 ± 23.84 | 617.75 ± 70.89 | $113.17 + 22.14$ | $52.22 + 7.35$ | 451.83 ± 101.79 |
| Wilcoxon signed ranks test | $p = 0.080$ | $p = 0.043*$ | $p = 0.225$ | $p = 0.080$ | $p = 0.043*$ |
| Cognitively Impaired | | | | | |
| Discharge | 35.15 ± 12.54 | 1058.13 ± 268.60 | $69.80 + 13.26$ | 35.42 ± 4.82 | 991.55 ± 472.66 |
| Follow-up | 67.20 ± 15.56 | 750.00 ± 4148.48 | 98.59 ± 46.69 | 46.54 ± 35.16 | 527.00 ± 7336.64 |
| Wilcoxon signed ranks test | $p = 0.043*$ | $p = 0.500$ | $p = 0.043*$ | $p = 0.043*$ | $p = 0.500$ |

Table 3.9 Comparison of Single-task Gait Parameters in Participants at Discharge and Follow-up

Notes: Statistical significant set at p ≤ 0.05, *statistically significant within group difference.

Notes: Statistical significant set at p ≤ 0.05, *statistically significant within group difference.

| Single-task Gait Variables | Stride Time (%CV) | Stride Length (%CV) | Double Stance (%CV) | Step Width (%CV) |
|-----------------------------------|-------------------|---------------------|---------------------|-------------------|
| Cognitively Normal | | | | |
| Discharge | 5.30 ± 2.26 | 5.62 ± 1.50 | 6.88 ± 1.36 | 38.72 ± 4.65 |
| Follow-up | 4.10 ± 2.25 | 3.81 ± 4.18 | 6.14 ± 0.82 | 39.65 ± 3.94 |
| Wilcoxon signed ranks test | $p = 0.500$ | $p = 0.686$ | $p = 0.225$ | $p = 0.345$ |
| Cognitively Impaired | | | | |
| Discharge | 6.69 ± 13.99 | 7.17 ± 2.59 | 7.13 ± 9.39 | 32.69 ± 2.95 |
| Follow-up | 12.58 ± 20.29 | 3.82 ± 29.08 | 4.81 ± 8.34 | 37.76 ± 27.52 |
| Wilcoxon signed ranks test | $p = 0.043*$ | $p = 0.686$ | $p = 0.893$ | $p = 0.080$ |

Table 3.11 Comparison of Single-task Gait Variability Parameters in Participants at Discharge and Follow-up

Notes: %CV = Coefficient of Variation, Statistical significant set at p ≤ 0.05, *statistically significant within group difference.

Table 3.12 Comparison of Dual-task Gait Variability Parameters in Participants at Discharge and Follow-up

| Dual-task Gait Variables | Stride Time (%CV) | Stride Length (%CV) | Double Stance (%CV) | Step Width (%CV) |
|---------------------------------|-------------------|---------------------|---------------------|------------------|
| Cognitively Normal | | | | |
| Discharge | 6.92 ± 2.59 | 3.13 ± 1.08 | 6.05 ± 2.94 | 37.80 ± 2.58 |
| Follow-up | 7.03 ± 2.81 | 2.35 ± 2.19 | 4.90 ± 2.29 | 40.90 ± 4.04 |
| Wilcoxon signed ranks test | $p = 0.500$ | $p = 0.686$ | $p = 0.345$ | $p = 0.043*$ |
| Cognitively Impaired | | | | |
| Discharge | 12.21 ± 44.97 | 7.42 ± 4.99 | 14.23 ± 35.87 | 33.49 ± 4.94 |
| Follow-up | 17.85 ± 47.41 | 4.53 ± 6.65 | 8.04 ± 38.33 | 36.90 ± 4.25 |
| Wilcoxon signed ranks test | $p = 0.173$ | $p = 0.345$ | $p = 0.249$ | $p = 0.345$ |

Notes: %CV = Coefficient of Variation, Statistical significant set at p ≤ 0.05, *statistically significant within group difference.

3.2.4 Comparison of Single and Dual-task Gait Parameters at Initial and Follow-up Assessments

Temporal-spatial gait parameters collected under single and dual-task conditions were compared within each group at discharge and follow-up using Wilcoxon Singed Ranks tests. At discharge, individuals in the cognitively normal group spent more time in double stance (p=0.043) and took more time to complete a stride (p=0.043) during dualtasking when compared to single-task conditions. Analysis of gait variability parameters indicated that individuals in the cognitively normal group experienced less stride length variability (%CV) in dual-task conditions than when performing single-task assessments at discharge. No differences in temporal-spatial or gait variability parameters were observed in this group during follow-up assessment.

The cognitively impaired group had differences in temporal-spatial gait parameters when comparing single and dual-task conditions. At the discharge assessment, this group had significantly slower gait velocity (cm/s) during dual-tasking (p=0.028). They also had slower stride times (p=0.028) and spent longer in the double stance period of gait (p-0.028). Follow-up assessment revealed similar changes to gait velocity during dual-task assessments (p=0.043). Stride length (p=0.043) and stride width (p-=0.043) were also significantly different when comparing single and dual-task assessment gait parameters at follow-up. With regards to gait variability parameters, the cognitively impaired group displayed significantly more stride time variability (%CV) in dual-task conditions when compared to single-task conditions (p=0.028) at discharge. This group did not have any differences in gait variability parameters between single and dual-task tests at the time of follow-up.

Tables 3.13 and 3.14 contain comparisons of single and dual-task temporal-spatial gait parameters under single and dual-task conditions at discharge and follow-up respectively. For results of Wilcoxon Signed Ranks test on single and dual-task differences in gait variability see Table 3.15 (discharge) and Table 3.16 (follow-up).

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| Gait Variables at Discharge | Gait Velocity (cm/s) | Stride Time (msec) | Stride Length (cm) | Step Width (cm) | Double Stance (msec) |
|------------------------------------|---|---------------------------|--------------------|------------------|--------------------------------|
| Cognitively Normal | | | | | |
| Single-task Straight Path | 69.60 ± 20.67 | 700.89 ± 64.53 | 100.97 ± 18.29 | $47.96 + 6.87$ | 490.13 ± 112.41 |
| Dual-task Straight Path | 66.50 ± 14.96 | 749.00 ± 72.93 | 100.19 ± 13.13 | 48.45 ± 5.12 | 501.71 ± 121.16 |
| Wilcoxon signed ranks test | $p = 0.080$ | $p = 0.043*$ | $p = 0.893$ | $p = 0.686$ | $p = 0.043*$ |
| Cognitively Impaired | | | | | |
| Single-task Straight Path | 35.15 ± 12.54 | 1058.13 ± 268.60 | 69.80 ± 13.26 | 35.42 ± 4.82 | 991.55 ± 472.66 |
| Dual-task Straight Path | 28.40 ± 11.32 | 1195.73 ± 485.09 | 67.69 ± 10.40 | 34.95 ± 3.84 | 1275.55 ± 1009.37 |
| Wilcoxon signed ranks test | $p = 0.028*$ | $p = 0.028*$ | $p = 0.249$ | $p = 0.345$ | $p = 0.028*$ |

Table 3.13 Comparison of Gait Parameters under Single-task and Dual-task Conditions at Discharge

Notes: Statistical significant set at p ≤ 0.05, *statistically significant within group difference.

Notes: Statistical significant set at p ≤ 0.05, *statistically significant within group difference.

| Gait Variables at Discharge | Stride Time (%CV) | Stride Length (%CV) | Double Stance (%CV) | Step Width (%CV) |
|------------------------------------|-------------------|---------------------|---------------------|------------------|
| Cognitively Normal | | | | |
| Single-task Straight Path | 5.30 ± 2.26 | 5.62 ± 1.50 | 6.88 ± 1.36 | 38.72 ± 4.65 |
| Dual-task Straight Path | 6.92 ± 2.59 | 3.13 ± 1.08 | 6.05 ± 2.94 | 37.80 ± 2.58 |
| Wilcoxon signed ranks test | $p = 0.893$ | $p = 0.043*$ | $p = 0.893$ | $p = 0.500$ |
| Cognitively Impaired | | | | |
| Single-task Straight Path | 6.69 ± 13.99 | 7.17 ± 2.59 | 7.13 ± 9.39 | 32.69 ± 2.95 |
| Dual-task Straight Path | 12.21 ± 44.97 | 7.42 ± 4.99 | 14.23 ± 35.87 | 33.49 ± 4.94 |
| Wilcoxon signed ranks test | $p = 0.028*$ | $p = 0.463$ | $p = 0.249$ | $p = 0.917$ |

Table 3.15 Comparison of Gait Variability Parameters under Single and Dual-task Conditions at Discharge

Notes: %CV = Coefficient of Variation, Statistical significant set at p ≤ 0.05, *statistically significant within group difference.

Notes: %CV = Coefficient of Variation, Statistical significant set at p ≤ 0.05, *statistically significant within group difference.

3.2.5 Comparison of Discharge and Follow-up Assessments – Between and Within Group Differences during Single and Dual-task Walking

Four different gait assessments were completed at both discharge and follow-up: singletask and dual-task straight path walking on the 6m GAITRite® System; single-task and dual-task L Tests. Time to complete these assessments were compared between cognitively normal and cognitively impaired groups at discharge and follow-up. The cognitively impaired group took more time to complete single-task (p=0.018) and dualtask (p=0.006) straight path assessments at discharge. Only differences in time to complete the single-task assessment remained at follow-up (p=0.047); the cognitively impaired group took longer to complete this assessment. When comparing times to complete the L test between these two groups, statistically significant differences were seen at both discharge and follow-up under single and dual-task conditions. During all four assessments, the cognitively impaired group had slower times relative to the cognitively normal group. See Table 3.13 for complete between group analysis of time to complete single and dual-task gait assessments at discharge and follow-up.

| Straight Path Walking | Initial | Initial | Follow-up | Follow-up Dual- |
|------------------------------|--------------------|--------------------|-------------------|------------------------|
| | Single-task | Dual-task | Single-task | task |
| Cognitively Normal | 8.79 ± 2.99 | 9.98 ± 2.80 | 6.82 ± 3.19 | 7.36 ± 4.45 |
| Cognitively Impaired | 19.33 ± 8.22 | 24.96 ± 8.54 | 9.00 ± 3.04 | 13.11 ± 10.13 |
| Mann-Whitney U test | $p = 0.018*$ | $p = 0.006*$ | $p = 0.047*$ | $p = 0.068$ |
| L Test | Initial | Initial | Follow-up | Follow-up Dual- |
| | Single-task | Dual-task | Single-task | task |
| | | | | |
| Cognitively Normal | 32.94 ± 13.78 | 34.68 ± 15.16 | 28.59 ± 8.63 | 31.63 ± 10.09 |
| Cognitively Impaired | 107.31 ± 52.17 | 116.29 ± 98.16 | 59.46 ± 50.70 | 72.99 ± 59.10 |

Table 3.17 Comparison of Single and Dual-task Gait Assessments in Cognitively Normal and Cognitively Impaired Individuals at Discharge and Follow-up

Note: Statistical significant set at $p \le 0.05$, $*$ denotes a statistically significant between group difference.

DTCs were calculated for all dual-task assessments using the previously mentioned methods. A negative dual-task cost indicates poorer performance during dual-task conditions compared to single-task conditions. Between groups comparisons of DTCgait and DTCcog were also performed for all tests at discharge and follow-up. The only significant difference observed was in the initial L Test DTCcog between cognitively normal and cognitively impaired individuals. The cognitively impaired group had a 26.90% higher DTCcog compared to the cognitively normal group (p=0.045).

| Straight Path Walking | Initial | Initial | Follow-up | Follow-up |
|------------------------------|--------------------|---------------------|--------------------|--------------------|
| | DTCgait | DTCcog | DTCgait | DTCcog |
| Cognitively Normal | -14.10 ± 12.60 | -10.12 ± 314.62 | -24.24 ± 10.21 | 29.23 ± 48.46 |
| Cognitively Impaired | -26.29 ± 18.55 | -26.18 ± 17.46 | -14.18 ± 47.61 | -7.22 ± 38.19 |
| Mann-Whitney U test | $p = 0.465$ | $p = 0.465$ | $p = 0.201$ | $p = 0.715$ |
| L Test | Initial | Initial | Follow-up | Follow-up |
| | | | | |
| | DTCgait | DTCcog | DTCgait | DTCcog |
| Cognitively Normal | -5.28 ± 4.08 | -46.02 ± 102.24 | -15.02 ± 5.65 | -41.50 ± 32.69 |
| Cognitively Impaired | -8.79 ± 46.77 | -72.92 ± 15.19 | -16.86 ± 14.73 | -51.17 ± 18.10 |

Table 3.18 Comparison of Gait and Cognitive Dual-task Costs in Cognitively Normal and Cognitively Impaired Individuals at Discharge and Follow-up

Notes: DTCgait = Gait dual-task cost, DTCcog = Cognitive dual-task cost, Negative values indicate poorer performance, Statistical significant set at $p \leq 0.05$, *statistically significant between group difference.

Within group changes to performance on the four above mentioned gait assessments were also performed. The cognitively normal group performed single-task (p=0.043) and dual-task (p=0.043) L Tests significantly faster at follow-up compared to discharge. The cognitively impaired group had significantly faster times to complete all four gait assessments at follow-up. The cognitively normal group had a higher DTCgait at followup compared to discharge (p=0.043). The cognitively impaired group experienced significantly less DTCcog during dual-task straight path walking (p=0.028) and L Test (p=0.046) assessments at follow-up compared to discharge. Table 3.15 has all within

group results for gait assessments at discharge and follow-up. See Table 3.16 for within group comparisons of DTCs at discharge and follow-up.

| | Straight Path Walking | | L Test | |
|-----------------------------|------------------------------|-------------------|--------------------|--------------------|
| | Single-task | Dual-task | Single-task | Dual-task |
| Cognitively Normal | | | | |
| Discharge | 8.79 ± 2.99 | 9.98 ± 2.80 | 32.94 ± 13.78 | 34.68 ± 15.16 |
| Follow-up | 6.82 ± 3.19 | 7.36 ± 4.45 | 28.59 ± 8.63 | 31.63 ± 10.09 |
| Wilcoxon signed ranks test | $p = 0.500$ | $p = 0.715$ | $p = 0.043*$ | $p = 0.043*$ |
| Cognitively Impaired | | | | |
| Discharge | 19.33 ± 8.22 | 24.96 ± 8.54 | 107.31 ± 52.17 | 116.29 ± 98.16 |
| Follow-up | 9.00 ± 3.04 | 13.11 ± 10.13 | 59.46 ± 50.70 | 72.99 ± 59.10 |
| Wilcoxon signed ranks test | $p = 0.043*$ | $p = 0.028*$ | $p = 0.028*$ | $p = 0.028*$ |

Table 3.19 Comparison of Gait Assessment Times in Participants at Discharge and Follow-up

Notes: Statistical significant set at $p \le 0.05$, *statistically significant within group difference.

| | Straight Path Walking | | L Test | |
|-----------------------------|------------------------------|---------------------|--------------------|---------------------|
| | DTCgait | DTCcog | DTCgait | DTCcog |
| Cognitively Normal | | | | |
| Discharge | -14.10 ± 12.60 | -10.12 ± 314.62 | -5.28 ± 4.08 | -46.02 ± 102.24 |
| Follow-up | -24.24 ± 10.21 | 29.23 ± 48.46 | -15.02 ± 5.65 | -41.50 ± 32.69 |
| Wilcoxon signed ranks test | $p = 0.500$ | $p = 0.893$ | $p = 0.043*$ | $p = 0.500$ |
| Cognitively Impaired | | | | |
| Discharge | -26.29 ± 18.55 | -26.18 ± 17.46 | -8.79 ± 46.77 | -72.92 ± 15.19 |
| Follow-up | -14.18 ± 47.61 | -7.22 ± 38.19 | -16.86 ± 14.73 | -51.17 ± 18.10 |
| Wilcoxon signed ranks test | $p = 0.173$ | $p = 0.028*$ | $p = 0.917$ | $p = 0.046*$ |

Table 3.20 Comparison of Gait and Cognitive Dual-task Costs in Participants at Discharge and Follow-up

Notes: DTCgait = Gait dual-task cost, DTCcog = Cognitive dual-task cost, Statistical significant set at $p \le 0.05$, *statistically significant within group difference.

Gait and cognitive DTCs were plotted against each other for discharge and follow-up dual-task assessments. See Figures 3.4 – 3.7 for a visual analysis of the trade off in DTCs by the cognitively normal and cognitively impaired groups. Negative values indicate a decrease in performance.

A negative DTCgait was seen in all participants during straight path and complex path walking at discharge. One participant in the cognitively impaired group performed the straight path assessment faster under dual-task conditions at follow-up; all other individuals had slower gait on straight path and complex path walk tests at follow-up. A wide range of DTCcog were seen across testing time points. During dual-task straight path assessment at discharge, a majority of individuals had a decrease in performance on the cognitive task when compared to performance during quiet sitting. A similar trend was seen during dual-task performance on the L Test at discharge and follow-up; only one individual had an improved performance on the cognitive task during walking. During follow-up assessment of dual-task straight path walking individuals had a wide distribution of DTCcog. Cognitively normal and cognitively impaired individuals have similar distributions of DTCs during all assessments.

Figure 3.4 Gait and Cognitive Dual-task Costs in Straight Path Walking at Discharge

Figure 3.5 Gait and Cognitive Dual-task Costs in Straight Path Walking at Follow-up

Figure 3.6 Gait and Cognitive Dual-task Costs on Dual-task L Test at Discharge

Figure 3.7 Gait and Cognitive Dual-task Costs on Dual-Task L Test at Follow-up

Chapter 4: DISCUSSION

4.1 General Discussion

Study 1 demonstrated that the developed functional mobility protocol is reliable for use in those with LEA. This protocol had excellent relative test-retest reliability across the population of amputees, as evidenced by the high ICC values in each of the three groups tested (BKA-vas, BKA-nonvas and AKA/bilat groups). Comparable values for absolute test-retest reliability were also found between all groups tested. Quantification of the MDC⁹⁵ allowed for comparison of absolute reliability values to the LOA values established in the Bland-Altman plots. The comparison of these values was used to establish agreement between the test and retest assessment time points. Analysis determined that results from these assessments adequately agree, so there should not be difficulties in interpreting results from multiple testing sessions.

It has previously been established that the single-task, or original version, of the L Test is a valid test with excellent inter and intrarater reliability (Deathe & Miller, 2005). The times to complete the L Test in the current study were comparable to those in the previous study, with longer times observed for those with dysvascular etiology or AKAs (Deathe & Miller, 2005). However the current study expands upon previous work by creating a reliable dual-task version of the test. No prior study has established a reliable dual-task testing protocol for use in the LEA population. Study 1 also makes novel contributions regarding the MDC95, and these values can now be used to investigate change in dual-task performance overtime.

The purpose of Study 2 was to investigate gait changes in older adults with an LEA between discharge and follow-up and to determine the relationship between cognition and gait in these individuals. The present study has demonstrated that gait differences exist between cognitively normal and cognitive impaired individuals at discharge from inpatient rehabilitation; these differences persist for 4 months after discharge. It also demonstrated that some changes in gait, generally improvements, occur between discharge and follow-up in both groups. DTCs were used to demonstrate the cognitive

load of performing straight path and complex path walking; this study adds novel information to the literature regarding DTCcog and DTCgait for older individuals with LEA. As there were numerous hypotheses proposed for Study 2, a summary table is provided in Appendix C. This offers an overview of whether the hypotheses were confirmed by the observed results or not supported by the current study.

It was hypothesized that cognitively normal individuals would walk faster and with less variability at both time points; Study 2 partially confirmed this hypothesis. Results demonstrated that the cognitively normal group had faster gait under straight path single and dual-task conditions at both assessment time points. Differences in gait speed have also been reported between healthy controls and those with mild cognitive impairment under single (Maquet et al., 2010) and dual-task conditions (Muir, Speechley, et al., 2012). Evaluating performance on the functional mobility measures revealed that the cognitively normal group performed the single-task L Test significantly faster at discharge and follow-up. These results support previous findings that indicate a connection between performance on outcome measures and cognitive impairment (Frengopoulos et al., 2017).

Comparable gait variability values were found between groups in this study. However, the cognitively impaired group did have higher variability in one gait parameter at discharge and one at follow-up. A higher stride time variability was observed during single-task assessment at follow-up and a higher stride length variability during dualtask assessment at discharge. This may indicate that the cognitively impaired group has more variable gait and may be more prone to adverse events due to this variability. As only one difference was observed at each assessment time point, differences in gait variability cannot be confirmed at this time. These trends in gait variability may be attributed in part to differences between groups with regards to changes in mobility aid use between discharge and follow-up. In the cognitively normal group, 80.0% of participants transitioned to a less supportive mobility aid between discharge and followup assessments, compared to only 50.0% in the cognitively impaired group. A change in

mobility aid could impact gait variability, therefore a larger study is needed to confirm differences in gait variability between groups.

Based on established trends in ambulatory potential for those with an LEA (Brooks et al., 2001; Czerniecki et al., 2012), it was hypothesized that an increase in gait velocity would be seen between discharge and follow-up assessments. This was true for the cognitively impaired group, who experienced a significant increase in gait velocity during both single and dual-task assessments; 32.05 cm/s faster at follow-up for single-task assessment and 20.45 cm/s faster for dual-task. Those in the cognitively normal group did not experience significant changes during this time, however, they did experience a trend towards improvement in gait velocity between discharge and follow-up.

This is the first study to report temporal-spatial gait parameters for individuals with LEA during single and dual-task conditions at multiple time points. However, one previous study has identified temporal-spatial parameters of those with LEA under single-task conditions (Parker et al., 2013). Gait velocities recorded during the follow-up assessment of cognitively normal individuals in Study 2 were comparable to the gait velocities found in this study for established community walkers (Parker et al., 2013). The cognitively impaired group had slower gait velocities at both discharge and followup when compared to previously reported values for fallers or those with amputations of vascular etiology (Parker et al., 2013). So while significant gains in gait velocity were made by the cognitively impaired group, they still walked at a slower pace under singletask conditions than established walkers in the community. However, the cognitively normal group had gait velocities and stride lengths similar to more experienced community ambulators upon discharge from inpatient rehabilitation. This highlights the functional differences in these groups at both discharge and follow-up.

The hypothesis that gait would be slower with more variability for both groups during dual-task conditions cannot be supported by the current study. The results from this study indicate that in general, gait variability does not change between single and dualtask conditions for either group in this study. The only gait variability parameter that

was significantly different was stride time variability for the cognitively impaired group at discharge. This may be related to the increase in stride time observed at this assessment time point (Dubost et al., 2008). Gait velocity decreased from single-task to dual-task conditions for the cognitively impaired group at discharge and follow-up. A decrease in gait velocity and an increase in gait variability has been demonstrated in health older adults, those with mild cognitive impairment and those with Alzheimer's disease (Beauchet, Dubost, Aminian, Gonthier, & Kressig, 2005; Hausdorff et al., 2008; Montero-Odasso et al., 2012; Muir, Gopaul, & Montero Odasso, 2012; Woollacott & Shumway-Cook, 2002). Changes to temporal-spatial gait parameters are prevalent during dual-task testing for a variety of other populations (Yogev et al., 2008). Typically observed changes to gait during dual-tasking include a decrease in stride velocity, along with an increase in stride time variability (Dubost et al., 2008) and an increase in the double stance phase of gait (Beauchet & Berrut, 2006; Brach et al., 2001; Gage et al., 2003). The lack of difference in gait variability between single-task and dual-task may indicate that LEA gait is more variable regardless of environmental conditions, however studies comparing normal controls and those with LEA are needed to confirm this.

Dual-task testing was used to reflect the complexities of community mobility in the research setting (Patla, 2001; Patla & Shumway-Cook, 1999). A decrease in DTCcog and DTCgait at follow-up was hypothesized for both groups of lower extremity amputees. It was expected that 3.5-6.0 months of community ambulation in complex environments would provide opportunities to acquire and practice these multitasking skills during gait for these individuals. However only the cognitively impaired group experienced significant decreases between discharge and follow-up. A decrease in DTCcog was observed for both straight path and L Test walking. No significant improvements in DTCs were made by the cognitively normal group, however an increase in DTCgait was observed during L Test walking at follow-up. Therefore the hypothesis is not supported by the current study. This may be related to power insufficiencies in this pilot study, so future investigations with larger sample sizes are needed to confirm these results.

The current study assessed the essential role of cognition in mobility through the use of dual-task testing. Based on previous research (Muir, Speechley, et al., 2012), it was hypothesized that those with cognitive impairment would have higher DTCs for all dualtask gait assessments due to the interaction of cognition and mobility during dual-task testing. Contrary to this hypothesis, cognitively normal and cognitively impaired groups did not have statistically significant differences in DTCcog or DTCgait during any gait assessments at discharge from inpatient rehabilitation. However, the cognitively impaired group did had a significantly higher DTCcog during the dual-task L Test at follow-up. Previous research has demonstrated that mobility is a complex process involving interactions between higher level cognitive processes, the musculoskeletal system and the somatosensory system (Patla, 2001; Woollacott & Shumway-Cook, 2002). Certain cognitive processes are also associated with the acquisition of prosthetic skills necessary for community ambulation, including memory, attention, visuospatial and executive functioning skills (Coffey et al., 2012; O'Neill, 2008; O'Neill & Evans, 2009). The results from the current study may be partially explained by the similar scores between groups on the ΔTMT, a measure of executive functioning. It may also be related to the fact that 40.9% of established community ambulators with an LEA using a prosthesis have to concentrate on each step while walking (Miller, Deathe, et al., 2001). This need to attend to walking may be contributing to the DTCs for both groups.

Results from the current study indicate that lower extremity amputees, regardless of cognitive status, did not utilize a posture first strategy during dual-tasking. Dual-task testing on both straight and complex paths in this study indicate that performance on gait decreases, while performance on the cognitive task may increase, decrease or remain the same. These results align with a study of elderly fallers who performed better on arithmetic tasks while walking, which may point to the use of a posture second strategy (Beauchet et al., 2007). Individuals with Parkinson's disease have also be shown to use a posture second strategy while walking under dual-task conditions (Bloem, Valkenburg, Slabbekoorn, & van Dijk, 2001). The lack of prioritization towards the mobility task at hand may point towards an increased falls risk (Yogev et al., 2008), as opposed to the posture first strategy that may be used to prevent instability and/or falls (Shumway-Cook & Woollacott, 2000). It has been shown that healthy young adults give priority to the motor task being performed, while having a decreased quality of performance on the secondary task, even when no prioritization instructions are given (Bloem, Valkenburg, Slabbekoorn, & Willemsen, 2001; Gerin-Lajoie, Richards, & McFayden, 2005; Lindenberger, Marsiske, & Baltes, 2000; Schrodt, Mercer, Giuliani, & Hartman, 2004). Some healthy older adults may also use this strategy (Bloem, Valkenburg, Slabbekoorn, & Willemsen, 2001). There is some evidence that those who have suffered a stroke use a posture first strategy somewhat successfully (Hyndman, Ashburn, Yardley, & Stack, 2006); while those with Parkinson's may utilize this strategy during balance tasks (Holmes, Jenkins, Johnson, Adams, & Spaulding, 2010).

Although the functional mobility of the cognitively impaired group was lower than that of the cognitively normal group, significant within group improvements were seen. Values for the dual-task L Test saw an improvement of 3.05 seconds for the cognitively normal and a 43.30 second improvement for the cognitively impaired. The MDC $_{95}$ values obtained in Study 1 ranged from 2.85-3.76 seconds, depending on etiology and level of amputation. This indicates that the improvements seen by some in the cognitively normal group and those in the cognitively impaired group are not only statistically significant, but also clinically relevant. Individuals with cognitive impairment may have lower scores on single and dual-task tests of functional mobility due to cognitive impairment in the domains necessary to learn prosthetic mobility skills (Hanspal & Fisher, 1991; O'Neill, 2008; O'Neill & Evans, 2009). The large improvements seen between discharge and follow-up for this group could indicate that it may take longer for these individuals to learn these new mobility skills compared to those that are cognitively normal.

There are other factors that may impact change in mobility performance for individuals with LEA that were not captured within the current studies. For example, participants may have access to other health services after discharge, particularly those that who have poorer functioning and need continued support for activities of daily living. Future studies should consider accounting for additional rehabilitation services within their analyses. As mentioned previously, a change from more supportive to less supportive mobility aid may also occur between discharge and follow-up. This change is considered an improvement in gross mobility on its own, but may not indicate improvement when analyzing absolute values on parameters such as gait velocity or variability. Changes in cognition or in depressive symptoms may also impact change in performance. As Study 2 was a pilot study with a small sample size many of these factors were not accounted for, however the larger study will account for change in mobility status, access to services and change in depressive symptoms when assessing change in performance.

4.2 Strengths and Limitations

A strength of Study 1 is that a large cross-section of individuals was recruited from the outpatient amputee clinic, allowing for the investigation of test-retest reliability across multiple sub groups found within the LEA population. This representative group means that reliability of the developed dual-task assessment protocols can be generalized to the population of lower extremity amputees as a whole. Another strength of this study is that the developed protocol allows for the calculation of both cognitive and gait DTCs, something that is lacking from many dual-tasking studies.

One strength of Study 2 is the use of a longitudinal design to investigate gait changes in lower extremity amputees over time. This meets a gap in the literature, as this is a challenging population to study post-discharge from inpatient rehabilitation. This design and the comprehensive evaluation of temporal-spatial gait parameters under both single and dual-task populations allowed for the analyses of many different aspects that contribute to the relationship between gait and cognition, which may ultimately relate to the increased falls risk in this population. This is the first study to directly investigate the relationship between gait and cognition in the LEA population using dual-task testing. Another strength of this study is that it is a representative sample of individuals discharged from the inpatient amputee unit during the recruitment period; 100% of individuals that met eligibility criteria consented to participation in the study. A third strength of this study is the calculation of DTCcog along with DTCgait, as many dual-
tasking studies only quantify the DTCgait. By accounting for a DTC in both cognition and gait, this study was able to identify trade-offs that may have occurred during dual-task testing.

There are some limitations to Study 2 that need to be identified. The main limitation relates to the small sample size of the pilot study, which leads to the results displayed being underpowered. Some differences between and within groups are approaching statistical significance and a larger sample would allow for the clarification of differences in these cases; demonstrating whether a difference does truly exist or not. Related to the limitation of the small sample size is also the type of analyses that could be performed with the data. This study made use of non-parametric analysis using mean ranks to compare differences, as the small sample size within groups meant more robust parametric tests could not be performed. The use of non-parametric tests itself is not a limitation, however these tests do not allow for the inclusion of confounding variables or covariates in models. The inclusion of certain confounding variables such as: etiology of amputation, type of gait aids used at each assessment time point, fear of falling, level of amputation, changes to balance confidence, resolution of health issues, and changes to the prosthetic limb would add valuable information and precision to the analyses. The inclusion of any of these variables may strengthen results and enhance differences between cognitively normal or cognitively impaired groups. These factors may also impact results by changing differences towards the null, indicating that changes seen are not due to level of cognitive impairment but are caused by other factors. A longitudinal study with a larger sample size within each group would be able to address these concerns.

4.3 Future Directions

The development of a reliable dual-task functional mobility protocol in Study 1 allowed for assessment of change in performance over time that was done in Study 2. Future studies using dual-task testing in this population can also use the values established here. This protocol may have use beyond the LEA population as well. Future studies could establish reliability in other populations. This would allow for comparisons in

performance between those with LEA, healthy older and young adults as well as other populations that exhibit mobility difficulties. Comparing the time it takes to complete testing and the level of dual-task cost between populations would lead to a better understanding of the interaction between cognition in mobility. It may also provide insight into the increased cognitive load of walking with a prosthesis for those with LEA.

Larger studies with a longitudinal design are needed to assess changes in functioning between discharge and follow-up. A larger study would also allow for analysis that could include confounding variables; this would help to confirm or refute the trends found in Study 2. One confounding variable to consider is the use of different types of prosthetic devices, particularly for those with AKAs. There is a wide variety of prosthetic knees and ankles that can be used and each may convey a different level of cognitive load; a microprocessor knees may require a different cognitive load compared to a locked knee prosthesis. Other confounding variables to account for include: changes to mobility aid use, mental health changes, physical activity levels, and changes to cognitive status.

A longer follow-up time frame (eg. 1 year), or the use of multiple follow-ups, post discharge is another future direction for these studies. Only three participants fell in the follow-up time frame of four to five months, even though previous studies have shown the prevalence of falls to be quite high in LEA population (Hunter et al., 2017; Kulkarni et al., 1996; Miller, Speechley, et al., 2001b). Extending the follow-up time frame may allow for the capture of more adverse events in this population and allow for the evaluation of associations related to falls.

It would be of interest to determine the extent to which individuals have reintegrated into the community after being discharged from inpatient prosthetic rehabilitation. The dual-task L Test protocol that was developed may better approximate community walking; dual-tasking is similar to daily activities as many require the multitasking of cognitive and mobility tasks. Investigating the relationship between performance on this dual-task protocol and ability to reintegrate into community may allow for the identification of individuals at risk for problems after discharge home. To take this one

step further, a randomized control trial investigating the difference between usual care during inpatient rehabilitation and the use of a cognitive or dual-task rehabilitation program would be of interest. A study of this design may help to reassess the way prosthetic rehabilitation is delivered and to determine if this population can have less adverse fall events and quicker motor learning effects by incorporating cognitive training alongside prosthetic training.

Chapter 5: CONCLUSION

A reliable dual-task functional mobility protocol has been developed for use in the LEA population. Relative and absolute reliability values were established across the population of lower extremity amputees. This protocol can be used in clinical or research settings to investigate dual-task functional mobility in the LEA population.

Improvement in dual-task functional mobility was observed between discharge and follow-up for cognitively impaired individuals, this was confirmed by comparing the magnitude of improvement to absolute reliability values. Differences in gait between cognitively impaired and cognitively normal individuals with LEA do exist, however both groups may also experience improvement in functioning after discharge from inpatient rehabilitation, particularly the cognitively impaired group. Although dual-task costs do not differ significantly between groups, the slower velocity of the cognitively impaired group indicates that these individuals may have a harder time multi-tasking. This study adds novel information to the literature with regards to the gait parameters observed in those with an LEA at discharge from rehabilitation and how this changes overtime. It is also the first study to use a reliable dual-task functional mobility protocol to investigate changes in dual-task performance overtime. Future studies can expand upon these results to investigate relationship between dual-task performance and adverse events in the LEA population. Improved understanding of the relationship between gait and cognition can help to identify individuals with LEA that may be at risk for adverse outcomes related to this difficulty.

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APPENDICES

Appendix A: Ethics Approval Notices

Research Ethics

Western University Health Science Research Ethics Board **HSREB Delegated Initial Approval Notice**

Principal Investigator: Dr. Susan Hunter
Department & Institution: Health Sciences\Physical Therapy, Western University

Review Type: Delegated
HSREB File Number: 107472
Study Title: Determining test-retest reliability of a dual-task functional mobility assessment in adults with a lower limb amputation
Study Title: Determining test-retenal G

HSREB Initial Approval Date: January 22, 2016
HSREB Expiry Date: January 22, 2017

works Announced and/or Despised for Information

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of **HSREB Continuing Ethics Review.**

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

LAWSON FINAL APPROVAL NOTICE

LAWSON APPROVAL NUMBER: R-15-605

PROJECT TITLE: Determining test-retest reliability of a dual-task functional mobility assessment in adults with a lower limb amputation

PRINCIPAL INVESTIGATOR: Dr. Susan Hunter

LAWSON APPROVAL DATE: January 25, 2016

Health Sciences REB#: 107472

Please be advised that the above project was reviewed by the Clinical Research Impact Committee and Lawson Administration and the project:

Was Approved

Please provide your Lawson Approval Number (R#) to the appropriate contact(s) in supporting departments (eg. Lab Services, Diagnostic

Imaging, etc.) to inform them that your study is starting. The Lawson Approval Number must be provided each time services are requested.

Dr. David Hill

V.P. Research

Lawson Health Research Institute

cc: Administration

Research Ethics

Principal Investigator: Susan Hunter Department & Institution: Health Sciences\Physical Therapy, Western University

Review Type: Full Board **HSREB File Number: 107109** Study Title: Falls during community reintegration after prosthetic rehabilitation in older adults with a lower extremity amputation

HSREB Initial Approval Date: October 01, 2015 **HSREB Expiry Date: October 01, 2016**

Documents Approved and/or Received for Information:

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

LAWSON FINAL APPROVAL NOTICE

LAWSON APPROVAL NUMBER: R-15-584

PROJECT TITLE: Falls during community reintegration after prosthetic rehabilitation in older adults with a lower extremity amputation

PRINCIPAL INVESTIGATOR: Dr. Susan Hunter

LAWSON APPROVAL DATE: December 15, 2015

Health Sciences REB#: 107109

Please be advised that the above project was reviewed by the Clinical Research Impact Committee and Lawson Administration and the project:

Was Approved

Please provide your Lawson Approval Number (R#) to the appropriate contact(s) in supporting departments (eg. Lab Services, Diagnostic

Imaging, etc.) to inform them that your study is starting. The Lawson Approval Number must be provided each time services are requested.

Dr. David Hill

V.P. Research

Lawson Health Research Institute

cc: Administration

Appendix B: Letters of Information and Consent

Faculty of Health Sciences and Department of Physical Medicine & Rehabilitation

Letter of Information – Patient

Determining test-retest reliability of a dual-task functional mobility assessment in adults with a lower limb amputation

Principal Investigators: Courtney Frengopoulos, Dr. Michael Payne MD MSc, Dr. Ricardo Viana MD and Dr. Susan Hunter PT PhD

Introduction

You are being invited to participate in a research study that will be looking at cognition and mobility in people with a lower extremity amputation who are currently using their prosthesis in the community. Cognition is a complex process that includes thinking, problem-solving, reasoning, gathering information and learning. These cognitive tasks play a part in all of the activities we do throughout the day, including walking. We are interested in studying how cognitive tasks, such as counting, affect how you walk with your prosthesis. We want to understand how doing walking and cognitive tasks at the same time affects your performance on a mobility test.

The purpose of this letter is to provide you with the information that will help you to decide whether you wish to participate in this study. It is important that you know why this study is being conducted and what it will involve. Please take your time to make a decision, and discuss this proposal with your family doctor, family members, and friends, as you feel inclined. Participation in this study is voluntary.

Description of study

If you agree to participate in this study, information will be collected on two occasions. Each assessment will take approximately 30 minutes to complete and will take place at Parkwood Institute. The first assessment will occur during your regularly scheduled appointment in the Outpatient Amputee Clinic and the other will be scheduled one week later at your convenience. In addition to the regular assessments that are performed as part of your usual medical care, you will perform two walking tests, a test of your cognition and a questionnaire about your fear of falling while performing different activities.

Participation and Withdrawal

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions, or withdraw from the study at any time with no effect on your future care. If you choose to withdraw from the study, any information that was provided will not be used for any study purposes.

We are seeking volunteers older than 18 years of age, have a lower extremity amputation, are currently using a prosthesis and have a functional use of the English language. If new information that impacts your ongoing eligibility to participate in the study becomes available after you have been enrolled, you will be informed by a member of the research team and the implications will be discussed with you. If during the administration of the cognitive tests you receive a score of less than 26 on the Montreal Cognitive Assessment, this score will be reported to your treating physician at the Parkwood Outpatient Amputee Clinic, Dr. Payne or Dr. Viana.

Risk and Benefits

Risks

The risks associated with taking part in this study are minor. The walking tests involve movements that are common in daily activities and thus do not pose any extra risk beyond these levels of activity. All tests will be conducted by a researcher with experience in the assessment of physical function in adults with a lower extremity amputation. Safety belts will be used and the researcher will always remain within arms' reach to ensure safety should you lose your balance.

Benefits

You may not benefit directly from your participation in this study. You will appreciate you have contributed information that will help to increase scientific understanding of mobility and cognition in people with a lower extremity amputation using a prosthesis.

Reimbursement for Participation in the study

You will not be paid to participate in this research project. However, you will be provided with a parking pass to cover the costs of parking to participate in the study. A \$10 Tim Horton's gift card will also be presented to participants upon completion of the second study assessment.

Confidentiality

All records and research materials that would identify you will be held confidential and, to the extent permitted by the applicable laws and regulations, will not be made publicly available. If you agree to participate in this study, you will be assigned a unique identification number that will be used on all documents related to this study. This unique number will be linked to your name and contact information on another "master list" of participants. This master list will be kept separately from other research information in a locked office. All information collected will be kept for a period of 15 years. If the results of this study were to be published in the medical literature, your identity will not be revealed.

Representatives of the University of Western Ontario's Health Sciences Research Ethics Board (HSREB) may contact you, or require access to your study related records in order to monitor the conduct of the research. For quality assurance (QA) purposes, representatives of Lawson QA Education Program may require access to study data.

Contacts

If you have any questions about this project, please contact the Principal Investigator, Dr. Susan Hunter.

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Research Ethics.

You do not waive your legal rights by signing the attached consent forms. Participation in this study is completely voluntary.

Faculty of Health Sciences and Department of Physical Medicine & Rehabilitation

Consent Form – Patient

Determining test-retest reliability of a dual-task functional mobility assessment in adults with a lower limb amputation

Principal Investigators: Courtney Frengopoulos, Dr. Michael Payne MD MSc, Dr. Ricardo Viana MD and Dr. Susan Hunter PT PhD

I have read the *Letter of Information*, have had the nature of the study explained to me, and I agree to participate. All questions have been answered to my satisfaction.

_________________________________ *Participant's Name (Printed)*

_________________________________ ___________ *Participant's Signature Date (dd/mm/yy)*

I confirm that I have explained the nature, purpose, and foreseeable effects of the trial to the participant whose name is printed above. The participant consented to participate by his/her personally signed signature.

_________________________________ ___________

_________________________________ ___________ *Name of Person Obtaining Consent Role in Role in Role in Study*

Signature of Person Obtaining Consent Date (dd/mm/yy)

Version Date: April 14, 2016 Page 3 of 3 Participant's initials:

School of Physical Therapy and Department of Physical Medicine & Rehabilitation

Letter of Information – Patient

Falls during community reintegration after prosthetic rehabilitation in older adults with a lower extremity amputation

Principal Investigators: Dr. Susan Hunter PT PhD and Dr. Michael Payne MD MSc

Introduction

You are being invited to participate in a research study that will be looking at balance, walking and falls in people who have a lower extremity amputation and completed rehabilitation for a prosthesis. We are interested in studying how your walking and balance change once you go home after your discharge from inpatient rehabilitation. We are also interested in whether you sustain any falls during this time.

The purpose of this letter is to provide you with the information that will help you to decide whether you wish to participate in this study. It is important that you know why this study is being conducted and what it will involve. Please take your time to make a decision, and discuss this proposal with your family doctor, family members, and friends, as you feel inclined. Participation in this study is voluntary.

Description of study

If you agree to participate in this study, information will be collected on two occasions. Each assessment will take approximately 60 minutes to complete on top of the usual evaluations performed as part of your medical care and each assessment will take place at Parkwood Institute. One assessment will be prior to your discharge from rehabilitation and the other assessment will be when you return to clinic for your regularly scheduled follow-up visit. In addition to the regular assessments that are performed as part of your usual medical care, you will perform: 1) at discharge - two walking tests, one balance tests, a questionnaire about falls prevention and five questionnaires related to your prosthesis and your cognitive health, and 2) at the follow-up clinic appointment - two walking tests, one

balance test, a questionnaire on falls prevention and the five questionnaires about your prosthesis and your cognitive health. At the discharge evaluation you will be given a calendar to record information on any falls that you may experience after you go home. A research assistant will contact you each month by phone to collect the information on falls starting one month after your discharge until your follow-up clinic visit. Results of the regular assessments of your amputation and mobility that are done as part of your usual care will be collected from your medical chart at the discharge assessment and the follow-up clinic visit for use in the study.

Participation and Withdrawal

Participation in this study is voluntary. You may refuse to participate, refuse to answer any of the questions, or withdraw from the study at any time with no effect on your future care.

We are seeking volunteers older than 50 years of age who have a lower extremity amputation and are using a prosthesis, have a functional use of the English language, and are able to walk 10m without the assistance of another person. However, there are certain conditions that would *exclude* you from participating in the study. These conditions are as follows: (1) any physical problem, beyond the lower extremity amputation, that significantly limits your movement (ex. arthritis in your hips, knees, or feet), and (2) if you are suffering from severe depression. If you are unsure whether any of these situations applies in your case, please feel free to ask the research staff.

Risk and Benefits

Risks

The risks associated with taking part in this study are minor. The walking and balance tests involve movements that are common in daily activities and thus do not pose any extra risk beyond these levels of activity. All tests will be conducted by a research assistant with experience in the assessment of physical function in adults with a lower extremity amputation. Safety belts will be used and the research assistant will always remain within arms' reach to ensure safety should you lose your balance.

Benefits

You may not benefit directly from your participation in this study. You will have contributed information that will help to increase scientific understanding of physical function and balance in people with a lower extremity amputation using a prosthesis.

Reimbursement for Participation in the study

You will not be paid to participate in this research project. However, you will be provided with a parking pass to cover the costs of parking to participate in the study. A \$10 Tim Horton's gift card will also be presented to participants upon completion of the second study assessment.

Confidentiality

All records and research materials that would identify you will be held confidential and, to the extent permitted by the applicable laws and regulations, will not be made publicly available. In order to contact you by phone between discharge and the follow-up clinic appointment we will collect your phone number, this information in your study records will be destroyed upon completion of your participation in the study. We will also be collecting your hospital identification number to allow us to collect the information from your regular evaluations at discharge and the followup visit. If you agree to participate in this study, you will be assigned a unique identification number that will be used on all the documents related to this study. This unique number will be linked to your name and contact information on another "master list" of participants. This master list will be kept separately from the other research information in a locked office. All information collected will be kept for a period of 15 years. If the results of this study were to be published in the medical literature, your identity will not be revealed.

Representatives of the University of Western Ontario's Health Sciences Research Ethics Board (HSREB) may contact you, or require access to your study related records in order to monitor the conduct of the research.

Contacts

If you have any questions about this project regarding:

Your rights as a research participant, please contact: Dr. David Hill, Scientific Director, Lawson Health Research Institute.

Injury or adverse events related to the study, please contact:

Dr. Susan Hunter, the Principal Investigator.

You do not waive any legal rights by signing the attached consent forms. You will receive signed copies of this *Letter of Information and Consent Form* for your records.

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Research Ethics.

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School of Physical Therapy and Department of Physical Medicine & Rehabilitation

Consent Form- Patient

Study Title: Falls during community reintegration after prosthetic rehabilitation in older adults with a lower extremity amputation

Principal Investigators: Dr. Susan Hunter PT PhD and Dr. Michael Payne MD MSc

I have read the *Letter of Information*, have had the nature of the study explained to me, and I agree to participate. All questions have been answered to my satisfaction.

_________________________________ *Participant's Name (Printed)*

_______________________________ _______________ *Participant's Signature Date (dd/mm/yy)*

I confirm that I have explained the nature, purpose, and foreseeable effects of the trial to the participant whose name is printed above. The participant consented to participate by his/her personally signed signature.

Name of Person Obtaining Consent Role in Study

___________________________________ ______________ Signature of Person Obtaining Consent **Date (dd/mm/yy)**

Version Date: August 22, 2016 Page 4 of 4 Participant's initials:

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Appendix C: Summary Table of Hypotheses for Study 2

CURRICULUM VITAE

A. EDUCATION

Masters of Science September 2015 – present

The University of Western Ontario Health and Rehabilitation Sciences

Bachelor of Health Science September 2011 – June 2015

The University of Western Ontario Honours Specialization in Rehabilitation Sciences

B. MSC THESIS

Dual-task Gait Assessment in Lower Extremity Amputees

Supervisor: Dr. Susan Hunter, PT PhD; School of Physical Therapy, University of Western Ontario, London, ON, Canada

C. AWARDS AND DISTINCTIONS

- \circ Frederick Banting and Charles Best Canada Graduate Scholarship Masters (CGS-M) Award from the Canadian Institutes of Health Research – 2016/2017
- o Western Graduate Research Scholarship 2016/2017
- o Health and Rehabilitation Sciences Graduate Student Conference Travel Award – 2017
- o Faculty of Health Sciences Graduate Conference Travel Award 2017
- o Faculty of Health Sciences Graduate Conference Travel Award 2016
- o Health and Rehabilitation Sciences Graduate Student Conference Travel Award - 2016
- o Western Graduate Research Scholarship 2015/2016

D. RESEARCH EXPERIENCE

Evaluator, WiiNWalk Study *May 2016 - Present* Parkwood Institute, London

Study Coordinator, Longitudinal Cognitive Vitality Study *November 2016 - Present* Parkwood Institute, London

Research Assistant, Part Time *March 2016 – October 2016*

Mobility in Aging Lab, University of Western Ontario, London

E. PUBLICATIONS

Papers in Peer-Reviewed Journals

Frengopoulos C, Burley J, Viana R, Payne M, Hunter SW. Association between MoCA scores and functional outcomes after inpatient rehabilitation for a lower extremity prosthesis. *Archives of Physical Medicine and Rehabilitation.* 2017;98(3):450-455.

[Role: concept and design of study, interpretation of data and statistical analysis, writing of final manuscript]

Cox P, Frengopoulos C, Hunter SW, Sealy M, Death B, Payne MWC. The Impact of Six Minute Walk Test Course Configuration for People with Lower Limb Amputations. *Physiotherapy Canada*. Epub ahead of print on January 24, 2017. [Role: interpretation of data and statistical analyses, writing of final manuscript]

Papers Submitted for Publication/Under Review

Frengopoulos C, Payne MWC, Viana R, Hunter SW. MoCA Item Score Analysis and Relationship to Rehabilitation Outcomes in Lower Extremity Amputees. *Archives of Physical Medicine and Rehabilitation*. Submitted January 7, 2017. ARCHIVES-PMR-D-17-00028

Thompson S, Frengopoulos C, Janes WCI, Modarresi S, Cox K, Lautenschlager NT, Hunter SW. Exercise programs to improve physical function in older adults with dementia living in long-term care: a systematic review. *Physiotherapy Canada*. Submitted December 21, 2016.

Published Abstracts

Frengopoulos C, Burley J, Viana R, Payne M, Hunter SW. Association between fear of falling and functional outcomes after inpatient rehabilitation for major lower extremity amputation: a retrospective chart audit. *Journal of Rehabilitation Medicine*. 48(1): 97

Peer Reviewed Abstracts

- Frengopoulos C, Payne M, Viana R, Hunter S. Determining Test-retest Reliability of a Dual-task Functional Mobility Assessment in Lower Extremity Amputees. World Confederation for Physical Therapy Congress 2017. Cape Town, South Africa. July 2- 4, 2017.
- Frengopoulos C, Janes I, Modarresi S, Thompson S, Hunter S. Influence of Path Configuration on Gait Performance During Dual-Task Testing in Young and Older Adults. World Confederation for Physical Therapy Congress 2017. Cape Town, South Africa. July 2-4, 2017.
- Frengopoulos C, Payne MWC, Viana R, Hunter SW. MoCA Item Score Analysis and Relationship to Rehabilitation Outcomes in Lower Extremity Amputees. 2017 International Society of Posture & Gait Research World Congress. Fort Lauderdale, USA. June 25-29, 2017.
- Frengopoulos C, Payne MWC, Viana R, Hunter, SW. Differences in gait speed between cognitively impaired and cognitively normal lower extremity amputees: Pilot study

preliminary data. 2017 International Society of Posture & Gait Research World Congress. Fort Lauderdale, USA. June 25-29, 2017.

- Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. Effect of Dual-Task Testing on Mobility Performance in Above and Below Knee Amputees. Canadian Association of Physical Medicine & Rehabilitation 65th Annual Scientific Meeting. Niagara Falls, ON. May 24th-27th, 2017.
- Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. Investigating Knowledge of Falls and Fall Prevention Among Lower Extremity Amputees: A Cross-Sectional Study. Canadian Association of Physical Medicine & Rehabilitation 65th Annual Scientific Meeting. Niagara Falls, ON. May 24th-27th, 2017.
- Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. Determining Test-Retest Reliability of a Dual-task Functional Mobility Protocol for Lower Extremity Amputees. Ontario Association of Amputee Care 2017 Conference. Toronto, ON. May 5th-6th, 2017.
- Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. Effect of Dual-Task Testing on Mobility Performance in Above and Below Knee Amputees. Ontario Association of Amputee Care 2017 Conference. Toronto, ON. May 5th-6th, 2017.
- Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. Determining Test-Retest Reliability of a Dual-task Functional Mobility Protocol for Lower Extremity Amputees. London Health Research Day. London, ON. March 28th, 2017.
- Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. Determining Test-retest Reliability of a Dual-task Functional Mobility Assessment in Lower Extremity Amputees. Health and Rehabilitation Sciences Graduate Research Conference 2017. London, ON. February 1, 2017.
- Frengopoulos C, Payne MWC, Hunter SW. Association between Balance Confidence and Time to Complete Functional Mobility Assessments in Lower Extremity Amputees: A Cross-Sectional Study. 7th Biennial Australia and New Zealand Falls Prevention Conference. Melbourne, AUS. November 27-29, 2016.
- Cox P, Frengopoulos C, Hunter SW, Sealy M, Death B, Payne MWC. The Impact of Six Minute Walk Test Course Configuration for People with Lower Limb Amputations. Canadian Association of Physical Medicine & Rehabilitation 64th Annual Scientific Meeting. London, ON. May 25-29, 2016.
- Frengopoulos C, Payne M, Viana R, Hunter SW. Determining test-retest reliability of a dual-task functional mobility assessment in adults with a lower limb amputation.

Health & Rehabilitation Sciences Graduate Research Conference. University of Western Ontario. London, ON. February 3, 2016.

- Frengopoulos C, Payne M, Viana R, Hunter SW. Quantifying Cognitive Demands of Ambulating with a Prosthesis in Lower Extremity Amputees. Health & Rehabilitation Sciences Graduate Research Conference. University of Western Ontario. London, ON. February 3, 2016.
- Frengopoulos C, Burley J, Viana R, Payne M, Hunter SW. Association between MoCA scores and functional outcomes after inpatient rehabilitation for major lower extremity amputation. Ontario Association Amputee Care 2015 Conference. London, ON. May 1-2, 2015.

F. PRESENTATIONS

Presentations at Professional Meetings (presenter underlined)

- Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. Effect of Dual-Task Testing on Mobility Performance in Above and Below Knee Amputees. Canadian Association of Physical Medicine & Rehabilitation 65th Annual Scientific Meeting. Niagara Falls, ON. May 24th-27th, 2017. *(Podium and Poster Presentations) – Awarded 1st Place Abstract*
- Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. Investigating Knowledge of Falls and Fall Prevention Among Lower Extremity Amputees: A Cross-Sectional Study. Canadian Association of Physical Medicine & Rehabilitation 65th Annual Scientific Meeting. Niagara Falls, ON. May 24th-27th, 2017. *(Poster Presentation)*
- Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. Determining Test-Retest Reliability of a Dual-task Functional Mobility Protocol for Lower Extremity Amputees. Ontario Association of Amputee Care 2017 Conference. Toronto, ON. May 5th-6th, 2017. *(Poster Presentation)*
- Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. Effect of Dual-Task Testing on Mobility Performance in Above and Below Knee Amputees. Ontario Association of Amputee Care 2017 Conference. Toronto, ON. May 5th-6th, 2017. *(Poster Presentation)*
- Frengopoulos C, Payne MWC, **Hunter SW**. Association between Balance Confidence and Time to Complete Functional Mobility Assessments in Lower Extremity Amputees: A Cross-Sectional Study. 7th Biennial Australia and New Zealand Falls Prevention Conference. Melbourne, AUS. November 27-29, 2016. *(Podium Presentation)*
- Cox P, Frengopoulos C, Hunter SW, Sealy M, Death B, Payne MWC. The Impact of Six Minute Walk Test Course Configuration for People with Lower Limb Amputations. Canadian Association of Physical Medicine & Rehabilitation 64th Annual Scientific Meeting. London, ON. May 25-29, 2016. (*Poster presentation*) *– Awarded 4th Place Poster*
- Frengopoulos C, Burley J, Viana R, Payne M, Hunter SW. Association between fear of falling and functional outcomes after inpatient rehabilitation for major lower extremity amputation: a retrospective chart audit. Canadian Association of Physical Medicine & Rehabilitation 63rd Annual Scientific Meeting. Vancouver, BC. May 20- 23, 2015. *(Poster presentation)*
- Frengopoulos C, Burley J, Viana R, Payne M, Hunter SW. Association between MoCA scores and functional outcomes after inpatient rehabilitation for major lower extremity amputation. Ontario Association Amputee Care 2015 Conference. London, ON. May 1-2, 2015. *(Podium presentation) – Awarded Best Student Research Presentation*

Presentations at Academic Conferences (presenter underlined)

Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. Determining Test-Retest Reliability of a Dual-task Functional Mobility Protocol for Lower Extremity Amputees. London Health Research Day. London, ON. March 28th, 2017. *(Poster Presentation)*

Other Institutional Presentations (presenter underlined)

- Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. A Dual-task Functional Mobility Protocol for Lower Extremity Amputees. Parkwood Institute Research Half Day Event. London, ON. April 21, 2017. *(Podium Presentation)*
- Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. Determining Test-Retest Reliability of a Dual-task Functional Mobility Protocol for Lower Extremity Amputees. Parkwood Institute Research Half Day Event. London, ON. April 21, 2017. *(Poster Presentation)*
- Frengopoulos C, Payne M, Holmes J, Viana R, Hunter S. Determining Test-retest Reliability of a Dual-task Functional Mobility Assessment in Lower Extremity Amputees. Health and Rehabilitation Sciences Graduate Research Conference 2017. London, ON. February 1, 2017. *(Podium Presentation)*
- Frengopoulos C, Payne M, Viana R, Hunter SW. Determining test-retest reliability of a dual-task functional mobility assessment in adults with a lower limb amputation. Health & Rehabilitation Sciences Graduate Research Conference. University of Western Ontario. London, ON. February 3, 2016. *(Oral presentation) – Awarded Best Masters Student Presentation*
- Frengopoulos C, Payne M, Viana R, Hunter SW. Quantifying Cognitive Demands of Ambulating with a Prosthesis in Lower Extremity Amputees. Health & Rehabilitation Sciences Graduate Research Conference. University of Western Ontario. London, ON. February 3, 2016. *(Poster presentation)*