The University of Hull

A biomechanical investigation of seated balance and upright mobility with a robotic exoskeleton in individuals with a spinal cord injury

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By

Stephen Clive Hayes, BSc (Hons), MSc

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Abstract

Spinal cord injury (SCI) is a complex medical condition with multiple sequelae. The level and severity of a lesion will determine the degree of disability and associated co-morbidities, the most obvious of which is paralysis. Other concomitant issues, such as muscle contractures, poor seated posture and fear of falling, can also lead to a reduced quality of life. Although there is currently no cure for SCI, many of the comorbidities can be managed or mitigated through technology and physical rehabilitation practices.

The aim of this thesis was to inform spinal cord injury (SCI) mobility rehabilitation, focusing on postural control and upright stepping using robotic assisted gait training (RAGT). A systematic review investigating RAGT use in SCI concluded that although RAGT has the potential to benefit upright locomotion of SCI individuals, it should not replace other therapies but should be incorporated into a multi-modality rehabilitation approach.

Seated postural control, upper-body posture and fear-of-falling in SCI individuals were also explored. Stability performance and control demand were compared between high- and low-level injury groups as was fear-of-falling. An individualised limit of stability boundary (LOS) facilitated the differentiation between high- and low-level injuries during static tasks; however, its use during dynamic tasks was limited and potentially influenced by fear-of-falling.

Few studies have quantified the user's motion inside a lower limb robotic exoskeleton (LEXO), and none have reported marker placement repeatability. Standard error of measurement was reported for three-dimensional trunk and pelvic orientations and hip,

knee and ankle angles in the sagittal plane during level walking. This revealed the marker set and placement to produce good levels of agreement between visits, with most values falling between the accepted standard of 2-5^{o}. These findings indicated that the marker placement was repeatable and could be used in the subsequent chapters involving motion capture of overground walking.

Three-dimensional gait parameters of able-bodied individuals walking with and without a LEXO at two speeds (comfortable (CMBL) and speed-matched (SLOW) to the LEXO) were investigated. Statistical parametric mapping revealed significantly different waveforms at the ANOVA level for all kinematic variables, however minimal differences in sagittal plane lower limb kinematics were identified between LEXO and SLOW gait, suggesting LEXO gait resembled slow walking when speed-matched. Altered kinematics of the pelvis and trunk during LEXO use suggest that overground exoskeletons may provide a training environment benefiting postural control training.

Finally, the biomechanical characteristics of able-bodied and SCI users walking in an overground LEXO were investigated. Variables associated with neuroplasticity in SCI (hip extension and lower limb un-loading) were not significantly different between groups, indicating that afferent stimuli to facilitate neuroplastic adaptations in individuals with a SCI can be generated during LEXO gait. Upper-body orientation facilitated stepping and maintained balance, thereby requiring the participant's active involvement.

This thesis has provided evidence that LEXOs can deliver appropriate stimuli for upright stepping and that upper-body engagement can facilitate postural control training, potentially leading to improved seated postural control.

Keywords: Spinal cord injury, biomechanics, robotic exoskeleton, gait, assisted walking, balance, postural control

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Dissemination

Presentations

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Published articles

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Hayes, S.C., White, M., White, H.S.F. and Vanicek, N. A biomechanical comparison of powered robotic exoskeleton gait with normal and slow walking:an investigation with able-bodied individuals. Clinical Biomechanics. Under review.

Prologue

My personal journey throughout the PhD process has been informative, challenging, enriching and very different to my initial expectations. I believe I have reached the end of this process having gained and refined a number of skills, developed as a researcher and as an individual. From a research perspective I have developed my understanding of statistical methods especially with respect to non-parametric data, I have been exposed to the processes involved in study publication and the peer review process. To solve some of the data analysis issues I have faced, I have begun to learn to programme in MATLAB. I have also been fortunate enough to meet numerous professionals and academics from different backgrounds through my PhD studies, which has led to my involvement in several other projects, some of which have led to publications themselves. The lessons and skills I have learnt in combination with my role as departmental biomechanics technician has greatly improved my ability to problem solve and has allowed me to take on extra responsibilities such as co-supervision of two research Masters students and involvement in a multi-centre research project as a research assistant. I will always be grateful for this experience and the other opportunities afforded me by this process and feel it has prepared me for my future career.

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Nomenclature

AB	Able-bodied
ADL	Activities of daily living
AP	Anterior-posterior
ASIA	American spinal injury association
AIS	American spinal injury association injury scale
BOS	Base of support
C 1-7	Cervical spine
CMBL	Comfortable
COG	Centre of gravity
COM	Centre of mass
COP	Centre of pressure
CPG	Central pattern generator
DOF	Degrees of freedom
FES	Falls Efficacy Scale
FIM-L	Functional Independence Measure-Locomotor section
ICC	Intraclass correlation coefficient
IQR	Interquartile range
ISCOS	International Spinal Cord Society
L 1-5	Lumbar spine
LEMS	Lower Extremity Motor Score
LEXO	Lower limb robotic exoskeleton
LOS	Limit of stability
MASCIP	Multidisciplinary Association for Spinal Cord Injury Professionals
MeSH	Medical Subject Headings
MFES	Modified Falls Efficacy Scale
ML	Medio-lateral
NSCISB	National Spinal Cord Injury Strategy Board
NLI	Neurological level of injury
NHS	National Health Service

PICO	Population, Intervention, Comparison and Outcome
QOL	Quality of life
QS	Quiet sitting
RAGT	Robot assisted gait trainer/ing
SCI	Spinal cord injured / injury
cSCI	Complete spinal cord injury
iSCI	Incomplete spinal cord injury
SCIC	Spinal cord injury centre
SCI-FI	Spinal cord injury – functional index
SCIRE	Spinal Cord Injury Research Evidence
SCS	Segment co-ordinates system
SEM	Standard error of measurement
SIA	Spinal Injuries Association
SRT	Sit and reach task
T 1-12	Thoracic spine
WISCI (II)	Walking Index for Spinal Cord Injury (II)
WHO	World Health Organisation
6MWT	Six minute walk test
10MWT	Ten metre walk test

Chapter 1 – Introduction

Spinal cord injury (SCI) is a complex medical condition with numerous comorbidities that currently has no cure. An SCI is a neurological insult caused by a lesion to any part of the spinal cord or its underlying anatomy and physiology. The level at which the spinal cord is damaged, and the severity of the injury will ultimately dictate the level of disability (Kirshblum et al., 2011). The higher the level of an injury the greater the level of disability.

SCIs can be complete or incomplete and may be non-traumatic or traumatic. Non-traumatic lesions are the result of a congenital complication, infectious disease, tumour or musculoskeletal pathology. Traumatic injuries are a consequence of a forceful event, a fall or high impact collision such as a road traffic incident (World Health Organisation, 2013a). Globally there are between 250,000 and 500,000 new cases of SCI every year suggesting a worldwide incidence of 40-80 cases per million, with up to 90% of cases classified as traumatic (World Health Organisation, 2013a). National Institute for Health and Care Excellence (NICE) guidelines for SCI indicate that there are approximately 1000 incidences in the UK each year and that there are 40,000 people living in the UK with a disability as a direct result of SCI (NICE Guidelines NG41, 2016).

The National Spinal Cord Injury Strategy Board's (NSCISB) advice on spinal cord injury management (National Spinal Cord Injury Strategy Board, 2012) and the NHS Clinical Advisory Group's Advice on Major Trauma (2011) detail a plan of care for SCI individuals

from pre-admission through acute care and rehabilitation. Both documents highlight that optimum care must consider the interaction of complex physiological, neurological and psychological components of spinal cord injury. The NSCISB further advise that any and all SCI individuals should be admitted to a Spinal Cord Injury Centre (SCIC) for acute care as early as possible and in situations where it is not possible, SCIC staff should be consulted regarding initial and ongoing care of the patient (National Spinal Cord Injury Strategy Board, 2012). Successful rehabilitation must therefore be individualised in order to maintain quality of life and limit the negative effects of associated sequela.

The rehabilitation pathway should be considered with respect to the acute, subacute and chronic stages of SCI (Nas et al., 2015). Furthermore, rehabilitation should be incorporated into patient care as soon as the patient is deemed medically stable (Harvey, 2016). Rehabilitation therapies and assistive technologies can then be used to facilitate independence (i.e. early stretching and limb positioning to prevent contractures) (Harvey, 2016), mobility (i.e. wheelchairs, walkers, crutches, functional electrical stimulation and robotic exoskeleton devices) (Anderson, 2004; Nam et al., 2017) and alleviate associated health conditions (i.e. pressure sores, bladder and bowel dysfunction) (Karimi, 2011). Due to the multifaceted nature of SCI, no single device or therapy is able to relieve the symptoms of all concomitant conditions. However, various researchers have indicated that movement, and the maintenance of good posture have positive effects on multiple sequelia (Carvalho et al., 2006; Ditor et al., 2005; Hubli & Dietz, 2013). Due to the evolving nature of SCI (especially in the early stages) and the associated co-morbidities, rehabilitation activities need to be continuously

administered, evaluated and adjusted to the needs and changing circumstances of the individual.

Postural control is a person's ability to maintain their centre of mass over their base of support (Horak, 1987) and is an integral component for all controlled movements, whether seated or standing. While postural control during independent standing is altered or inherently impossible for some SCI individuals, seated postural control, is important when performing daily tasks. They may develop compensatory adjustments including, a kyphotic posture when seated, which can contribute to reduced respiratory capacity (Minkel, 2000), increased likelihood of pressure sores (Vette et al., 2014), limited mobility due to reduced range of motion at the shoulder joint, and feelings of social exclusion as eye to eye communication is more challenging (Alm et al., 2003). Each of these factors can contribute to reduced quality of life (Shin & Sosnoff, 2013).

The most obvious consequence of an SCI is paralysis of the nerves inferior to the lesion. The incapacity of the neuromuscular system below the level of injury not only affects independent mobility but will have negative consequences for postural control, leading to various co-morbidities, including contractures of muscles resting in a shortened state (Diong et al., 2012), postural orthostatic hypotension, a sudden drop in blood pressure due to adoption of an upright body position (Popa et al., 2010) and increased risk of falling (Forslund et al., 2017). Upright stepping is one rehabilitation practice that has been shown to reduce the impact of numerous SCI comorbidities, including those already detailed, through movement and physiological changes that occur throughout the body. For example, upright stepping has the capacity to increase blood flow

throughout the muscles of the lower body, which can help prevent and repair pressure sores whilst also alleviating pressure from bony prominences (Regan et al., 2009). The cyclic motion of stepping also causes multiple muscles in the lower body to repeatedly and passively, move through a range of motion in a controlled manner that should not activate the stretch reflex caused by rapidly increasing tension to the muscle spindles (Tortora & Grabouwski, 1996), reducing the likelihood of contractures. Gait training and upright stepping have also been linked to reductions in spasticity of the lower limb muscles (Thuret et al., 2006).

Various methods of facilitating upright stepping in paralysed individuals exist including, therapist assisted body-weight support systems (Field-Fote & Roach, 2011), mechanical reciprocating gait orthoses (Dobkin et al., 2006) and powered robotic exoskeletons (Alcobendas-Maestro et al., 2012; Esquenazi et al., 2012). Each of these approaches was developed to provide gait impaired individuals with a highly repetitive, task-specific training modality. It is of interest for SCI individuals and rehabilitators to find the most complementary forms of rehabilitation, the fact that the aforementioned gait training methods provide other therapeutic benefits may be of particular advantage. However, clinical guidelines available in the UK related to the use of powered robotic exoskeletons in rehabilitation are limited to stroke rehabilitation (NICE clinical guidelines for stroke rehabilitation in adults CG162) (NICE, 2013) and a NICE medtech innovation briefing (MIB93) (NICE, 2017). Thus, providing healthcare professionals with information about emerging technologies that they may be considering in their practice but with limited guidance related to expected outcomes.

This thesis will address a gap in the evidence-based recommendations for the treatment of chronic SCI by investigating the biomechanics of postural control and upright stepping in a group of individuals with spinal cord injury at the thoracic level. The overall aim of this thesis was to provide evidence that can be used to facilitate postural control monitoring and to inform clinical recommendations for the use of robotic exoskeletons for the ongoing rehabilitation of chronic SCI individuals. A systematic review of the scientific literature relating to the use of robotic exoskeleton technologies and their functionality related to temporal-spatial characteristics of gait was undertaken. Subsequently the relationship between seated balance, and neuromuscular control was investigated to ascertain whether injury level could be used as an indicator of postural control. Finally, biomechanical analysis of a partial weight-bearing robotic exoskeleton system was completed for overground gait. Comparisons of the kinematics of SCI and able-bodied users to comfortable- and speed-matched gait were then made in order to identify the feasibility of the exoskeleton technology as a functional mobility tool or rehabilitation device. The ultimate goal of this thesis was to inform current SCI rehabilitation practices related to facilitating the mobility of individuals with a SCI, with respect to balance, postural control and upright stepping using robotic exoskeleton technologies.

1.1 Thesis structure

Chapter 2 is a narrative review of the current literature relating to spinal cord injury and rehabilitation therapies and technologies associated with postural control and mobility. Starting with a review of the anatomical and physiological factors of spinal cord injury and associated comorbidities, subsequent sections explore the biomechanics of postural

control, upright mobility/stepping and current and emerging rehabilitation practices. This chapter concludes with the specific objectives and hypotheses for this thesis.

Chapter 3 is a systematic review of the literature exploring robotic exoskeleton technologies as a rehabilitation tool after spinal cord injury. The review compares overground with treadmill-based systems focusing on the temporal-spatial parameters of upright stepping.

Chapter 4 is a general methods section for the empirical studies carried out in this thesis. The ethical review process and participant inclusion/exclusion criteria are explained and the biomechanical procedures, quality of life assessment tools and subsequent analyses are detailed.

Chapter 5 is the first empirical study of this thesis. The chapter's primary objective was to explore the relationships in 1) stability performance, 2) control demand and 3) posture with A) SCI disability level and B) fear of falling. A secondary objective was to investigate the use of an individual limit of stability boundary relative to seated postural control in both static and dynamic tasks.

Chapter 6 is the first of three studies that focuses on the user's biomechanics within a lower-limb robotic exoskeleton (LEXO). Its purpose was to assess the repeatability of the

primary researcher's marker placement using the adapted 6 degrees of freedom marker model used to accommodate the LEXO device.

Chapters 7 and 8 focus on the biomechanical analysis of the gait parameters (e.g., kinematics, kinetics and temporal-spatial) experienced by able-bodied individuals ambulating within a LEXO compared to comfortable and speed-matched normal walking, and between able-bodied and individuals with a SCI respectively. These chapters highlight the differences between stereotypical and LEXO gait patterns and the complex upper-body control required to operate an overground LEXO.

Chapter 9 is a general discussion, providing a summary of the thesis findings. The limitations of the thesis are discussed and future directions for research are identified.

Chapter 10 is the concluding statement of this thesis, detailing the key findings.

Chapter 2 - Literature Review

The following chapter will focus on spinal cord injury and rehabilitation and consists of five main sections. The first section will highlight the causes, epidemiological factors associated with spinal cord injury (SCI) and classification of injury. The second section details acute management and physical rehabilitation and the current guidelines in the UK and other high-income countries. The third section discusses the impact of balance in sitting and standing for SCI individuals and its relationship to quality of life. The fourth section concentrates on neural plasticity, motor learning and their relationship to the injured spinal cord and physical rehabilitation. The fifth and final section specifically focuses on upright stepping and gait training as a rehabilitation tool.

2.1. Spinal cord Injury

Spinal cord injury can occur through both traumatic and non-traumatic events, resulting in lesions at a single or multiple sites, preventing the transmission of motor, sensory and pain information and disrupted autonomic nervous system function (Kirshblum et al., 2011). The remainder of this literature review will focus on traumatic SCI. Injury to the spinal cord is usually a result of mechanical deformation caused by displacement of the surrounding anatomical structures, such as the intervertebral discs and vertebrae (Mattucci et al., 2018). These mechanical insults to the spinal cord can occur at any level and over varying time periods, ranging from an almost instantaneous incident to months (Dumont et al., 2001; Sekhon & Fehlings, 2001). Most injuries to the cord are a result of specific patterns of injury to the spinal column. Sekhon and Fehlings (2001) indicate that fracture-dislocations (40%) and burst fractures of the vertebral bodies (30%) are the

most likely causes with ruptured discs and missile injuries common alternatives. Injury to the spinal cord is a two-stage process (Dumont et al., 2001). The initial mechanical insult comprises the primary stage (Ahuja et al., 2016; Dumont et al., 2001), whilst the second stage is the result of numerous cellular functions and biochemical reactions leading to continued cellular degeneration and cell death occurring from 15 minutes post injury through 2 months (Park et al., 2004).

Numerous mechanisms have been associated with stage two of SCI, including oxidative stress induced cell death, ischemia, inflammation and apoptosis (Ahuja et al., 2017). The administration of low dose methylprednisolone within eight hours of injury acts to decrease oxidative stress and increase anti-inflammatory factors according to a series of National Spinal Cord Injury Study clinical trials I - III (Bracken, 2002). Early surgical decompression to reduce residual pressure on the spinal cord is currently part of the guidelines provided by the American Association of Neurological Surgeons and the Congress of Neurological Surgeons (Ahuja et al., 2016). These two treatment options are contentious issues, with many believing there to be a lack of clinical evidence of the benefits for both immediate and long-term outcomes, as evidenced in the NICE Guidelines for Spinal injury: assessment and initial management (2016). The contention here highlights the differences in treatment approach and the lack of agreement in the current understanding of SCI within high income countries such as the UK and United States of America (USA).

2.2. Injury classification

Multiple descriptors exist which are used to identify and stratify lesion level and severity of SCI, the most basic being the descriptors of paraplegia and tetraplegia. Paraplegia is the loss or impairment of motor and or sensory function in the sacral, lumbar or thoracic regions of the spinal cord, lower limb and trunk function can be compromised but arm function is typically spared. Tetraplegia is the result of injury to the cervical region and encompasses impairment of the arms along with the aforementioned impairments (Kirshblum et al., 2011). The most appropriate and specific descriptors are the international standards examination for neurological level and the ASIA (American Spinal Injury Association) Impairment Scale (AIS) (Kirshblum et al., 2011). The neurological level of injury (NLI) can be identified based on the sensory and motor functions related specifically to muscles and areas of skin which are innervated by particular spinal cord nerve roots. Each nerve root pair will innervate a myotome and a dermatome (Figure 2.1). Sensory level disruption/impairment can be determined using dull and sharp stimulation to both sides of the body, a left and right sensory level can be defined based on the individuals' ability to recognise and discriminate between sensations at different dermatomes (Kirshblum et al., 2011). Motor level can be evaluated via muscle function on each side of the body using manual muscle testing techniques. The most caudal segment revealing normal sensory and motor function (with intact sensory and motor function rostrally) dictates the NLI (Kirshblum et al., 2011). Although the NLI has been identified as the most appropriate form of assessment (Kirshblum et al., 2011) its reliance on dermatome testing creates an inherent issue in relation to accurate diagnosis of impairment. The reported widespread discrepancies in the production of dermatome maps, the flawed methodology that original maps were

based upon (Challoumas et al., 2018) and the accepted (but often ignored) overlapping of dermatomal zones (Ladak et al., 2014) can lead to inconsistencies in injury level identification. In conjunction with the NLI, the AIS can be used to determine the severity or completeness of the injury. Severity is graded from A, complete motor and sensory injury to E, normal motor and sensory function has been restored post previous deficit (Figure 2.2).

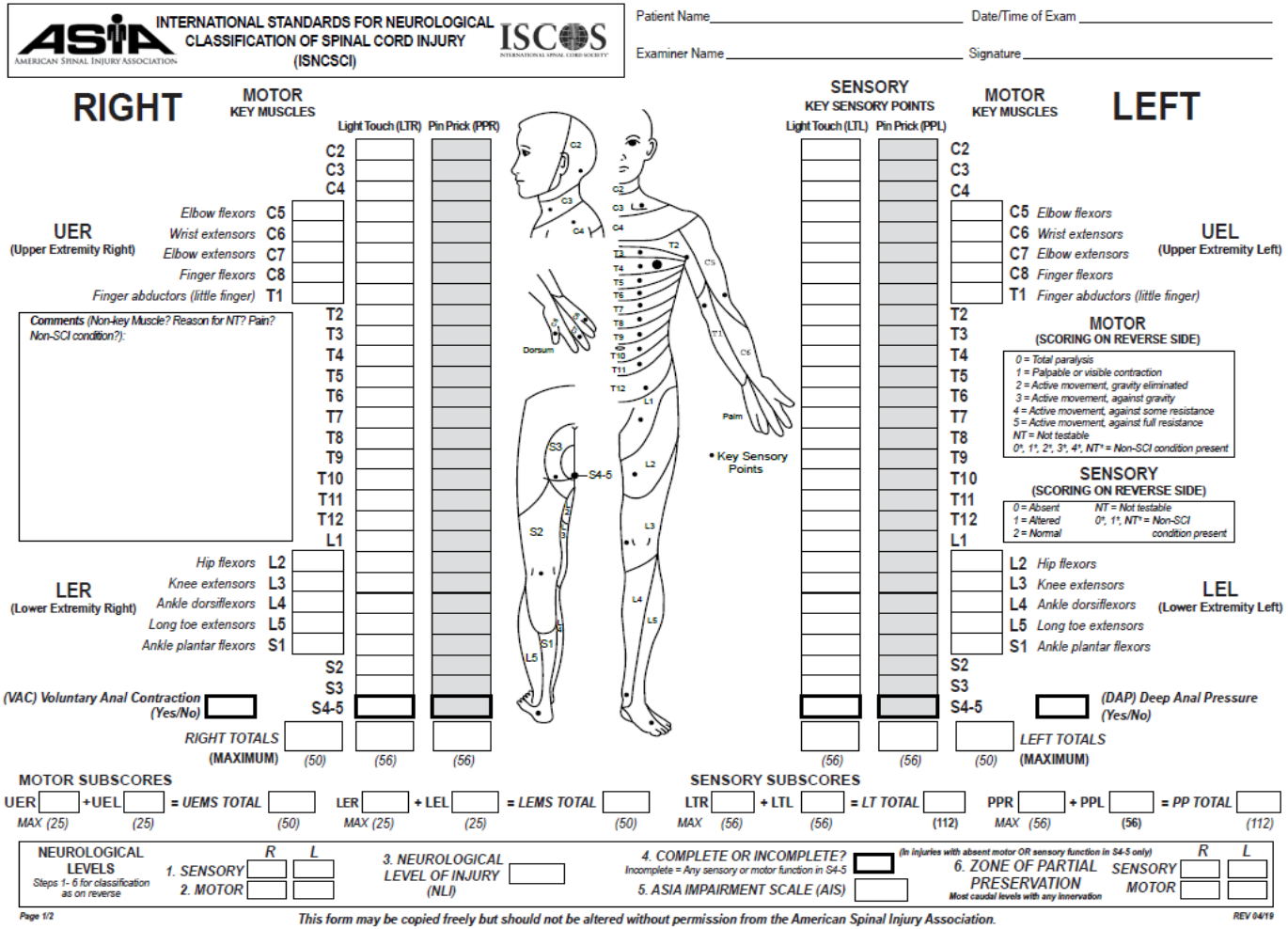


Figure 2.1 American Spinal injuries Association International Standards Worksheet, depicting dermatomes and motor and sensory assessment criteria. Kirshblum et al. (2011).

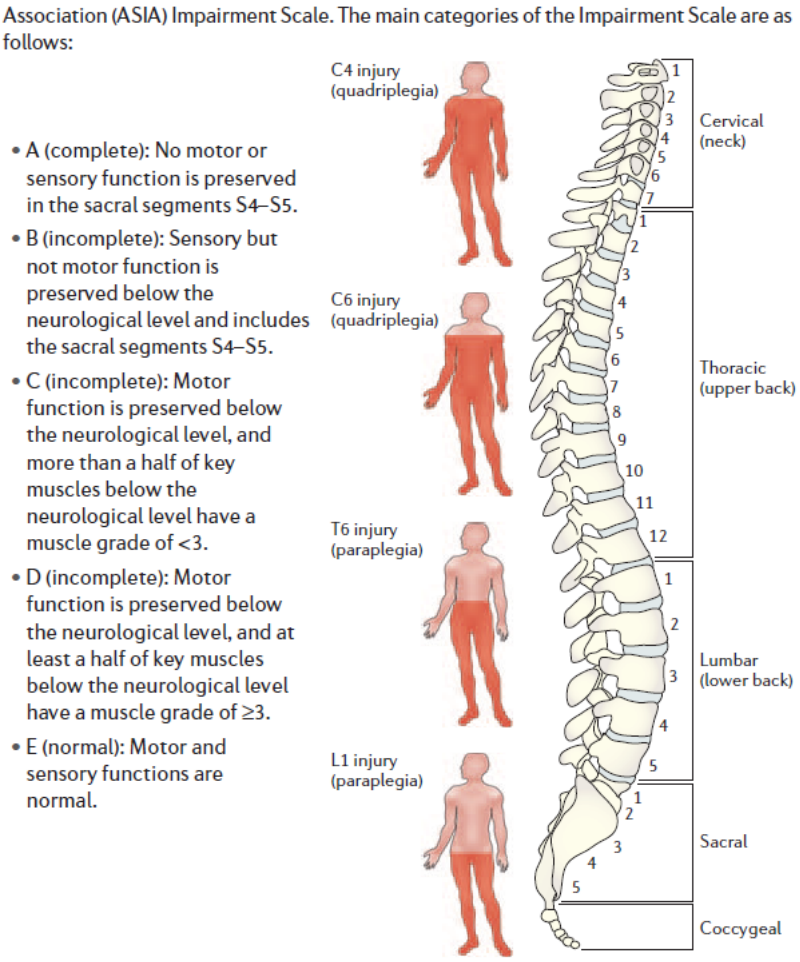


Figure 2.2 Descriptive representation of the ASIA Impairment Scale. Adapted from Thuret et al. (2006), detailing the requirements for each grade point of the scale ranging from A (complete motor and sensory injury) to E (Motor and sensory function normal, although only after an injury has been sustained).

2.3. Level of injury

Identification of SCI level is not a straightforward process, both anatomical and neurological factors need to be considered. Rekand et al. (2012) report 10 to 15% of patients present with a discrepancy between the anatomical and neurological level. Furthermore, some patients (10-15%) experience multiple fractures to the spinal column which can have implications on neurological outcomes, playing a significant role in the secondary stages of SCI as described above (Gardner & Kluger, 2004). Injury

demographics for the USA in the early part of the century reveal that 56% of injuries occurred at the cervical level (Chen et al., 2016). A report by the Spinal Injuries Association (SIA) (2009) showed that during the 2007-2008 financial period, 50% of new SCIs in England and Wales occurred at the cervical level and that 71% of all new injuries were as a result of a traumatic event. The smaller vertebrae and smaller, weaker muscles of the cervical spine coupled with its relatively large range of motion (ROM) compared to the lower sections may explain the large incidence rates of cervical injuries (Sekhon & Fehlings, 2001). Furthermore, headfirst impacts during sporting activities such as rugby, American football, alpine skiing/snowboarding, horse riding and mountain biking along with road traffic collisions resulting in a vehicle roll over can lead to cervical level SCI as the force of the accelerated mass of the torso is absorbed by the neck (Dressler et al., 2019; Saari et al., 2011). With the level of SCI playing such a significant role in determining the subsequent functional capacity of an individual, the fact that the greatest proportion occur in in the cervical spine and that this number appears to be rising, it is a concerning picture that will have consequences for both individuals and the health services that they rely on.

2.4 Epidemiology

Although there are various estimates of world-wide incidence and prevalence of traumatic SCI, a lack of conformity in measurement practices, outcome measures and reporting has made it extremely challenging to produce accurate values. Incidence and prevalence rates are known to differ between and across countries with incidence rates ranging from 2.3 per million in Italy (Rekand et al., 2012) to 83 per million in Alaska, USA (Wyndaele & Wyndaele, 2006). The median incidence rate in Western Europe has been

estimated to be approximately 16 per million per year (Lee et al., 2014) and a report into the overall care of the spinal cord injured patient in the south of England in the UK identified incidences of spinal trauma with confirmed spinal cord damage between 10 – 12 per million per year (Gardner & Kluger, 2004). Grundy and Swain (2002) suggest that incidence rates in the UK were more similar to the rate across Western Europe, reaching up to 15 per million. Prevalence rates have been even more challenging to identify as limited studies have been published in this area (Rekand et al., 2012) especially in areas of the world with limited or no research into SCI (Cripps et al., 2011). Although accurate global prevalence rates are not possible to report, some World Health Organisation areas can be reported, and some have been predicted. Prevalence rates in Canada as of 2010 were reported to be 1184 per million population (Farry and Baxter, 2010 in Lee et al., 2014) and in the USA as data values range from 721 to 4187 up to the year 2008 (Lee et al., 2014). In Australia the prevalence was reported as 681 per million population in 1997 with approximately 10,000 individuals living with an SCI in 1997, prediction forecasting suggests that by 2021 this could increase to nearly 12,000. Lee *et al*. (2014) suggest Western Europe had approximately 280 to 316 per million population living with traumatic SCI in 2011. It is estimated that around 40,000 individuals in the UK were living with a disability due to SCI in 2016 (NICE Guidelines NG41, 2016).

The international Spinal Cord Injury Core Data Set was established to facilitate registration of world-wide spinal cord injury data in a uniform fashion (Biering-Sørensen et al., 2017). Although it is not common practice across the globe, numerous high-income countries and their respective SCI associations report information using the suggested formats (Devivo et al., 2006). Patient gender, age, date of injury, admission

and discharge dates, the mechanism of injury and neurological information along with various other data have all been deemed as useful and are part of the International SCI Core Data Set reporting structure (Biering-Sørensen et al., 2017). Road traffic collisions are typically reported as the highest ranking cause of incident for most countries with falls, sports injuries, violence and work related incidents typically shifting position on the scale depending on geographical location, economic standing of the country and culture (Lee et al., 2014; Rekand et al., 2012). The incidence of sports related injuries is rising in high income countries such as the UK, Australia, Canada and the USA whereas road traffic and work-related accidents are increasing in lower and middle income countries such as India, Brazil and Ethiopia, due to roads becoming busier and less stringent safety standards than those found in higher income countries (Sekhon & Fehlings, 2001). SCI most often occur in young males aged 18 - 32 years (Lee et al., 2014) however, in recent years there has been an increase in the average age at time of injury (Rekand et al., 2012) due in part to the increasing number of elderly individuals experiencing SCIs due to low level falls from a height of less than 6 feet (Lee et al., 2014; Mattucci et al., 2018).

2.5. Consequences and symptoms of SCI

The long-term consequences and symptoms of SCI are many, varied, subject to change over time and can impact multiple areas of life for the individuals and their families (Simpson et al., 2012). As previously described the level and severity of injury dictates a number of factors such as degree of paralysis, subsequent mobility, neurologic regulation of autonomic systems and somatic control (Kirshblum et al., 2011; Nas et al., 2015). Secondary sequelia can occur as a consequence of the primary deficits such as

pressure sores (Richardson & Meyer, 1981), muscle contractures (Diong et al., 2012) and mental health issues such as depression and anxiety (DeSanto-Madeya, 2009; Dijkers, 2004). Each of these factors has considerable economic, social and quality of life (QOL) implications.

The economic costs associated with SCI are high for both the individual and the healthcare systems. The individual may have to consider not only loss of earnings but long-term costs such as medication, structural changes to their home, changes to transport arrangements and possible home care (Harvey et al., 1992). The health services must consider the costs of the pre-hospital care, emergency care, inpatient care, short and long-term rehabilitation, community care and any re-admission (Donovan et al., 2017). Lifetime care costs for individuals living with SCI in the USA estimated in 2011, were predicted for a 25 year old individual affected by a C1-C4 (AIS A-C) at 5.4 million Dollars, a C5-C8 (AIS A-C) at 4.2 million Dollars, T1-S5 (AIS A-C) at 2.9 million Dollars and any level AIS D would cost approximately 2.1 million Dollars (Cao et al., 2011). These values were drastic increases on those predicted in the 1990s, primarily due to two factors, an improvement in the life expectancy of SCI individuals and the costs of rehabilitation and acute care rising faster than inflation (Cao et al., 2011).

Donovan et al. (2017) reported that a completed consultant episode for an SCI individual cost £7649 compared to £1758 for general inpatient care in the UK in 2012-13. The average length of stay in a Specialist Spinal Cord Injury Centre (SCIC) was 116 days (range 65 – 177 days) in 2007-08 (Spinal Injury Association, 2009). An updated report by the Spinal Injuries Association, entitled “A Paralysed system?” (Rose, 2015) indicated the

cost of a bed in a SCIC in the UK was between £495 and £968 (ventilator bed) per day. Both reports highlight delayed admission to a SCIC from a normal hospital and delayed discharge as an extensive issue resulting in significant costs for the NHS.

Social reintegration has been identified as an important factor in SCI rehabilitation (Barclay et al., 2016) but the long-term involvement of individuals post injury in the community is paramount as it is positively linked to life satisfaction (Carpenter et al., 2007; Song, 2005). Craig et al. (2015) provide evidence to suggest that six months post discharge many SCI individuals perceive restrictions to social reintegration. These restrictions or social barriers, have been reported by numerous researchers and consist of but are not limited to: transport (public and/or private), public infrastructure, personal costs, lack of social support, mental health issues (depression/anxiety), fear of humiliation, mobility and pain (Anderson, 2004; Barclay et al., 2016; Craig et al., 2015; Song, 2005). In the UK, particular issues related to social reintegration are the provision of an appropriate support or homecare package and appropriate wheelchairs and mobility aids for those that need them. According to the Spinal Injuries Association (Rose, 2015) both the issues of homecare and wheelchair provision lie in the grey area of who is responsible for the economic cost, the healthcare provider (clinical commissioning group) or social services, which often leads to further delays in discharge and social reintegration. A draft report by the New South Wales Agency for Clinical Innovation suggested that discharge barriers in Australia were equivalent to those identified in the UK, and that 17.5% of all bed days, between January 2008 – July 2013 were occupied by individuals clinically ready for discharge (New, 2015). This suggests

that to improve social reintegration, economic factors of both the individual and healthcare systems need to be considered.

2.6. Acute management and rehabilitation

The current state of injury management and rehabilitation of SCI in the UK is based on a model first introduced by Sir Ludwig Guttman during World War II when he developed the first UK based SCIC at Stoke Mandeville which opened on 1st February 1944 (Guttmann, 1967). It was Guttman's belief that acute treatment and long-term rehabilitation should not be seen as separate entities but a continuum which would enable the individual in question to reintegrate into society (Guttmann, 1967). This model, although modified as numerous medical advancements have occurred, is in operation today and there are currently eleven SCICs operating in the UK (British Association of Spinal Cord Injury Specialists, 2019). As previously indicated the limited number of beds and specialist facilities available can mean delayed admission or in some cases no admission to a SCIC. In these instances, it is recommended that local hospital staff receive input from specialist SCIC staff (National Specialised Commissioning Group, 2011; National Spinal Cord Injury Strategy Board, 2012). It has been suggested that the earlier rehabilitation commences the better the long-term outcomes will be for the individual (Nas et al., 2015).

In the UK the National Spinal Cord Injury Strategy Board (NSCISB) established in 2010, formulated the national care pathways for SCI care and rehabilitation (Osman et al., 2017). According to the NSCISB service specification (NHS England, 2013) the

rehabilitation pathway of the SCI individual should be individualised based on goals established by the individual, the multi-disciplinary therapy team and any relevant community partners. The stages of rehabilitation should be considered as acute, subacute and chronic (Nas et al., 2015). The acute and subacute phases should primarily focus on preventing complications such as pressure sores, contractures and breathing difficulties (Nas et al., 2015). Towards the end of these early phases', focus should be on strengthening of the upper body, commensurate with AIS injury level (Nas et al., 2015) and education of how to manage not only the physical adaptations but associated comorbidities (Evardone et al., 2018).

2.7. Current practices in chronic SCI rehabilitation

The situation surrounding SCI rehabilitation once individuals have been discharged from SCICs or hospitals in the UK varies from person to person and has a significant impact on the individual's future life. As reported previously, the difficulty in agreeing funding for ongoing support packages is a complex issue which will be affected by the local NHS trust, Clinical Commissioning Group and social services. However, post discharge, individuals should have the required skills and support to be able to tackle the challenges associated with reintegration into society and their everyday home life (World Health Organisation, 2011). Limited research into this area has occurred in the UK and although only a small sample of participants were included, Dickson et al. (2011) completed a qualitative analysis of individuals' returning to their home lives post discharge in the UK. Ten of 17 participants interviewed explained how post-discharge there was limited or no support, either physically or psychologically. The authors did note that subsequent

to their research, participants were provided with a 24 hour a day plan of their homecare procedures and provided with access to psychological support if required (Dickson et al., 2011). The research by Dickson et al. (2011) indicates that although every effort is made to try and ensure SCI individuals can reintegrate into society the reality is that once the structured support of the hospital or SCIC is no longer available barriers can cause isolation.

'The New Pathways' for SCI rehabilitation (NHS England, 2013) detail that specialist nurses should be available for outreach visits and telephone communication for patients discharged to their homes. Furthermore, full discharge planning should commence on admission to an SCIC and the goals and requirements should be identified by the multi-disciplinary team, the individual and the appropriate community teams. Due to the multi-faceted nature of SCIs, the varying capacities of each individual and the different sequelia, each discharge plan and rehabilitation pathway will be different. As a consequence, there is no single rehabilitation pathway used for SCI rehabilitation, there is however a general consensus that patient-focused goal setting is an important component of their rehabilitation (Byrnes et al., 2012; Cameron et al., 2018; Hammell, 2007). Rehabilitation guidelines therefore, typically focus on specific aspects of rehabilitation rather than an inclusive programme, examples from the Multidisciplinary Association for Spinal Cord Injury Professionals (MASCIP) website include resources on vocational rehabilitation, weight management following SCI, seating and standing following SCI and management of neuropathic pain (MASCIP, 2018).

The economic standing of countries such as Canada and Australia and their respective healthcare systems are equivalent to that of the UK and its NHS. Clinical Practice Guidelines exist for both the Canadian and Australian healthcare systems and in similar fashion to the UK, there appears to be limited information specifically detailing the care pathway for SCI individuals. Individualised guidelines focusing on specific components of rehabilitation are available, usually from a particular province, state or external agency rather than the respective central Clinical Practice Guideline databases. Examples from the New South Wales State Spinal Cord Injury Service include guidelines for the treatment and management of autonomic dysreflexia (a sudden and dramatic increase in blood pressure caused by stimuli below the lesion level, Karlsson, 1999), pain management, psychological adjustment post SCI, skin and pressure area management and management of the neuropathic bowel (New South Wales State Spinal Cord Injury Service, 2018). Spinal Cord Injury Research Evidence (SCIRE) is an international collaboration based in Canada that reviews SCI research and current practice for rehabilitation and community reintegration. Its main purpose is to provide clinicians and researchers with up to date, concise evidence of current knowledge and best practice. The website hosts numerous guidelines focused on specific areas of treatment and rehabilitation such as the SCI Action Canada Physical Activity Guidelines (SCIRE, 2019). Although this resource contains a substantial volume of research and is easily accessible, like in the UK, the clinical care guidelines appear to be limited.

2.8. Physical rehabilitation

Although the ultimate goal of physical rehabilitation practices and therapies should be to facilitate the complete recovery of SCI individual's, realistically, this is currently

beyond the capacity of clinicians, therapists and researchers. The development and implementation of treatments that improve the functional capacity of individuals to physically perform activities of daily living (ADL) and improve QOL are therefore of paramount importance (Anderson, 2004). There are a large number of rehabilitation interventions and practices available for use with SCI individuals, the use of each should be based upon sound evidence. Unfortunately, there are a relatively limited numbers of high quality, randomised controlled trials to provide sufficient evidence for many of these practices (Harvey et al., 2009). As a consequence, many interventions are at risk of becoming common practice based on limited evidence and the perceptions of patients and clinicians (Harvey, 2016).

The spectrum of rehabilitation techniques and practices available ranges from simple home-based, stretching, positioning programmes and passive movements to prevent contractures (Harvey, 2016), through to the use of standard strength training (resistance based) programmes (Devillard et al., 2007) to functional electrical stimulation and / or the use of robotics to facilitate gait like movements (Nam et al., 2017). van Langeveld et al. (2011) suggested that most physiotherapists spend the majority of their time focusing on basic interventions such as stretching and strength training to facilitate basic activities and improve body function, rather than complex, activity specific rehabilitation. This conventional approach is based on the principle of providing functional compensations (learning new movement strategies) to enable the completion of basic tasks.

2.9. Balance and postural control

Postural control and balance are fundamental to the majority of human movement and nearly all ADL (Pollock et al., 2000). In its simplest form, balance is achieved by maintaining the centre of mass (COM) over the base of support (D A Winter et al., 1990), which requires the manipulation and control of posture. Due to the bipedal, upright posture of humans, this is a challenging task requiring constant monitoring and correction. The small base of support provided by the feet is separated from the COM by a multi-segmented system (Hodges et al., 2002) with the upper-body contributing to over fifty percent of the individual's body mass (Thorstensson et al., 1984). Even in sitting where the base of support is increased, postural control can be challenging as the ability to adjust the base of support in response to a perturbation is limited. Besides the influences of gravity and the internal fluctuations of the body associated with respiration and heartbeat (Bouisset & Duchêne, 1994; Hodges et al., 2002) the human body must maintain postural control throughout voluntary movement of its limbs (altering COM position) and external perturbations, both expected and unexpected (Shahvarpour et al., 2016). Failure to do so can lead to negative consequences such as task failure or even falling.

2.9.1. Postural control mechanisms

Postural control was once considered as a simple system of reflex movements responding to sensory information. This is no longer the case with postural control known to be a complex motor-skill utilising both sensory and motor systems (Horak, 2006) to effect voluntary, reactive, predictive and combination strategies (Pollock et al.,

2000). The systems that combine to maintain postural control consist of sensory components (vestibular, visual and somatosensory), a cognitive processing component (CNS), and a motor component (musculo-skeletal system) (Horak, 2006; Winter et al., 1990).

The vestibular system provides sensory information about the orientation and accelerations of the body to the cerebral cortex; its location in the inner ear, however, compromises the ability of the vestibular to reflect body position if the head is subject to a sudden movement (Martini et al., 2015). The visual system provides information about the environment and orientation of the body. Although this system is not affected in the same way as the vestibular system by sudden movements it still has its vulnerabilities. Occlusion of the eyes or visual interference can lead to either no information or incorrect information being fed into the cerebral cortex. The proprioceptive aspect of the somatosensory system is comprised of the muscles, tendons and the receptors that identify and respond to tension and pressure. This system provides information on the position, orientation and movement of limbs as well as the pressure and forces acting at the base of support (Inglis et al., 1994). It can be compromised by injury to any part of the system including the peripheral nervous system. Based upon the previously explored consequences of SCI it is evident that postural control and balance will be negatively affected at multiple levels depending on numerous factors such as severity, lesion height and other associated sequelia.

The strategies used to maintain postural control depend on a variety of factors; the activity, the environment, the nature of a perturbation, learned strategies available to

the individual and the influence of impairment to any sensory or motor system (Horak, 2006; Pollock et al., 2000). The variety of postural information available to the CNS in able-bodied individuals creates a redundancy. Compensatory information from another system will usually enable the maintenance of postural control in ideal circumstances. The negative consequence of this is that any impairment to one system, can be masked by the adaptive responses of the other two. Reduced capacity in specific environments is highly likely, for example individuals with a vestibular impairment may struggle with postural control in the dark (Horak, 2006). Although it is evident that postural control is complex, researchers have attempted to gain understanding by separating the task by situation. Sitting, standing and walking are three common situations, which are often further categorised through the balance task requirement; quiet sitting or stance, expected perturbation, unexpected perturbation or voluntary movement (D A Winter et al., 1990). Postural control strategies are situation dependant; ankle, hip and stepping strategies have been established as mechanisms used to maintain balance relative to increased perturbation sizes respectively (Horak, 1987; Karlsson & Lanshammar, 1997).

2.9.2. Postural control assessment

Methods of assessing postural control are many and varied, however, quiet stance and sitting research has routinely employed centre of pressure (COP) changes from a single force plate (Shin & Sosnoff, 2013; D. A. Winter et al., 1996). In order to understand the use of COP to quantify postural control the relationship between centre of gravity (COG), COM and COP will be explored. The COG is the vertical vector from the COM to its intersection with the horizontal plane; it is the weighted average of the individual body segments. The COP is the location of the vertical component of the ground reaction

force (GRF) vector. COP is a measurable variable of the neuromuscular control of the COG (D. A. Winter et al., 1996), which healthy individuals should be capable of manipulating to compensate for the inherent sway of the COM. Accelerating COP in the opposite direction to COM sway maintains the COG within the base of support and therefore ensures postural control (Błaszczyk, 2016; Ruhe et al., 2011; D. A. Winter et al., 1996). Previous researchers have used varying methodological approaches to COP data collection and processing, somewhat limiting the capacity for comparison (Błaszczyk, 2016; Carpenter et al., 2001). For instance, sample duration and frequency along with different filtering processes can impact outcome variables (Carpenter et al., 2001). Furthermore, COP metrics have been subject to time domain and frequency domain analysis with different approaches used to try and interpret the output. Examples such as COP trajectory length, velocity, maximum range of movement and acceleration in both individual horizontal planes as well as combined, and even more specific assessments such as dimensionless stability parameters based on phase analysis (Błaszczyk, 2016; Raymakers et al., 2005) have all been used in the past.

As discussed above the mechanisms used to maintain postural control during standing have been explored and various strategies have been identified, specifically, ankle, hip and as a last resort stepping (Horak, 1987; Karlsson & Lanshammar, 1997) to ensure control and prevent falling. The nature of sitting postural control, even during travel in either in a vehicle or using a wheelchair, substantially alters the strategies available to the individual to prevent a fall, especially in the case of a large perturbation. Essentially if the individual is to remain seated, they cannot step. The response most like stepping would be to put a hand out for support, and in situations where the seat is elevated and

out of reach of any supporting surface (as can frequently be the case in a wheelchair) the individual would be unable to utilise this strategy. Although this poses a challenge for the individual, it does provide an opportunity for a specific tool to be used in the assessment of seated postural control that is not a viable option in standing or walking. Preuss and Popovic (2010) suggested qualitatively defining the limits of stability in sitting based on COP values during directional leaning tasks in 8 directions around the body. Shin and Sosnoff (2013) expanded on this work by asking individuals to rotate at the hips and lower back whilst seated to draw a continuous arc around the body using COP data, which could be superimposed over the base of support. In both instances an ellipse was fitted to the data to generate a single boundary (Preuss and Popovic, 2010; Shin and Sosnoff, 2013). Said boundaries were then used in conjunction with COP data from quiet sitting tasks to calculate a stability margin. The concept being that the smaller distance from the limit of stability boundary of the COP trace the greater the instability. Although currently restricted to laboratory situations, the benefit of this approach is that the limit of stability boundary would in theory be applicable to any situation in which a wheelchair user may find themselves.

The majority of other test methods of balance and postural control are clinical assessments, Sibley et al. (2015) identified 66 different clinical measures published between 1986 and 2014. Of these, some consisted of single balance tasks whilst others such as the Berg Balance Scale (Berg et al., 1989) were comprised of multiple tasks. It could however be argued that some of these particular assessments do not measure postural control directly but the capacity of an individual to complete a motor task. For example, alternate stepping on to a bottom step may be affected by balance but may

also be affected by the capacity of an individual to step. Horak (2006) suggested the systems framework for postural control as a method of identifying appropriate tests to assess balance. They postulated that each of the six components should be tested as part of a balance and postural control assessment. The six components are biomechanical constraints, movement strategies, sensory strategies, orientation in space, control of dynamics and cognitive processing (Horak, 2006). Each of these components is discussed in the following section relative to SCI in order to facilitate the understanding that the impact each of these components plays within the impaired system.

2.9.3. Postural control in SCI

Stabilisation of the spine has been conceptualised as consisting of three interdependent subsystems (Panjabi, 1992a). The passive system, comprising of the vertebrae, intervertebral discs and the ligaments of the spinal column. The active system, comprising the muscles and tendons that can apply force to the spinal column, and the neural system, the CNS and peripheral nervous system that can detect and initiate movement. The anatomical range of motion (ROM) of the spinal column consists of the neutral zone; an area where muscular activity is absent and minimal resistance is offered by the passive structures of the spinal column, and an elastic zone, where column movement occurs under high levels of resistance from passive and active structures (Panjabi, 1992b). The size of the neutral zone has been shown to increase with injury and a larger neutral zone has been identified as an indicator of spinal instability. It appears that one consequence of SCI is an increase in the instability of the spinal column. Based on its biomechanical function and its primary role as an anchor for movement of

the limbs, any instability will negatively impact posture and postural movement (Izzo et al., 2013). When compounded with the neurological deficits caused by SCI, postural control will clearly be compromised (Reeves et al., 2006).

It has been demonstrated that internal perturbations caused by homeostatic cardio-respiratory functions and neuromuscular noise impact postural control of able-bodied individuals (Kuznetsov & Riley, 2012; Reeves et al., 2006). Postural disturbances resulting from respiratory movement are usually attenuated by the lower limb and the trunk musculature during standing (Hodges et al., 2002; Kuznetsov & Riley, 2012). As previously explored, increasing the base of support is a useful strategy to help maintain postural control; by sitting the base of support increases. However, the larger base of support achieved through sitting is partially negated in able-bodied individuals relative to perturbation compensation, due to the reduced number of body segments that can be manipulated in response (Bouisset & Duchêne, 1994). The principle of abundance (Gelfand & Latash, 1998) suggests that the CNS takes advantage of all of the degrees of freedom (DOF) available to it in order to solve a motor task, rather than attempting to simplify the problem by locking or fixing any joints and removing the DOF from the equation (Kuznetsov & Riley, 2012). Put simply, to maintain postural control, an able-bodied individual's CNS will make use of musculature controlling every joint above and below the COM to compensate for perturbations. If sitting increases the difficulty of internal perturbation management by limiting the joints available to the CNS in able-bodied individuals, direct damage to the CNS will have serious consequences for impaired populations based on its ability to receive, process and respond to afferent information.

It has been shown that increased motor task demands raise the requirement for stability of the trunk (Cholewicki et al., 2000). The limitations of the CNS and muscular control due to SCI are further exposed when self-imposed movements or external perturbations require motor responses to prevent loss of or maintain control, such as when reaching beyond the base of support. Anticipatory and compensatory postural adjustments use feedforward and feedback mechanisms respectively to prepare or respond to perturbations (Aruin, 2002). Activation of the trunk musculature has been evidenced in both anticipatory and compensatory adjustments to provide trunk stability (Cholewicki et al., 2000; Stokes et al., 2000). Injuries to the thoracic spine and higher present with significant trunk musculature control issues (Chen et al., 2003) and neuromuscular impaired persons typically use their arms and or external devices for support (Minkel, 2000). In instances where their arms are not used for support, researchers have reported the use of non-postural muscles such as the latissimus dorsi and trapezius pars ascendes by SCI individuals as compensatory mechanisms for functional loss of the erector spinae muscles (Potten et al., 1999; Seelen et al., 1997, 1998). Furthermore, altered activation patterns have been identified for those individuals with the capacity to still recruit postural muscles (Bjerkefors et al., 2009). It is therefore apparent that this is a variable that can be trained using rehabilitative techniques and that the use of measures of stability will allow methods of quantification to demonstrate where improvements are evident.

Co-contraction of antagonistic trunk muscles can be used to increase trunk stiffness in able-bodied individuals (Lee et al., 2006). This is one strategy that can be employed to

facilitate greater postural stability. For SCI individuals with higher lesions, the co-contraction method appears to be a viable approach to stability, although the muscles in question are compensatory, non-postural muscles. Seelen et al. (1997) identified the use of the pectoralis major and serratus anterior as shoulder girdle stabilisers preventing simple scapular retraction when the latissimus dorsi and trapezius contract to maintain postural control. Moreover, static muscular contractions held for prolonged periods lead to fatigue (Reeves et al., 2007), suggesting that this option would not be suitable for tasks of long duration or multiple events.

A secondary factor to strategy selection is the speed at which said strategies can be employed. Able-bodied individuals have been reported to be able to respond to unexpected postural disturbances during standing between 73-110 ms (Horak & Nashner, 1986). Stokes et al. (2000) demonstrated that during sitting, able-bodied neuromuscular response latencies to an unexpected perturbation were between 25-150 ms. Although overlapping, it is clear that the range of response latencies in sitting is much greater than those in standing, suggesting that the size of the perturbation and the number of degrees of freedom available interact resulting in the broad response time. Seelen et al. (2001) demonstrated during a reaching task that reaction times of high thoracic SCI individuals were no different from those of able-bodied controls whereas low thoracic injured individuals had significantly slower responses. They postulated that the number of available postural control strategies in lower level injured individuals was greater and more challenging to implement, leading to the increased reaction times (Seelen et al., 2001).

Although various researchers have investigated alternative muscular activation strategies, identified changes in anticipatory and compensatory balance strategies and acknowledged differences in neuromuscular reaction times, limited progress has been made to facilitate seated balance control post SCI. The diminished reactive capacity of such individuals is directly associated with an increase in falls incidence as much as six times compared to the general population (Sibley et al., 2015). This alone suggests that further research into the postural control and balance mechanisms of SCI individuals is warranted.

2.10. Falls in SCI

The capacity to sit unsupported is of particular importance in the completion of activities of daily living for many SCI individuals (Boswell-Ruys et al., 2010a); a substantial proportion of these tasks will be completed from a wheelchair for many. Approximately 40-60% of manual wheelchair users report falls which comprise upwards of 60% of non-fatal accidents for wheelchair users (Boswell-Ruys et al., 2010b). Nelson et al. (2010) identify the wheelchair as one of the most important devices in use by the mobility impaired; they reported that 204 (31%) of 659 SCI participants, suffered 553 falls. Of the 204 participants 95 experienced an injury as a result of a fall, with 208 injurious falls being reported, one individual even experienced a fatal event (Nelson et al., 2010). Fourteen percent of the 208 injurious events were deemed serious with head injuries being the most frequent. A separate study with 149 SCI participants reported a 64% falls rate over a one year period, detailing a total of 306 falls, with 70 resulting in injury and 7 of these deemed serious (Forslund et al., 2017). Although it is not possible to categorically define the reason for falling as an inability to maintain postural control, the

fact that the most common situations resulting in a fall were during transfers and wheelchair manoeuvring on uneven ground and obstacles, suggests that the greater instability rather than chair design was the overriding factor. Links between fear of falling and neurological impairment have been established (Hellström & Lindmark, 1999; van Vliet et al., 2013) which can lead to self-imposed restrictions in physical activity and social integration (Forslund et al., 2016; Hellström & Lindmark, 1999; Wirz et al., 2010).

Increases in balance disorders and risk of falling has traditionally been linked to ageing (Horak, 2006), with most work related to fear of falling focused in gerontology (Boswell-Ruys et al., 2010b). In respect to SCI and specifically individuals that require the use of a wheelchair, their risk of falling is high irrespective of age (Nelson et al., 2010). Boswell-Ruys et al. (2010b) suggest that this high risk of falling leads to warranted and un-warranted concerns, and that both should be considered in rehabilitation. As previously alluded to, the fear of falling can have negative self-imposing consequences, however, the warranted concerns highlight safety factors that should be considered. SCI individuals with more challenging co-morbidities and other health problems may be more negatively affected by both warranted and un-warranted fears related to falling (Forslund et al., 2016). Firstly, individuals with the capacity to get up from the floor reported less fear, even when falls were a common occurrence for the individual (Forslund et al., 2016). Secondly, length of time since injury has been associated with falling; fewer falls occur as years since injury increases (Nelson et al., 2010). It is likely that the reduction in falls, as time since injury increased, was due to improved skill level and more developed compensation strategies related to balance tasks (Forslund et al., 2017). Despite the trend of reduced falls over time, recurrent falling in the past has been

one of the best predictors of future falls (Forslund et al., 2017; Nelson et al., 2010). Paradoxically, SCI individuals who experience greater numbers of falls also appear to display less fear of falling (Forslund et al., 2017). It appears that those individuals who experience the greatest number of falls are the most functionally independent.

Rehabilitation to improve physical capacity in SCI individuals is vital in order to minimise the debilitating, negative cycle of reduced physical capability and poor health and fitness (Haisma et al., 2006). The use of intensive task specific training to improve balance in SCI individuals may help to improve unsupported sitting, which in turn may provide individuals with not only the confidence but the capacity to be more physically active. The effects of such training programmes may arise through improved compensatory strategies related to the use of alternative muscles (Seelen et al., 1997) or through neural plastic changes in the peripheral and central nervous systems (Boswell-Ruys et al., 2010a).

2.11. Neurological considerations of SCI

A recent interest in neural plasticity by researchers has led to the development of activity-based therapies, which are founded on the activation of muscles below the lesion level, with the aim of retraining neural circuitry to recover particular motor skills (Jones et al., 2014). The concept of neural plasticity refers to the reorganisation of neural pathways, which is believed to occur in motor learning for skill acquisition (Dhawale et al., 2017), motor recovery and compensation post injury (Hubli & Dietz, 2013; Roby-Brami et al., 2003).

2.11.1. Central Pattern Generators

Before exploring the concepts of neural plasticity further, this section will focus on the neural circuitry that facilitates motor control, which is the ability to organise and elicit voluntary movement (Cech & Martin, 2012). The spinal cord contains groups of nerve cells (or networks) that are capable of processing and generating motor control patterns (Illis, 1995). The existence of these neural networks explains the automaticity of the spinal cord and its capacity to control motor function. Motor control of the body is highly complex, it often requires the coordination of multiple limbs each with several joints, whilst maintaining postural control. Roy et al. (2012) identified four principles that underpin the premise of neural motor control, automaticity of spinal cord networks, the addition of sensory information to these networks, the capacity for the networks to learn and the importance of the higher level input from the brain, therefore it is imperative to explore these in further depth

To handle the different motor functions of the body, lower level neural networks can generate cyclic movements. These networks are referred to as central pattern generators (CPGs). The existence of CPGs in the lumbosacral region of the spinal cord responsible for locomotion is generally accepted based on initial work in animals at the start of the 20th Century by Sherrington (1910) and Graham Brown (1914; 1911). This work was supported and expanded upon by various authors from the 1960's onwards (Guertin, 2009). Evidence that CPGs are responsible for locomotor control in humans is less prevalent, however, several authors observed various phenomenon indicating the existence of CPG's in humans (Dietz, 1992; Duysens & Van de Crommert, 1998). Furthermore, van Hedel and Dietz (2010) identified that although CPGs are capable of

generating rhythmic, stepping like movements, walking in humans still has a significant reliance upon supraspinal input. As has previously been established, spinal cord lesions prevent the transmission of information up and down the spinal cord, signals can only travel as far as the intact neural cells exist. Below the level of a lesion the anatomical and physiological structures and process of the body should, at least in the early stages of injury, be intact (Reier et al., 2017). Although supraspinal activation and environmental input to the locomotor CPGs is not possible, afferent input provided by external movement of the lower limbs has been shown to trigger the lumbosacral locomotor CPGs (Dimitrijevic et al., 1998; Duysens & Van de Crommert, 1998). Over time the capacity of CPGs below the level of a lesion begin to degrade if not activated. Appropriate afferent input has the capacity to prevent degradation of the neuronal circuit (Hubli et al., 2011) and can be used in rehabilitation to potentially retrain the lower level neural circuitry. The timely application of appropriate rehabilitation techniques is therefore clearly important in order to prevent this neural degradation.

2.11.2. Neural plasticity

Neural plasticity has several implications for SCI rehabilitation based on the type of remodelling; at the cellular level, the individual neuron and at the multi-cell level, effecting groups of neurons (Hallet, 2004). Adaptations to the response strength of synapses and or alterations to the inhibition or excitation levels of particular synapses are fast acting neural-plastic changes (Hallet, 2004). Large numbers of neural networks are chronically inactive or supressed due to tonic inhibition, which has been suggested by Benjamin et al. (2010) as a controlling mechanism for motor activity. The triggering

of a specific motor response to external stimuli requires disinhibition of a particular neural network and often inhibition of competing motor responses, which would be energy expensive and in direct contrast to the primary objective of the motor task (Benjamin et al., 2010). Early and persistent afferent stimulation of neural circuitry can lead to lower excitation requirements of particular synapses and greater inhibitory responses of contradictory motor networks (Hallet, 2004). This neural plastic adaptation can occur in both beneficial and negative fashions. Although the physical anatomy of the spinal cord and peripheral nervous system below the level of the lesion remains intact, over time physiological adaptations occur such as reduced spinal reflexes and a significant reduction in electromyographical activity (Dietz & Müller, 2004). These adaptations are believed to occur through changes in the balance of excitatory and inhibitory capacity of the spinal interneuronal circuits (Hubli et al., 2011). Slower neuro-plastic adaptations occur in the form of anatomical remodelling such as the sprouting of axon collateral fibres. These newly formed pathways can form synapses with intact neurons leading to a possible bypass of damaged neural tissue on the other side of the body, which may partially explain the capacity for incomplete SCI (iSCI) individuals to regain some functional capacity (Reier et al., 2017).

The idea that neural plasticity has a substantial role to play in SCI rehabilitation can be linked to the principals of motor learning. It has been evidenced that the healthy central nervous system (CNS) adapts continuously throughout life and that said changes are activity dependant (Wolpaw, 2010). This theory underpins some of the mechanisms related to activity-based therapy, facilitating the restoration of, or compensation for lost function. Essentially the repetition of a specific motor task leads to neural adaptations

in the form of either anatomical reorganisation or excitatory and inhibitory capacity of a synaptic pathway (Hallet, 2004; Reier et al., 2017). Activity-based therapies use a multitude of interventions, including: body-weight supported stepping, robotic assisted gait training (RAGT), functional electrical stimulation, resistance training, developmental sequencing (strengthening of the primary stabilising muscles of the core) and task specific, high repetition motor activity (Jones et al., 2014).

Body weight supported stepping with manual assistance by a therapist and RAGT interventions have both been developed to target neural plastic adaptations based on activation of latent, lumbo-sacral CPGs. Various authors have shown that the CPGs in the lumbo-sacral region can (even without supraspinal input) trigger and maintain alternating flexion and extension movements of the hind limbs in response to appropriate afferent input (Dietz et al., 2002; Pang & Yang, 2000; Sherrington, 1910). Both hip extension and limb unloading have been identified as mechanisms triggering hip flexion (Hallet, 2004). Essentially as the hip joint is extended, the muscle spindle in the iliopsoas and associated hip flexors send afferent signals to the interneuronal circuits in the spinal cord, eliciting an excitatory response to flex the hip joint and an inhibitory response leading to relaxation of the hip extensors. This reduces tension in the hip flexors and causes a shift from stance to swing phase (Reier et al., 2017). Dietz et al. (2002) specifically identified the role of limb loading and unloading in CPG activation, demonstrating that although limb load plays an important role in step initiation it is only this information coupled with afferent input from hip position that successfully activates the step response. Similar plastic adaptations occur during the relearning of motor behaviour post SCI to those identified during motor learning of new skills based on

repetitive movement. These adaptations take the form of a shift in the excitatory and inhibitory balance of specific interneuronal synapses (Hubli et al., 2011; Reier et al., 2017). That these same adaptations have been identified in both incomplete and complete SCI individuals suggesting that the automaticity of the spinal cord can be influenced (the neuronal networks can learn) without supraspinal input. However, the same lack of higher level input limits the learning capacity of the networks and increases the requirement for task specificity to be employed in motor training protocols (Barbeau, 2003; Behrman et al., 2006; Edgerton et al., 1997).

2.12. Upright Stepping Post SCI

A variety of methods exist to facilitate the upright stepping of SCI individuals, ranging through therapist assisted body-weight supported treadmill training (Dobkin et al., 2006; Field-Fote & Roach, 2011), treadmill based RAGT (Alcobendas-Maestro et al., 2012; Hidler et al., 2008; Swinnen et al., 2015), therapist assisted or reciprocating gait orthoses assisted overground walking (Arazpour et al., 2013; Dobkin et al., 2006) and overground RAGT (Arazpour et al., 2014; Esquenazi et al., 2012; Zeilig et al., 2012). A literature review by Díaz et al. (2011) categorised RAGT system into five groups, treadmill, footplate, overground and stationary gait trainers plus active foot orthoses. The primary purpose of all these therapeutic modalities is to provide the mobility impaired individual with task specific, highly repetitive, step training. Understanding each of these modalities, investigating safety for patient use, which patient group they may be most beneficial for, which ones are most cost effective, and how they may impact ADLs, comorbidities and subsequent QOL of SCI individuals comprises a

substantial body of work, much of which has been completed after the publication of the review by Díaz et al. (2011). Although a great deal of work has been undertaken, some of the challenges detailed by Díaz et al. (2011) in the concluding remarks of the review are yet to be met such as the development of standardised protocols for the assessment of gait improvement in individuals that use RAGT.

2.12.1. Benefits of upright stepping

Several potential benefits of upright stepping in SCI individuals have been identified, principally the temporary negation of the deleterious effects of being chair or bed bound (Hubli & Dietz, 2013). Many individuals (especially those with motor complete SCIs, ASIA A and B) may not experience functional improvements in gait but may see significant improvements in accompanying sequelia following therapeutic standing and upright stepping. Standing and upright stepping have been linked to improved bone mineral density in SCI individuals based on the reversal of increased bone resorption which is due to limited mechanical load and muscular contractions (Carvalho et al., 2006). Bladder and bowel management have been reported as improved after upright stepping, although no clinical research has investigated the physiological underpinning of these reports (Karimi, 2011). Orthostatic hypotension during postural challenge is another common comorbidity of SCI individuals with the severity linked directly to injury level (Popa et al., 2010). Several factors have been identified as potential causes, including the absence of mechanical pumping of lower limb muscles to facilitate venous return (Claydon et al., 2006). Muscular contractions as low as 15% of possible maximal force have been shown to restrict blood flow into muscles in healthy able-bodied individuals (Karlsen et al., 2009). This compression of intramuscular veins via muscle

contraction during static balance and dynamic exercise activities acts as a pump, forcing blood to return to the heart (Sousa et al., 2012). It has been demonstrated that upright stepping can lead to positive adaptations in blood pressure control for iSCI individuals (Ditor et al., 2005).

Spasticity is a very common comorbidity of SCI which can lead to reduction in QOL through negative implications on ADL, self-care, physical rehabilitation modalities, quality of sleep and the generation of pain (Adams & Hicks, 2005; Kheder & Nair, 2012). Although different in pathophysiology and expression, spasticity can be used as an umbrella term for increased muscle tone, flexor spasms, hyper-reflexia and clonus (Adams & Hicks, 2005; Sheean, 2002). Most SCI individuals with spasticity, present with hyperactive tendon and stretch reflexes as a result of an imbalance in excitatory and inhibitory control (Adams & Hicks, 2005). An example of this imbalance from a muscle physiology perspective is evident between reciprocal inhibition and co-contraction. Control of these mechanisms is regulated at both the cortical and spinal levels. Removal of supraspinal input can lead to pathological co-contraction (Sheean, 2002) or reciprocal facilitation (activation of the antagonist muscle rather than relaxation) (Xia & Rymer, 2005). Smith and Knikou (2016) have linked reciprocal facilitation to poor motor recovery and further suggested that individuals with stronger reciprocal inhibition present with reduced spasticity. Limited evidence is available to suggest that supported standing can be used to mediate lower limb spasticity (Newman & Barker, 2012), whereas upright stepping and gait training have been linked to reduced spasticity of the lower limbs (Thuret et al., 2006) based largely on the neuro-plastic adaptations that

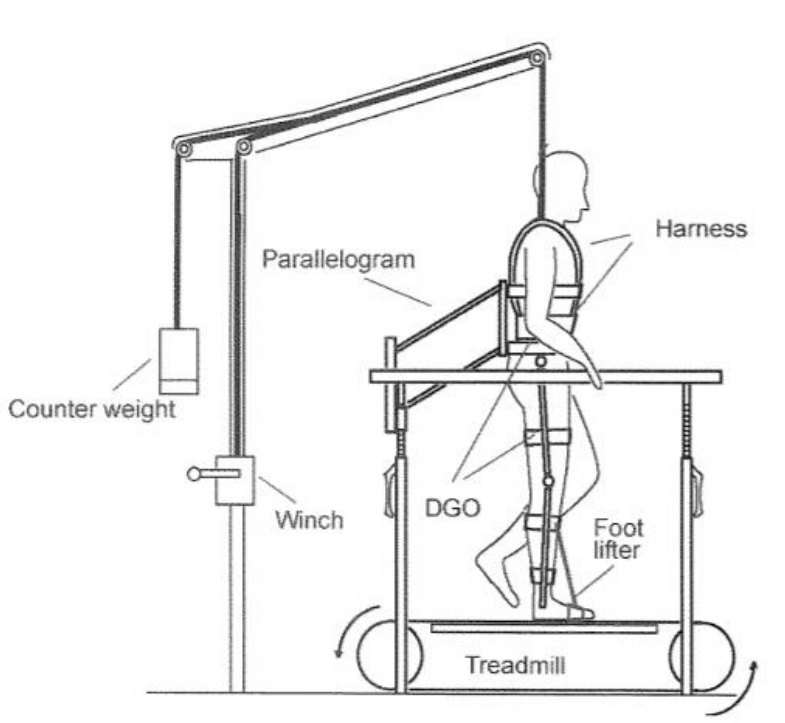
occur below the level of the lesion from peripheral afferent stimulation (Stevenson et al., 2015).

Compromised postural control is another associated sequelia with SCI, often leading to a kyphotic posture and a posteriorly tilted pelvis whilst seated. This postural adaptation facilitates a hollow body shape changing the typically S shaped spinal column to a C shape (Alm et al., 2003; Minkel, 2000). This position increases the base of support and uses the tension in passive ligament and tendon tissues around the lumbar spine to maintain an upright position with limited muscle activation and a lower energy expenditure (Janssen-Potten et al., 2001). The negative consequences associated with this postural adaptation are increased risk of back and neck pain, reduced functional lung capacity, social exclusion through the inability to communicate face to face with standing adults, reduced upper extremity mobility and increased risk of pressure sores (Alm et al., 2003; Minkel, 2000; Vette et al., 2014). Pressure sores are a direct consequence of elevated pressure over bony protuberances due to reduced regional blood flow; improvements in blood flow have been demonstrated to act preventatively as well as to facilitate healing when pressures sores occur (Regan et al., 2009). Upright stepping has the capacity to help alleviate both postural issues and the development of pressure sores. The requirement to maintain balance and postural control during upright stepping training (especially in over-ground modalities) provides a training stimulus facilitating a more upright posture. Secondly, standing and stepping reduce pressure over the bony landmarks specifically affected during sitting: the ischial tuberosities (Janssen-Potten et al., 2001; Sonenblum et al., 2014) and sacrum (Minkel, 2000), whilst also increasing regional blood flow around the gluteal muscles through up

regulation of the mechanical pumping mechanism associated with improved venous return.

2.12.2. Robotic exoskeletons

As identified by Díaz et al. (2011), various robotic exoskeleton devices have been developed to facilitate upright stepping (Figure 2.3). Although of different design and utilising different mechanisms to drive limb motion, the focus of said devices requires some standard components. Namely a structural support mechanism to provide the individual with the physical support to stand and secondly some form of mechanised limbs or platforms to provide the motion stimulus. Treadmill based systems such as the Lokomat® (Hocoma, Switzerland) consist of a harness system to support the individuals body weight, a parallelogram shaped bracket fitted between the user and the support railings of the treadmill to ensure only vertical movement of the whole body is possible to facilitate upright standing and a set of robotic lower limbs with articulated joints to function as hips, knees and ankles. The joints at the hips and knees are powered by active drive units and the movement of the ankle is essentially passive, allowing the treadmill belt to dictate ankle movement as the foot moves relative to the shank (Colombo et al., 2000).



A

B

Figure 2.3. representations of robotic exoskeletons A) the Lokomat® (Hocoma, Switzerland) adapted from Colombo et al. (2000) and B) the ReWalk™ adapted from ReWalk (2014).

Overground systems have typically followed a similar approach to design regarding the use of articulated limbs to match those of the user. The difference between these designs and the treadmill system are two-fold. Firstly, there is no body weight support system available as there is no structure available to provide said support. The robotic legs therefore have to be strong and stable enough to hold the body weight of the individual; crutches, a walking frame or parallel bars are then required for balance in most cases (Zeilig et al., 2012). Secondly, the ankle position cannot be dictated by the treadmill belt transitioning under the body, and as the risk of falling is much greater, toe clearance is of vital importance to prevent tripping. The various systems have identified different mechanisms to facilitate this movement. The ReWalk™ relies on the use of a spring-loaded mechanism to pull the foot into dorsiflexion when the heel is unloaded (Esquenazi et al., 2012), whereas the REX™ (Rex Bionics, Melbourne, Australia) is a fully automated system with ten high speed, high torque linear actuators that control all of the joints of the lower body (Lajeunesse et al., 2016). The other primary differences between the treadmill based and overground exoskeleton devices are power supply and triggering mechanism.

Treadmill based systems are for obvious reasons stationary and can therefore run off the same power supply as the treadmill itself, furthermore triggering stepping in the devices is simple as the device is required to step when the treadmill is active, as a result the drive speed of the belt will to an extent dictate the speed of movement of the robotic limbs. Overground systems require different power options with batteries being stored in back packs (ReWalk™) or within the pelvic brackets and limbs of the devices themselves, and have different charge and usage times (Lajeunesse et al., 2016). Finally,

movement triggering is facilitated using different methods within these devices. The ReWalk™ relies on the use of a tilt sensor located on the pelvic bracket to initiate stepping whereas the EKSO™ (EKSO Bionics, Richmond, California) uses weight transfer within the device and muscular input from the individual from sensor housed within the body attachments. Although a number of these devices have been in development for some years now they are still in their infancy and as technology and understanding of their capabilities improves the capacity for these devices in rehabilitation and mobility needs to be explored.

2.13. Aims and objectives

The overall aim of this thesis was to provide evidenced-based information to rehabilitation centres, healthcare professionals and researchers involved with SCI mobility with respect to both balance and upright stepping using robotic assisted gait training (RAGT) devices. The following aims, objectives and hypotheses were established for each study to ensure this overarching aim was achieved:

2.13.1. Systematic review

The aim of the systematic review in chapter 3 was to identify the most appropriate form of RAGT for individuals with either complete (cSCI) or incomplete (iSCI) spinal cord injury.

The primary objective was to identify if overground and treadmill-based RAGT systems produced different upright stepping characteristics in SCI populations.

It was hypothesised that overground RAGT systems would facilitate the appearance of more natural upright stepping in SCI individuals than treadmill-based RAGT systems.

The secondary objective was to identify any differences in the use of RAGT systems for cSCI and iSCI populations.

The secondary hypothesis was that overground systems would be most effective in a rehabilitation environment for individuals with an iSCI and that individuals with a cSCI would receive the same benefits from both overground and treadmill-based RAGT.

The final objective was to identify if an overground or treadmill-based RAGT system resulted in greater improvements in functional gait outcome measures in SCI individuals.

The final hypothesis was that overground RAGT training would result in improvements in functional gait outcome measures including greater distance walked in the six-minute walk test (6MWT) and faster times in the ten metre walk test (10MWT).

2.13.2. Balance and postural control

The aim of chapter 5 was to quantify seated postural control in thoracic SCI individuals.

The first objective of this study was to explore any relationships in 1) stability performance, 2) control demand and 3) posture with A) SCI disability level and B) fear of falling.

> It was hypothesised that individuals with a higher level of disability and/or a greater fear of falling would present with poorer seated postural stability as quantified by greater centre of pressure excursion.

The second objective was to investigate the use of an individualised limit of stability boundary during static and dynamic seated postural control tasks and to determine if it could provide useful insights into risk of falling.

> It was hypothesised that the use of the limit of stability boundary, in conjunction with centre of pressure data from static and dynamic seated tasks, would serve as indicators of falls risk.

The third objective was to assess if sagittal postures could be used to distinguish SCI injury level during quiet sitting.

> The third hypothesis was that sagittal postural angles could be used to differentiate between low- and high-injury level in thoracic SCI individuals.

The final objective was to explore the impact of injury level and fear of falling on ADL, as injuries to the thoracic spine influence an individual's capacity to utilise their core musculature.

Finally, it was hypothesised that a higher level of injury would positively correlate with a greater fear of falling and that a greater fear of falling would positively correlate with poorer self-reported scores in mobility and self-care.

2.13.3. Lower limb robotic exoskeleton gait

A series of three studies were designed to investigate the movement characteristics of robotic exoskeleton gait in chapters 6 through 8.

The aim of chapter 6 was to assess the repeatability of the primary researcher's marker placement and the adapted six degrees of freedom (6DOF) marker model, designed to facilitate 3D kinematic data collection of the whole body and the exoskeleton during LEXO use.

It was hypothesised that marker placement would be repeatable and that the use of the adapted 6DOF model would yield good levels of agreement across repeated sessions. Secondary hypotheses based on the nature of the LEXO device were that: 1) the kinematics of the LEXO device would be more repeatable than those of the user's body; 2) reliability across sessions would be high, as the novel task of stepping in the LEXO should generate high levels of variability; and 3) sagittal plane angles would present with the lowest levels of error.

The aim of chapter 7 was to compare the 3D gait parameters of able-bodied individuals walking overground with and without a LEXO at two different speeds: self-selected comfortable (CMBL) vs. slow (SLOW), speed-matched to the LEXO.

The primary objective was to evaluate the effects of the device on the temporal-spatial and whole-body kinematic gait parameters.

It was hypothesised that: 1) walking with the LEXO would alter the temporal-spatial characteristics of the gait cycle to resemble those of SLOW walking; 2) SLOW walking and LEXO gait would present with similarly reduced angles and ROM at the hip, knee and ankle (device-controlled joints) relative to CMBL walking, but that LEXO walking would elicit increased excursions of the trunk and pelvis

The secondary objective was to compare the individual GRF components with and without the device.

It was hypothesised that peak vGRFs would be similar across all three conditions despite the use of crutches (in the LEXO condition) and different walking velocities. It was however anticipated that any differences identified would be smallest between the two speed-matched conditions. It was also hypothesised that the anterior-posterior forces would be lower in the LEXO condition, because of the lack of propulsion required to move the limb into swing due to robotic control.

The overarching aim of chapter 8 was to assess whether biomechanical differences exist between able-bodied and SCI individuals during overground LEXO walking.

The first objective was to compare the temporal-spatial characteristics of the two groups.

> It was hypothesised that there would be no significant difference in the temporal-spatial variables between the two groups.

The second objective was to identify any differences in range of motion (ROM) and peak joint angles of the lower limbs between the SCI and able-bodied users, and between the LEXO device itself and its user.

> It was hypothesised that the SCI users would generate smaller ROM and peak angles (in the sagittal plane) than the SCI group, and that the SCI individuals would move within the constraints set by the motors.

The third objective was to evaluate upper body movement of the individuals, in conjunction with whole body centre of mass movement (COM) in the vertical and medio-lateral directions, as an indicator of postural control.

> It was hypothesised that the SCI group would have less COM control than the able-bodied group, which would result in greater trunk excursion angles in the sagittal and frontal planes.

The final objective was to compare the GRFs of the two groups.

It was hypothesised that there would be no difference between the able-bodied group and the individuals with a SCI as there should be no difference in walking speed.

Chapter 3 - The effects of robot assisted gait training on temporal-spatial characteristics of people with spinal cord injuries: A systematic review

Adapted from:

Hayes SC, James Wilcox CR, Forbes White HS, Vanicek N. The effects of robot assisted gait training on temporal-spatial characteristics of people with spinal cord injuries: A systematic review. *J Spinal Cord Med*. 2018;41(5):529-543. doi:10.1080/10790268.2018.1426236

3.1. Introduction

An estimated 500,000 spinal cord injuries (SCIs) occur worldwide every year (World Health Organisation, 2013b). The most life-impacting result of a spinal cord injury is paralysis or mobility impairment (DeSanto-Madeya, 2009; Field-Fote et al., 2005; Kirshblum et al., 2011; Zeilig et al., 2012). In most cases of SCI, the subsequent requirement of a wheelchair enforces the user to adopt a seated position from which activities of daily living, social interaction and mobility are undertaken (Minkel, 2000; Nooijen et al., 2009). A number of SCI comorbidities are negatively impacted by a continuously seated posture and a less active lifestyle; reduced bone mineral density (Bauman et al., 2009; Edwards et al., 2014), increased chance of pressure sores (Vette et al., 2014), reduced respiratory capacity (Minkel, 2000; Vette et al., 2014), increased risk of coronary heart disease (Bauman & Spungen, 2008) and bladder and bowel dysfunction (Benevento & Sipski, 2002). These sequelae, along with a reduced capacity for mobility, have a direct impact on the quality of life of SCI individuals (Song, 2005; Swinnen et al., 2010). There is currently no treatment that can completely restore motor and or sensory function after an SCI (Thuret et al., 2006). The primary goal of rehabilitation must therefore be to improve the quality of life for SCI individuals by

attenuating the deleterious consequences of the associated comorbidities (Gómara-Toldrà et al., 2014).

Upright mobility may have a beneficial effect on a number of SCI comorbidities, including those listed above (Mikolajewska & Mikolajewski, 2011; Swinnen et al., 2010), therefore upright locomotor training can be an effective component of physical rehabilitation for patients with a number of neurological injuries and disorders (including stroke, multiple sclerosis, cerebral palsy and SCI) (Swinnen et al., 2015). In incomplete spinal cord injured (iSCI) individuals, locomotor training has the potential to facilitate improved functional ambulation by driving neural plasticity at the spinal level, through afferent feedback to central pattern generators (Hubli & Dietz, 2013). Although voluntary movement below the level of lesion in complete spinal cord injured (cSCI) individuals cannot be recovered, the negative effects of being chair- or bed-bound are temporarily reduced through upright stepping (Hubli & Dietz, 2013). There are currently a number of locomotor training methods available to SCI individuals; these include body weight support treadmill training or overground gait training (Dobkin et al., 2006) with either manual assistance from therapists, functional electrical stimulation, robotic assisted gait training (RAGT) or a combination of these to facilitate stepping (Labruyère & van Hedel, 2014; Nooijen et al., 2009; Ramanujam et al., 2018, 2017; Thuret et al., 2006; Zeilig et al., 2012). A number of RAGT systems have been developed, both treadmill-based and overground (Díaz et al., 2011).

Limited information is available regarding physiotherapeutic gait improvement programmes (van Hedel & Dietz, 2010) and the prescription of RAGT in SCI rehabilitation in the UK. The clinical guidelines provided by the UK's National Spinal Cord Injury

Strategy Board and the National Health Service (NHS) Clinical Advisory Group only detail care from pre-admission to acute rehabilitation (2010). Other guidelines provided by various clinical bodies advise on pressure ulcer management (NICE, 2014), movement and handling of individuals with SCI (Spinal Cord Injury Centre Physiotherapy Lead Clinicians, 2013) and guidance on standing post SCI (Spinal Cord Injury Centre Physiotherapy Lead Clinicians, 2013). Information linked directly to the use of RAGT is limited to NICE medtech innovation briefings (MIB93) (2017) and in the NICE clinical guidelines for stroke rehabilitation in adults (CG162) where electromechanical gait training is advised as part of research studies (NICE, 2013). In conjunction with the limited information available from formal guidelines, there is no consensus among practitioners and clinical researchers regarding the efficacy of RAGT (Field-Fote et al., 2005) and which types of RAGT system are most beneficial for the user. Thus, it is difficult to determine which systems will provide the most appropriate treatment for each individual based on their clinical need and associated comorbidities.

A number of different RAGT systems have become commercially available and others are in development. The choice of system is often governed by availability, with the main considerations centred around user safety and the users' current capacity. Although these considerations are of the utmost importance, the potential exists for different types of RAGT systems to be more appropriate for use with specific populations due to the nature of an individuals' injury and the clinical goals of the locomotor training. Therefore, the aim of the current systematic review was to identify if overground and treadmill-based RAGT systems produced different upright stepping characteristics in SCI populations. It is acknowledged that most facilities will only possess a single RAGT system but will treat a broad spectrum of patients. Rehabilitation centres and healthcare

professionals need evidence-based information to make the most suitable choice when purchasing rehabilitation equipment. A secondary aim was to identify any differences in the use of RAGT systems for cSCI and iSCI populations. The final aim was to identify if an overground or treadmill-based RAGT system resulted in greater improvements in functional gait outcome measures in SCI individuals.

Overground RAGT requires balance and postural control to facilitate ambulation unlike treadmill-based RAGT systems where individuals can rely on the body weight support component of the system to facilitate standing (Labruyère & van Hedel, 2014). Based on this principle, the primary hypothesis of this review was that overground RAGT systems would facilitate the appearance of more natural upright stepping in SCI individuals than treadmill-based RAGT systems. The secondary hypothesis was that overground systems would be most effective in a rehabilitation environment for iSCI individuals based on the training principles of specificity, repetition and problem solving in motor learning (Field-Fote et al., 2005; Hornby et al., 2011; Levin et al., 2015) and that cSCI individuals would receive the same benefits from both overground and treadmill-based RAGT. The final hypothesis was that overground RAGT training would result in improvements in functional gait outcome measures including greater distance walked in the six-minute walk test (6MWT) and faster times in the ten meter walk test (10MWT).

3.2. Methods

A systematic computer-based search of the literature was conducted to identify studies using RAGT devices with SCI populations. Titles and abstracts were screened by two

independent reviewers using pre-defined inclusion and exclusion criteria. Quality assessment of the included papers and data extraction were completed by the same independent researchers. Upright stepping parameters were identified as walking speed, step length, cadence, stride width, toe clearance height, duration of gait cycle, duration of stance phase and duration of swing phase (Kirtley, 2006; König et al., 2014).

This systematic review was approved by the local ethics committee for the School of Life Sciences at the University of Hull (Reference number 1718031) and follows the principles of the Declaration of Helsinki.

3.2.1. Search Strategy

A search of the literature was performed for the period of January 1990 to May 2015 in the following databases: PubMed (Medline), Web of Science (Thomson Reuters), Physiotherapy Evidence Database (PEDro, Centre of Evidence-Based Physiotherapy) and the Cochrane Library (Cochrane Controlled Trials Register, Wiley Online Library). A manual search of reference lists of relevant reviews and included studies was also conducted by the same single reviewer. The search strategy was devised using the PICO (Population, Intervention, Comparison and Outcome) methodology (Boland et al., 2014). This methodology allows the search strategy to be formulated by identifying search terms under one of the four headings listed (Table 3.1). Key words and phrases were combined from the four categories using Boolean operators (AND, OR, NOT) to search each database; MeSH (Medical Subject Headings) terms were used to search PubMed and the Cochrane Library. Using the inclusion/exclusion criteria, two

researchers completed an independent screen of the collated publications to identify eligible papers based on their titles, key words and abstracts. A consensus method was used to agree the preliminarily accepted studies (van Tulder et al., 2003); full-text copies of papers were obtained and reviewed independently against the inclusion and exclusion criteria by the same two researchers.

Table 3.1. Search terms and phrases associated with each variable of the PICO methodology used in the search strategy. The Boolean operator OR was used between terms in each column and the term AND was used between columns.

Population	Intervention	Comparison	Outcome
Spinal cord injury / injuries	Lower extremity gait	Treadmill	Walking
Spinal fractures	lower limb gait	Overground	Unaided gait / walking
SCI	gait ataxia	Complete SCI	Gait / walking endurance
Paraplegia / paraplegic	Lower extremity robotics	Incomplete SCI	Temporal-spatial parameters: Speed / velocity
Quadriplegia / Quadriplegic	lower limb robotics	Physical therapy	Cadence / step rate
Paralysis	Motorised / robotic rehabilitation	Gait training	Step / stride length
	Motorised / robotic physical rehabilitation		Robotic assisted independence
	Motorised / robotic medicine		Reduced impairment to body function
	Motorised / robotic gait		Self-reported quality of Life
			Spasticity
			ROM / range of motion
			FIM / functional independence measure

3.2.2. Inclusion and exclusion criteria

The inclusion/exclusion criteria was formulated using the same PICO methodology (Boland et al., 2014).

3.2.3. Inclusion

Studies were included if:

- The population consisted of adult (18+ years) human participants with at least one group of SCI individuals (cervical, thoracic or lumbar). Studies with SCI individuals with either complete or incomplete lesions with an A – D American Spinal Injury Association (AISA) Impairment Score (Kirshblum et al., 2011) were accepted.
- They used any overground or treadmill-based robotic locomotor training system with a primary focus on gait function in or out of the assistive device.
- Comparisons were made between: conventional therapies and robotic locomotor systems, overground systems and treadmill-based systems, or cSCI populations and iSCI populations.
- Temporal-spatial gait parameters were reported. Studies may also have included variables related to quality of life, social participation, range of motion, balance, spasticity, kinematics and/or kinetics and subjective independence measures.

All forms of study design were included apart from case reports or case series in order to maximise the data available.

3.2.4. Exclusion

Studies were specifically excluded if:

- The focus was on populations of stroke or hemiplegia patients or if comparisons were made between any populations other than able-bodied and SCI individuals.
- They used only body weight support systems or orthotics with no robotic limb driving component or used functional electric stimulation in conjunction with RAGT.

- The primary outcome measure was cardio respiratory or related to bone mineral density.

3.2.5. Data Extraction

Data were extracted from each study under seven categories by the lead researcher, reference information, study design, population, intervention, comparison groups, outcome measures and results. Reference data included the year of publication, country of origin and the journal name. Population was inclusive of participant sex, mean age, injury level, American Spinal Injury Association Impairment Scale classification (AIS), time since injury, sample size, sample drop out and sample size using RAGT. Intervention recorded the device(s) used, session duration and frequency and training walking speed. Comparison groups detailed which comparisons were made by each study; either population to population, intervention types or both. The primary outcomes extracted from each study were walking speed, temporal-spatial parameters and functional walking test data. Secondary outcomes were the Functional Independence Measure-Locomotor section (FIM–L) (Stineman et al., 1994), Lower Extremity Motor Score (LEMS) (Steeves et al., 2007) and the Walking Index for Spinal Cord Injury (II) (WISCI-II) (Dittuno & Dittuno Jr, 2001).

3.2.6. Quality Assessment

Each study was evaluated using a checklist devised to assess the methodological quality of randomised and non-randomised studies (Downs & Black, 1998). The checklist comprised of 27 questions over five sections: reporting, external validity, internal validity - bias, internal validity – confounding and power. Each question was scored out

of one except questions five and 27 which were scored out of two and five respectively, with a maximum score of 32 possible. The higher the score the higher the quality of the study. Each study was assessed independently by two researchers and discrepancies were resolved by discussion.

3.3. Results

3.3.1. Search Results

The initial search returned 3252 studies (PubMed 1843, Web of Knowledge 1314, Physiotherapy Evidence Database 0 and Cochrane Library 95). Duplicate studies (396) were removed leaving 2856 papers for the first stage of review. After the initial review process based on title, keywords and abstracts 25 studies remained. A single study was identified in manual searches of the reference sections of pertinent studies. Full text copies of the remaining 25 studies were obtained for evaluation against the full inclusion exclusion criteria (Figure 1). Three of the studies were identified to have been based on the same cohort with one of the studies published prior to study completion as a preliminary report; this study was excluded from this review. The remaining two studies were included as they focused on different aspects of gait and upright stepping using the same participant cohort. A total of twelve studies were included in the final analysis.

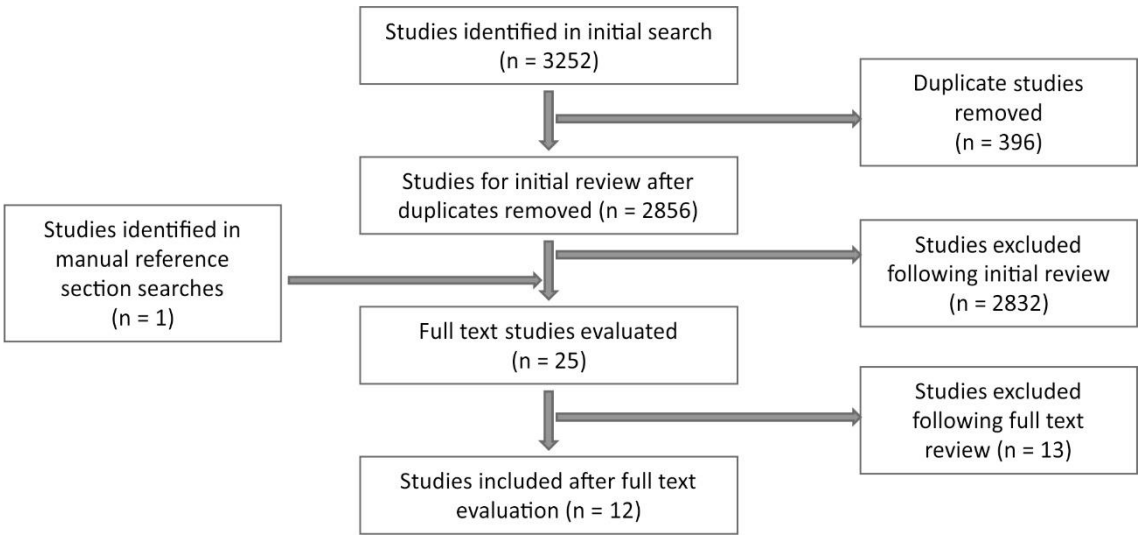


Figure 3.1. Search methodology and results PRISMA flowchart.

3.3.2. Included studies

Descriptive data of the included studies are reported in Table 3.2. There was a sum of 521 participants; 505 participants were SCI individuals and the remaining 16 were able-bodied individuals. The number of participants recruited ranged from five (Arazpour et al., 2013) to 130 (Benito-Penalva et al., 2012). Eight of the studies included participants with American Spinal Injury Association (ASIA) scores C and D (Alcobendas-Maestro et al., 2012; Benito-Penalva et al., 2012; Esclarín-Ruz et al., 2014; Field-Fote & Roach, 2011; Hornby et al., 2005; Labruyère & van Hedel, 2014; Niu et al., 2014; Varoqui et al., 2014). Hornby et al. (2005) also included SCI individuals with ASIA B and Benito-Penalva et al. (2012) included participants with ASIA A and B. The remaining three studies only included participants with ASIA levels A – B (Arazpour et al., 2013, 2014; Fineberg et al., 2013). The injury level of participants recruited ranged from C1 to L3 although one study did not report the injury levels included (Benito-Penalva et al., 2012).

Table 3.2. Study characteristics and population data for included studies.

			Population								
Study	Study type	Country of origin	Sample size (N)	RAGT users (N)	Non-RAGT users / Controls (N)	Drop out (N)	Sex	Mean age (Years)	ASIA	Injury level	TSI (years)
Alcobendas-Maestro (2012)	RCT	Spain	80	40	(40) SCI	5	M / F	47	C-D	C2-T12	0.25 - 0.5
Arazpour (2013)	CT Cross-over	Iran	5	5	(5) SCI	0	M / F	27	A-B	T6-T12	0.75 - 4.25
Arazpour (2014)	CT	Iran	7	7	(3) AB	0	M / F	28	A-B	T6-T12	0.75 - 4.25
Benito-Penalva (2012)	Longitudinal	Spain	130	46	(84) SCI	25	M / F	45	A-D	NR	NR
Esclarin (2014)	Randomised Open Control	Spain	88	44	(44) SCI	5	M / F	42	C-D	C2-L3	0.3 - 0.4
Nooijen (2009)	RCT	USA	85	12	(39) SCI (10) AB	24	M / F	38	C-D	C3-T10	>1
Field-Fote (2011)	RCT	USA	74	15	(59) SCI	10	M / F	41	C-D	C3-T10	>1
Fineberg (2013)	Cross Sectional	USA	9	6	(3) AB	0	M / F	44	A-B	T1-T11	6.25
Hornby (2005)	RCT	USA	35	10	(25) SCI	5	NR	NR	B-D	T10 ↑	<1
Labruyère (2014)	Randomised Cross-over	Switzerland	9	9	(9) SCI	1	M / F	59	C-D	C4-T11	>1
Nui (2014)	CT	USA	40	20	(20) SCI	0	M /F	46	B-D	T10 ↑	8.2
Varoqui (2014)	CT	USA	30	15	(15) SCI	0	M / F	48	C-D	T10 ↑	9.9

AB = Able-Bodied, ASIA = American Spinal Injury Association, CT = Controlled Trial, NA = Not applicable, NR = Not Reported, RCT = Randomised Controlled Trial, SCI = Spinal cord injury, TSI = Time since injury.

3.3.3. Excluded studies

Thirteen studies were excluded from this review based on the full text review process. Eight of the excluded studies were case series and three studies had no temporal spatial parameters reported. One study was excluded as no RAGT system was used and another was only a preliminary report of the work by Field-Fote and Roach (2011) and Nooijen et al. (2009).

3.3.4. Quality assessment

A quality assessment tool designed to evaluate randomised and non-randomised trials was used to assess study quality for this review as few randomised control trials have been completed in this subject area and none were identified using overground RAGT systems. The twelve studies included in the current review were independently quality assessed by both reviewers; after the initial review process differences in quality assessment scores were discussed and a consensus was reached. Table 3.3 presents the results of this assessment and overall scores for each study. The median total score for the 12 studies was 24 out of 32. The larger randomised controlled trials received the higher scores. The study by Esclarín-Ruz et al. (2014) received the highest score of 25 and the lowest score of 13 was attributed to the study by Hornby et al. (2005). The majority of studies performed poorly in reporting adverse events and in all three questions related to external validity. The three overground RAGT studies scored poorly in internal validity-confounding and power relative to the other studies.

Table 3.3. Methodological quality assessment scoring using an assessment tool for randomised and non-randomised trials (Downs & Black, 1998).

	Reporting										External Validity			Internal Validity - Bias							Internal Validity - Confounding						Power	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	
Study	Hypothesis / Aims	Outcomes	Patient Information	Interventions	Principle confounders	Findings	Variability Estimates	Adverse Events	Withdrawals	Exact Probability	Represents Population Asked	Represents Population Included	Represents Facilities	Participant Blinding	Researcher Blinding	Data Dredging Clear	Follow up Adjustments	Appropriate Statistics	Intervention Compliance	Validity & Reliability	Participant Groups from Same Population	Recruitment Groups & Time Periods	Randomisation	Hidden Randomisation	Confounding Adjustment	Withdrawal Accounted for	Power	Total Score
Alcobendas -Maestro (2012)	**1**	**1**	**1**	**1**	**1x**	**0**	**0**	**0**	**1**	**1**	**1**	**1**	**0**	**0**	**1**	**0**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**0**	**1**	**0**	**5**	**23**
Arazpour (2013)	1	1	1	1	1x	1	1	0	1	1	0	0	0	0	0	0	1	1	1	0	0	1	0	0	1	1	3	18
Arazpour (2014)	**1**	**1**	**1**	**1**	**0**	**1**	**0**	**0**	**1**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**1**	**1**	**1**	**0**	**0**	**0**	**0**	**1**	**2**	**15**
Benito-Penalva (2012)	1	1	0	1	1x	1	1	0	0	1	1	1	0	0	0	0	1	1	1	1	1	1	1	0	1	0	5	22
Esclarin (2014)	**1**	**1**	**1**	**1**	**2**	**1**	**1**	**0**	**0**	**1**	**1**	**1**	**0**	**0**	**1**	**0**	**0**	**1**	**1**	**1**	**1**	**1**	**1**	**0**	**1**	**1**	**5**	**25**
Nooijen (2009)	1	1	1	1	2	1	0	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	0	1	1	5	23
Field-Fote (2011)	**1**	**1**	**1**	**1**	**0**	**1**	**1**	**1**	**1**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**0**	**1**	**1**	**5**	**23**
Fineberg (2013)	1	1	1	1	0	1	1	0	1	0	0	0	0	0	0	1	0	1	1	1	1	0	0	0	0	1	2	15
Hornby (2005)	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**1**	**1**	**1**	**0**	**0**	**0**	**5**	**13**
Labruyèrel (2014)	1	1	1	1	2	1	1	0	0	1	0	0	0	0	1	0	0	1	1	1	1	1	1	0	0	0	3	19

	Reporting										External Validity			Internal Validity - Bias							Internal Validity - Confounding						Power	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	
Study	Hypothesis / Aims	Outcomes	Patient Information	Interventions	Principle confounders	Findings	Variability Estimates	Adverse Events	Withdrawals	Exact Probability	Represents Population Asked	Represents Population Included	Represents Facilities	Participant Blinding	Researcher Blinding	Data Dredging Clear	Follow up Adjustments	Appropriate Statistics	Intervention Compliance	Validity & Reliability	Participant Groups from Same Population	Recruitment Groups & Time Periods	Randomisation	Hidden Randomisation	Confounding Adjustment	Withdrawal Accounted for	Power	Total Score
Nui (2014)	**1**	**1**	**1**	**1**	**2**	**1**	**1**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**0**	**1**	**1**	**5**	**24**
Varoqui (2014)	1	1	1	1	2	1	1	0	0	1	0	0	0	0	0	1	1	1	1	1	1	1	1	0	1	1	5	24

1 = Yes, item addressed appropriately, 0 = No, item not addressed or unable to determine. Q5 1x = Partially addressed, 2 = item addressed appropriately

3.3.5. Interventions

Table 3.4 presents intervention information. Only three of the studies included in this review examined overground RAGT systems , one used the ReWalk™ (ARGO Medical Technologies Ltd., Yokneam, Israel) (Fineberg et al., 2013) a commercially available overground RAGT system and two used a custom-built powered gait orthosis (Arazpour et al., 2013, 2014). Nine of the studies included in this review used the Lokomat® (Hocoma AG, Volketswil, Switzerland), a commercially available treadmill-based RAGT system. The number of sessions each participant received using the RAGT system ranged from 11 to 60 across four to 24 weeks (Table 3.4). Walking speeds of the RAGT systems were set relative to the participant's capacity in eight of the twelve included studies. Two of the studies selected specific speeds, 1.5 and 2.0 km/h (Benito-Penalva et al., 2012; Hornby et al., 2005), and one of the studies did not report training speed. Population and intervention comparisons were made across the different studies, three studies compared RAGT use in SCI individuals to able-bodied controls (Arazpour et al., 2014; Fineberg et al., 2013; Nooijen et al., 2009) and two of these studies investigated overground RAGT systems. No studies were found that reported a direct comparison between overground RAGT and treadmill-based RAGT systems.

Table 3.4. Intervention data for included studies, detailing RAGT device used, outcome measures and training protocol parameters.

Study	Device	Total Number of sessions	Duration (weeks)	Training Speed	Control - Comparison Group	Outcome Measures
Alcobendas-Maestro (2012)	Lokomat®	40	8	NR	SCI - OGT	10mWT, 6MinWT, FIM-L, WISCI II, LEMS,
Arazpour (2013)	PGO	24	8	Patient centred	SCI - HKAFO SCI - IRGO	Speed recorded during testing, distance walked without stopping
Arazpour (2014)	PGO	30	6	Patient centred	AB control	Speed recorded during testing, step length, cadence, Joint ROM
Benito-Penalva (2012)	Lokomat®	40	8	1.5 km/h	SCI - Gait Trainer	10mWT, WISCI II, LEMS
Esclarin (2014)	Lokomat®	40	8	Patient centred	SCI - OGT	10mWT, 6MinWT, FIM-L, WISCI II, LEMS
Nooijen (2009)	Lokomat®	50	12	As fast as possible	SCI - TM+PT SCI - TM+ES SCI - OGT +ES AB control	Cadence, step length, stride length, symmetry index, intra-limb coordination, timing of knee extension onset
Field-Fote (2011)	Lokomat®	60	12	As fast as possible	SCI - TM+PT SCI - TM+ES SCI - OGT +ES	10mWT, 2MinWT, LEMS
Fineberg (2013)	ReWalk™	11-41	20-24	Patient centred	AB control	Speed recorded during testing, vGRF
Hornby (2005)	Lokomat®	24	8	2.0 km/h	SCI - TM BWS+PT SCI - BWS OGT	10mWT, 6MinWT, FIM-L, WISCI II, LEMS, TUG
Labruyère (2014)	Lokomat®	16	4	1-2 km/h	SCI - Strength training	10mWT, gait symmetry, WISCI II, LEMS, BBS
Nui (2014)	Lokomat®	12	4	1.5 – 3.4 km/h	SCI - Control group	10mWT, 6minWT, TUG, ankle MVC
Varoqui (2014)	Lokomat®	12	4	1.5 – 3.0 km/h	SCI - Control Group	10mWT, 6minWT, TUG, ankle ROM and ankle MVC

AB = Able-Bodied, BBS = Borg Balance Scale, BWS = body weight support, ES = electrical stimulation, FIM-L = Functional independence measure – Locomotor section, HKAFO = Hip knee ankle foot orthosis, IRGO = Isocentric reciprocating gait orthosis, LEMS = Lower Extremity Motor Score, MVC = Maximal Voluntary Contraction, NR = not reported, OGT = Overground Gait Training, PGO = Powered Gait Orthosis PT = Physiotherapist, ROM = Range of Motion, TM = treadmill, TUG = Timed Up and Go, WISCI II = Walking Index for Spinal Cord Injury, 10mWT = 10 meter timed walk test, 2minWT = 2 minute walk test, 6minWT = 6 minute walk test. Gait Trainer = a cable driven platform step simulating gait training device

3.3.6. Walking speed

Walking speed was recorded as an outcome measure in all of the studies and reported in eleven of the studies (speed and distance walked were reported in Field-Fote and Roach (2011) but not in Nooijen et al. (2009) as the two studies reported different aspects of the same data set). Eight studies provided walking speed based on the 10mWT; each of these reported walking speed pre- and post-intervention and demonstrated an increase in speed irrespective of the intervention method (Table 3.5). Hornby et al. (2005) did not find any significant differences between interventions in speed and did not report any values. The three studies that focused on overground RAGT systems recorded speed during their respective data collection procedures and not as part of a standardised test.

Table 3.5. Average walking speed for treadmill and overground RAGT and control groups.

Study (Treadmill RAGT)	Walking Speed (m/s)					
	RAGT			Control		
	Pre	Post	Diff	Pre	Post	Diff
Alcobendas-Maestro (2012)	0.3*	0.4*	0.1	0.3*	0.3*	0.0
Benito-Penalva (2012)	0.06	0.25	0.19	0.09	0.28	0.18
Esclarin (2014)	0.36	0.47	0.11	0.32	0.42	0.10
Field-Fote (2011)	0.17	0.18	0.01	0.18	0.24	0.06
Labruyère (2014)	0.62	0.66	0.04	0.58	0.64	0.06
Nui (2014)	0.48	0.56	0.08	0.53	NR	NA
Varoqui (2014)	0.56	0.64	0.08	0.56	NR	NA
Hornby (2005)	No significant differences between groups (data NR)					

Study (Overground RAGT)	SCI		Control	
Arazpour (2013)	RAGT	0.35	HKAFO	0.23
			IRGO	0.25
Arazpour (2014)	SCI RAGT	0.40	AB Control	1.22
			AB RAGT	0.87
Fineberg (2013)	Min assist	0.16	AB Control	1.36
	No assist	0.31		

AB = Able-Bodied, HKAFO = Hip knee ankle foot orthosis, IRGO = Isocentric reciprocating gait orthosis, NA = Not applicable, NR = Not Reported, Min = Minimum.

** Only reported to 1 decimal place.*

The values reported are averages for all participants associated with each group irrespective of completeness or level of injury.

The average walking speeds reported by Arazpour et al. (2013, 2014) for the SCI individuals using the overground RAGT system were greater than either SCI group in the study by Fineberg et al. (2013). The average post-intervention walking speed reported for cSCI individuals only in the study by Benito-Penalva et al. (2012) was 0.207 m/s; this was slower than the participants who walked without assistance in all three overground RAGT studies. It was however faster than the ReWalk™ walking speed for the group requiring minimal assistance (Fineberg et al., 2013). Further comparison is difficult as time since injury and injury level were not reported by Benito-Penalva et al. (2012).

3.3.7. Walking distance

Walking distance was reported by seven of the 12 studies (Table 3.6). Hornby et al. (2005) reported that no significant difference existed between groups but did not provide any data to support this claim. Two of the remaining studies showed a significant increase in walking distance after RAGT-use compared to traditional overground gait training ($p < 0.05$ and $p = 0.047$, (Alcobendas-Maestro et al., 2012; Esclarín-Ruz et al., 2014) respectively, and two of the studies showed no significant between-group differences (Niu et al., 2014; Varoqui et al., 2014). Field-Fote and Roach (2011) recorded the distance walked over a two-minute time period and found that non-RAGT overground gait training produced a significant improvement in walking distance whereas RAGT use did not. Walking distance was only reported by a single study for overground RAGT systems; cSCI participants using the overground RAGT were able to walk approximately a third further (120 meters) when compared to using a non-powered reciprocating gait orthosis (90 – 96 meters) (Arazpour et al., 2013).

Table 3.6. Walking distances from studies reporting distance of treadmill or overground RAGT groups and control groups.

Study	Walking Distance (m)					
	RAGT			Control		
	Pre	Post	Diff	Pre	Post	Diff
Alcobendas-Maestro (2012)	110.1	169.4	59.3	82.3	91.3	9.0
Esclarin (2014)	102.5	172.51	70.01	93.8	132.52	38.72
Field-Fote & Roach (2011)	16.8	17.9	1.2	22.2	28.6	6.4
Nui (2014)	160.84	165.20	4.36	163.22	NR	NA
Varoqui (2014)	206.96	208.87	1.91	205.6	NR	NA
Hornby (2005)	No significant differences between groups (data NR)					
Study (Overground RAGT)	SCI			Control		
Arazpour (2013)	RAGT	120		HKAFO	90.2	
				IRGO	96.4	

Diff = Difference, HKAFO = Hip knee ankle foot orthosis, IRGO = Isocentric reciprocating gait orthosis, NA = Not applicable, NR = Not Reported.

3.3.8. Stepping characteristics

Three studies measured temporal-spatial parameters other than walking speed (Table 3.7). Cadence and step length were reported by two studies (Arazpour et al., 2014; Nooijen et al., 2009) and symmetry was reported by Nooijen et al. (2009) and Labruyere and van Hedel (2014). Arazpour et al. (2014) reported average cadence and step length for each group identifying a reduced cadence and step length compared to able-bodied normal walking. Furthermore, they demonstrated that step length was restricted by the RAGT system but that cadence was controlled by the individual as able-bodied individuals using the RAGT had an increased cadence compared to normal walking (Table 3.7). Nooijen et al. (2009) did not report values for cadence and step length but provided the average differences for pre- and post-intervention. However, the results in Table 3.7 suggest that the treadmill-based RAGT system was less effective at maximising stepping characteristics than the other interventions used. Nooijen et al. (2009) identified significantly reduced cadence for SCI individuals pre- and post-training and a significantly shorter step length was identified for the weaker leg pre-training, which was consistent with the study by Arazpour et al. (2014). No significant differences were identified between pre- and post-training interventions in either study reporting symmetry data (Labruyère & van Hedel, 2014; Nooijen et al., 2009) (Table 3.7).

Table 3.7. Stepping characteristics of SCI and able-bodied controls from those studies reporting temporal-spatial data other than walking speed.

Study	Stepping Characteristics		
	Cadence (steps/min)		
Arazpour (2014)	SCI RAGT	49	
	AB Control	90	
	AB RAGT	106	
	Cadence (steps/min) pre-post intervention difference		
Nooijen (2009)	RAGT	↑1.5	AB vs SCI
	TM+PT	↑2.3	SCI took significantly less steps both pre- and
	TM+ES	↑3.9	post-training
	OGT +ES	↑5.0	
	Step Length (cm)		
Arazpour (2014)	SCI RAGT	44.15	
	AB Control	62.66	
	AB RAGT	49.00	
	Step Length (cm) pre-post intervention difference		
Nooijen (2009)	RAGT	≤0.01	AB vs SCI
	TM+PT	↑2.3	SCI took significantly shorter steps with the
	TM+ES	↑3.9	weaker leg pre-training in RAGT group. Post-
	OGT +ES	↑5.0	training weaker and pre- and post- with
			stronger (e.g., no significant differences).
	Symmetry Index pre-post intervention difference		
Labruyère (2014)	RAGT	↑0.02 (pre 0.91 post 0.93)	
	ST	↑0.03 (pre 0.93 post 0.96)	
	6-month Follow Up	0.92	
Nooijen (2009)	No significant difference identified		AB vs SCI
	pre- and post-training		SCI symmetry significantly lower pre-training.
	p > 0.05		Post-training no significant difference

ES = Electrical Stimulation, OGT = Overground Gait Training, PT = Physiotherapist, ST = strength training, TM = Treadmill, ↑= increase.

3.3.9. Functional gait measures

Table 3.8 presents the results of the functional measures used in each study to assess physical improvement and gait quality. The LEMS was reported by six studies and all demonstrated an increase in score post-training irrespective of the intervention type. The WISCI-II was reported by five studies producing similar findings to the LEMS. All studies showed an increase in WISCI-II score post-intervention. The results for these two measures provided by Labruyère & van Hedel (2014) did not show the marked improvents seen in the other studies. This is most likely due to the higher scores

achieved prior to intervention; the pre intervention scores reported by Labruyère & van Hedel (2014) are greater than the majority of scores reported by the other studies post intervention. Only three studies used the FIM-L; all three demonstrated an improvement post-intervention. No functional measures were used by any of the studies that used an overground RAGT system.

Table 3.8. Change in functional outcome measure scores reported by treadmill-based RAGT studies.

Study	LEMS		WISCI-II		FIM-L	
	RAGT	Control	RAGT	Control	RAGT	Control
Alcobendas-Maestro (2012)	↑7	↑5	↑12	↑5	↑6	↑3
Benito-Penalva (2012)	↑7.1	↑9.3	↑5.3	↑5.1	NM	
Esclarin (2014)	↑7.2	↑3.9	↑7.0	↑6.0	↑3.4	↑2.9
Field-Fote (2011)	↑1.2	↑1.4	NM		NM	
Hornby (2005)	Significant increase for all modalities (data NR)		Significant increase for all modalities (data NR)		Significant increase for all modalities (data NR)	
Labruyère (2014)	↑0.7	↑1.0	↑0.8	↑0.4	NM	

FIM-L = Functional Independence Measure – Locomotor section, LEMS = lower extremity motor score, NM = not measured, WISCI-II = Walking Index for Spinal Cord Injury, ↑= increase.

3.4. Discussion

The primary aim of this review was to identify if overground or treadmill-based RAGT systems produced different upright stepping characteristics in SCI individuals. The limited number of studies included in this review, that focused on the use of overground RAGT systems, and the low quality scores of said studies, highlight that the evidence related to the use of overground RAGT is limited. A recent systematic review into gait speed in overground RAGT use only identified a total of 106 independent studies of which 15 were deemed eligible for inclusion but none of these were randomised controlled trials (Louie et al., 2015). A larger body of evidence on the use of treadmill-based RAGT systems was available, however comparisons across studies were still

limited due to the differences in participant demographics and training protocols. The single temporal-spatial parameter reported by all of the studies included in the current review was walking speed and even this was measured using different methods. The treadmill-based RAGT studies all measured walking speed using a 10mWT whereas the overground based studies all measured walking speed over different distances. Further temporal-spatial characteristics were only reported by three of the included studies limiting the conclusions that could be drawn on the effectiveness of the different RAGT devices to improve stepping characteristics. As a result of these limitations it is not possible to accept or reject the primary hypothesis about whether overground RAGT systems encourage the appearance of a more stereotypical upright stepping pattern compared to treadmill-based RAGT systems.

The secondary aims of this review were to identify any differences in the use of RAGT systems with respect to the completeness of injury and to identify if any differences were evident between treadmill and overground RAGT systems relative to functional outcome measures post-training. Research into the use of treadmill-based RAGT is predominantly focused on the iSCI populations and no studies using overground RAGT based systems were identified by this review that recruited iSCI individuals. The novel concept that overground RAGT systems have been designed as functional mobility aids for everyday use (Chen et al., 2013) has dominated the scope of the research into these devices rather than their capacity in rehabilitative therapy. As such, research has tended to focus on safety and functional capacity of the device (Esquenazi et al., 2012; Zeilig et al., 2012) rather than the potential for rehabilitation. More research investigating the use of RAGT systems in iSCI vs cSCI is warranted.

3.4.1. Temporal-spatial characteristics

Walking speed as an indicator of walking capacity in populations with mobility deficits has been well documented (Fritz & Lusardi, 2009; Schmid et al., 2007; van Hedel, 2008). Standardised methods of assessment such as the 10mWT have been developed, their level of reliability and validity must be reported according the specific clinical population. Validity and reliability data are available for different populations including SCI (Bohannon, 1997; Lam et al., 2008; Schmid et al., 2007). The larger and higher scoring methodological studies included in this review (predominantly those focusing on treadmill RAGT systems) used the 10mWT as an outcome measure for walking speed. Four of the studies found no significant difference in walking speed between the RAGT training interventions and the more conventional training methods (Alcobendas-Maestro et al., 2012; Benito-Penalva et al., 2012; Esclarín-Ruz et al., 2014; Hornby et al., 2005). However, Field-Fote and Roach (2011) and Labruyère and van Hedel (2014) found the RAGT to be less effective than the alternative methods. This suggests that the use of treadmill-based RAGT is no better than conventional gait training methods to improve walking speed. Two studies compared treadmill RAGT use to control groups with no intervention. Varoqui et al. (2014) found the use of treadmill RAGT training to have a significant impact on walking speed with an increase of 0.08 m/s (Table 3.5) equivalent to 13.4%. Although Niu et al. (2014) showed an overall improvement in walking speed, they explicitly differentiated between individuals with high and low walking capacity and advocated the use of RAGT in individuals with a higher functional capacity. This approach to identifying patients based on high or low walking capacity would exclude the use of treadmill RAGT in cSCI populations.

The 10mWT completed in the treadmill RAGT studies was always carried out overground and without the aid of robotic devices, however individuals were able to use orthotics and walking aids (i.e. elbow crutches) to facilitate ambulation. Conversely, the overground RAGT studies always measured walking speed with the device. Arazpour et al. (2014) calculated the average speed of five trials over a six-meter walkway. Fineberg et al. (2013) calculated walking speed for each individual once participants were capable of ambulating ten meters using the RAGT system without pausing and Arazpour et al. (2013) measured walking speed around a 40-meter rectangular walkway. All of the SCI participants had complete injuries and would not have been able to ambulate without some form of mechanical assistance. The principles of motor learning may have played a substantial role in the outcome of these results (Hubli & Dietz, 2013). Participants in the treadmill-based studies may not have performed as well in an overground walking test due to task specificity.

Categories of functional ambulation post-SCI have been identified, with specific walking speeds used to define thresholds for each (van Hedel, 2008). The SCI participants not requiring assistance in the overground RAGT studies achieved average speeds between 0.31 - 0.4 m/s (Table 3.5). These speeds were below the threshold of 0.44 m/s that differentiates someone who can ambulate outdoors with aid from someone who can walk indoors but is dependent upon a wheelchair outdoors. Only four of the studies using treadmill-based RAGT systems reported speeds that were above this threshold post intervention, however the initial average walking speed for three of these four studies was already faster than 0.44 m/s (Table 3.5). Although faster walking speed was identified by most of the studies included in this review, no rehabilitation modality

enabled a large enough improvement to facilitate community ambulation in participants below the 0.44 m/s threshold.

This review identified limited evidence of other stepping characteristics reported during and post-RAGT use in SCI individuals. The nature of the overground RAGT systems and the requirement for the user to shift their own body weight in order to initiate and or control ambulation can impact stepping characteristics such as step length, cadence, stance and swing time (Esquenazi et al., 2012; Zeilig et al., 2012). The body weight support component and passive, cyclic, predefined movements produced by a treadmill-based RAGT system using a trajectory control strategy (Chen et al., 2013) will eliminate natural variation in stepping characteristics (Fleerkotte et al., 2014; Hidler et al., 2008). Field-Fote and Roach (2011) found that the use of the treadmill-based RAGT system was the only modality they tested not to show an increase in walking speed post-training and similarly Nooijen et al. (2009) found that the RAGT group showed the least improvement in cadence and step length. Field-Fote and Roach (2011) suggested that training should potentially focus on repetitive step initiation rather than taking advantage of afferent activation of the spinal locomotor centres being triggered by the continuous movement of the treadmill belt. Although overground RAGT still uses a trajectory control strategy to move the lower limbs, balance and postural control of the upper body are needed to maintain smooth ambulation. This suggests that the use of overground RAGT, in conjunction with other rehabilitative modalities, such as strength training may be an effective strategy for gait rehabilitation in iSCI individuals.

3.4.2. Functional outcomes

Six treadmill-based RAGT studies reported distance walked as a functional outcome; only one overground RAGT study reported walking distance. Alcobendas-Maestro et al. (2012) and Esclarin et al. (2014) both found treadmill RAGT training produced larger improvements in walking distance than conventional overground gait training. The remaining four studies did not find treadmill RAGT to elicit any increase in walking distance (Table 3.6). Field-Fote and Roach (2011) used a two-minute walk test, instead of the six-minute test used by the other studies. Consequently, direct comparisons were not possible as fatigue may have had an effect. Mechanical or reciprocating gait orthoses have been designed to enable paraplegic individuals to ambulate. In some cases, without their assistance, walking would not be possible; however, they have been shown to produce an inefficient gait with high energy costs (Massucci et al., 1998). The use of overground RAGT systems can significantly reduce the energy costs of walking for the SCI population resulting in an increase in walking distance and ambulation time (Arazpour et al., 2013).

None of the overground RAGT based studies provided data on any other functional outcome measures. A number of the treadmill-based RAGT studies provided results from functional outcome measures that demonstrated an increase in capacity irrespective of rehabilitation modality (Table 3.8). Although balance is an important component of walking, only one study included in this systematic review presented data from a clinical balance measure, Berg balance scale (Labruyère & van Hedel, 2014). They identified no significant differences in balance between treadmill RAGT and strength training. The body weight support component of treadmill RAGT prevents the possibility

of individuals falling, thus minimising the requirement of balance control (Labruyère & van Hedel, 2014), unlike in overground RAGT where balance is constantly required to initiate and maintain stepping.

3.4.3. Clinical implication

The general consensus from this systematic review is that the use of RAGT, in any form, can be positive for both cSCI and iSCI individuals as long as it is not used as the sole rehabilitation method. The secondary hypotheses can therefore be partially accepted as cSCI individuals will receive the same benefits in terms of gait training from both system types and RAGT can be part of a rehabilitation programme leading to improved functional gait outcomes. Evidence suggests that specificity is one of the most important factors of gait training. Both the highest and lowest scoring studies in this review identified the potential benefits of the stimulation of central pattern generators in the spinal locomotor centres that can lead to positive neural plastic changes (Esclarín-Ruz et al., 2014; Hornby et al., 2005). Esclarín-Ruz et al. (2014) Alcobendas-Maestro et al. (2012) and Labruyère and van Hedel (2014) also identified strength increases as one of the key contributors to improved gait in iSCI individuals.

Passive movement has been identified as a potential limitation for RAGT both by a number of studies included (Field-Fote & Roach, 2011; Labruyère & van Hedel, 2014; Nooijen et al., 2009) and excluded from this review (Fleerkotte et al., 2014; Lam et al., 2011; Ramanujam, Cirnigliaro, et al., 2017). Adaptive programmes providing resistance to movement at specific phases of the gait cycle are now possible in treadmill-based RAGT systems (Duschau-Wicke et al., 2010; Lam et al., 2011). This development

encourages patient engagement during rehabilitation and has the potential to introduce task variability, facilitating motor learning (Hidler et al., 2008; Labruyère & van Hedel, 2014; Ramanujam, Cirnigliaro, et al., 2017).

The practical implications of the different types of RAGT systems have been acknowledged from two perspectives which may be relevant to clinicians. Field-Fote and Roach (2011) suggested that overground walking was potentially a more cost effective and appropriate intervention as the equipment was cheaper than a RAGT system. However the use of RAGT reduces the number of staff required to train a single patient, limits the physical exertion by therapists, and allows for longer and more intense training sessions (Hornby et al., 2005).

3.4.4. Strengths and limitations

The strengths of this systematic literature review include identifying and evaluating studies related to RAGT use in SCI populations and providing an up to date overview of the current literature. The use of a methodological assessment tool has enabled study quality to be quantified, thereby identifying research strengths and areas of good practice such as the use of valid and reliable data collection tools, excellent intervention compliance and clear outcome reporting. Furthermore, the identification of areas of poor practice, with associated limitations, have been highlighted, focusing on the reporting of adverse events and external validity, specifically associated with the representation of the entire population. The limitations of this review are predominantly related to the small number of research studies in this field, the varied outcome measures used by researchers working with SCI populations and the number of papers

excluded based on the lack of temporal-spatial data. As such it was difficult to answer fully some of the aims presented at the start of this review. Finally, overground RAGT studies appear to be in their infancy and more research needs to be undertaken relative to their capacity as rehabilitative devices.

3.5. Conclusion

The evidence discussed above suggests that RAGT has the potential to provide SCI individuals with benefits related to upright locomotion. However, there is no consensus about which systems are most effective for particular patient groups based on temporal-spatial characteristics alone. The use of RAGT in SCI rehabilitation appears to have a number of positive effects beyond the scope of this review, but the most important and clinically meaningful finding is that RAGT should be used as part of a multi-modality rehabilitation approach and not as a replacement for other therapies.

3.6. The impact of this systematic review on the remainder of this thesis

The undertaking of this systematic review made it clear that there was an obvious lack of investigation into the efficacy and use of overground exoskeletons in the literature. The primary focus of existing work appeared to be on safety and tolerance of use rather than the rehabilitative or mobility capacity of the devices. Furthermore, there was a lack of consensus regarding the methods of collecting and reporting outcome measures and a paucity of data related to temporal-spatial parameters in RAGT studies. The low quality scores attributed to the overground RAGT studies was highlighted and it was also noted that an important difference between overground and treadmill based systems was the

requirement to balance. The remainder of the work in this thesis was partially shaped by these outcomes. To tackle the issue of poor quality scores related to overground studies a repeatability study was devised and implemented to ensure the data collection procedures during RAGT use were robust. Secondly, temporal-spatial data were included in each of the RAGT studies and was clearly reported. The movement of the individual rather than the device was also identified as a primary focus in order to investigate whether the device was able to generate a movement pattern representative of normal gait, therefore, providing appropriate afferent stimulation to the spinal cord.

Chapter 4 - General methods, equipment and outcome measures

4.1. Introduction

The methods section of this thesis will detail the general procedures followed throughout, including ethical approval, participant inclusion/exclusion criteria and the equipment and measures used for each empirical study. The specific testing protocols for normal walking and LEXO walking will be described. Three dimensional model building and data processing will be explored, however data analysis procedures are detailed in the methods sections of relevant chapters. The specific protocols used for the postural control chapter will be detailed within the chapter itself.

4.2. Ethical approval

These studies were reviewed and approved by the Sport, Health and Exercise Sciences research ethics committee at the University of Hull in March 2015 (Application numbers: gait-based studies, 1415213 and postural control study 1516175). The participant information and informed consent documents (Appendix 1) can be found at the end of this thesis. Able-bodied participants were recruited from the local community by word of mouth. Spinal cord injured (SCI) individuals were identified and approached initially by the lead physiotherapist and robotic gait trainer at Cyclone Mobility (Sunk Island, East Yorkshire) as per local research ethics committee approval. All participants fulfilled the inclusion and exclusion criteria detailed below in order to be eligible for study involvement.

4.3. Inclusion criteria

Inclusion criteria are presented for all participants involved in this thesis. The gait-based studies required able-bodied participants and spinal cord injured (SCI) exoskeleton users. The postural control based study again required able-bodied individuals and SCI individuals however exoskeleton use and experience was not included in the inclusion or exclusion criteria in the postural control study to try and increase the pool of viable participants.

4.3.1 Gait studies

Spinal cord injured individuals were included in the gait studies if they had suffered from a motor-complete SCI (ASIA A - B) at T2 or below, were aged 18-60 years with the capability to travel to the Human Performance Laboratory at the University of Hull for a single testing session lasting approximately 4 hours. Individuals were required to measure 155-190 cm in height and have a mass of less than 100 kg based on ReWalk™ design and safety requirements and to ensure they would fit in the exoskeleton. Individuals had to be an experienced user of the ReWalk™ (defined as a user capable of completing the basic skill assessment defined by RW with a minimum of 20 hours' previous use) and were capable of transferring between stable level surfaces. Individuals must have been able to tolerate upright positioning for at least 30 continuous minutes, without experiencing light headedness, a drop in blood pressure or other adverse reactions to ensure minimal risk of orthostatic hypertension. Finally, participants were required to have arm, trunk and some hand function.

Able-bodied participants were required to be healthy, with no musculoskeletal injuries, aged 18-60 years, between 155-190 cm in height and have a mass of less than 100 kg. They were not expected to have any prior experience with the ReWalk™.

4.3.1. Postural control studies

Spinal cord injured individuals included in the postural control study were required to meet the same inclusion criteria as those individuals recruited for the gait studies with one exception. Individuals were not required to have experience of robotic exoskeleton. Able-bodied individuals were required to fulfil the same requirements as those involved in the gait studies but were age, height and weight matched to the SCI participants as closely as possible.

4.4. Exclusion criteria

Participants were excluded from all experiments if they suffered from any form of life-limiting illness or disorder other than SCI (e.g., cancer and neurological disorders); were osteoporotic as defined by a T-score of -2.5 SD below the bone mineral density of a young healthy adult; had a lower limb fracture in the past 2 years; experienced damage to the integumentary system; had a history of stroke and/or abnormal blood pressure regulation; or were unable to complete 20 minutes of moderate physical activity. The following exclusion criteria were observed for the gait studies: severe spasms (Ashworth score of 4.0), or flexion contractures at the hip and knee (limited to 35 and 20 degrees respectively) or a lower limb length discrepancy of more than two centimetres.

4.5. Participant demographics

4.5.1 Gait based studies

A total of twelve participants took part in the gait-based studies in this thesis: eight able-bodied (n=8, 5 males and 3 females) and four SCI individuals (n=4, 3 males and 1 female). Participant characteristics for the gait-based studies are presented in Table 4.1. All participants gave written informed consent prior to testing and were re-consented prior to each follow-up session. The studies in this thesis were completed using a sample of convenience due to the limited number of experienced ReWalk™ users available to attend testing in Hull. At the time of testing, Cyclone Mobility Ltd. was the sole supplier and trainer of ReWalk™ exoskeletons in the UK. The UK ReWalk™ trainer was physiotherapist Matt White, based on clinical notes from the time he reports a total of 20 individuals in the UK with a SCI that were trained and sufficiently experienced to partake in the study by the end of the testing period. Two of which lived in Yorkshire (one of whom was unable to partake due to injury), two in the Manchester area and one in the Lincolnshire area who were all approached and consented for the study. All consented participants completed the entire protocol.

Table 4.1. Participant characteristics for gait-based studies

Participant Number	Designation	Age	Gender	Height (cm)	Body Mass (kg)	Injury Level
LEXO AB 1	AB	30	Male	174.1	90.2	N/A
LEXO AB 2	AB	26	Male	169.0	77.8	N/A
LEXO AB 3	AB	28	Male	170.5	67.5	N/A
LEXO AB 4	AB	23	Female	165.0	71.5	N/A
LEXO AB 5	AB	23	Female	177.2	77.9	N/A
LEXO AB 6	AB	42	Male	177.8	77.4	N/A
LEXO AB 7	AB	26	Male	171.4	72.6	N/A
LEXO AB 8	AB	24	Female	172.1	77.9	N/A
Mean (SD)		**27.75 (6.25)**		**172.13 (4.24)**	**76.6(6.7)**	
LEXO SCI 1	SCI	40	Female	177.8	55.0	ASIA A (T9)
LEXO SCI 2	SCI	50	Male	175.0	77.0	ASIA B (T4)
LEXO SCI 3	SCI	21	Male	178.0	60.1	ASIA B (T10)
LEXO SCI 4	SCI	32	Male	193.0	71.5	ASIA A (T5)
Mean (SD)		**35.75 (10.64)**		**180.95 (7.06)**	**65.9 (8.8)**	

Prior to testing all participants were contacted and asked to bring tight-fitting shorts or leggings and a tight-fitting t-shirt, if participants did not have either of these items they were provided by the principle investigator. All participants were asked to bring socks for the LEXO sessions but shoes were provided so as not to damage the participants' own footwear. Able-bodied participants were asked to wear trainers for their normal gait session. Able-bodied participants were requested to attend the laboratory on several occasions; once for a normal comfortable and slow speed gait analysis session and twice for LEXO gait sessions. Spinal cord injured participants were only requested to attend the laboratory on one occasion for a LEXO gait session.

4.5.2. Postural control study

A total of twelve participants were recruited for this study: eight SCI individuals, separated in to high- (n = 6) and low-level (n = 2) injury groups (defined as high-level at or above T8, (Minkel, 2000)) and four able-bodied individuals (age, height and weight matched). Participant characteristics are presented in Table 4.2. All participants gave written informed consent prior to testing. A sample of convenience was used for this study due to the limited number of individuals eligible for recruitment. All participants were asked to bring a tight fitting t-shirt for testing. If participants did not have a suitable shirt the principal investigator provided one. All participants were required to attend the laboratory for a single testing session lasting approximately two hours.

Table 4.2. Participant characteristics for the postural control study

Participant Number	Designation	Age	Gender	Height (cm)	Body Mass (kg)	Injury Level
PC1	SCI High	47	male	178	90	T5 (ASIA A)
PC2	SCI High	41	male	173	76	T4 (ASIA B)
PC3	SCI High	50	male	175	77	T4 (ASIA B)
PC4	SCI High	55	male	176	89	T4 (ASIA B)
PC5	SCI High	47	female	168	48	T6 (ASIA B)
PC6	SCI Low	58	male	182	79	T12 (ASIA C)
PC7	SCI Low	58	female	155	62	T9 (ASIA B)
PC8	SCI High	24	female	163	92	T2 (ASIA B)
Mean (SD)		**47.5 (10.5)**		**171.3 (8.2)**	**76.6 (14.2)**	
PC9	AB	45	male	178	77	N/A
PC10	AB	47	female	158	96	N/A
PC11	AB	51	male	172	75	N/A
PC12	AB	25	female	178	71	N/A
Mean (SD)		**42 (10.0)**		**171.5 (8.2)**	**79.8 (9.6)**	

4.5.3. Height and Mass

The height of all able-bodied participants was recorded in the laboratory using a free-standing stadiometer (SECA, Germany). Participants were instructed to remove their shoes and stand on the stadiometer where their head was positioned in the Frankfurt horizontal plane, defined as a line from the tragus of the ear through the inferior orbital rim, parallel to the floor (Stewart et al., 2011). Body mass of all AB participants was identified from the static trial when participants stood motionless on one of the force plates (Kistler, GmbH, Winterthur, Switzerland). Body weight was measured in Newtons (N) and converted into mass (kg) by dividing the value in N by 9.81 m/s^2. As such the body mass of all able-bodied participants was measured in the clothing and footwear they were tested in. The height and body mass of the SCI individuals was determined using the following methods. Height was determined using a tape measure (SECA, Hamburg, Germany) while the participant lay prone on a treatment table. Body mass (kg) was again calculated from the body weight (N) derived from the force plate (AMTI, Massachusetts, USA) reading of the individual in their wheelchair minus the weight of a force plate reading of the wheelchair only.

4.6. ReWalk™

The ReWalk™ (Figure 4.1) is a wearable robotic exoskeleton which provides support and power to the lower limbs enabling SCI individuals to stand and walk (ReWalk, 2016). It is comprised of a rigid pelvis-like structure that links the two robotic limbs. Each limb consists of thigh and shank segments with motors that drive the hip and knee through pre-programmed angles; step time is programmed to take between 600 and 1500 ms

dependent on user experience. The footplates are designed to fit inside the individual's shoes and articulate with the shank segments via a spring loaded mechanism that facilitates dorsiflexion (Esquenazi et al., 2012; Zeilig et al., 2012). The ReWalk™ is powered by a battery pack and control unit carried in a backpack by the individual; commands are relayed to the control unit via a wireless wrist strap device. Once the ReWalk™ has received a command to walk, movement is initiated by the user. A tilt sensor located on the left pelvic support detects the individual's upper body orientation which in turn activates motors at the hip and knee to drive the leg forward (Díaz et al., 2011; Fineberg et al., 2013; ReWalk, 2016; Spungen et al., 2013; Zeilig et al., 2012). The user is required to use crutches or parallel bars to maintain balance and facilitate clearance for the swinging leg during ambulation (Zeilig et al., 2012).

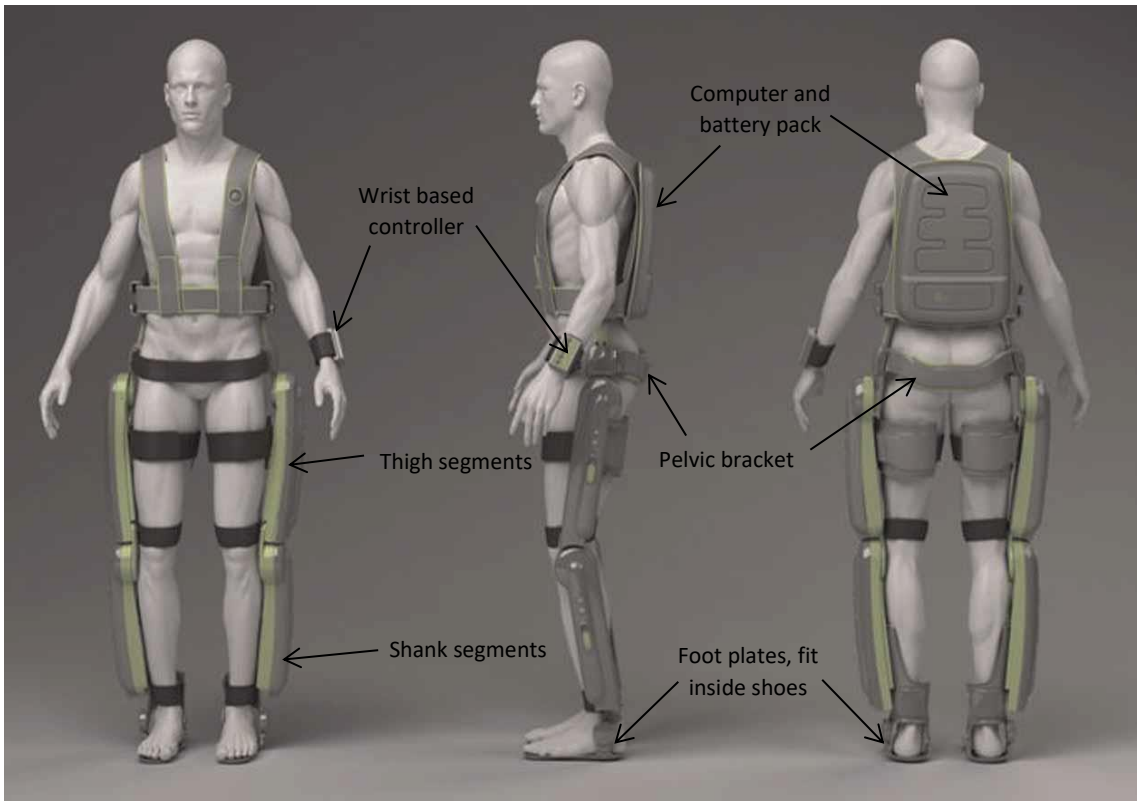


Figure 4.1. The ReWalk™ Adapted from Zeilig et al. (2012).

4.6.1. ReWalk™ fitting

Fitting of the ReWalk™ was based on pelvic width, thigh and shank lengths, and foot size. Pelvic brackets were tried against each individual to identify which size fitted best. The sizes ranged from 29 to 37 cm, in increments of 2 cm. Thigh length was measured from the greater trochanter to the lateral epicondyle of the femur, bilaterally; shank length was measured from the lateral epicondyle of the femur to the base of the heel whilst the foot was in a neutral position, bilaterally. In instances where a limb length discrepancy of less than 2 cm was evident, a mean was calculated for the length of each segment. Three footplate sizes were available (small, medium and large) and were selected based on the closest fit to the individual (Table 4.3). The ankle joint was fixed in 10 degrees of dorsiflexion for all participants based on a recommendation from the ReWalk™ trainers clinical experience, as this was the maximum dorsiflexion range available in the device. Hook and loop strapping was used to secure the participant's limbs into the ReWalk™ across the lower chest, pelvis, upper and lower thighs, and just below the knee. The foot plates of the ReWalk™ were located inside the footwear and a soft insole was placed on top of the footplate before the individual's foot was put into the shoe. The hook and loop fastenings of the footwear were used to secure the foot and lower shank to the ReWalk™.

Table 4.3. ReWalk™ fitting characteristics

Participant Number	Pelvic bracket size (cm)	Thigh length (cm)	Shank length (cm)	Footplate size	Delay between steps (ms)
LEXO AB 1	35	44	49	L	0
LEXO AB 2	31	43.5	39	L	0
LEXO AB 3	31	43	46	L	0
LEXO AB 4	33	40	40	M	0
LEXO AB 5	33	46	43	L	0
LEXO AB 6	31	45.5	52	L	0
LEXO AB 7	31	39	48	L	0
LEXO AB 8	33	43	52	L	0
LEXO SCI 1	31	44	52	M	0
LEXO SCI 2	35	45	51	L	0
LEXO SCI 3	29	43	51	L	0
LEXO SCI 4	35	46	55	L	0

4.6.2. ReWalk™ settings

The computer control unit was programmed via USB connection to a laptop and the ReWalk™ graphical user interface. The interface allows the user to configure the ReWalk™ by specifying hip and knee flexion angles, the angle at which the tilt sensor will initiate movement, the time between steps, and the step duration. For all users, the hip flexion angle was set at 22 degrees, the knee flexion angle was set at 46 degrees and the tilt delta angle was set at 7 degrees based on manufacturer recommendations, the clinical recommendation of the ReWalk™ trainer and the fact that these were the settings the individuals with an SCI usually used. Hip extension is not adjustable and is fixed at 8 degrees. For all participants the step latency was set at 0 ms (Table 4.3), thus ensuring any temporal differences between individuals was due to individual control rather than an enforced pause between steps and step duration was set at 700 ms, again a setting that the individuals with a SCI were pre-exposed too.

4.6.3. Walking aids

All individuals eligible to complete the gait study needed to be able to ambulate in the LEXO using elbow crutches and with minimal (a guiding hand on the backpack with minimal force) to moderate (a hand holding on to each side of the pelvic bracket to facilitate weight transfer during a single step) assistance from the trainer. Any trial where moderate assistance was used to maintain ambulation during contact with the force plates was noted and removed from the analysis. Participants used either a double movement, similar to a modified three-point gait pattern, or four-point gait pattern. Modified three-point gait is the advancement of the two crutches at the same time as one of the legs, to facilitate weight-bearing on an affected limb (Whittle, 2012). ReWalk™ users have adapted this, moving the two crutches forward between each step. Doubling the number of crutch movements creates a stable base, ensuring that a minimum of two points of contact are maintained at all times. Four-point gait is the separate and alternating movement of each leg and each crutch (Whittle, 2012). All able-bodied participants were instructed to use a four-point gait pattern, two of the SCI participants had opted to use a modified three-point gait pattern when initially learning to use the device and were allowed to do so throughout the testing. To standardise testing, and to minimise the training time for able-bodied participants, the wireless control device was operated by the ReWalk™ trainer.

4.7. Motion capture system

Ten Qualisys Oqus 4.0 infra-red cameras were used with Qualisys Track Manager (QTM) (software version 2.13, Qualisys, Gothenburg, Sweden) to capture three-dimensional

(3D) kinematic data at 100 Hz. Passive retro-reflective markers were positioned onto the participant's body (in specific locations) which reflect the infra-red light emitted from the cameras' LED lens surround, directly back into the lens.

The ten cameras were positioned around the 30 m^3 measurement volume (6 m long, 2.5 m wide and 2 m high) using wall mountings and height adjustable tripods (Figure 4.2).

The camera exposure times and marker thresholds were adjusted for each camera individually to allow optimal marker tracking. The exposure times ranged from 210-330 µs and marker thresholds ranged from 20-30%. The 3D tracker parameters had a prediction error of 30 mm the maximal residual was set to 10 mm and the minimum trajectory length was set to two frames.

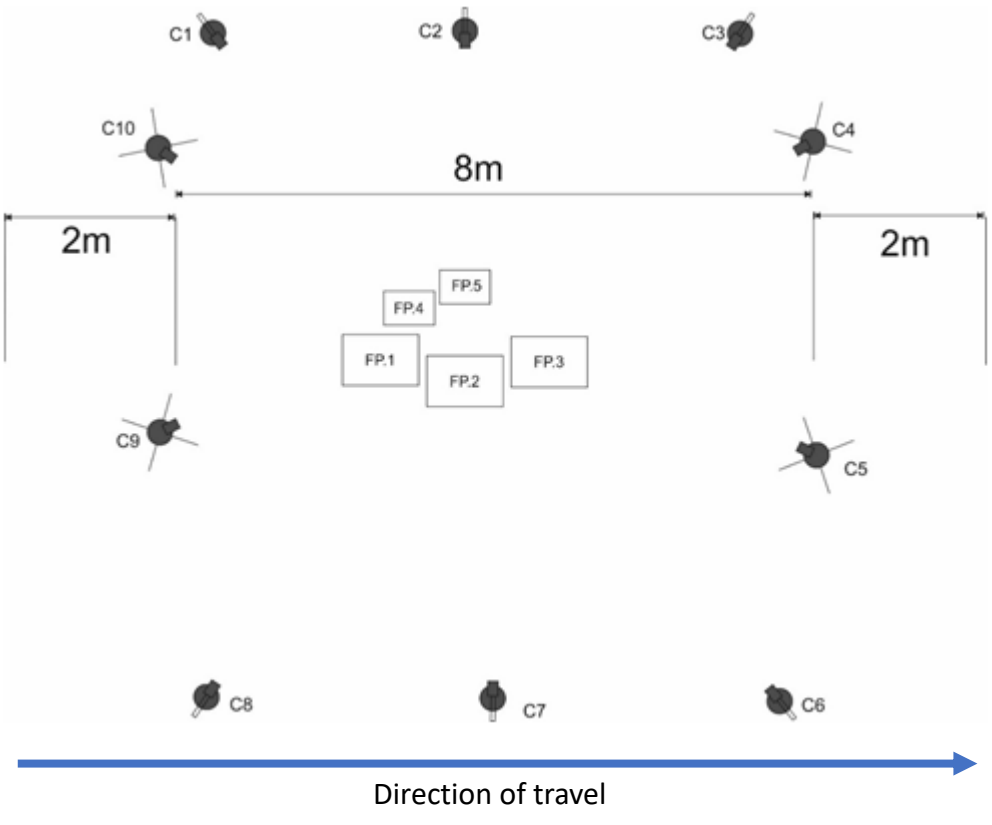


Figure 4.2. Gait study data collection walkway, camera and force plate locations.
The crosses through cameras 4,5,9 and 10 depict tripods as these cameras were moveable within the laboratory, all other cameras were wall mounted and this in a fixed position.

4.7.1. Force Data

Two Kistler (9286AA) force plates (FP4 and FP5, Figure 4.2) with built in charge amplifiers were used to measure force and centre of pressure (COP) in all trials. The force plates were embedded into the floor. The force data were synchronised with the motion capture system via a Kistler 5695A digital acquisition system (GmbH, Winterthur, Switzerland) and its 64 channel USB-2533 AD board. All force data were collected in QTM software at a sampling frequency of 1000 Hz. The two Kistler force plates are subject to an automatic operate signal that zeros each plate before a measurement. It was important to ensure the force plates were clear of any load prior to each trial (Qualisys Track Manager user manual, 2011). The force plate locations were specified in the project based on the laboratory co-ordinate system relative to the laboratory origin during calibration. A single AMTI (Massachusetts, USA) force plate was used to capture the weight of each individual prior to testing. The AMTI force plates are much larger and the wheelchairs of the SCI participants fit on the plate facilitating the data collection.

4.7.2. Calibration

The motion capture system was calibrated using a 749.9 mm calibration wand and 780 mm by 580 mm L frame, which dictated the orientation of the x and y axes and the location of the axes origin. The L frame was positioned in the centre of the camera set up aligned with the corner of the middle force plate identified as FP2 (Figure 4.3). This ensured that the laboratory co-ordinate system always originated from the same

location and allowed the location of the force plates to be pre-assigned in the software settings. Calibration was completed over a 60-second period using 2000 frames evenly distributed throughout the measurement; during this time the wand was systematically moved throughout the data capture volume. A calibration was accepted if a visual inspection of the volume in the 3D view within the software did not show any gaps and the residual values for each camera were below 1.5 mm.

The co-ordinate system was defined so that the long arm of the L frame pointed along the positive x-axis, the short arm pointed along the positive y-axis and the positive z-axis was perpendicular to these, vertically upwards. The origin of the L frame was defined as 0, the end marker on the short arm (A) was positioned 550 mm from this. The markers located on the long arm of the L frame were located 200 mm and 750 mm from the origin (B and C respectively) (Figure 4.3). This system ensured that, in the vertical z-axis, all markers would have a positive value and that the greater this value the more superior a marker was located. The y-axis was defined as the medio-lateral axis when participants were walking and the x-axis was defined as the direction of progression during walking. Marker locations were identified in each frame of each trial based on Cartesian co-ordinates relative to this laboratory co-ordinate system.

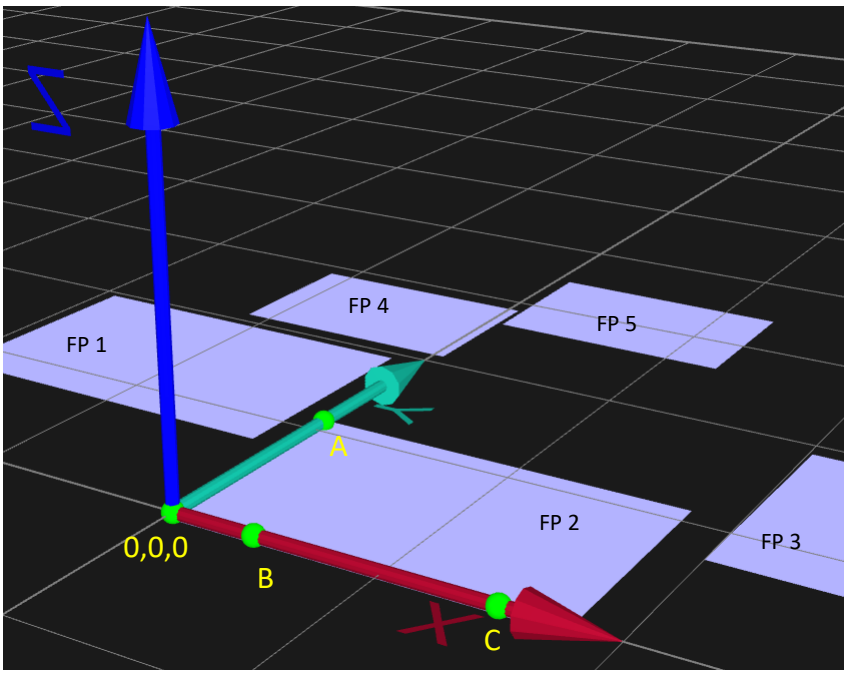


Figure 4.3. Position of calibration L frame, its markers and the origin of the laboratory co-ordinate system.

4.7.3. Degrees of Freedom

In order to describe the location of a point in 3D space, three Cartesian co-ordinates can be used to define its three degrees of freedom. To apply this same principle to a freely moving rigid body, a further three degrees of freedom must be used to describe the orientation of the body as well as its translation (Li, 2006). A full body six degrees of freedom (6DOF) model was used to track the different segments of the body and identify its Pose (position and orientation) (Buczek et al., 2010; Cappozzo et al., 1995). A 6DOF model assumes that each segment of the body is rigid and that there are no joint constraints associated with the individual segments. The lack of joint constraints reduces the risk of joint angle error and prevents the compounding of error at the more distal joints (Collins et al., 2009). A 6DOF model was used to track the movement of each able-bodied participant during normal and slow walking. Although the nature of the ReWalk™

prevents the more distal segments from having six degrees of freedom, as it is designed to facilitate sagittal plane motion only, a 6DOF model was used in all trials to maintain a repeatable method and ensure that any differences identified between trials were not as a result of different data collection and processing techniques.

Markers were placed directly on the skin over anatomical bony landmarks and were used to define the proximal and distal ends of each segment. A minimum of three non-colinear markers (tracking markers) is required for the tracking of a rigid body (Ladin, 1995). For the purposes of redundancy, a fourth marker was used on all segments to maintain data quality and to track the translation and orientation of each segment. Where possible the four tracking markers were affixed to rigid shells (marker clusters) that were securely positioned onto the segments and held in place with double sided tape and an elasticated overwrap.

4.7.4. Marker Placement

Two whole-body marker sets were used during data collection dependent upon condition. All marker sets used 14 mm passive retro-reflective markers mounted on a round plastic disc 16 mm in diameter and 2 mm deep. Gait marker set 1 consisted of 81 markers (Figure 4.4) and gait marker set 2 consisted of 105 markers (Figure 4.5). Gait marker set 1 was used for able-bodied normal walking and gait marker set 2 was used to collect all ReWalk™ gait data, the extra markers included were used to define the exoskeleton and the crutches. In all conditions participants were required to wear form fitting clothing to allow for accurate marker placement. Markers were affixed to the skin or tight clothing individually or as a marker cluster using double sided tape. Four types

of markers will be referred to: anatomical markers - markers used to define anatomical locations; tracking markers - markers used to track the movement of the individual segments; virtual marker - markers created in Visual3D as part of the model building procedure; and technical markers - markers used to define body locations and objects that were not based on anatomical landmarks. Anatomical markers were located according to the calibrated anatomical systems technique (CAST) principles (Cappozzo et al., 1995) and the model was further adapted to include principles proposed by Rab et al. (2002) related to the generation of the shoulder joint centers (further details presented in Table 4.6). Technical and tracking markers were attached to the ReWalk™ and crutches in the same way. Due to the nature of the model used and the restrictions of marker locations based on the ReWalk™, some anatomical and technical markers were also used as tracking markers. Exact marker locations and designations can be seen in Figures 4.4 and 4.5.

Once an individual was fully marked up, a static trial was captured with the individual standing in the anatomical position (or as close to the anatomical position as possible). This static trial was used as a calibration file during model building. After the static trial, anatomical and technical markers that were not required for tracking were removed from the participant before data collection.

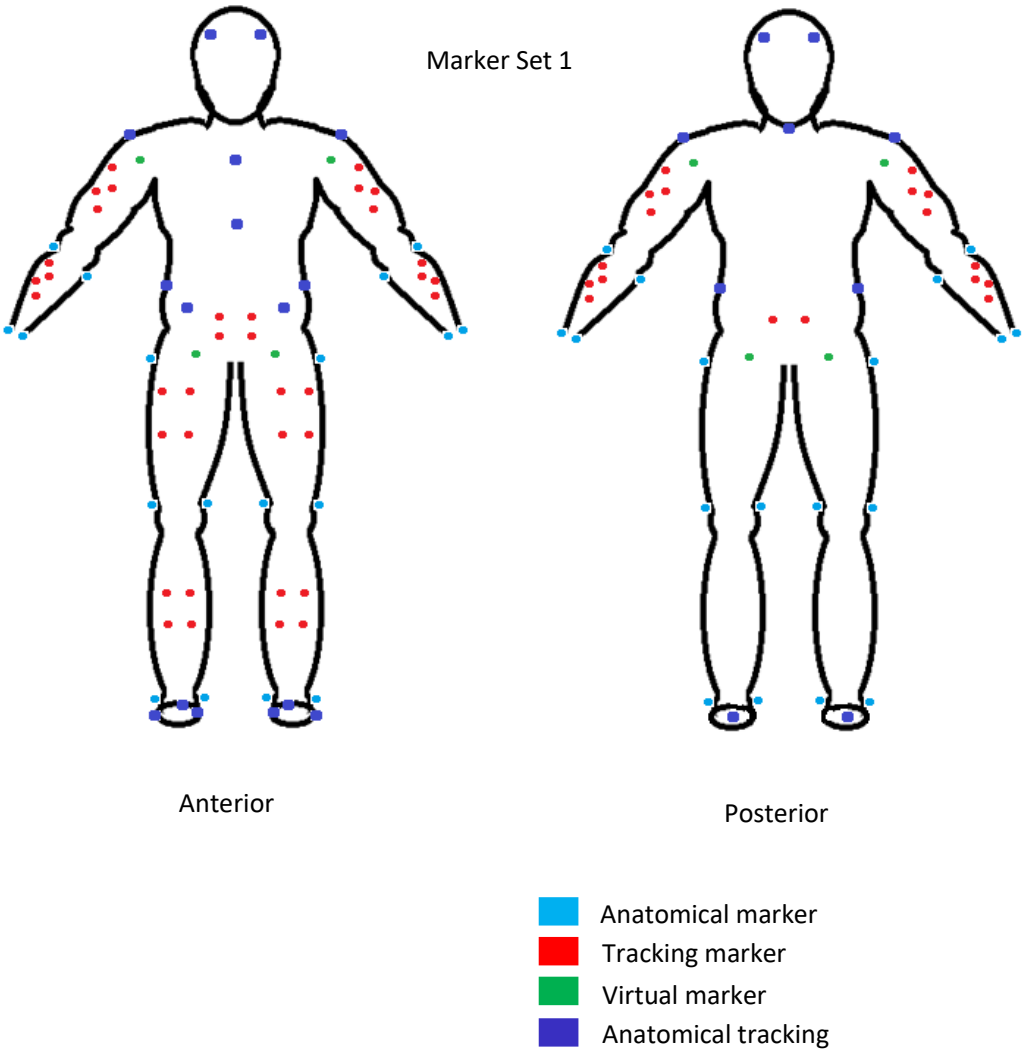


Figure 4.4. Marker set 1 including the position and type of marker.

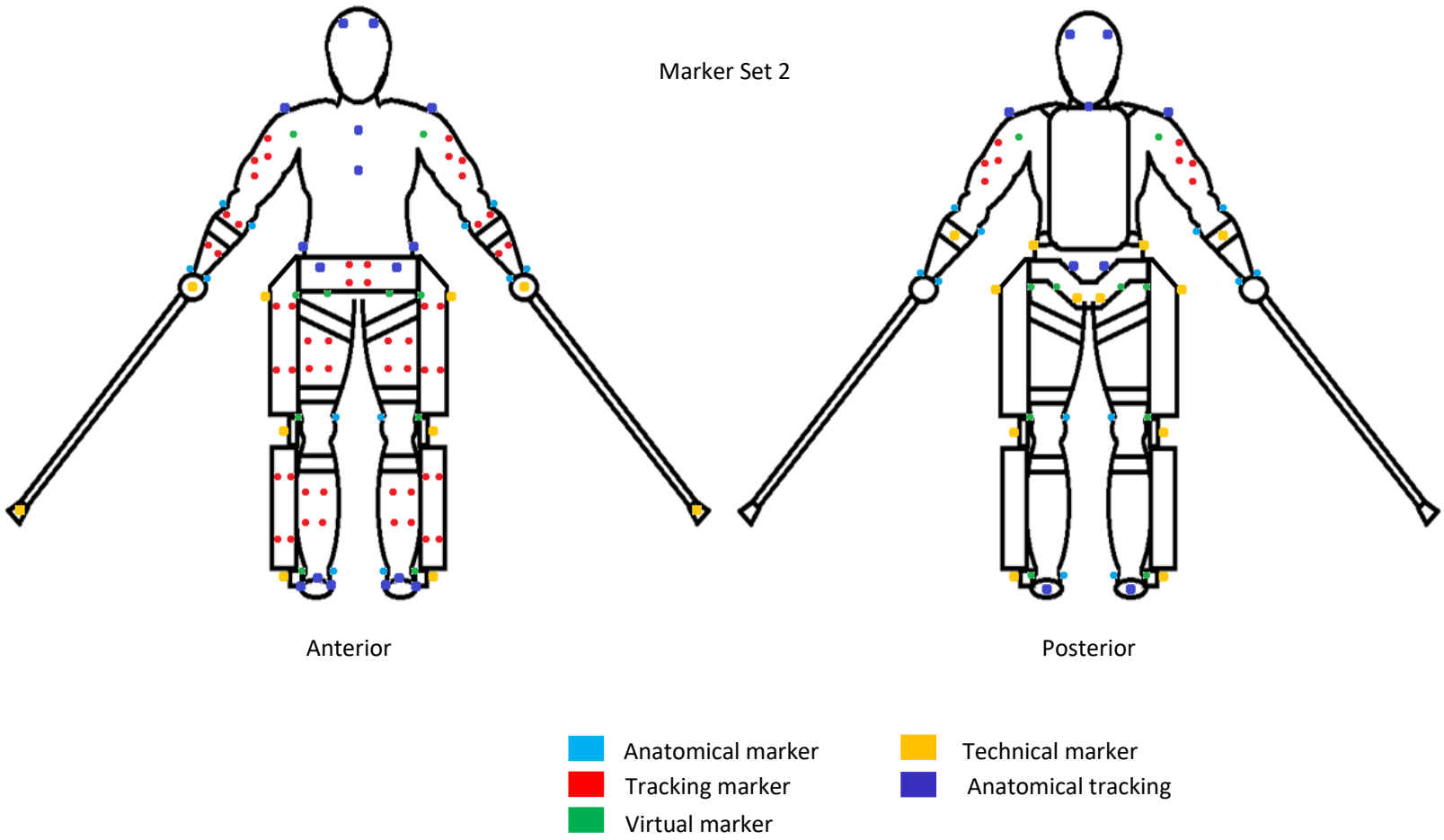


Figure 4.5. Marker set 2 including the position and type of marker.

4.7.4.1. Marker Set 1 (whole body)

After a static trial was collected for able-bodied gait, 22 anatomical markers were removed leaving a total of 55 markers to be tracked during dynamic trials with a minimum of four tracking markers on each of the 13 segments (Tables 4.4, 4.5, 4.7, and Figure 4.4). Four virtual markers were added to the model during the model building process in Visual3D to create joint centres for the shoulder and hip joints, bilaterally (Table 4.6, Figure 4.4).

4.7.4.2. Marker Set 2 (whole body + ReWalk™)

After a static trial was collected for ReWalk gait, 24 anatomical and technical markers were removed leaving a total of 81 markers to be tracked during dynamic trials with a minimum of four tracking markers on each of the 20 segments (Tables 4.4, 4.5, 4.7 and Figure 4.5). Ten virtual markers were added to the model during the model building process to create joint centres for the shoulder and hip joints bilaterally, and lateral segment locations for the ReWalk™ thigh and shank segments (Table 4.6, Figure 4.5).

Table 4.4. Anatomical markers

Anatomical Markers

Segments	Right / Left	Abbreviation	Full name and location
Head	R+L	AH	Anterior Head
	R+L	PH	Posterior Head
Trunk		C7	Cervical Spinous Process 7
	R+L	AC	Acromion Process
		JN	Jugular Notch
		XP	Xiphoid Process
Upper arm	R+L	LE	Lateral Elbow (Humeral Epicondyle)
	R+L	ME	Medial Elbow (Humeral Epicondyle)
Lower arm	R+L	LW	Lateral Wrist (Radial Styloid Process)
	R+L	MW	Medial Wrist (Ulna Styloid Process)
Pelvis	R+L	IC*	Iliac Crest
	R+L	ASIS	Anterior Superior Iliac Spine
	R+L	PSIS	Posterior Superior Iliac Spine
	R+L	GT*	Greater Trochanter
Thigh	R+L	LK*	Lateral Knee (Femoral Epicondyle)
	R+L	MK	Medial Knee (Femoral Epicondyle)
Shank	R+L	LA*	Lateral Ankle (Malleolus)
	R+L	MA	Medial Ankle (Malleolus)
Foot	R+L	CAL	Calcaneus
	R+L	1^{st}Met	1st Metatarsal
	R+L	2^{nd}Met	Dorsum of 2nd Metatarsal
	R+L	5^{th}Met	5th Metatarsal
	R+L	LMMal	Lower Medial Malleolus (inferior to Malleolus, in line with 1^{st}Met)
	R+L	LLMal	Lower Lateral Malleolus (inferior to Malleolus, in line with 5^{th}Met)

** Denotes markers that are not used in marker set 2 due to use of the ReWalk™.*

Table 4.5. Technical markers

Technical Markers

Segments	Right / Left	Abbreviation	Full name and location
Foot	R+L	LLA*	Lower Lateral Ankle (inferior to malleolus)
	R+L	LMA*	Lower Medial Ankle (inferior to malleolus)
Crutches	R+L	PC	Posterior Crutch (rear of elbow support)
	R+L	AC	Anterior Crutch (tip of hand grip)
	R+L	DC	Distal Crutch (inferior, posterior aspect of support)
ReWalk™ Pelvis	R+L	RWIC	ReWalk™ Iliac Crest (tip of torso support)
	R+L	RWIT	ReWalk™ Ischial Tuberosity (Posterior bracket of ReWalk™ pelvis)
	R+L	RWGT	ReWalk™ Greater Trochanter (Moveable axis of the ReWalk™ pelvis and thigh segments)
ReWalk™ Thigh	R+L	RWLK	ReWalk™ Lateral Knee (Moveable axis of the ReWalk™ thigh and shank segments)
ReWalk™ Shank	R+L	RWLA	ReWalk™ Lateral Ankle (Moveable axis of the ReWalk™ shank and foot segments)

** Denotes the only technical markers used in marker set 1.*

Table 4.6. Virtual markers

Virtual Markers

Segments	Right / Left	Abbreviation	Full name and location	Start point	End Point / co-ordinates system	ML	AP	Axial
Head	R+L	Ear	Mid-point between anterior & posterior head	PH	AH	N/A	N/A	0.5
		C7_Stern	Mid-point between C7 and JN	C7	JN			0.5
Trunk	R+L	SJC	Virtual Shoulder Joint Centre	AC	N/A LAB co-ordinates system	(Marker_Radius+0.08* Distance(L AC,R AC))	0.0	-(Marker_Radius+0.17 *Distance(L AC,R AC))
Pelvis	R+L	HJC	Virtual Hip Joint Centre	N/A	N/A Pelvis co-ordinates system	0.36*ASIS_Distance* RPV_ML_Direction ± dependant on direction	0.19*ASIS_Distance* RPV_AP_Direction ± dependant on direction	-0.3*ASIS_Distance* RPV_Axial_Direction
	R+L	VIC	Virtual Iliac Crest	HJC	N/A LAB co-ordinates system	0.0	0.0	0.5*ASIS_Distance
		PL	Pelvis Lateral	Lab Origin	N/A Pelvis co-ordinates system	0.1	0.0	0.0
		PLP	Pelvis Lateral Projection	Lab Origin	Lab y	Projected from PL	N/A	N/A
Thigh	R+L	VLK*	Virtual Lateral Knee	MK	N/A LAB co-ordinates system	Width of knee	0.0	0.0
Shank	R+L	VLA*	Virtual Lateral Ankle	MA	N/A LAB co-ordinates system	Width of ankle	0.0	0.0
Foot	R+L	LA_Floor	Lateral Ankle Floor	Lab Origin	Lab x (on a line)	Project from LLM	N/A	N/A
	R+L	MA_Floor	Medial Ankle	Lab Origin		Project from LMM	N/A	N/A
	R+L	5^{th}Met_Floor	5^{th} Metatarsal Floor	Lab origin	Lab y (on a plane)	Project from 5^{th}Met	N/A	N/A
	R+L	1^{st}Met_Floor	1^{st} Metatarsal Floor	Lab Origin		Project from 1^{st}Met	N/A	N/A

Segments	Right / Left	Abbreviation	Full name and location	Start point	End Point / co-ordinates system	ML	AP	Axial
Laboratory		Lab Origin	Virtual marker at the laboratory origin	N/A	LAB co-ordinates system	0.0	0.0	0.0
		Lab x	Virtual marker in the x direction from origin	Lab Origin		0.1	0.0	0.0
		Lab y	Virtual marker in the y direction from origin	Lab Origin		0.0	0.1	0.0
		Lab z	Virtual marker in the z direction from origin	Lab Origin		0.0	0.0	0.1
		Lab Lateral	Lateral projection from the PLP	Lab Origin	Projected from PLP	N/A	N/A	N/A
ReWalk™ Pelvis	R+L	RHJC*	ReWalk™ Hip Joint Centre	RWGT	N/A LAB co-ordinates system	0.0423 ± dependant on direction	0.0	0.0
ReWalk™ Thigh	R+L	RKJC*	ReWalk™ Knee Joint Centre	RWLK	N/A LAB co-ordinates system	0.0396 ± dependant on direction	N/A	N/A

** Denotes virtual markers used in Marker Set 2 only*

Table 4.7. Tracking markers

Tracking Markers

Segments	Right / Left	Abbreviation	Full name / Location name
Head	R+L	AH	Anterior Head
	R+L	PH	Posterior Head
Trunk		C7	Cervical Spinous Process 7
		JN	Jugular Notch
		XP	Xiphoid Process
Upper arm	R+L	A1	Arm 1
	R+L	A2	Arm 2
	R+L	A3	Arm 3
	R+L	A4	Arm 4
Lower arm	R+L	FA1	Forearm 1
	R+L	FA2	Forearm 2
	R+L	FA3	Forearm 3
	R+L	FA4	Forearm 4
Pelvis		P1	Pelvis 1
		P2	Pelvis 2
		P3	Pelvis 3
		P4	Pelvis 4
Thigh	R+L	TH1	Thigh 1
	R+L	TH2	Thigh 2
	R+L	TH3	Thigh 3
	R+L	TH4	Thigh 4
Shank	R+L	SH1	Shank 1
	R+L	SH2	Shank 2
	R+L	SH3	Shank 3
	R+L	SH4	Shank 4
Foot	R+L	Calc	Calcaneus
	R+L	1st Met	1st Metatarsal
	R+L	2nd Met	Dorsum of 2nd Metatarsal
	R+L	5th Met	5th Metatarsal
Crutches	R+L	PC*	Posterior Crutch (rear of elbow support)
	R+L	AC*	Anterior Crutch (tip of hand grip)
	R+L	DC*	Distal Crutch (inferior, posterior aspect of support)
ReWalk™ Pelvis	R+L	RWIC*	ReWalk™ Iliac Crest (tip of torso support)
	R+L	RWIT*	ReWalk™ Ischial Tuberosity (Posterior bracket of ReWalk™ pelvis)
	R+L	ASIS	Anterior Superior Iliac Spine
ReWalk™ Thigh	R+L	RWT1*	ReWalk™ Thigh Segment 1
	R+L	RWT2*	ReWalk™ Thigh Segment 2
	R+L	RWT3*	ReWalk™ Thigh Segment 3
	R+L	RWT4*	ReWalk™ Thigh Segment 4
ReWalk™ Shank	R+L	RWS1*	ReWalk™ Shank Segment 1
	R+L	RWS2*	ReWalk™ Shank Segment 2
	R+L	RWS3*	ReWalk™ Shank Segment 3
	R+L	RWS4*	ReWalk™ Shank Segment 4

** Denotes a marker that is only used in marker set 2.*

4.7.5. Static Trials

Once each participant was marked up, a static trial was captured; the static file was used in the model building process to define the local co-ordinate systems for each segment. Static trials for all participants were collected over eight seconds. Participants were required to stand in the anatomical position (Kirtley, 2006).

Once captured, the static file was checked to ensure that all makers were visible and distinguishable and the markers were correctly identified and labelled before two frames of data were exported as a C3D file to be used in the model building process in Visual3D (C-Motion, Rockville, MD, USA).

4.7.6. Motion Trials

4.7.6.1 Able-bodied normal walking trials

Able-bodied participants were asked to walk along a 12 m walkway that passed through the calibrated volume at a self-selected and pre-defined (based on ReWalk™ speed) walking pace. Prior to testing, the start and end points of the walk were adjusted to give participants the best chance of stepping onto the force plates without altering their stride pattern. Participants were instructed to start from the same point each time and to walk straight ahead, as naturally as possible, at a self-selected or pre-defined pace. Each participant was required to complete ten trials with a clean foot strike on each force plate.

4.7.6.2. ReWalk™ walking trials

Spinal cord injured participants were recruited from a population of experienced ReWalk™ users identified by Cyclone Technologies Ltd (Sunk Island, East Yorkshire) and as such required only a short period of re-familiarisation to the ReWalk™ prior to data collection. Able-bodied participants had no previous experience of the ReWalk™ and were given a training session prior to testing. All able-bodied participants were capable of ambulating in the ReWalk™ with minimal to moderate assistance after one hour of training.

All participants were required to walk over the force plates through the calibrated volume to enable the capture of kinematic and GRF data. Prior to data collection, participants were aligned with the Kistler force plates and a starting point was identified for each individual in order to facilitate good contacts with the force plates. At least one step with each foot was required before contact with the force plates to ensure that the gait pattern was not based on step initiation (Kirtley, 2006) and at least one further step was required for each foot after the gait cycle associated with the GRF data. All participants managed to achieve a single foot strike on each force plate enabling double support time to be calculated. Participants were instructed where possible to ensure that the crutches did not come into contact with the force plates. Trials with double contacts or crutch contact were excluded from analysis. Between six and ten trials were collected per participant and participants were allowed to rest as often as required. For safety reasons, a qualified ReWalk™ trainer followed the participants at all times and provided support where necessary, taking care not to stand on the force plates. Support was defined as the minimum physical assistance required to ensure the participants maintained balance and forward movement, usually taking the form of a simple hand on the

back to prevent the user over-balancing posteriorly or a hand on the pelvic bracket of the ReWalk™ to prevent a lateral deviation.

4.8. Data processing

4.8.1. Motion capture data

The static trials and first trial of each testing session were manually processed for each participant; a label list was loaded into QTM and the appropriate markers were identified and labelled. QTM has an inbuilt AIM function (automatic identification of markers) that uses the distances and angles between specific markers in movement trials (then added to an existing model) to identify and label trajectories in files with the same marker set up. These AIM models can be 'educated' by adding more movement trials to the model, including those of different participants. Using this principle, two AIM models were generated: one for able-bodied gait and one for ReWalk™ gait. The remaining motion files were processed using the AIM function. All gait motion files were cropped to ensure GRF data from the force plates, and one left and one right stride, were included. All data were exported from QTM in C3D format maintaining the synchronised kinematic and kinetic data.

4.8.2. Model building

Two biomechanical models were generated in Visual3D: one for able-boded gait and one for ReWalk™ gait based on the average marker locations of each static file. Each model was created as a 6DOF link model using the 'Visual3D Hybrid 3D Model' option. A 6DOF link model is a collection of individual rigid bodies (segments) and landmarks with unconstrained

articulated joints. Visual3D defines a joint as the distal end of one segment and the proximal end of the following segment (Visual3D, 2013). To create a model, each segment must have markers to identify proximal and distal endpoints as well as the medial and lateral aspects. Anatomical and technical markers were used for this purpose and were visible during the static calibration files. The location of tracking markers relative to these segment-defining markers allows segments to be tracked during dynamic trials as long as a minimum of three markers can be seen in each frame.

Each body segment had a local co-ordinate system or a segment co-ordinate system (SCS). The SCS was generated from the location of the segment-defining markers and had an origin at the proximal endpoint of the segment. Segment endpoints were created based on the mid-point of the medial and lateral markers. The line between these endpoints formed the z-axis with a positive direction of distal to proximal. The same markers were used to define the frontal plane of the segment. The y-axis of the SCS was defined as the vector that was perpendicular to the frontal plane and the z-axis with a positive direction of posterior to anterior (based on the marker labels). The x-axis of the SCS was then created based on the Right-Hand Rule. All movements for each segment were reconstructed using the Cardan rotation sequence X, Y, Z with the Right-Hand Rule being applied about the SCS.

Both full-body gait models were comprised of sixteen principal segments making up the anatomical body: head, trunk, two pelvis segments (a CODA pelvis and Visual3D pelvis), left and right upper arms, left and right forearms, left and right thighs, left and right shanks, left and right feet, and left and right virtual feet. The ReWalk^{TM} model consisted of an additional

seven segments: a ReWalk™ pelvis, left and right ReWalk™ thigh segments, left and right ReWalk™ shank segments, and left and right crutches.

All segments created were 'Visual3D segments' apart from the CODA pelvis. The CODA pelvis is a segment model that uses the ASIS and PSIS marker locations to define its pose (Bell et al., 1989, 1990). Its origin was defined as the mid-point between the two ASIS markers. The x-y plane was created between the left and right ASIS markers and the mid-point of the PSIS markers. These anatomical locations cause this plane and the corresponding SCS to be anteriorly tilted by approximately 20 degrees (Figure 4.6). The Pelvis of the ReWalk™ did not however present with the same anterior tilt. To facilitate a direct comparison a second Visual3D pelvis segment was created for kinematic analysis using the automatically generated hip joint centres, created by the CODA pelvis segment, based on calculations by (Bell et al., 1989, 1990).

RHJC = (0.36*ASIS_Distance,-0.3*ASIS_Distance),

LHJC = (-0.36*ASIS_Distance,-0.3*ASIS_Distance)

(Bell et al., 1989, 1990)

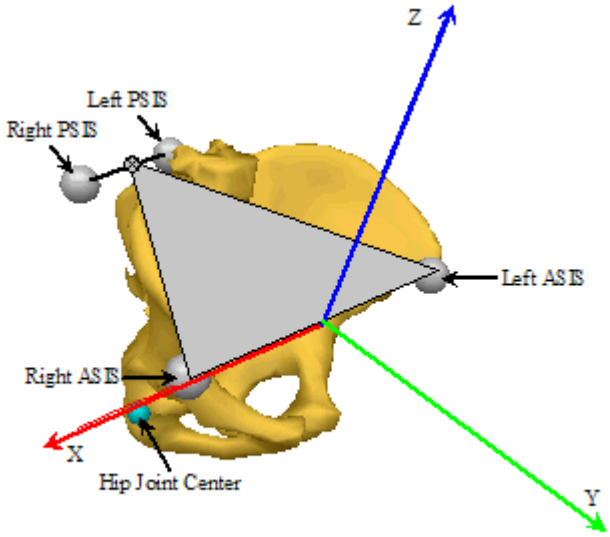
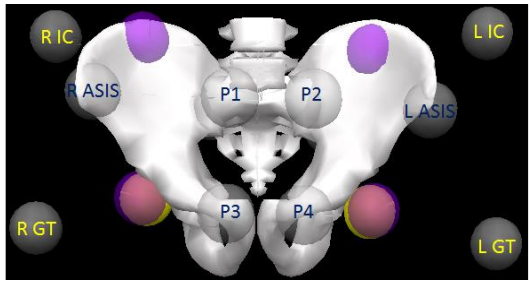
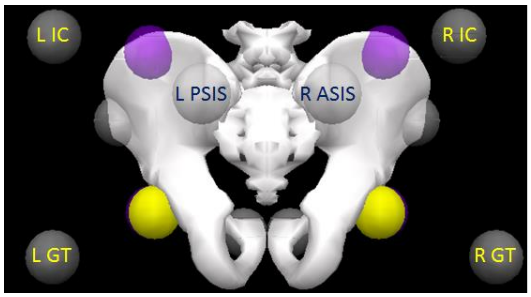


Figure 4.6. CODA Pelvis. (Visual3D Wiki, C-Motion, 2015)

The Visual3D pelvis (figure 4.7.A) was generated using virtual markers due to the location of the ReWalk™ limbs. Virtual markers were used to create the Visual3D pelvis segment in both models. The distal markers were the hip joint centre locations (derived from the CODA pelvis) and the proximal markers were the virtual iliac crest markers. The latter were defined based on a superior projection from the hip joint centre locations using the equation 0.5*ASIS_Distance (Visual3D, 2013). The Visual3D pelvis segment had a frontal plane parallel to the floor (no anterior tilt). Thigh segments (Figure 4.7.B) were modelled using the hip joint centre and a radius to define the proximal endpoints. Medial knee markers were used for the distal endpoint along with either the lateral knee marker or the virtual lateral knee marker (ReWalk™ model). A cluster of four tracking markers was used to track each thigh segment (Manal et al., 2000).

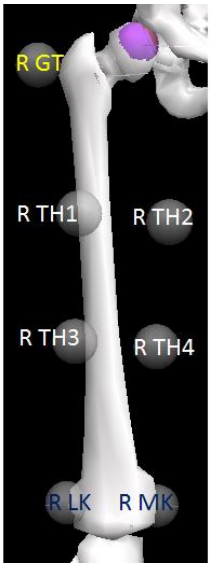


Anterior



Posterior

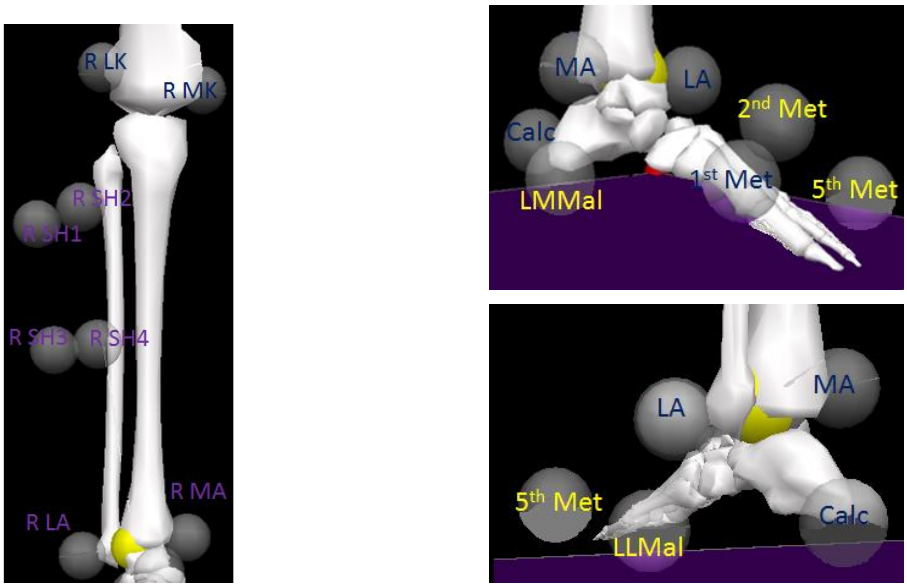
(A)



(B)

Figure 4.7. Visual3D Pelvis segment (A) and Visual3D Thigh segment (B).
R = right, L = left, IC = iliac crest, GT = greater trochanter, P = pelvis, ASIS = anterior superior iliac spine, LK = lateral knee, ML = medial knee and TH = thigh.

Shank segments were modelled in the same fashion using the knee markers to identify proximal locations and ankle markers to locate the distal locations (Figure 4.8.A). In the RW model, the lateral markers were replaced with virtual markers that were created based on anthropometric measurements of the knee and ankle joints. The foot segments were modelled for the processing of kinetic data only (identification of contacts with the force plates). The virtual foot segments were created to establish a neutral ankle angle in static standing (Figure 4.8.B). The SCS for the virtual foot segments were rotated to ensure that flexion and extension rotations occurred about the x-axis, inversion and eversion occurred about the y-axis, and abduction and adduction occurred about the z-axis.



(A) (B)

Figure 4.8. Visual3D shank segment (A). Visual3D Foot Segment (B).
R = Right, L = Left, LK = lateral knee, MK = medial knee, SH = shank, LA = lateral ankle, MA = medial ankle, calc = calcaneus, LMMal = lower medial maleolus and LLMal = lower lateral maleolus.

The upper body (in both models) was modelled in order to track the whole body centre of gravity and was based on a modified upper extremity model proposed by Rab et al. (2002). The trunk was modelled as a single segment using the iliac crest markers and acromion markers to define the proximal and distal borders (Figure 4.9.A). The head was modelled using virtual markers between the anterior and posterior head markers and a virtual endpoint between the jugular notch and C7 marker (Figure 4.9.B). Both SCS were rotated to follow the lower limb conventions: sagittal movement occurring about the x-axis with the positive direction pointing laterally to the right of the individual; frontal plane movement occurring about the y-axis with the positive direction as anterior; and transverse plane movements occurring about the z-axis with the positive direction running inferior to superior (Rab et al., 2002). The upper and lower arms were modelled using the same process as the thighs and shanks (Figure 4.10.A and B).

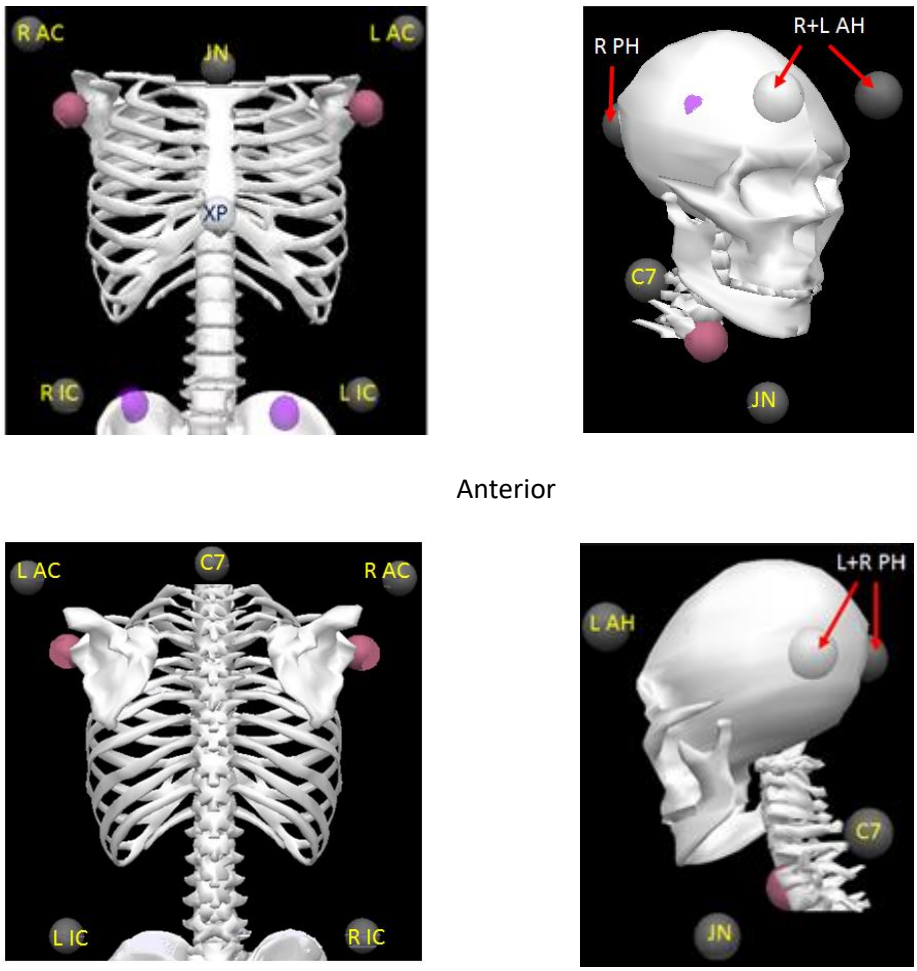
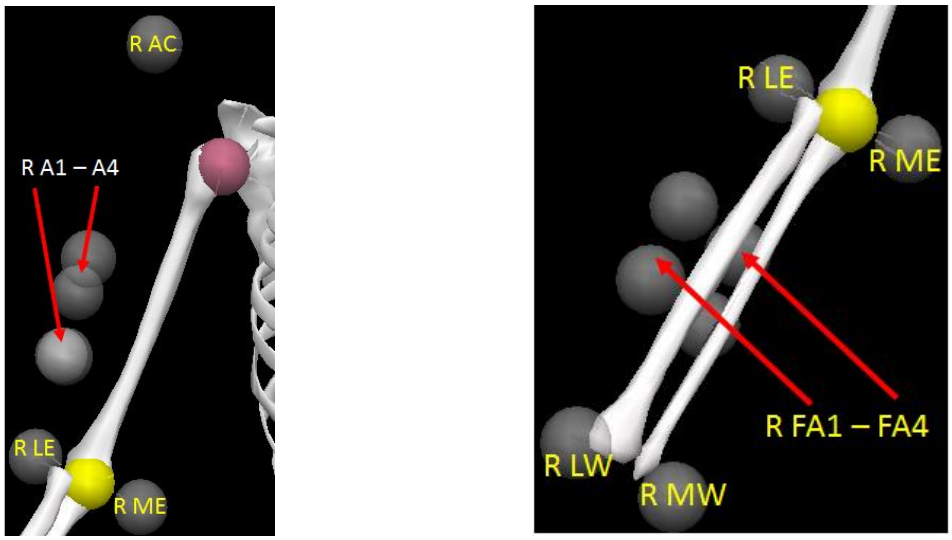


Figure 4.9. Visual3D trunk segment (A). Visual3D head Segment (B).
R = right, L = left, JN = jugular notch, XP = xyphoid process, AC = acromion process, IC = iliac crest, C7 = cervical 7, PH = posterior head and AH = anterior head.



(A) (B)

Figure 4.10. Visual3D upper arm segment (A). Visual3D forearm segment (B).
R = right, A = arm, LE = lateral elbow, ME = medial elbow, LW = lateral wrist, MW = medial wrist and FA = forearm.

The individual ReWalk™ segments and crutches were modelled as cylinders, the length of each segment was defined by the proximal and distal makers and the radius of each segment was calculated based on the circumference of the individual components (as recorded from the manufacturers specifications). The SCS for each ReWalk™ segment was created to follow the same conventions as the lower limb segments. All segments in Visual3D are modelled as geometric shapes, and the mass, moment of inertia and centre of gravity for each segment can be calculated. Any segment created as a recognised anatomical segment has its mass and inertial properties based on data and regression equations by Dempster (1955) relative to the body mass of the individual participant. The masses for the ReWalk™ segments were derived from averaged force plate readings of each segment over a 3-second period and were added to the model to enable the calculation of the user and ReWalk™ centre of mass (COM).

4.8.3. Kinematics

The purpose of creating the different models was to calculate the specific joint angles of the body and the ReWalk™ separately. The ankle angle was defined as the angle between the virtual foot and the shank; the knee angle represented the angle between the shank and the thigh; the hip angle was the angle between the thigh and the Visual3D pelvis. The orientation of the pelvis was the angle between the Visual3D pelvis and the virtual lab created by Visual3D. The orientation of the trunk segment was defined as the angle between the trunk and the Visual3D pelvis. ReWalk™ angles were calculated in the same manner: ReWalk™ ankle angle was between the virtual foot and the ReWalk™ shank; the ReWalk™ knee angle was the angle between the ReWalk™ shank and ReWalk™ thigh; and the ReWalk™ hip angle represented the angle between the ReWalk™ thigh and the ReWalk™ pelvis.

4.8.4. Centre of mass

The whole-body COM was calculated for each individual for all walking trials in Visual3D. The COM of each segment was calculated based on the assumption that each segment was a rigid geometric shape with a known mass (Visual3D, 2013). The COM of the entire model was then calculated based on the mechanical principles defined by Hanavan (1964). During the ReWalk™ walking trials, the ReWalk™ segments were included in the calculations to define the entire system's COM.

4.9. Gait analysis

All data were interpolated using a third order polynomial. Kinematic and kinetic data were low-pass filtered using fourth order Butterworth filters. Kinematic data were filtered with a cut-off frequency of 6.0 Hz based on generating optical marker position data (Ren et al., 2008; Winter et al., 1974). Kinetic data were filtered with a cut-off frequency of 30 Hz based on the principle that 95% of the signal power for medial-lateral force data is contained with the 27th harmonic and a cut-off of 30Hz would enable this information to be retained unlike the cut-off of 6 Hz used for the kinematic analysis (Giakas & Baltzopoulos, 1997).. All data were normalised to the gait cycle and gait events were determined using kinetic data. In all gait trials, the gait cycle began at initial contact (0%) and terminated with the following foot contact for the ipsilateral limb (100%). Temporal-spatial characteristics, joint angles, GRF data and centre of mass displacement were defined and calculated as part of a user-created gait report template.

The following joint angular definitions were used:

	Positive	**Negative**
Sagittal plane	Flexion Dorsiflexion Anterior tilt	Extension Plantarflexion Posterior tilt
Frontal plane	Adduction Obliquity up	Abduction Obliquity down
Transverse plane	Internal rotation	External rotation

4.9.1. Gait variables

The variables used to identify biomechanical differences in able-bodied normal gait and able-bodied ReWalk™ gait and SCI ReWalk™ gait included temporal-spatial parameters: walking speed (m/s), cadence (steps/min), step length (normalised to % leg length) and support times (% gait cycle). Dynamic peak joint angles and ROM were calculated for ankle and knee joints in the sagittal plane only as the ReWalk™ device is only designed to facilitate sagittal plane motion. Peak hip joint angles and ROM were examined in the sagittal and frontal planes, although the ReWalk™ is again only designed to facilitate sagittal plane motion of the hip, anecdotal evidence from clinicians suggested that during swing phase the individuals swinging limb falls medially. Pelvic and trunk orientation were defined in all three planes (degrees) as the movements of these segments were not constrained by the device. Peak GRF (normalised to body mass) (N/kg) in the vertical, anterior–posterior and medio-lateral directions were analysed after being normalised to body weight. Kinematic and GRF data from the left and right limbs were averaged for each session and for each participant as the movement parameters programmed into the LEXO were the same for each leg.

4.10. Conclusion

This chapter has described the tools and processes used to capture and analyse the data for the three gait studies presented in this thesis it has also described the ethics process, participant demographics and inclusion / exclusion criteria for all empirical studies included in this thesis. The procedures described herein were selected based on a review of the current literature in the relevant areas of gait analysis, with the aim to understand the biomechanical factors associated with SCI rehabilitation. The postural control chapter has its own detailed

methods section describing the equipment and process used. Whereas the three gait based studies detail the application of the tools and process described above.

Chapter 5 – An exploratory investigation into seated static and dynamic postural control of spinal cord injured individuals and able-bodied controls

5.1. Introduction

Sitting unsupported in healthy able-bodied individuals is a task taken for granted, it is however an impressive feat of neuromuscular control and intersegmental coordination, which may be negatively affected following a motor and/or sensory impairment (Boswell-Ruys et al., 2009). Many SCI individuals complete most activities of daily living (ADL) from a seated position (Minkel, 2000; Shin & Sosnoff, 2013; Tsai et al., 2017) including general mobility and basic self-care tasks. As a result, reduced postural control in sitting has been associated with poor functional outcomes in SCI individuals and reduced quality of life (QOL) (Qi et al., 2018). Furthermore, poor postural control during sitting can lead to increased incidence of secondary conditions such as fracture or injury from falls (Edwards et al., 2014), the development of pressure sores (Alm et al., 2003), reduced respiratory capacity (Vette et al., 2014), and pain (Janssen-Potten et al., 2001; Minkel, 2000).

In able-bodied individuals, seated upright posture is regulated and maintained through tension of the posterior chain trunk musculature (Milosevic et al., 2017a). It has been demonstrated that trunk control is the most important consideration during quiet sitting for SCI individuals, with the support provided from the feet being limited and passive (Milosevic et al., 2015). The kyphotic C-shaped posture adopted by many SCI individuals facilitates trunk stability through the rigidity of the passive structures of the spinal column (Janssen-Potten et al., 2001). As discussed in section 2.12.1, compensatory

postural control strategies developed by SCI individuals with thoracic level lesions (or higher) include the use of non-postural trunk muscles. However, these adapted muscle recruitment and activation patterns are often still insufficient to fully compensate for instability (Gauthier et al., 2013). Consequently, thoracic SCI individuals demonstrate greater postural sway during sitting than able-bodied individuals, irrespective of the use of their arms for support, especially in the medial-lateral direction (Milosevic et al., 2017a). Furthermore, during unsupported (no use of arms) sitting, stability in the anterior-posterior direction was reduced in the SCI groups compared with able-bodied individuals (Milosevic et al., 2017a). As the participants in the study by Milosevic et al. (2017a) were asked to place their hands on their thighs in the supported sitting trials, increased stability in the anterior-posterior and not the medial-lateral direction was a predictable conclusion. This hand positioning would have braced the trunk in the anterior-posterior direction but provided very little support in the medial-lateral directions. This suggests that the positioning of an individual's arms to improve supported sitting postural control should be direction specific.

Current tests used for the measurement of seated postural control in SCI individuals within clinical settings are often underused and/or inappropriate (Arora et al., 2018; Harel et al., 2013). Jørgensen et al. (2011) reported on the lack of consensus among clinical specialists about the use of a valid, reliable and easy-to-use instrument for the evaluation of sitting balance and postural control in patients with SCI. In a recent systematic review investigating general balance and postural control measures, Arora et al. (2018) identified 31 different balance and postural control measures overall; however, only five constructs and 12 specific balance scales were used in the assessment

of seated balance and/or postural control as opposed to standing balance. Although numerous assessments of postural control in SCI individuals exist, the task remains complex, partly in response to the difficulty of separating postural control from the environment or activity in which it is being performed (Abou et al., 2018). Examples of such tests are the sit and reach, and seated trunk excursion tests, which have been shown to produce reasonable agreement with centre of pressure (COP) excursion data under the seated body (Field-Fote & Ray, 2010). These tests also provide useful information in a clinical setting without the capacity to measure COP (Field-Fote & Ray, 2010; Sprigle et al., 2007). Centre of pressure variables can be split into distance/area and velocity based measures. Distance/area variables provide information relative to stability performance, and velocity derived variables are indicators of control demand (Grangeon et al., 2013). The combination of stability performance and control demand provides information on postural control (Grangeon et al., 2013). The clinical tests identified above are unable to provide information related to control demand and subsequently cannot answer questions about postural control.

No single clinical measure can inform clinicians about the afferent input required by the CNS to interpret the centre of gravity (COG)[1] position (D. A. Winter et al., 1996). Balance is often defined as the ability to maintain centre of mass (COM)[2] over the base of support (BOS)[3] (Winter et al., 1990). Although always requiring constant neuromuscular alterations, static balance is a comparatively simple task compared to dynamic balance, when the body must maintain equilibrium under more challenging circumstances, and

[1] The centre of gravity is the vertical projection of the COM onto the floor.
[2] The centre of mass is the summed location at which a body's mass acts.
[3] The base of support is demarcated by the area under the body in contact with the supporting surface and any support aid.

intrinsic and external challenges must be overcome to prevent falling (Shahvarpour et al., 2016). The challenge of maintaining balance during standing is due mainly to two factors: the large vertical distance between the COM and the BOS, and the small BOS relative to the height of the body (Hodges et al., 2002). In sitting, the BOS is increased and the COM is vertically closer to the BOS. However there are fewer available degrees of freedom to respond to perturbations as there are less moveable body segments to respond to a challenge (Bouisset & Duchêne, 1994). For SCI individuals with thoracic and higher level injuries, the capacity to respond to perturbations is further reduced as even fewer degrees of freedom are available. COP[4] measures alone only provide information about the neuromuscular responses to the fluctuating displacement of the COG within the base of support (Shin & Sosnoff, 2013). The location of the COP relative to a pre-defined limit of stability (LOS)[5] boundary can be used to interpret the COP data relative to falls risk (Preuss & Popovic, 2010; Shin & Sosnoff, 2013). A large COP path length may not put an individual at risk of falling if that path stays comfortably inside the BOS. However, a COP path that is very close to, or that exceeds, the LOS boundary may provide useful information about the risk of falling.

One of the best predictors of falling, is a history of recurrent falls (Forslund et al., 2017; Nelson et al., 2010). However, SCI individuals experience fewer as time since injury increases (Nelson et al., 2010), likely as a result of improved compensatory strategies (Forslund et al., 2017). Although fear of falling and risk of falling can be considered independent of each other (Legters, 2002; Maki et al., 1991), Forslund et al. (2017)

[4] The centre of pressure is a two dimensional projection of the vertical ground reaction force vector. Its location is a representation of the position of the GRF within the base of support.
[5] The limit of stability is defined by the position of the COG relative to the outer limit of the base of support.

suggest that in SCI individuals who fell recurrently, displayed less fear of falling than those who fall less frequently. Moreover, fear of falling has been linked to self-imposed restrictions in social participation and physical activity (Forslund et al., 2016; Hellström & Lindmark, 1999; Wirz et al., 2010). Such fears can be warranted or unwarranted, but restrict mobility and basic self-care unnecessarily where fears are unwarranted (Boswell-Ruys, et al., 2010b). It is possible that the use of an individualised LOS boundary during postural control testing may provide useful information about risk of falling and that it may be possible to link this to fear of falling in SCI individuals.

Various attempts have been made to identify the impact of injury level on postural control and sitting balance. Chen et al. (2003) identified differences in dynamic sitting balance during a functional reaching task in high- and low-level thoracic SCI, but did not find any differences in postural sway during quiet sitting. Milosevic et al. (2017a) also reported minimal differences in postural control between high- and low-level thoracic SCI individuals, although the control strategies that were used differed. Using EMG to assess muscle activation patterns, the same researchers demonstrated that individuals with higher levels of thoracic SCI relied on greater co-contraction in non-postural muscles (latissimus dorsi and trapezius) (Milosevic, et al., 2017b) whereas the low-level SCI and able-bodied individuals relied more on the lumbar and thoracic erector spinae muscles. The requirement to use non-postural muscles for postural control creates a trade-off between maintaining stability and task performance (Seelen et al., 1997, 2001), thereby impacting ADL performance and risk of falling.

The reliance on non-postural muscles, such as the latissimus dorsi, to maintain posture, as a compensatory strategy for the lack of lower trunk erector spinae muscle control (Do et al., 1985) in high-level thoracic SCI individuals, suggests a greater reliance on the passive structures of the spinal column to maintain a seated upright position. The reliance on passive structures is evidenced in the aforementioned kyphotic C-shaped posture. The activation of non-postural muscles such as the trapezius, serratus anterior and pectoralis major (Seelen et al., 1998), which all insert or originate from the shoulder girdle, are used stabilise the trunk, facilitating upper extremity based tasks. These adaptations suggest an altered posture may be adopted and that said posture could be measured using sagittal plane two-dimensional postural angle analysis.

The aim of this exploratory chapter is to quantify seated postural control in thoracic SCI individuals. The primary objective of this study was to explore any relationships in 1) stability performance, 2) control demand and 3) posture with A) SCI disability level and B) fear of falling. The second objective was to investigate the use of an individualised limit of stability boundary during static and dynamic seated postural control tasks and to determine if it could provide useful insight into risk of falling. The third objective was to assess if sagittal postures could be used to distinguish SCI injury level during quiet sitting. The final objective was to explore the impact of injury level and fear of falling on ADL, as injuries to the thoracic spine and higher impact an individual's capacity to utilise their core musculature. It was hypothesised that individuals with a higher level of disability and a greater fear of falling would present with poorer seated postural stability. Furthermore, that the use of the LOS boundary in conjunction with COP data from static and dynamic seated tasks would serve as indicators of falls risk which could

be specifically related to control demand. The third hypothesis was that sagittal postural angles could be used to differentiate between low- and high-injury level in thoracic SCI individuals. It was hypothesised that a higher level of injury would positively correlate with a greater fear of falling and that a greater fear of falling would positively correlate with poorer self-reported scores in mobility and self-care.

5.2. Methods

5.2.1 Participants

Eight SCI participants (mean [SD]: age 47 [10] years; height 171 [8] m; mass 77 [14] kg) and four able-bodied participants (age 42 [10] years; height 172 [8] m; mass 80 [10] kg) completed this study. Participant characteristics are presented in Table 4.2 (section 4.5). SCI individuals were recruited from private physiotherapy and specialist neurological rehabilitation facilities for this study. Low SCI injuries were defined as those below T8 and high injuries were defined as those at or above T8 (Minkel, 2000). Able-bodied control participants were recruited from the local university community and were age-gender- and height-matched to the SCI participants as closely as possible. All participants gave their written informed consent prior to testing.

5.2.2. Protocol

Upon arrival to the laboratory, participants were asked to don a form fitting top to allow markers to be placed on specific bony landmarks to facilitate postural analysis. Markers were placed on C7, T8, the right acromion process and the 5th metacarpal of the right hand. All participants were then asked to complete three activities: quiet sitting, a sit

and reach task, and a limit of stability task. The quiet sitting and sit and reach tasks were each completed three times and the limit of stability task was completed once per participant. Centre of pressure data were captured through Kistler's Bioware (version 5.2.0.2), using a single Kistler (9286AA) force plate (GmbH, Winterthur, Switzerland) sampling at 100 Hz. The (x,y) (0,0) coordinates were located at the exact centre of the force plate and all COP data were recorded relative to this location. The force plate was mounted into a custom-made height adjustable seat with a removable back support and no armrests. Two-dimensional (2D) video footage was captured using a standard digital video camera (Sony, HDR-CX240E, Tokyo, Japan) at 25 Hz. The camera was placed perpendicular to the participant's plane of motion to capture the sagittal view, five metres from the lateral border of the seat. The width of the force plate mounting frame (affixed to the top of the seat) was used as a calibration object in the 2D video from which all measurements could be calculated from (Figure 5.1). The calibration object was 65 cm in length and was defined at each end by coloured tape that contrasted with the background. Prior to data collection the seat height was adjusted using the telescopic legs, so that the participant could sit with their hips, knees and ankles at ninety degrees, with their feet flat on the floor.

The quiet sitting task required the participants to sit on the force plate, otherwise unsupported, for 30 seconds at a time. Participants were instructed to maintain their balance and natural posture for the duration of the test without holding onto the seat. No specific instruction was given regarding the positioning of their hands apart from to ensure they did not use them to support themselves. Participants were told to call out and grab onto a support if at any time they began to fall. The only other instruction was

to keep their hands off the force plate for the duration of the test. The quiet sitting task was completed three times, between each trial the participant transferred off of the force plate back to their wheelchair to allow for it to be reset. Centre of pressure (COP) data and 2D video footage were recorded throughout each trial. Stills from this footage were used to assess posture using the methods of van Niekerk et al. (2008) which allows head, cervical and thoracic angles to be calculated from a 2D still image of the sagittal plane.

The second task was the sit and reach task (SRT), which required the participants to sit with a natural posture, to raise their right arm directly in front of them until it was parallel to the floor and level with the shoulder. Once in this position, participants were asked to lean as far forward as possible and return to the original position without using their left hand to hold onto anything for support. They were instructed to keep their shoulders square to the frontal plane. The horizontal displacement of the marker placed on the lateral aspect of the 5^{th} metacarpal of the right hand was tracked using the 2D digital video, providing the distance reached. The COP displacement in the anterior-posterior direction was used as a secondary measure to ascertain stability performance and control demand during the task.

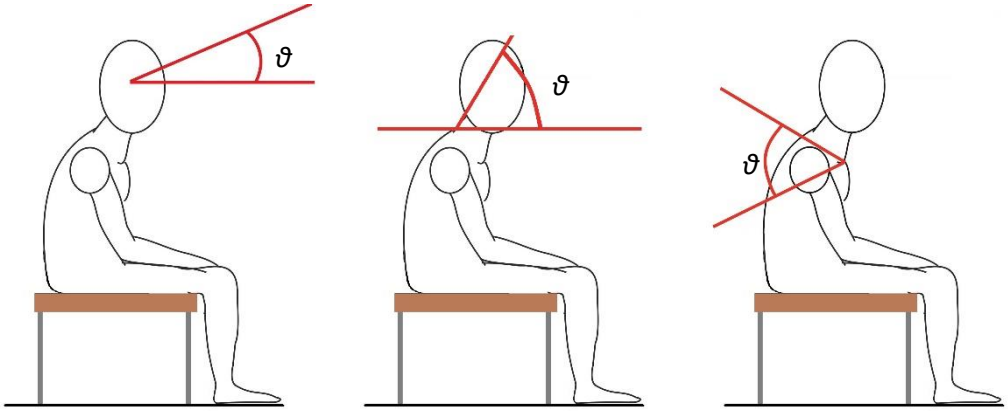
The final task was based on the work of Shin and Sosnoff (2013). Participants were asked to sit on the force plate with their arms by their sides but not touching the force plate. They were then instructed to trace an ellipse with their upper body by pivoting at the hips and lumbar spine/vertebrae clockwise, leaning anteriorly, laterally to the right, posteriorly and laterally to the left repeatedly for 30 seconds. Data were recorded using

the force plate; no video was captured as the test administrator was positioned next to the participant to provide physical support to prevent falling if a participant leaned over too much.

5.2.3 Data processing

5.2.3.1 2D video data

All 2D video data were processed in SiliconCoach Live (The Tarn Group, Dunedin, New Zealand). To generate the 2D postural angles, still images were taken from each video at the mid-point of the 30-second trial. A single frame was assessed from each trial. The sagittal head angle, cervical angle and thoracic angle were calculated using the methods of van Niekerk et al. (2008) (Figure 5.1). Shoulder protraction – retraction angle and arm angle were not included in the analysis as described by van Niekerk et al. (2008) as the participants were given some instruction about arm position, they were asked not to rest them on their legs or on the force plate. As a consequence, the arm position of the individual participants would not have been a true representation of their normal posture, limiting the capacity for such data to be used in clinical interpretation.



Angle formed by line between lateral canthus of the eye and the midpoint of the tragus intersecting with the horizontal line through the tragus

A

Angle formed by line between midpoint of the tragus and the spinous process of C7 intersecting with the horizontal line through the spinous process of C7

B

Angle formed by line between the spinous process of C7 and the manubrium intersecting with the line through the spinous process of T8 and the manubrium

C

Figure 5.1. Experimental set up depicting where postural angles were measured from 2D still images captured during the quiet sitting task. (A) head angle, (B) cervical angle and (C) thoracic angle (modified from van Niekerk *et al*., (2008)).

The horizontal displacement of the 5th metacarpal marker in the sagittal plane during the SRT was measured by manually tracking the position of the marker frame by frame and measuring the distance between the two most extreme points. In order to achieve this, the distance calibration process was completed in SiliconCoach Live by highlighting the two end points of the calibration object and entering the known length (65 cm). Once this was completed the original position of the 5th metacarpal marker was highlighted, the video was then manually progressed frame by frame, when the marker was deemed to have reached its furthest point from its original position the distance between said position and the original location were measured using the horizontal measurement tool. Three frames before and after the chosen frame were measured (seven measurements in total) to ensure the maximum distance was identified and the

greatest distance achieved was recorded for that trial. Participants completed the SRT three times and the average score was calculated.

5.2.3.2 Centre of pressure data

Centre of pressure data were processed in MATLAB (R2018b). As each trial was completed with each participant sat on the force plate in a slightly different location, a correction factor was applied to all of the data. In the quiet sitting and SRT trials, a Euclidian correction was used to centre the first data point at (x,y) co-ordinates (0,0) with all subsequent data points corrected relative to this new orientation. The LOS data again used a Euclidian correction however the centre of the LOS COP trace was re-located to the (0,0) coordinates of the force plate. All COP data were filtered using a fourth order Butterworth (cut-off frequency 5 Hz). Once filtered and corrected, an ellipse function (fit_ellipse, Ohad Gal, 2003) was used to fit an ellipse to the LOS data to create a LOS boundary. The ellipse function uses the location of every data point relative to every other to identify a centre point, it then generates a long and a short axis and plots an ellipse based on these parameters.

The radial distances of path length (mm), radial range (mm) (diagonal line of the two furthest data points on a plot of the COP data), and mean and maximum velocities (mm/s) for each displacement variable were calculated for quiet sitting and LOS data from the anterior-posterior and medial-lateral (x,y) time series data using the following formula.

$$Radial\ distance = \sqrt{AP^2 + ML^2}$$

Circumference (mm) and area (mm^2) were calculated for the LOS boundary, and the mean and minimum distance of each quiet sitting trial relative to the individual's LOS boundary was identified (mm). Finally, the minimum distance of the SRT COP displacement from the LOS boundary (mm), and the mean and maximum velocities (mm/s) of the SRT COP displacement were calculated.

5.2.3.3 Quality of Life

Participants completed three QOL assessment tools following the balance tasks. Self-reported balance confidence was quantified using the Modified Falls Efficacy Scale; functional capacity was assessed using the SCI-FI Quality of Life Self-care short-form; and overall quality of life was measured with the Quality of Life Basic Mobility short-form tools.

5.2.3.4 Modified Falls Efficacy Scale

The Modified Falls Efficacy Scale (MFES) is a fourteen-item questionnaire requiring individuals to assess their fear of falling whilst completing activities of daily living such as taking a bath or shower, answering the door or telephone, and uses a visual analogue scale (VAS) between 1 (very confident) and 10 (not confident at all) (Hill et al., 1996). The MFES was developed from the Falls Efficacy Scale, created by Tinetti et al. (1990), to include more challenging outdoor community-based activities (Hill et al., 1996). Test–retest reliability of the original Falls Efficacy Scale has been assessed in a several clinical populations including geriatric adults (r = 0.71) (Tinetti et al., 1990) and stroke patients (ICC = 0.97) (Hellström & Lindmark 1999). Criterion validity was assessed in an SCI

population where the concurrent validity with the Berg Balance Scale was reported as excellent (r = -0.81) (Wirz et al., 2010). As the MFES incorporates the entire original scale, the reliability and criterion validity should be considered. Moreover, the MFES test-retest reliability has been reported as high (ICC = .93), and internal consistency has been demonstrated to be high (Cronbach's alpha = 0.95) in a healthy elderly population (Hill et al., 1996). John et al. (2010) used the MFES in a study investigation postural control and fear of falling in low-level SCI individuals (below T8). They reported re-test reliability as high (ICC = .58) and internal reliability as excellent (Cronbach's alpha = 0.97). A copy of the MFES can be found in appendix 2.

5.2.3.5 Spinal Cord Injury Functional Index

The Spinal Cord Injury Functional Index (SCI-FI) is a bank of questions that can be used to self-assess the physical consequences of SCI, focusing on functional ability rather than burden of care (Heinemann et al., 2014). It consists of 275 items across five domains and was developed as part of the Spinal Cord Injury Quality of Life Measurement System. The five domains are: basic mobility, self-care, fine motor functioning, wheelchair mobility and ambulation (Tulsky et al., 2015). Each domain was designed to focus on a specific set of functional movement characteristics and provide reliable measurements across a range of abilities and injury levels. The validity and reliability of each domain have been quantified for both individuals with tetraplegia and paraplegia. This thesis will use the self-care and basic mobility domains only; test-retest reliability was reported as ICC = 0.98 for tetraplegia and 0.97 for paraplegia for both domains (Jette et al., 2015). The SCI-FI was designed to be administered via computer-adaptive testing; short-form versions of each domain were developed using a subset of bank items to make

administration of the test easier and less time-consuming. The short-form versions of the SCI-FI allow physical function to be assessed with similar reliability to the computer-adaptive testing method. Self-care short-form consists of 11 items, presents with good internal consistency (Cronbach's alpha 0.94 tetraplegia and 0.94 paraplegia) and a high level of agreement (ICC = 0.91 tetraplegia and 0.90 paraplegia) with the full item bank. Basic mobility short-form consists of 11 items, presents with good internal consistency (Cronbach's alpha 0.95 tetraplegia and 0.89 paraplegia) and a high level of agreement (ICC = 0.97 tetraplegia and 0.93 paraplegia) with the full item bank (Heinemann et al., 2014). Copies of the SCI-FI short-form basic mobility and self-care questionnaires can be found in appendices 3 and 4.

5.2.4 Statistical analysis

Pearson's *r* or Spearman *ρ* correlations were conducted for each kinematic and COP variable against injury level and against fear of falling using the MFES score depending upon normality. Correlations with level of SCI disability were calculated for all participants, and subsequently without the able-bodied group to ensure their data did not bias the results. Correlations were run with and without outliers to assess the effect an outlier may have on the result; in all cases where this was undertaken the result was reported with the outlier removed due to the difference. Established thresholds of negligible (0.1 to 0.3), moderate (0.3 to 0.5) and large (> 0.5) were used for interpretation (Cohen, 1988).

Due to the limited number of participants in each group (HIGH = 6, LOW = 2 and AB = 4), percentage difference, Hedge's g effect sizes and 95% confidence intervals were

calculated for all variables. Percentage difference was calculated between each group using the equations in Figure 5.2. Hedges' g effect sizes were calculated using a pooled and weighted standard deviation (Hedges & Olkin, 1985). Established thresholds of small (0.2–0.49) medium (0.5–0.79) and large (≥0.8) thresholds were used for interpretation of Hedges' g (Cohen, 1992). Participants were grouped based on level of disability, with able-bodied individuals considered to have no injury and thus no disability and SCI individuals deemed to have a greater disability as injury level increased. The SCI low-level injury group (LOW) were defined as individuals with injuries below T8, and the high-level injury group (HIGH) were defined as individuals with injuries at or above T8, as suggested by Minkel (2000). No other inferential statistics were run due to the small sample size in each group.

$$\%\, diff\ HIGH\ Vs.\ LOW = \left(\frac{LOW - HIGH}{LOW} \right) \times 100$$

$$\%\, diff\ HIGH\ Vs.\ AB = \left(\frac{AB - HIGH}{AB} \right) \times 100$$

$$\%\, diff\ LOW\ Vs.\ AB = \left(\frac{AB - LOW}{AB} \right) \times 100$$

Figure 5.2. Percentage difference formula for each group comparison.

5.3. Results

Spearman's ρ correlations were run for all variables relative to level of disability due to the non-parametric distribution of the injury level data when the AB group were included (Table 5.1). Twelve of 19 variables presented with statistically significant ($P < 0.05$) strong positive correlations, and two variables presented with statistically significant ($P < 0.05$) strong negative correlations. The significant relationships for nine distance/area based variables suggested that as level of disability increased, stability performance decreased.

Once the AB group data were removed, Pearson's r and Spearman's ρ were conducted again for each variable based on the normality of the data relative to injury level. Table 5.2 presents either the r or ρ depending upon distribution. When considering only the SCI data, the number of significant correlations dropped to three: quiet sitting range, SRT minimum distance from LOS boundary and head angle (presented in Table 5.1).

Correlations were also run for all variables with fear of falling for the SCI participants. Only the COP for quiet sitting range presented with a significant ($P < 0.05$) strong negative correlation. No other variables showed any correlations.

Table 5.1. Spearman and Pearson correlations and significance (P = 0.05) for all variables relative to injury level and fear of falling.

Correlation relative to injury level	All participants		SCI participants only				Correlation relative to fear of falling	SCI participants only			
	Spearman (ρ)	Sig (p)	Pearson (r)	Sig (p)	Spearman (ρ)	Sig (p)		Pearson (r)	Sig (p)	Spearman (ρ)	Sig (p)
QS path length	**-.74**	**0.006**	-.66*	0.108			QS path length	-.50	0.212		
QS range	**-.58**	**0.049**			**-.94**	**0.002**	QS range			**-.76**	**0.028**
QS COP velocity mean	-.29	0.356	-.53	0.173			QS COP velocity mean	-.51	0.202		
QS COP velocity max	-.50	0.099	-.50	0.204			QS COP velocity max	-.44	0.274		
QS minimum distance from LOS	**.80**	**<0.001**			.04*	0.937	QS minimum distance from LOS			-.14*	0.760
QS mean distance from LOS	**.75**	**0.005**			-.22*	0.632	QS mean distance from LOS			-.43*	0.337
LOS path length	**.90**	**<0.001**	.69	0.601			LOS path length	.48	0.233		
LOS range	**.67**	**0.018**			.37*	0.413	LOS range			.18*	0.702
LOS COP velocity mean	.56	0.061	.06	0.881			LOS COP velocity mean	.14	0.736		
LOS COP velocity max	.56	0.061	.19	0.660			LOS COP velocity max	.24	0.566		
LOS circumference	**.77**	**0.004**			-.11*	0.812	LOS circumference			-.25*	0.589
LOS area	**.75**	**0.005**			-.22*	0.632	LOS area			-.43*	0.337
SRT minimum distance from LOS	**.90**	**<0.001**			**.98***	**0.005**	SRT minimum distance from LOS			**-**.40*	0.600
SRT marker displacement	.04	0.904			.15*	0.805	SRT marker displacement			.60*	0.208
SRT COP velocity mean	**.71**	**0.022**	.71	0.116			SRT COP velocity mean	.20	0.635		
SRT COP velocity max	**.71**	**0.023**	.42*	0.048			SRT COP velocity max	.25	0.552		
Head angle	**.60**	**0.038**	**.80***	**0.031**			Head angle	.27*	0.556		
Cervical angle	**.65**	**0.024**	.23	0.583			Cervical angle	.24	0.560		
Thoracic angle	**.60**	**0.041**	-.00	0.992			Thoracic angle	-.40	0.328		
MFES	N/A	N/A	.83*	0.860							
SCI-FI basic mobility	N/A	N/A	**.85**	**0.008**			SCI-FI basic mobility	.54	0.171		
SCI-FI self-care	N/A	N/A	.03	0.935			SCI-FI self-care	.31	0.459		

P = significance, SCI = Spinal cord injury, QS = Quiet sitting, LOS = Limit of stability, max = Maximum, SRT = Sit and reach, MFES = Modified Falls Efficacy Scale, SCI-FI = Spinal cord injury – Functional Index, COP = Centre of pressure

* = outlier removed

Alpha level = 0.05

5.3.1 Centre of Pressure

Limit of stability COP plots, and the associated ellipse representing a LOS boundary for each participant, are presented in Figure 5.3. Typical quiet sitting COP path length superimposed over the LOS boundary profiles for each individual can be seen in Figure 5.4 and SRT plots are in Figure 5.5.

Temporal-spatial parameters are reported in Table 5.2. Minimal differences were identified between the AB and LOW group for quiet sitting path length (1%, g = 0.61). Temporal measures showed only small and moderate differences for quiet sitting velocity measures and the maximum SRT COP velocity. All other variables presented with large effect sizes and larger percentage differences, as seen between the AB and HIGH injury groups.

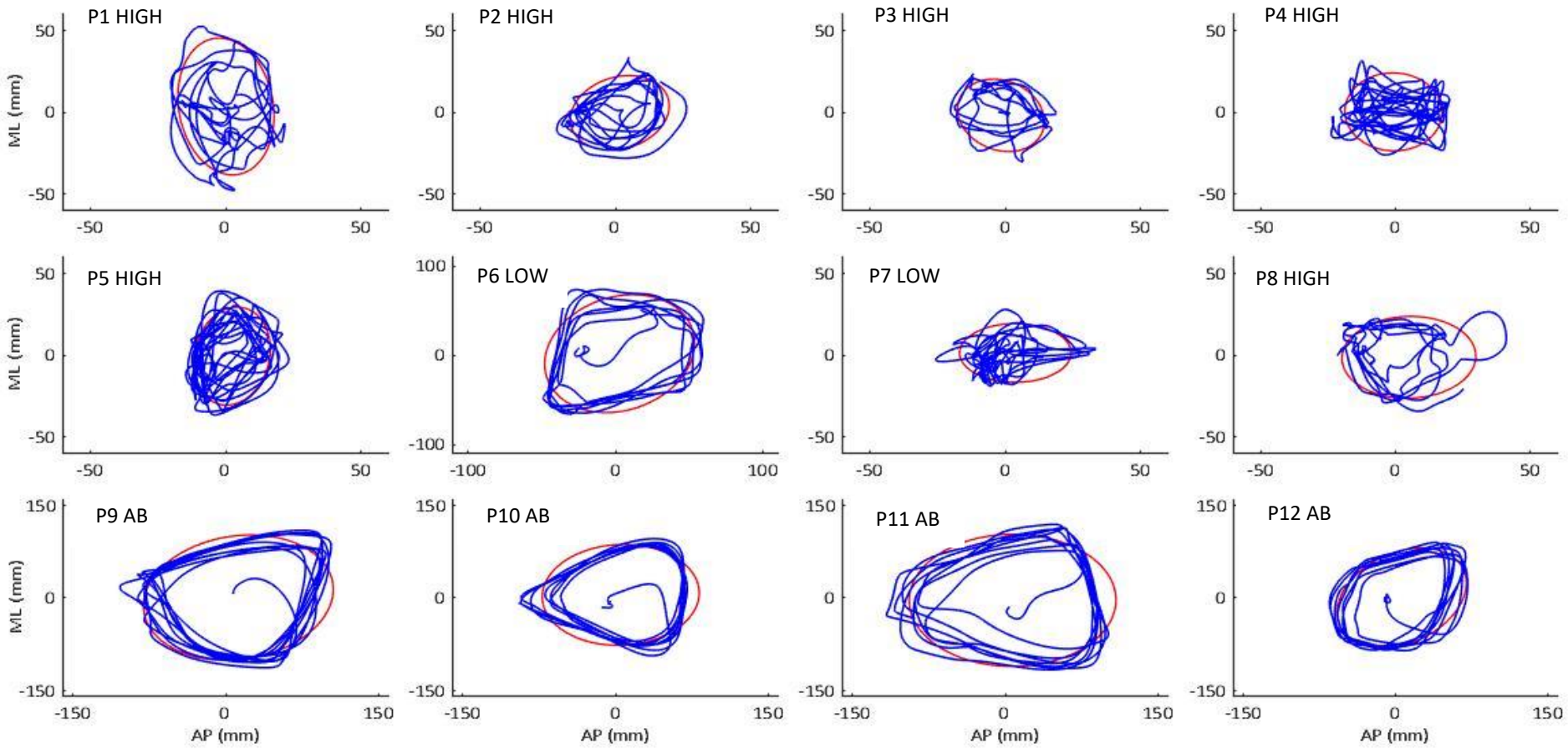


Figure 5.3. Individual limit of stability centre of pressure plots and the fitted ellipse boundary. All SCI participants plots were scaled -50 to +50 mm in each direction apart from P6 who was scaled at -100 to +100 mm in each direction. All AB participant plots were scaled at -150 to +150 mm in each direction.

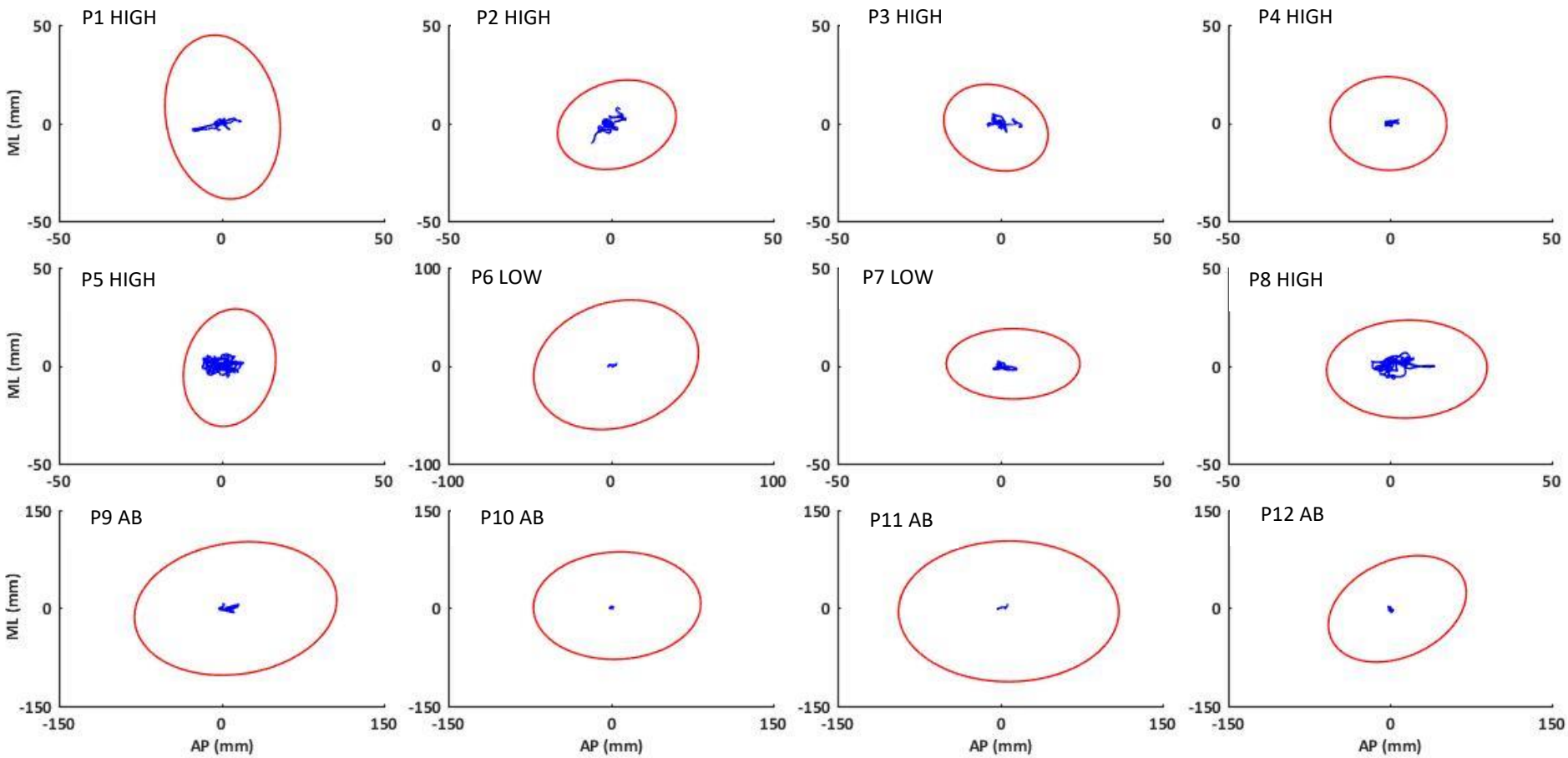


Figure 5.4. Typical quiet sitting centre of pressure plots and the individual limit of stability boundary profiles for each participant. All SCI participants plots were scaled -50 to +50 mm in each direction apart from P6 who was scaled at -100 to +100 mm in each direction. All AB participants plots were scaled at -150 to +150 mm in each direction.

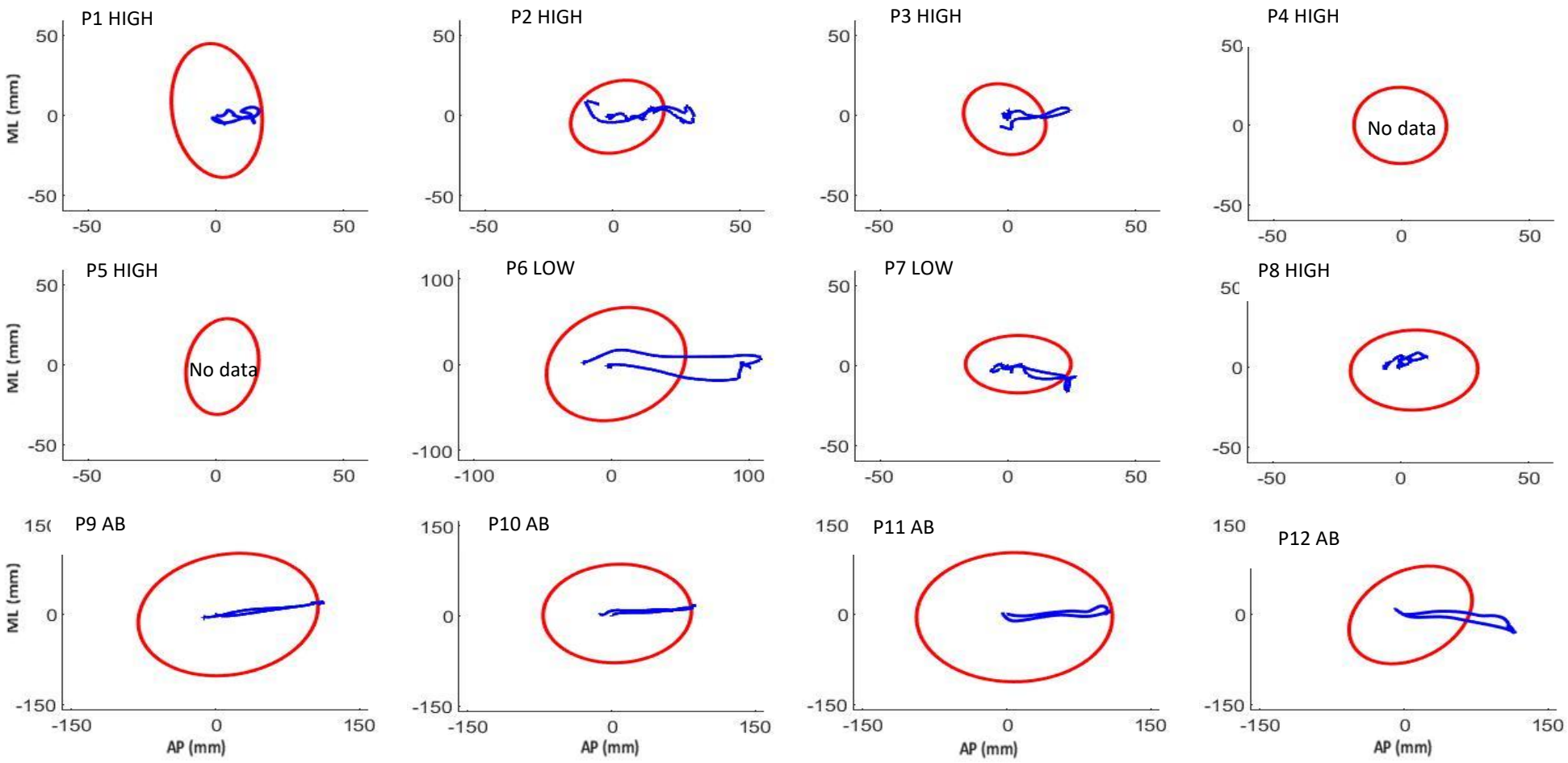


Figure 5.5. Typical sit and reach centre of pressure plots and the individual limit of stability boundary profiles for each participant. NB participants 4 and 5 did not complete the SRT test resulting in the absence of data. All SCI participants plots were scaled -50 to +50 mm in each direction apart from P6 who was scaled at -100 to +100 mm in each direction. All AB participants plots were scaled at -150 to +150 mm in each direction.

Table 5.2. Median (interquartile range) postural control and balance data for LOW- and HIGH-level spinal cord injured individuals and able-bodied controls (percentage difference, Hedges' g effect sizes and 95% confidence intervals).

	Median (IQR)						Percentage difference			Effect sizes (95% CI)		
Units = mm unless otherwise stated	HIGH		LOW		AB		HIGH vs LOW	HIGH vs AB	LOW vs AB	HIGH vs LOW	HIGH vs AB	LOW vs AB
QS path length	184	(85.7)	59	(7.5)	60	(18.5)	-211	-207	1	0.79 (2.44 to -0.85)	**-1.72 (0.09 to -3.52)**	0.61 (2.24 to -1.02)
QS range	9	(4.1)	4	(0.1)	6	(1.7)	-146	-62	34	**0.88 (2.53 to -0.78)**	**-0.83 (0.82 to -2.48)**	**1.74 (3.56 to -0.07)**
LOS path length	1129	(503.2)	1733	(611.6)	4307	(1427.3)	35	74	60	-0.49 (1.12 to -2.11)	**4.79 (7.63 to 1.95)**	**3.33 (5.62 to 1.04)**
LOS range	36	(5.7)	55	(21.2)	113	(23.5)	17	68	51	**-1.30 (0.42 to -3.03)**	**7.58 (11.62 to 3.53)**	**3.58 (5.95 to 1.20)**
QS minimum distance from LOS	8	(4.7)	29	(15.5)	73	(15.1)	73	89	61	**-1.39 (0.35 to -3.13)**	**6.34 (9.83 to 2.84)**	**2.83 (4.95 to 0.71)**
QS mean distance from LOS	23	(3.5)	39	(19.5)	89	(21.8)	41	74	56	**-1.62 (0.17 to -3.40)**	**7.40 (11.37 to 3.44)**	**3.21 (5.45 to 0.97)**
SRT minimum distance from LOS	4	(11.1)	32	(30.1)	1	(14.4)	88	-325	-3422	**-1.23 (0.48 to -2.94)**	0.61 (2.24 to -1.02)	**-0.93 (0.73 to -2.60)**
SRT marker displacement (% seated height)	5.2	(4.3)	33.2	(18.0)	55.8	(14.7)	84	91	41	**-1.74 (0.08 to -3.55)**	**9.37 (14.24 to 4.51)**	**1.83 (3.67 to 0.00)**
LOS circumference	138	(23.4)	244	(123.3)	557	(135)	44	75	56	**-1.60 (0.18 to -3.38)**	**7.45 (11.43 to 3.46)**	**3.20 (5.00 to 0.74)**
LOS area (mm^2)	134	(50.5)	576	(460.0)	2481	(1204)	77	95	77	**-1.83 (0.00 to -3.67)**	**4.91 (7.80 to 2.02)**	**2.87 (5.00 to 0.74)**

	Median (IQR)						Percentage difference			Effect sizes (95% CI)		
Units = mm/s unless otherwise stated	HIGH		LOW		AB		HIGH vs LOW	HIGH vs AB	LOW vs AB	HIGH vs LOW	HIGH vs AB	LOW vs AB
QS COP velocity mean	31	(25.0)	11	(0.2)	11	(4.4)	-177	-198	-8	**0.88 (2.54 to -0.78)**	**-1.29 (0.43 to -3.01)**	0.47 (2.09 to -1.15)
QS COP velocity max	238	(165.8)	68	(9.8)	72	(41.8)	-251	-231	6	**0.83 (2.48 to -0.82)**	**-1.15 (0.55 to -2.84)**	0.76 (2.40 to -0.88)
LOS COP velocity mean	137	(104.5)	158	(10.3)	316	(122.0)	13	57	50	0.76 (2.41 to -0.88)	**1.66 (3.45 to -0.14)**	**1.94 (3.80 to 0.08)**
LOS COP velocity max	703	(432.8)	924	(197.3)	1337	(512.1)	24	47	31	0.32 (1.93 to -1.28)	**1.20 (2.90 to -0.51)**	**1.11 (2.80 to -0.58)**
SRT COP velocity mean	80	(31.0)	108	(29.4)	163	(75.9)	26	51	34	-0.54 (1.08 to -2.16)	**2.03 (3.92 to 0.15)**	**1.02 (2.70 to -0.66)**
SRT COP velocity max	302	(131.7)	520	(165.6)	703	(110.1)	42	57	26	**-0.86 (0.80 to -2.51)**	**2.27 (4.22 to 0.32)**	0.53 (2.15 to -1.09)

AB = Able-bodied, SCI = Spinal cord injured, COP = Centre of pressure, QS = Quiet sitting, LOS = Limits of stability, SRT = Sit and reach, IQR = interquartile range, max = maximum, CI = Confidence interval

5.3.2 Postural angles

Table 5.3 presents postural angle data for each individual and each group, although large effect sizes were evident between the LOW- and HIGH-level injury groups, the limited sample sizes and the spread of the data made it difficult to draw group conclusions. By examining the data on a case by case basis, it was possible to identify three SCI and one AB individual that presented with more slouched postures than the other participants (participants 1, 2, 8 and 10).

Table 5.3. Postural angle data for all participants including median (interquartile range), percentage difference, Hedges' g effect sizes and 95% confidence intervals for LOW- and HIGH-level spinal cord injured individuals and able-bodied (AB) controls.

Units = degrees	Group	Head angle Mean of 3 trials	(SD)	Cervical angle Mean of 3 trials	(SD)	Thoracic angle Mean of 3 trials	(SD)
P1	HIGH	10	(8)	23	(2)	49	(1)
P2	HIGH	14	(1)	26	(3)	42	(1)
P3	HIGH	12	(0)	42	(2)	58	(5)
P4	HIGH	39	(0)	50	(1)	59	(3)
P5	HIGH	22	(4)	67	(4)	56	(3)
P6	LOW	15	(1)	35	(0)	57	(3)
P7	LOW	16	(1)	49	(5)	71	(1)
P8	HIGH	24	(2)	36	(1)	51	(2)
P9	AB	18	(1)	52	(1)	81	(1)
P10	AB	17	(1)	56	(2)	59	(4)
P11	AB	17	(1)	50	(1)	71	(1)
P12	AB	20	(1)	58	(1)	72	(1)
High	Median (IQR)	15	(3)	39	(19	57	(7)
Low	Median (IQR)	31	(7)	43	(7)	55	(4)
AB	Median (IQR)	18	(2)	54	(5)	71	(6)

	Head angle		Cervical angle		Thoracic angle	
	Group percentage differences	Effect Size (95% CI)	Group percentage differences	Effect Size (95% CI)	Group percentage differences	Effect Size (95% CI)
HIGH vs LOW	53	**-1.67 (0.12 to -3.47)**	10	**-0.93 (0.73 to -2.60)**	-3	**-1.55 (0.22 to -3.32)**
HIGH vs AB	16	**1.05 (2.73 to -0.63)**	28	**1.13 (2.83 to -0.56)**	21	**1.84 (3.68 to 0.00)**
LOW vs AB	-79	**-1.03 (0.65 to -2.71)**	20	0.63 (2.26 to -1.00)	23	0.67 (2.30 to -0.96)

AB = Able-bodied, IQR = interquartile range, CI = Confidence interval

5.3.3 Quality of life

SCI-FI and MFES date were recorded for the SCI individuals only. Results are reported in Table 5.4. Although the percentage difference between the two groups was largest for the MFES, it appears that fear of falling was not influenced by injury level (g = 0.00).By considering individuals on a case-by-case basis, it appears that P6 (low-level injury) self-reported fewer mobility issues than all other participants, and that P5 (high-level injury) had the least issues with self-care tasks. These two participants also presented with the highest falls efficacy scores, suggesting they feared falling less than the other participants.

Table 5.4. Quality of life questionnaire scores for LOW- and HIGH-level spinal cord injured individuals (group median score and interquartile range, percentage difference, Hedges' g effect sizes and 95% confidence intervals).

		Quality of life assessment tools		
	Group	MFES	SCI-FI BM	SCI-FI SC
P1	HIGH	5.36	51.41	55
P2	HIGH	3.55	52.7	56.58
P3	HIGH	8.39	50.17	51.03
P4	HIGH	2.35	50.58	54.39
P5	HIGH	8.34	53.62	65.01
P6	LOW	8.64	57.88	56.58
P7	LOW	4.7	52.26	56.58
P8	HIGH	2.45	50.58	53.84
Median (IQR)	HIGH	4.45 (4.87)	51.00 (1.80)	54.70 (2.21)
Median (IQR)	LOW	6.67 (1.97)	55.07 (2.81)	56.58 (0.0)
Percentage difference		33	7	3
Effect Size (95% CI)		0.00 (1.60 to -1.60)	**-1.04 (0.64 to -2.72)**	**0.89 (2.55 to -0.76)**

IQR = interquartile range, CI = Confidence interval, MFES = Modified Falls Efficacy Scale, SCI-FI = Spinal Cord Injury – Functional Index, BM = Basic Mobility, SC = Self-care

5.4. Discussion

The first of the four objectives of this study were to explore the relationships between 1) stability performance, 2) control demand, 3) postural angles with A) SCI disability level and B) fear of falling. Based upon initial analysis of the 16 COP variables that were investigated, eight presented with significant positive correlations and two presented with significant negative correlations (Table 5.1). Although these findings concurred with the work of Milosevic et al. (2017a) who suggested that individuals with thoracic SCI sway more than AB individuals, identifying trends among the SCI cohort proved difficult. Once data were plotted, it was clear that the presence of the AB data drastically altered the shape of the correlation. With the exclusion of the AB data, quiet sitting COP range (ρ = -0.937, P = 0.002) and sit and reach COP distance from the LOS boundary (ρ = 0.975, P = 0.005) were the only variables that produced a strong significant correlation. Both variables were displacement based and can only therefore provide insight into stability performance and not control demand. Chen et al. (2003) reported similar findings related to quiet sitting, suggesting that these findings could be explained by a ceiling effect when measuring static postural control. In this study, a dynamic movement task was included; however, it is possible that an individuals' 'true' LOS may differ from the LOS boundary they produced during testing. For example if a person has a fear of falling (especially when required to move their COM towards the edge of their BOS) this may result in a smaller LOS boundary than they are actually capable of generating, which may have had a detrimental effect on our ability to interpret these results. Future work could employ the use of a harness to remove said fear, providing an environment enabling the exploration of whether the measured LOS is representative of a 'true' LOS.

Although it is not possible to accept that fear of falling was correlated with poorer postural stability based on the data presented in this study, individual inferences can be derived from the data. This relates to the secondary objective of this chapter, that the use of an individualised LOS boundary could be used with COP data from static and dynamic seated tasks to infer neuromuscular control. With respect to the quiet sitting COP data and the LOS boundary, differences in the postural stability were clearly identified between the SCI and AB groups (HIGH vs. AB g = 6.43 and 7.40; LOW vs. AB g = 2.83 and 3.21 respectively, Table 5.2). A smaller LOS boundary and a larger quiet sitting COP area resulted in a smaller minimum distance from said boundary as seen in Figure 5.4 suggesting an increased risk of falling. These findings are in agreement with the work of Shin and Sosnoff (2013) who identified that SCI individuals present with smaller stability boundaries and greater levels of instability than AB individuals. In the current chapter, the reduced area of stability and the increased requirement to recover the COG from close proximity to the LOS boundary suggested an increased control demand, as those individuals who expressed these traits also presented with the greatest COP velocity data. The mean and maximum quiet sitting COP velocity data which showed the high group had a mean velocity of ~20 mm/s and a maximum velocity of ~170 mm/s greater than the low and AB groups. The increased demand and reduced capacity to maintain postural control may have negative consequences in a variety of situations, especially if unexpected external perturbations are experienced such as when inside a moving vehicle or travelling in a wheelchair on uneven ground (Kamper et al., 1999).

The use of the LOS boundary in the dynamic task raised two issues. Firstly, participants were asked to intentionally move towards the boundary, directly challenging stability, requiring

high levels of neuromuscular control and the capacity to use different COM control strategies to preserve stability (Preuss & Popovic, 2010). The second factor that may have influenced the outcome of the dynamic task was fear of falling during the LOS test. The difference between an actual LOS and an individual's perceived LOS has not been identified in an SCI population (Shin and Sosnoff, 2013). Although beyond the scope of the current study, it is possible to postulate that fear of falling may have influenced some of the participants' LOS boundary. Participant seven (injury level T9, LOW-level injury group) presented with the second smallest LOS circumference (121 mm) and ranked fourth in fear of falling with an average score of 4.7 (Table 5.4) on the MFES. This same individual, when undertaking the SRT test produced a COP trace that exceeded their LOS boundary (as did a number of participants, Figure 5.5), rendering the minimum distance from the LOS boundary result irrelevant. These results highlight that consideration of the LOS boundary in isolation may be misleading, and that it should be used in conjunction with other metrics, corroborating the findings of Shin and Sosnoff (2013). The current results indicate that visual representations of the data can complement numerical results during dynamic tasks, and thereby provide a more meaningful interpretation of postural control tasks. Furthermore, the influence of fear of falling should be considered during interpretation as it may have a significant impact on an individual's willingness to undertake a task (Forslund et al., 2016; Wirz et al., 2010). Although falls history is often seen as a useful indicator of future falls, its link in SCI individuals to fear of falling has been questioned as individuals who experience a greater number of falls appear to show less fear, possibly as most falls do not result in injury and some falls may just be accepted as the price of an active lifestyle. (Forslund et al., 2016). Furthermore, the use of a validated fear of falling questionnaire is suggested when exploring the impact of LOS on postural control. The

author has been unable to identify a validated SCI specific fear of falling questionnaire, as such future research could focus of the development and testing of such a tool.

The COP velocity results in the current study suggest that HIGH-level SCI individuals have a greater control demand than LOW-level SCI or AB individuals in quiet sitting, corroborating previous work (Milosevic et al., 2017a; Milosevic et al., 2015; Shirado et al., 2004). However, during the dynamic tasks (LOS and SRT), differences between the HIGH- and LOW-level SCI individuals were less obvious, with smaller percentage differences and smaller effect sizes (Table 5.2). The graphical representations of the LOS COP data in Figure 5.3 provides a visual representation of the differences between the AB and SCI cohorts; it also illustrates the differences of the SCI cohort at the individual level. Individuals with higher-level injuries have been shown to use co-contraction of non-postural muscles as a control strategy more often than individuals with low-level or no injury (Milosevic et al., 2017a; Milosevic et al., 2017b). The higher the level of injury, the greater the impairment to the sensory pathways within the spinal cord, potentially resulting in less muscular control (Potten et al., 1999) and fewer postural control options. Seleen et al. (2001) postulated that individuals with lower level thoracic SCI may have a greater number of responses to choose from resulting in an increased latency. This may be a factor related to postural control demand during dynamic tasks. An increase in the time to respond would potentially allow the COG to fall further and accelerate for longer before the appropriate response was able to regain control. Postural responses to specific disruptions can be learnt, and pre-existing knowledge of the magnitude and direction of a perturbation can enable the most appropriate response to be executed based on central control (Horak et al., 1989). However, the automated (pre-learned) postural responses can

be scaled to a particular perturbation using both central and peripheral mechanisms (Horak et al., 1989). It is therefore possible that the reduced capacity of the peripheral nervous system in high-level injured individuals is effectively excluded leaving the CNS to control the response scaling. This mechanism would reduce the latency of a response as peripheral information would not be relayed to the CNS prior to a postural control reaction. This could explain the increased speed in the LOW-level individuals relative to those in the HIGH-level group. It is however also possible that the increased speed of the COP in the LOW-level group was similar to that of the AB group who were able to move faster as they had greater muscular control, strength and the capacity to use afferent peripheral information (Table 5.2).

The third objective was to see if sagittal plane posture analysis could be used to identify the injury level of SCI individuals, it was hypothesised that sagittal plane postural angles could be used to differentiate between AB, LOW- and HIGH-level thoracic SCI individuals. Although it is not possible to generalise the findings of this study, because of the low participant numbers in each group, exploring individual data on a case-by-case basis can still provide some useful information. As previously stated, many SCI individuals adopt a kyphotic posture during sitting (Minkel, 2000). Using the photographic methods of van Niekerk et al. (2008), such a posture would present as a smaller thoracic angle (Figure 5.1). The results in Table 5.3 show a smaller thoracic angle for participants 1, 2 and 8 (49^{o}, 42^{o} and 51^{o} respectively), all of whom were high-level injury group, compared to the other participants. Able-bodied participant 10 presented with a much smaller thoracic angle (59°) than the other AB participants also suggesting a slight kyphosis. Minkel (2000) highlighted that due to the kyphotic curvature in the thoracic spine, and their often seated position, SCI individuals are frequently vertically

lower down than the average standing adult. Consequently, SCI individuals regularly develop neck pain from a requirement to look up to interact with standing adults. A more acute angle at the cervical spine would suggest a larger cervical lordosis, as seen in the three identified SCI participants (23^{o}, 26^{o}, and 36^{o}, respectively) (Table 5.3). Participant 10, an AB individual, did not however present with the same acute cervical angle as kyphotic SCI individuals (56^{o}). Firstly, the kyphosis was not as pronounced but secondly, the AB individual would be able to stand to interact with other individuals on the same level. These results support previous findings that greater thoracic kyphosis can be compensated for by a greater cervical lordosis (Endo et al., 2016). In order to try and reduce the occurrence of neck pain in SCI individuals, it may be appropriate to work toward correcting thoracic posture as well as cervical posture where it is possible to do so with training or orthotic supports.

The final hypothesis of this study was that a higher level of injury would lead to a greater fear of falling and subsequently poorer outcomes on the associated QOL measurement tools. At initial assessment this did not appear to be the case. There were no correlations between MFES and the SCI-FI basic mobility or self-care results (Table 5.1). However, once participant 3 was identified as an outlier based, on the visual representation of their fear of falling score relative to injury level, a second correlation was run without the outlier data. The adjusted correlation data revealed that as fear of falling decreased (indicated by a higher score on the MFES) perception of basic mobility improved (r = .83 p = 0.021). There was however still no significant relationship between fear of falling and self-care (r = .69 p = 0.088). When coupled with the percentage differences and effect sizes presented in Table 5.4, these data suggest that injury level and fear of falling may play a role in perceived QOL relative to ADL. John et

al. (2010) suggest that fear of falling in SCI individuals may be influenced by the circumstances surrounding the injurious event, as falling is a prevalent cause. Moreover, those authors further suggest that even when ADL are practised, fear and doubt of performing said tasks is often still a contributing factor. As our participants were not made aware of how they had performed on any of the tasks until after the entire testing session was completed, positive or negative reinforcement from the tasks should not have influenced the results of the questionnaires. As can be seen in Figure 5.5, four of the SCI individuals who completed the SRT task, and 3 of the AB group, all exceeded their LOS boundary. Several reasons for this are possible. A known task such as reaching forward, a common task in ADL (Field-Fote and Ray, 2010), may elicit less fear of falling (Adkin et al., 2006). In the AB group they may have transferred more weight on to their feet (Milosevic, et al., 2017a). In the SCI group it is possible that individuals had more experience in dealing with the particular neuromuscular control requirements for a familiar movement such as the SRT, especially as the movement was predominantly in the sagittal plane meaning that alternative muscular activation patterns, using the non-postural muscles around the shoulder joint, may be used to compensate for the lack of postural control musculature (Milosevic, et al., 2017b; Shirado et al., 2004). By contracting the non-postural latissimus dorsi and trapezius against the passive structures of the body that provide support in the anterior-posterior direction (which use the mechanical advantage supplied by the length of the BOS), individuals could potentially achieve greater control than in the medio-lateral direction.

The primary limitations of this study were the small sample size overall, particularly in the low-level injury group, limiting the capacity to interpret the results, especially as these low

numbers made the use of inferential statistics inappropriate. Future work should consider the impact of fear of falling on the LOS boundary and the potential differences between perceived and actual LOS. As previously indicated within this study, the use of a harness would enable further exploration of the LOS related to fear of falling. Furthermore, the development of an SCI specific fear of falling questionnaire should be considered.

5.5. Conclusion

This was an exploratory study to try and identify relationships between injury level and postural control in SCI individuals. When an able-bodied control group was included in the analysis, a number of significant strong correlations were identified. However, it was not possible to identify relationships based on injury level in the SCI cohort once the able-bodied data were removed from the analysis. Postural angles did not identify level of disability and injury level. However, the 2D photographic measurement procedures detailed here could be used in a clinical setting to provide objective measurements related to posture in SCI individuals. The use of an individualised LOS boundary relative to COP parameters during a static sitting task was shown to be effective at differentiating between high- and low-level thoracic SCI individuals. Although conclusions from quantitative data based on the COP distance from the LOS boundary during the dynamic tasks could not be made, as some individuals were able to exceed the perceived LOS boundary, it has the capacity to function as a visual representation to support the numerical data. The capacity to move beyond the LOS boundary may be linked to fear of falling during an unfamiliar task. Consequently, it is

advised that fear of falling assessments are conducted along with postural control measures in future research and during clinical application.

This chapter has illustrated that although postural angles and seated COP parameters do not correlate with spinal cord injury level, the use of these tools on an individual basis can elicit information that would be beneficial to target rehabilitation practices. One such example would be to facilitate improved cervical spine posture by targeting thoracic extension. It was also evidenced that fear of falling may have different implications dependent upon the task and that more commonly completed movements appeared to be influenced less by fear than a novel or unfamiliar task. It is therefore suggested that the inclusion of more unfamiliar tasks may be beneficial in rehabilitation practices.

5.6. Impact of this chapter on the thesis

The primary outcomes of this chapter were directly related to sitting balance and postural control. It is, however, clear that the remainder of this thesis was predominantly based on gait and upright stepping. The suggestion that upright stepping in an overground RAGT device may provide a potentially positive environment for balance training in individuals with a SCI from chapter 3, coupled with the concept that novel or unfamiliar tasks may elicit different responses in postural control rehabilitation became a secondary focus of the remaining work.

Chapter 6 – Repeatability of marker placement on individuals wearing a powered robotic exoskeleton

6.1. Introduction

Inferences made by researchers through scientific investigation must be based on valid and reliable outcome measures obtained through robust and repeatable data collection procedures (Atkinson & Nevill, 1998). Variations are inherent in the subjects and participants associated with the life sciences and are a natural component of living beings affected by diurnal rhythms and the nature of biological systems (de Vet et al., 2006). Other sources of variation in research can be attributed to numerous factors: measurement tools, experimental design, inter-rater and intra-rater differences (Bland & Altman, 1996a). The current project's use of gait analysis to assess ambulation is based upon standard practice in research and clinical monitoring of movement disorders (Davis et al., 1991). As with all human movement, natural variability exists within normal and antalgic gait patterns; combined with possible errors related to data collection and processing, interpretation can be flawed.

One of the main issues related to reliability testing in medical science is understanding the differences between agreement, reliability, repeatability, and reproducibility as these terms are often used interchangeably in the literature (de Vet et al., 2006). Agreement assesses how similar the scores of repeated measurement are to each other and allows for an objective assessment of the accuracy of a testing procedure or piece of equipment. Agreement is also calculated and reported on the same scale as the original measurements (Bartlett & Frost, 2008). Reliability assesses the variability between study subjects; a high level of reliability will allow subjects to be distinguished

from each other, whereas a low reliability will not, as measurement error will be larger than the true value (Bartlett & Frost, 2008; de Vet et al., 2006). Repeatability refers to repeated measures made under the same controlled conditions; and reproducibility refers to repeated measures made under changing conditions such as the use of different equipment (Bartlett & Frost, 2008).

Repeatability testing in gait analysis is often reduced to a single number per variable to represent the reliability of data collected across the entire cycle. Gait analysis provides vast amounts of information used to quantify human movement; in order to enable interpretation, time dependant discrete variables are often reported based on peak values (Sadeghi et al., 2000). Pathological or abnormal gait is usually compared to 'normative' data using these peak values (McGinley et al., 2009). To ensure appropriate interpretation, data quality needs to be optimised; sources of error include soft tissue movement artefact (Manal et al., 2000) and instrumental error (Cappozzo et al., 2005). Soft tissue artefact was minimised through the use of rigid shell marker cluster (Manal et al., 2000) and instrumental error was negated as much as possible through camera calibration, the use of static calibration files for pose estimation and appropriate filtering techniques to reduce signal noise (Chiari et al. 2005). No repeatability data related to 3D marker coordinates, measured with motion capture technology during robotic exoskeleton use, has been identified in the literature. Due to the structure of the LEXO, locating anatomical landmarks on the lateral aspects of lower-limb joints is challenging. Furthermore, the device would occlude any markers placed on the lateral landmarks.

The current thesis recruited both spinal cord injured (SCI) and able-bodied individuals in order to study LEXO gait. Due to the difficulty associated with SCI individuals attending

the laboratory and donning and doffing the LEXO, the current repeatability work will be completed with able-bodied participants. The capacity of a lower limb robotic exoskeleton (LEXO) to produce repeated steps based on programmable variables should produce limited step-to-step variability of the device. It is possible that the novel task of walking in a LEXO for an able-bodied cohort may increase movement variability of the user compared to normal gait (Caballero et al., 2017; Wolpert & Flanagan, 2016) as the individuals learn to move within the constraints of the LEXO. The increased movement variability, and the inherent variability within human movement, will reduce the repeatability compared to the LEXO. The results of this investigation needed to be applicable to both populations, the main focus of the repeatability assessment will therefore focus on agreement to assess maker placement repeatability across testing sessions, rather than reliability.

The aim of this chapter was to assess the repeatability of the primary researcher's marker placement and the adapted six degrees of freedom (6DOF) marker model (Section 4.7.4.) designed to facilitate 3D kinematic data collection of the whole body and the exoskeleton during LEXO use. In order to achieve this, agreement and reliability assessments were carried out on repeated measures of able-bodied participants during LEXO use with at least one week between sessions. It was hypothesised that marker placement would be repeatable and that the use of the adapted 6DOF model would yield good levels of agreement across repeated sessions. Secondary hypotheses based on the nature of the LEXO device were that 1) the kinematics of the LEXO device would be more repeatable than those of the users' body, 2) reliability across sessions would be high, as the novel task of stepping in the LEXO should generate high levels of variability, and 3) sagittal plane angles would present with the lowest levels of error.

6.2. Methods

6.2.1. Participants

Eight able-bodied participants (mean ± SD: age 28 ± 6 years: height 1.72 ± 0.04 m; body mass 77 ± 7 kg) were recruited for this study. All participants gave written informed consent prior to testing. Individual participant details can be found in Table 4.1 (section 4.5) and inclusion and exclusion criteria can be found sections 4.3 and 4.4, respectively.

6.2.2. Experimental protocol

Participants completed the same protocol during two visits to the Human Performance Laboratory at the University of Hull with at least one week between visits. All participants were asked to wear skin-tight clothing to allow retroreflective markers to be affixed to the body as described in section 4.7.4. During the first visit, each participant was fitted for the ReWalk™ as described in section 4.6 prior to marker placement. Retro-reflective markers were affixed to the participant's body to track the movement of the individual inside the LEXO and to the ReWalk™ itself to track the kinematics of the LEXO. Kinematic and ground reaction force data were collected for ten trials per participant per visit. No specific walkway distance was set but each participant was required to have completed at least one step with each foot prior to contacting, and following contact with, the force plate to ensure the data analysed were not based on step initiation or termination (Kirtley, 2006). Trials were repeated by individuals if a trial was deemed incomplete due to user error; for example, stopping mid walk. A qualified ReWalk™ gait

trainer followed each participant (avoiding contact with the force plates) to provide physical balance support or correction only if or when required.

6.2.3. Data analysis

In order to investigate the repeatability of data collection procedures pertaining to this thesis, both agreement and reliability were calculated on repeated measures of kinematic data. Standard error of measurement (SEM) was used to report agreement and intraclass correlation coefficients (ICCs) were used to assess intra-rater reliability.

All kinematic and kinetic data were processed as described in section 4.8. Kinematic and GRF data from the left and right limbs were averaged for each session for each participant as the movement parameters programmed into the LEXO are the same for each leg. Kinematic variables included range of motion (ROM) of the trunk and pelvis in all three planes, sagittal plane hip, knee and ankle and frontal plane hip ROM, as well as fifteen other discrete angles of the pelvis, hip, knee and ankle (Table 6.1).

Table 6.1. List of angles including discrete time points at each joint

Pelvis	Hip	Knee	Ankle
Peak anterior tilt (LR)	Peak flexion	Peak flexion (LR)	Peak dorsiflexion (TS)
Peak posterior tilt	Peak extension	Peak flexion (swing)	Peak plantarflexion (swing)
Peak anterior tilt (swing)	Peak adduction (stance)		
Peak inferior obliquity	Peak abduction (swing)		
Peak superior obliquity			
Peak internal rotation			
Peak external rotation			

LR = Loading response, TS = Terminal swing

Standard error of measurement was calculated for the specific angle of each joint in each plane for each time point of the time normalised gait cycle using the following formulae (Bland & Altman, 1996b).

$$\text{SEM} = \sqrt{\frac{\sum deviations^2}{degrees\ of\ freedom}}$$

The point-by-point level of agreement was averaged to provide an overall SEM for each joint in each plane. Each time point was also plotted in order to present the SEM across the entire gait cycle (Schwartz et al., 2004). Values were deemed acceptable at <2°, reasonable between 2-5° and questionable at >5° (McGinley et al., 2009). If the peak joint angle reached is small, such as during hip adduction (typical value ~5°, Saunders et al., 1953) and the measurement error is deemed acceptable at 2°, this may still comprise a substantial proportion of any variation between sessions. Whereas if a peak joint angle is large (knee flexion in swing, typical values between 60 to 70° Whittle, 2007), and the SEM was reasonable (e.g. 4°), confidence in any between session variability would be more appropriate for the knee during sagittal plane flexion (5.7%) than for the hip during frontal plane adduction (40%). To quantify this issue and provide context for each relative joint angle, SEM as a percentage of peak angle was also calculated.

Intraclass correlation coefficients and their 95% confidence intervals were calculated for all kinematic variables described above, using SPSS statistical package (SPSS V22, IBM statistics, Armonk, NY) based on a mean rating (k = 8), absolute agreement, 2-way mixed-effects model (Koo & Li, 2016). Interpretation of ICC values were based on thresholds of poor (> 0.50), moderate (0.50 to 0.75), good (0.75 to 0.90) and excellent (< 0.90) (Koo & Li, 2016).

6.3. Results

All participants completed 10 trials during each testing session without any adverse events and received minimal physical support from the ReWalk™ gait trainer.

6.3.1. Standard error of measurement

Level of agreement was based on the SEM at each time point over a normalised gait cycle. Unlike the ICCs, the SEM was not calculated for discrete values relative to specific gait events. The values reported in Table 6.2 are averaged SEM for the duration of the gait cycle. Based on the level of acceptable variation suggested by McGinley et al. (2009), the level error for all but the trunk angle in the sagittal plane was deemed clinically acceptable, or reasonable with consideration.

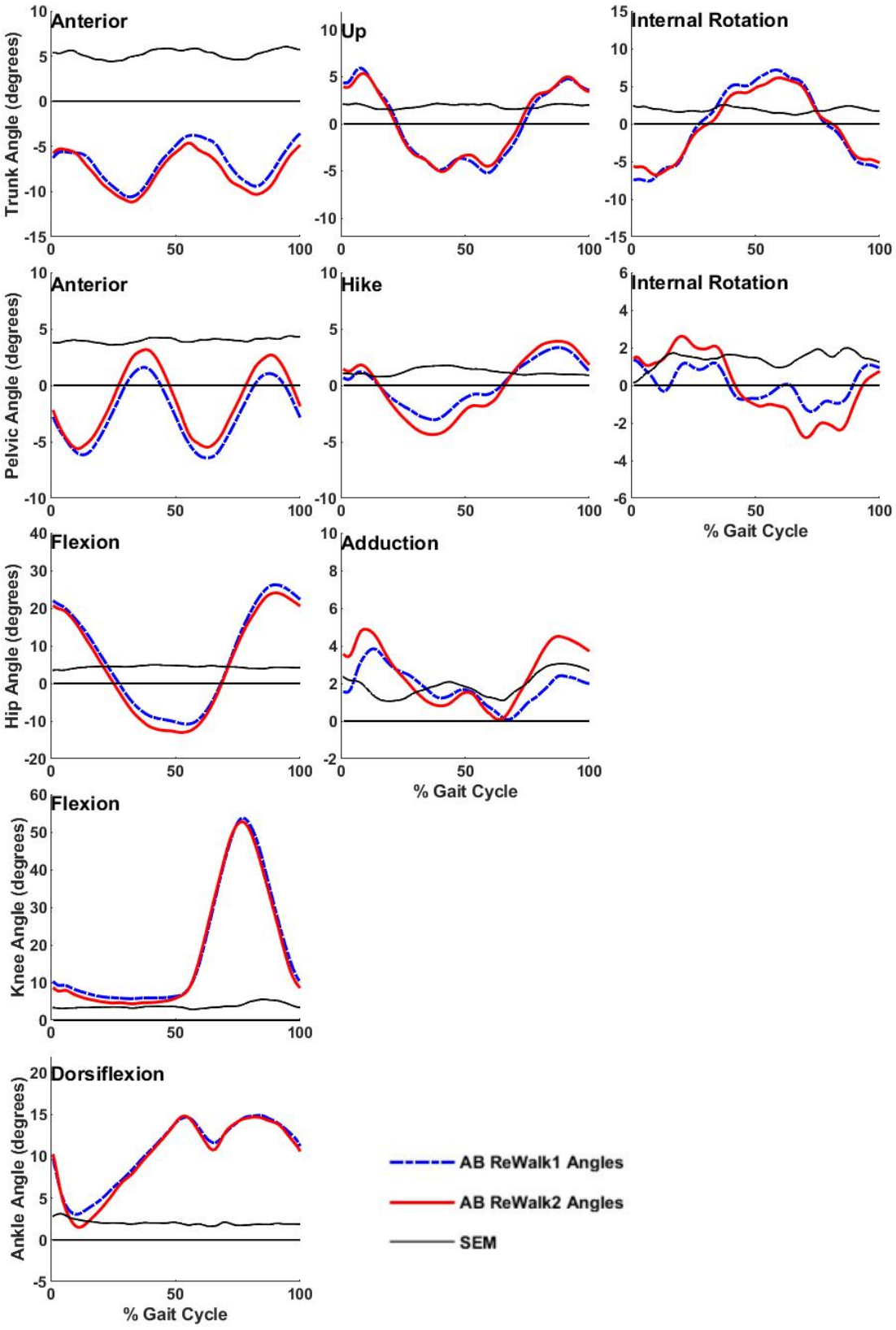
Table 6.2. Average Standard Error of Measurement (SEM) and 95% Confidence Intervals of absolute segment and relative joint angles of the user and LEXO, including SEM as a percentage of peak angle from repeated LEXO gait sessions.

	Body Angles				ReWalk™ Angles			
	SEM (Degrees)	95% Confidence Intervals	Peak Angle	SEM % Peak Angle	SEM (Degrees)	95% Confidence Intervals	Peak Angle	SEM % Peak Angle
Trunk angle (sagittal)	5.28	(-5.07 to 15.64)	10.6	48.5		N/A		
Trunk angle (frontal)	1.89	(-1.81 to 5.59)	5.7	33.5		N/A		
Trunk angle (transverse)	1.87	(-1.80 to 5.54)	7.2	26.1		N/A		
Pelvic angle (sagittal)	3.99	(-3.83 to 11.80)	6.0	66.8	2.12	(-2.03 to 6.27)	5.9	36.4
Pelvic angle (frontal)	1.18	(-1.14 to 3.51)	3.9	31.3	1.09	(-1.05 to 3.22)	3.6	30.7
Pelvic angle (transverse)	1.40	(-1.35 to 4.15)	2.1	75.0	1.23	(-1.18 to 3.64)	2.5	49.2
Hip angle (sagittal)	4.37	(-4.20 to 12.95)	25.2	17.4	2.53	(-2.43 to 7.48)	22.1	11.5
Hip angle (frontal)	1.92	(-1.84 to 5.67)	4.4	44.9	2.68	(-2.57 to 7.92)	6.6	41.8
Knee angle (sagittal)	3.72	(-3.57 to 11.01)	53.2	7.0	1.75	(-1.68 to 5.18)	48.4	3.6
Ankle angle (sagittal)	2.03	(-1.95 to 6.00)	14.9	13.7	1.13	(-1.08 to 3.34)	9.2	12.3

SEM = Standard Error of Measurement

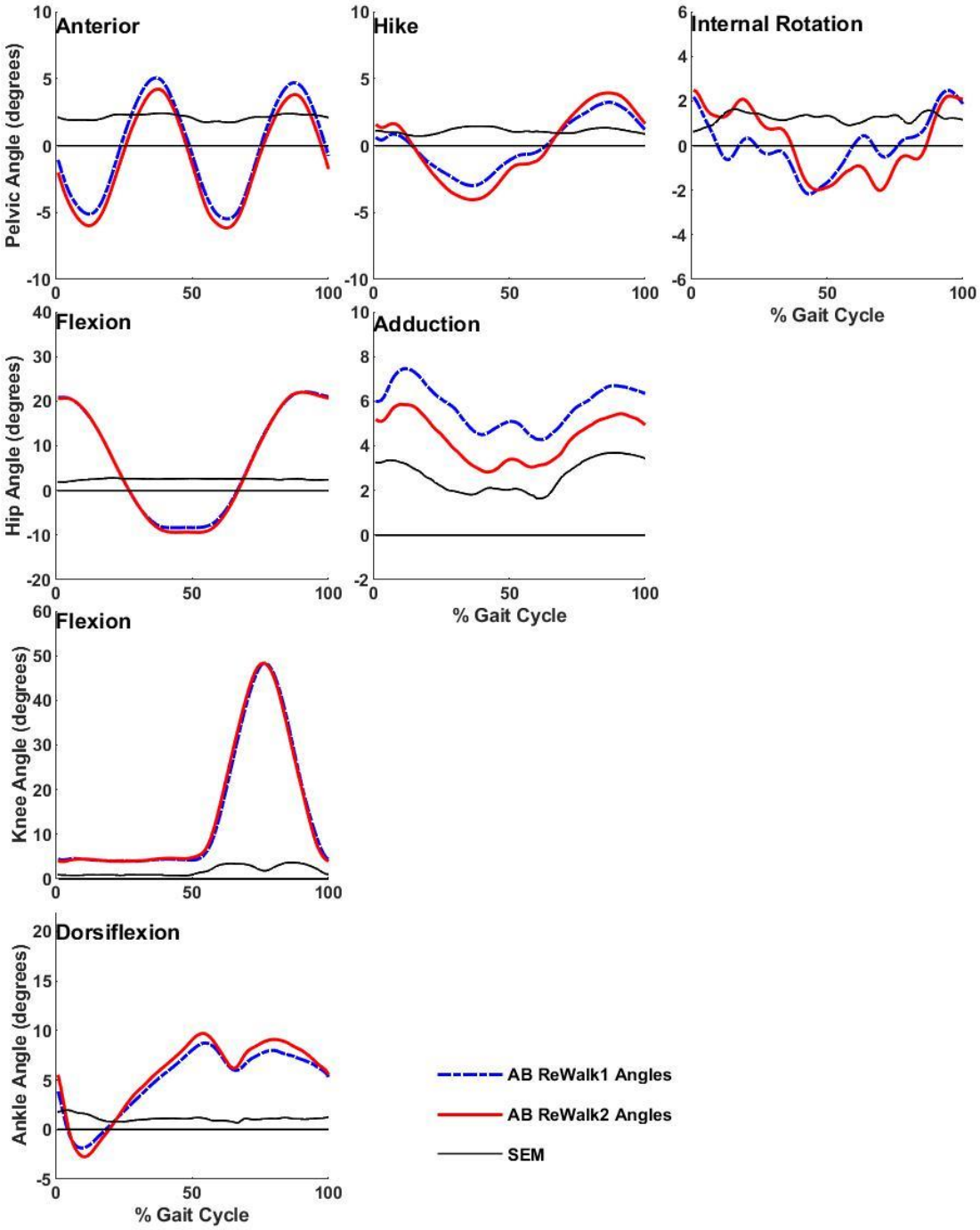
Peak angle and SEM % Peak angle calculated from averages of session 1 and session 2

Visual representation of the data (Figures 6.1 and 6.2) shows that even error levels deemed acceptable need to be considered with respect to the size of the measurement. The SEM for the frontal and transverse planes of the trunk and pelvic segments and hip joint angle all present average SEM values of less than 2^{o} (Table 6.2). When comparing these SEM values to the greatest angle achieved for each joint, the level of variance in some instances was as high as 75 percent of the recorded peak angle (Table 6.2).



Anterior tilt, flexion, dorsiflexion, up, adduction and internal rotation are positive.

Figure 6.1. Average able-bodied ReWalk™ user angles and standard error of measurement.



Anterior tilt, flexion, dorsiflexion, up, adduction and internal rotation are positive.

Figure 6.2. Average able-bodied ReWalk™ device angles and standard error of measurement.

6.3.2. Intraclass correlation coefficients

Reliability measures for segment and joint kinematic profiles for the users' body within the LEXO can be found in Table 6.3. Reliability of the 3D model as expressed by the ICC estimate for each variable ranged from excellent in hip ROM (sagittal), to poor in pelvic posterior tilt (sagittal) based on the guidelines of reporting ICCs for reliability research (Koo & Li, 2016). The majority of results appear to fall into the poor or moderate categories, with six variables demonstrating good reliability and only one variable deemed excellent. When considering the 95% confidence intervals, all but one variable displayed potentially poor reliability.

Table 6.3. Intraclass correlation coefficients and 95% confidence intervals of specific body joint angles from repeated ReWalk™ gait sessions.

	Mean Difference (Degrees)	Between participant variability	Within participant variability	ICC	95% Confidence Interval
Trunk ROM (sagittal)	0.02	0.01	1.11	0.85	(0.15 to 0.97)
Trunk ROM (frontal)	1.05	0.74	2.99	0.77	(0.00 to 0.96)
Trunk ROM (transverse)	1.67	1.18	2.55	0.83	(0.25 to 0.97)
Pelvic ROM (sagittal)	-1.77	1.25	1.65	0.57	(0.00 to 0.91)
Pelvic ROM (frontal)	-1.41	1.00	1.34	0.53	(0.00 to 0.90)
Pelvic ROM (transverse)	-1.71	1.21	1.82	0.00	(0.00 to 0.78)
Pelvic anterior tilt loading	-1.88	1.33	3.19	0.68	(0.00 to 0.94)
Pelvic posterior tilt	-0.45	0.32	3.01	0.00	(0.00 to 0.82)
Pelvic anterior tilt swing	-1.77	1.25	3.32	0.66	(0.00 to 0.93)
Pelvic inferior obliquity	0.91	0.65	1.00	0.24	(0.00 to 0.84)
Pelvic superior obliquity	-0.37	0.26	0.68	0.65	(0.00 to 0.93)
Pelvic internal rotation	-0.73	0.52	0.76	0.21	(0.00 to 0.83)
Pelvic external rotation	0.80	0.56	1.03	0.66	(0.00 to 0.93)
Hip ROM (sagittal)	-0.30	0.21	0.90	0.91*	(0.58 to 0.98)
Hip ROM (frontal)	-0.70	0.49	1.02	0.08	(0.00 to 0.81)
Hip flexion	2.34	1.65	3.21	0.74	(0.00 to 0.95)
Hip extension	2.30	1.63	3.69	0.55	(0.00 to 0.91)
Hip adduction stance	0.39	0.27	1.41	0.72	(0.00 to 0.95)
Hip abduction swing	1.09	0.77	1.04	0.88	(0.36 to 0.98)
Knee flexion loading response	-0.28	0.20	0.90	0.76	(0.00 to 0.95)
Knee flexion swing	0.47	0.34	3.64	0.54	(0.00 to 0.83)
Knee ROM (sagittal)	0.87	0.61	2.63	0.24	(0.00 to 0.86)
Ankle dorsiflexion terminal stance	-0.25	0.18	1.75	0.72	(0.00 to 0.95)
Ankle plantarflexion swing	0.25	0.17	1.73	0.75	(0.00 to 0.95)
Ankle ROM (sagittal)	1.10	0.78	2.09	0.00	(0.00 to 0.54)

ICC = Intraclass Correlation Coefficients
Green colour = good reliability, amber colour = moderate reliability, red colour = poor reliability
* = excellent reliability

6.4. Discussion

The primary aim of this chapter was to assess the repeatability of the marker placement procedures. A specific focus was placed upon the 6DOF marker model used to facilitate the recording of joint and body angles inside the LEXO (Section 4.7), due to the restrictions on lower-limb and caudal trunk maker placement. In order to achieve this aim, both SEM and ICCs were calculated to assess agreement and intra-rater reliability, respectively. The SEM measures presented in Table 6.2 show agreement across the two

sessions to be acceptable, suggesting marker placement was repeatable. Agreement was also shown to be closer for the markers placed on the LEXO than those affixed to the user, as hypothesised. The use of SEM as an assessment of repeatability enables the calculation of agreement at each time point across the gait cycle, enabling a point-by-point evaluation (Schwartz et al., 2004). Combining this with an easily interpretable output (same units as the original data) (Bland & Altman, 1996b) offers several benefits. The provision of an average error value for an entire time series enables quick and easy comparison across joints and planes of motion, and the ability to plot the point-by-point data on the same figure as the original data means that error values can be identified for specific discrete time points.

Intraclass correlation coefficients can be used to assess reliability of repeated measures at discrete time points within the gait cycle. Based on the ICCs reported in Table 6.3, the repeatability of the marker placement would be classed as poor. Reliability testing assesses the variability between participants with regard to measurement error; therefore, if the between-subject variability is small compared to the measurement error, ICC values will be poor as the ability to discriminate between subjects is minimal (de Vet et al., 2006). LEXOs are designed to generate cyclic, gait-like patterns based on fixed, programmable variables. A comparison of the between- and within-participant variability reported in Table 6.3 evidences the limited capacity to differentiate between participants. The hypothesis that ambulating in the LEXO would have resulted in good levels of reliability must be rejected irrespective of the high levels of agreement.

In the current study, SEM was calculated for the user's body angles as well as for the angles of the LEXO. Markers placed on the device were located at fixed points requiring no palpation, and soft tissue artefact was not a factor as each segment was a true rigid body. The pose estimation and orientation of each segment relative to the others was computed based upon the principles of classical mechanics (Cappozzo et al., 2005). It was hypothesised that the SEM of the LEXO joints would be lower than the corresponding joints of the user. The data presented in Table 6.2 indicate that this was correct except for the frontal plane of the hip. Although instrumental error will always be a component of 3D motion capture, advances in camera technology, software and marker tracking capabilities have gone a long way to reduce this, with marker-less motion tracking systems being advanced more recently (Mündermann et al., 2006). Standardised calibration procedures (as described in section 4.7.2) have also helped to reduce error (Chiari et al., 2005). As marker placement and soft tissue artefact have been eliminated as sources of error for the LEXO angles, another factor must have been responsible for the reduced level of agreement.

The ReWalk^{TM} was not designed to facilitate ab-adduction movements, as such there is no true 'hip joint centre' about which frontal plane motion can occur. The reduced level of agreement may be as a result of the movement occurring about more than one axis at different stages of the motion, or even the axis of rotation itself moving throughout the gait cycle. Frontal plane movement of the LEXOs thigh segment occurs when the user loads the supporting limb after initial contact, pushing it towards the midline of the body (adduction), and the limb enters the swing phase. As the LEXOs foot lifts from the ground, the combined mass of the LEXO segments and user's leg cause the swinging

limb to fall towards the midline of the body. As can be seen in Figure 6.3, a thin steel support runs from the pelvic bracket into the top of the thigh segment of the device; it is highly likely that it is within this structure of limited flexibility where the movement occurred.

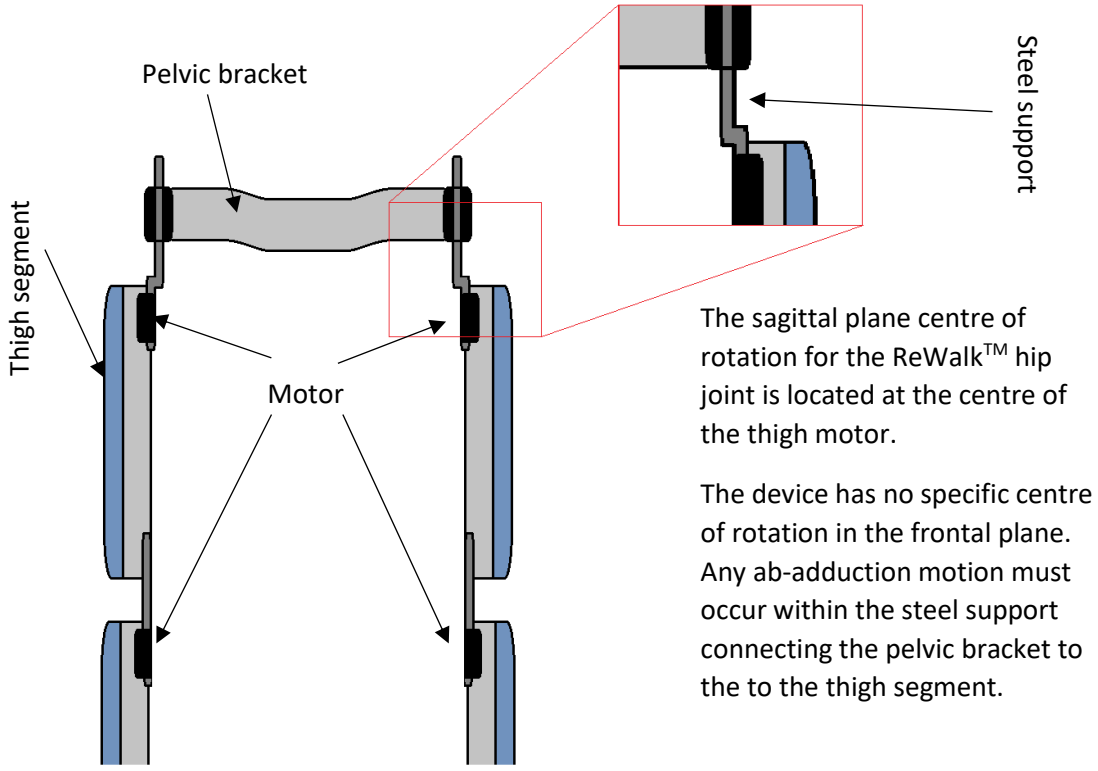


Figure 6.3. Schematic representation of the ReWalk™, highlighting the structure of the link pelvic bracket and thigh segment.

Knowing the level of error associated with a measurement alone does not provide all of the information needed for clinical interpretation; acceptable levels of variation must be identified. The level of error and its acceptability must be considered in the context of the data collected and its proposed use (McGinley et al., 2009). Regarding the frontal plane hip angle, the SEM as a percentage of the peak angle for both body angles and ReWalk™ angles (44.9 % and 41.8 % respectively) should be considered, as should the

95% confidence intervals (Table 6.2). These factors suggest that although the SEM is greater for the ReWalk™, as a percentage of the peak angles experienced, the relative agreement across testing sessions favours that of the device rather than the user's body within the device (Table 6.2).

The reported SEM and ICC values revealed that the kinematics in the sagittal plane were not as repeatable as some of the kinematics identified in the frontal and transverse planes (Tables 6.2 and 6.3). This concurs with the results presented by Schwartz et al. (2004), who showed the frontal plane kinematics of the hip to be the most repeatable based on the smallest SEM value, suggesting some data during LEXO use are equivalent to normal walking. Nevertheless, by considering the SEM as a percentage of the peak angle identified for each variable, it is clear that the lower limb sagittal plane kinematics are the most repeatable. The greater sagittal plane SEM (~3^{o} compared to the frontal and transverse plane parameters) is offset by the much larger ROM for each joint in this plane. Percentage SEM values of the hip (17.4%), knee (7%) and ankle (13.7%) show the lowest relative error of all variables assessed (Table 6.2).

6.4. Conclusion

The repeatability analysis carried out to assess the agreement and reliability of the 3D motion capture data collection procedures reveals that the agreement between sessions is a more important factor for the evaluation of the marker set and the primary researcher's capacity to use it effectively. The mechanical focus of the ReWalk™ device is to facilitate a sagittal plane bipedal gait motion; as such the sagittal plane kinematics

must be accurately represented in all future analyses. The programmable and mechanical aspects of the device itself deliver highly repeatable movements that have been demonstrated in the results herein. The high level of agreement presented for the between-session kinematic data suggests the methods are repeatable and capable of delivering accurate and consistent results in the subsequent chapters.

Chapter 7 - A biomechanical comparison of powered robotic exoskeleton gait with normal and slow walking: An investigation with able-bodied individual

7.1. Introduction

Lower-limb robotic exoskeletons (LEXOs) are wearable robots that provide external support to facilitate bipedal locomotion. Using motors, they assist the movement of a user's limbs through pre-defined joint ranges of motion (ROM). LEXO devices are intended to facilitate gait training/rehabilitation and upright mobility for those with limited or no independent walking capacity (Louie et al., 2015). Although LEXOs are designed and programmed to replicate normal walking patterns, the methods used to affix the devices to the user's body (typically hook and loop fabric) allow a degree of flexibility and movement within the system. Consequently, the user's kinematics may not expressly reproduce those of the device.

Numerous LEXOs are available, and several studies have compared overground LEXOs to able-bodied gait (Fineberg et al., 2013; Arazpour et al., 2014; Ramanujam et al., 2017). Peak vertical ground reaction forces (vGRFs), between the LEXO gait of spinal cord injured (SCI) individuals and stereotypical able-bodied gait, have been reported as similar in magnitude when no external support was required from a therapist, even in light of the significantly faster walking speed of the able-bodied individuals (Fineberg et al., 2013). However, Arazpour et al. (2014) demonstrated that the temporal-spatial and ROM characteristics of SCI and able-bodied individuals using a LEXO were significantly reduced compared with normal walking. Although Ramanujam et al. (2017) and Arazpour et al. (2014) concurred regarding temporal-spatial characteristics, the two

studies differed with regards to their kinematic findings. Arazpour et al. (2014) tracked the motion of the LEXO, but not the user inside the device. Ramanujam et al. (2017) noted that the SCI ROM was not significantly different from able-bodied LEXO walking, and their kinematic data were representative of the user inside the device.

Most likely due to the challenges associated with marker occlusion and placement restrictions, only three studies have been identified that have investigated the user's kinematics rather than those of the LEXO exclusively (Ramanujam et al., 2017, Hidler et al., 2008 and Knaepen et al., 2014). Two of these studies assessed the kinematics of the human-robot interaction. An active marker system was used to investigate able-bodied movement inside the treadmill-based Lokomat® system (Hocoma AG, Volketswil, Switzerland). The findings revealed significant differences between the kinematics of the individual and the device, and revealed step-to-step variability of the body independent of the Lokomat's® prescriptive pattern (Hidler et al., 2008). Knaepen et al. (2014) evaluated the human-robot interaction of a powered knee exoskeleton. As the device was a unilateral single joint orthotic, restrictions on marker placement would have been minimal and the data presented were not representative of a full-body LEXO.

It is well established that speed can influence almost all aspects of gait (Kirtley et al., 1985; Schwartz et al., 2008; Chung and Wang, 2010) and that individuals affected by neurological or motor deficits often walk more slowly than healthy, abled-bodied individuals (Lelas et al., 2003; Hanlon and Anderson, 2006). Comparing gait data between clinical populations and healthy controls has become almost routine, however this could lead to unreasonable goal setting expectations for individuals with different pathologies. Hanlon and Anderson (2006) suggested that maximising an individual's

function at their self-selected speed should be the primary outcome of gait rehabilitation. As a result, 'normal' speed dependent kinematic changes should be expected (i.e., reduced hip hyperextension as a result of naturally slower walking speed in healthy, able-bodied individuals). The same may be suggested of LEXO devices; it has been established that most individuals using overground LEXOs typically ambulate between 0.14 - 0.4 $m \cdot s^{-1}$ (Louie et al., 2015; Arazpour et al., 2014). Therefore, kinematic profiles matching these speeds could be expected. However, to the best of the authors' knowledge, no previous research has compared the gait patterns of healthy able-bodied individuals walking at such slow walking speeds with LEXO gait.

The ReWalk™ (ARGO Medical Technologies Ltd, Yokneam, Israel) is a commercially available overground LEXO, with United States of America Federal Food and Drug Administration approval and European Union CE marking (He et al., 2017) which provides external support through seven articulated rigid segments around the lower limbs and pelvis. It uses motors at the hip and knee joints to drive flexion and extension movements, facilitating an externally powered gait pattern based on the user's body orientation. This arrangement controls the movement of the lower limbs whilst leaving the upper body freely moveable. Several studies have evidenced the safety of the ReWalk™ (Zeilig, et al., 2012 & Esquenazi, et al., 2012), and have reported on the reduced physiological cost of powered LEXO walking, as opposed to non-powered reciprocating gait orthoses (Arazpour, et al., 2013) for SCI individuals. However, to date no studies have investigated the effects of LEXO use on whole-body kinematics or on ground reaction forces (GRFs) other than the vertical component. Furthermore, no studies have compared user kinematics with speed-matched able-bodied walking. Gait rehabilitation protocols and activities often initially start at slow speeds, with the intent

to increase walking speed to a self-selected (more functional) level over time (Swinnen et al., 2013). These initial slow walking speeds may more closely resemble those that can be achieved using LEXO devices.

The purpose of this study was to compare the 3D gait parameters of able-bodied individuals walking overground with the ReWalk™, and without a LEXO at two different speeds: self-selected comfortable (CMBL) vs. slow (SLOW), speed-matched to the LEXO. This information may inform practitioners on the use of LEXOs during different stages of a person's rehabilitation, and according to their rehabilitation goals. The primary objective was to evaluate the effects of the device on the temporal-spatial and whole-body kinematic gait parameters. The secondary objective was to compare the individual GRF components with and without the device. It was hypothesised that: 1) walking with the ReWalk™ would alter the temporal-spatial characteristics of the gait cycle to resemble those of SLOW walking; 2) SLOW walking and LEXO gait would present with similarly reduced angles and ROM at the hip, knee and ankle (device-controlled joints) relative to CMBL walking, but that LEXO walking would elicit increased excursions of the trunk and pelvis; and 3) based on the work of Fineberg et al. (2013), peak vGRFs would be similar across all three conditions despite the use of crutches (in the LEXO condition) and different walking velocities. It was however anticipated that any differences identified would be smallest between the two speed-matched conditions. It was also hypothesised that the anterior-posterior forces would be lower in the LEXO condition, because of the lack of propulsion required to move the limb into swing due to robotic control.

7.2. Methods

7.2.1. Participants

Eight able-bodied participants (mean[SD]: age 28[6] years: height 1.72[0.04] m; mass 77[7] kg) completed this study. They were healthy adults between 23-42 years old and 165–178 cm tall, with a mass of 68-90 kg, without neurological, mobility or musculoskeletal injury. Ethical approval was provided by the University departmental review board. All participants gave written informed consent prior to testing.

7.2.2. Protocol

Participants were fitted for the ReWalk™ on their initial laboratory visit and standardised settings were programmed according to manufacturer specifications (ReWalk™, 2014). Step initiation was triggered at 7° anterior tilt of the pelvic bracket sensor. Peak hip and knee flexion angles were set at 22° and 46°, respectively. Peak hip extension was fixed at 8°. Step time was set to 700 msec and the minimum delay between steps was set to 0 msec. Participants were required to use elbow crutches (during the LEXO condition only, similarly to the study conducted by Fineberg et al. (2013)) and were provided with footwear that fit the LEXO footplates.

Participants wore form fitting clothing throughout. During the CMBL and SLOW speed walking conditions, participants wore their own flat footwear and 81 retro-reflective markers (14 mm). During LEXO testing, 73 markers were used to track the body due to restrictions of the LEXO (Figure 7.1). Body segments were defined by an endpoint or joint-centre based on anatomical locations established using the calibrated anatomical systems technique (Cappozzo et al., 1995). Clusters of tracking markers were affixed to

each body segment and tracked using the six-degrees-of-freedom principles (Buczek et al., 2010). Three-dimensional kinematics were captured with ten Oqus 4.0 cameras (Gothenburg, Sweden) at 100 Hz and synchronised with two floor integrated Kistler (9286AA) force plates (Winterthur, Switzerland) sampling at 1000 Hz via Qualisys Track Manager software version 2.15 (Gothenburg, Sweden).

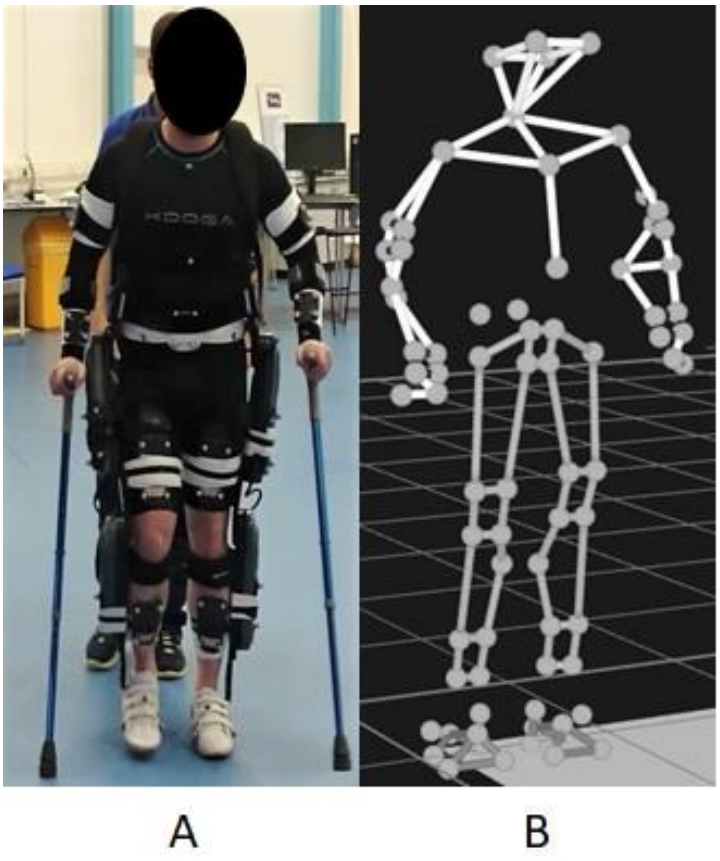


Figure 7.1. A) Subject wearing the ReWalk™ and B) Qualisys Track Manager representation of marker set.

Participants completed the CMBL speed walking trials along a 12-meter walkway at their preferred walking speed. Subsequently, the starting point of each LEXO trial was designated to facilitate GRF data collection. At least one step with each foot was required pre and post force plate contact to ensure the data were representative of steady-state gait. A LEXO gait trainer walked behind each participant to provide physical

support if needed. Kinetic data were discarded if the participant made an incomplete foot contact with the force plate. Finally, the SLOW walking trials were speed-matched to the LEXO condition (0.44 m/s ± 5%), where walking speed was controlled using electronic timing gates located five meters apart (Brower Timing Systems, Utah, USA). Ten walking trials were captured and analysed for each condition; the kinematic and kinetic data were averaged across both limbs. The LEXO walking data is the same as data set 1 from the repeatability study in chapter 6.

7.2.3. Data reduction

3D marker coordinate and GRF data were processed in Visual3D version 5 (C-Motion, Rockville, MD, USA). Kinematic data were interpolated using a third order polynomial. Kinematic and kinetic data were low-pass filtered using fourth order Butterworth filters (cut-off frequencies of 6 and 30 Hz, respectively). Joint kinetics were not calculated as the lower limb joints were robotically assisted by the LEXO motors. All variables were normalised to the gait cycle starting with initial contact. GRFs were normalised to body mass for CMBL and SLOW walking, and combined body + ReWalk^{TM} mass for LEXO walking. All kinematic data were representative of the participant's movements inside the LEXO, allowing for a direct comparison of the user's kinematics with the CMBL and SLOW walking conditions.

7.2.4. Statistical analysis

Temporal-spatial and vGRF load and decay rate data were analysed using a one-way repeated measures ANOVA. Post-hoc analyses with a Bonferroni adjustment were used in the event of significant findings ($P<0.05$) (SPSS statistical package V22, IBM statistics,

Armonk, NY). Partial ω^2 effect sizes were reported for the model and Cohen's *d* for the post-hoc tests. Established thresholds of small (0.01–0.05), medium (0.06–0.13) and large (≥0.14) were used for interpretation of Partial ω^2 (Rodriguez, 2006) and small (0.2–0.49) medium (0.5–0.79) and large (≥0.8) thresholds were used for interpretation of Cohen's *d* (Cohen, 1992). All data were assessed for normality and outliers using Shapiro-wilk test (*P>0.05*) and box plots. Outliers identified were replaced with a value either 0.01 larger than the second largest value or 0.01 smaller than the second smallest value, maintaining the spread of the data but reducing the effect of the outlier (Field, 2009). Significance (*P<0.05*) and effect size were not affected by transforming the data, therefore the original data were used in the final analysis. In the event that Mauchley's test of sphericity was violated, a Greenhouse-Geisser correction was used. Kinematic and GRF waveforms were analysed using a 1d statistical parametric mapping (SPM) one-way repeated measures ANOVA (alpha level set at 0.05) (SPM 1d ANOVArm). Post-hoc comparison t-tests with a Bonferroni adjustment (alpha level set at 0.017) were used to compare the three conditions (LEXO vs. CMBL, SLOW vs. CMBL, and SLOW vs. LEXO) over the entire gait cycle where significant differences were detected at the model level (Matlab 19a; SPM 1d). Analysis was conducted topologically and the timeframe of any significant differences between conditions were reported as a percentage of the gait cycle.

7.3. Results

7.3.1. Temporal-spatial characteristics

Temporal-spatial parameters are presented in Table 7.1. Significant differences and large effect sizes were identified for all variables at the ANOVA level. Post-hoc analyses revealed significant differences for all variables between comfortable and slow gait speeds. The differences identified for double support and swing times between LEXO and slow gait were noteworthy as they were independent of speed and were not evident between the comfortable and LEXO conditions.

Table 7.1. Mean (standard deviation) temporal-spatial data for normal, slow and LEXO gait (one-way repeated measures ANOVA, significance set at 95%, post-hoc test with Bonferroni correction 95% confidence intervals and Cohen's *d* effect sizes).

	Comfortable Gait		Slow Gait		LEXO Gait		Significance		Effect Size (ω_p^2)
Walking speed (m/s)	1.54	(0.07)	0.44	(0.03)	0.41	(0.03)	F(2, 14) = 1392.41,	***P* < 0.001**	0.991
Double support time (%)	21	(3.25)	37	(3.54)	25	(2.95)	F(2, 14) =57.838,	***P* < 0.001**	0.826
Cadence (steps/min)	117	(4)	52	(5)	49	(2)	F(2, 14) = 1150.176,	***P* < 0.001**	0.990
Stance time (%)	61	(1.7)	68	(1.7)	63	(1.7)	F(2, 14) = 45.675,	***P* < 0.001**	0.788
Swing time (%)	40	(1.7)	32	(1.7)	38	(1.9)	F(2, 14) = 53.715,	***P* < 0.001**	0.815
Step length (% leg length)	88	(7.0)	58	(6.4)	55	(4.5)	F(2, 14) = 179.972,	***P* < 0.001**	0.937
Stride width (% leg length)	16	(1.8)	20	(2.8)	19	(1.6)	F(2, 14) = 14.165,	***P* < 0.001**	0.523

Post-Hoc Analysis	**Comfortable Gait Vs LEXO Gait**				**Comfortable Gait Vs Slow Gait**				**LEXO Gait Vs Slow Gait**			
	Mean Difference	Sig (*P*)	95% Confidence Intervals	Effect Size (*d*)	Mean Difference	Sig (*P*)	95% Confidence Intervals	Effect Size (*d*)	Mean Difference	Sig (*P*)	95% Confidence Intervals	Effect Size (*d*)
Walking speed (m/s)	1.11	**<0.001**	1.02 to 1.2	-1.50	1.07	**<0.001**	1.0 to 1.7	-5.04	-0.03	0.177	-0.1 to 0.0	-1.37
Double support time (%)	-4	0.124	-8.7 to 1.0	1.09	-16	**<0.001**	-20.8 to -10.7	5.05	-12	**<0.001**	-16.3 to -7.5	3.72
Cadence (steps/min)	68	**<0.001**	64.2 to 71.7	5.93	66	**<0.001**	60.3 to 71.1	4.73	-2	0.452	-8.0 to 3.5	-0.57
Stance time (%)	-2	0.095	-5.2 to 0.4	21.8	-8	**<0.001**	-10.7 to -5.2	21.10	-6	0.177	-8.0 to -3.1	-1.38
Swing time (%)	2	0.241	25.6 to 33.7	-1.2	8	**<0.001**	5.3 to 10.7	-4.96	6	**<0.001**	4.2 to 8.1	-3.64
Step length (% leg length)	33	**<0.001**	-8.6 to 2.7	5.9	30	**<0.001**	25.6 to 33.7	15.36	-3	0.773	-8.6 to 2.7	-0.62
Stride width (% leg length)	-3	**0.020**	-5.0 to -0.5	-1.73	-5	**0.005**	-7.3 to -1.7	-2.03	-2	0.294	-4.7 to 1.1	-0.82

ω_p^2 = partial omega squared, Sig = Significance
alpha level 0.05

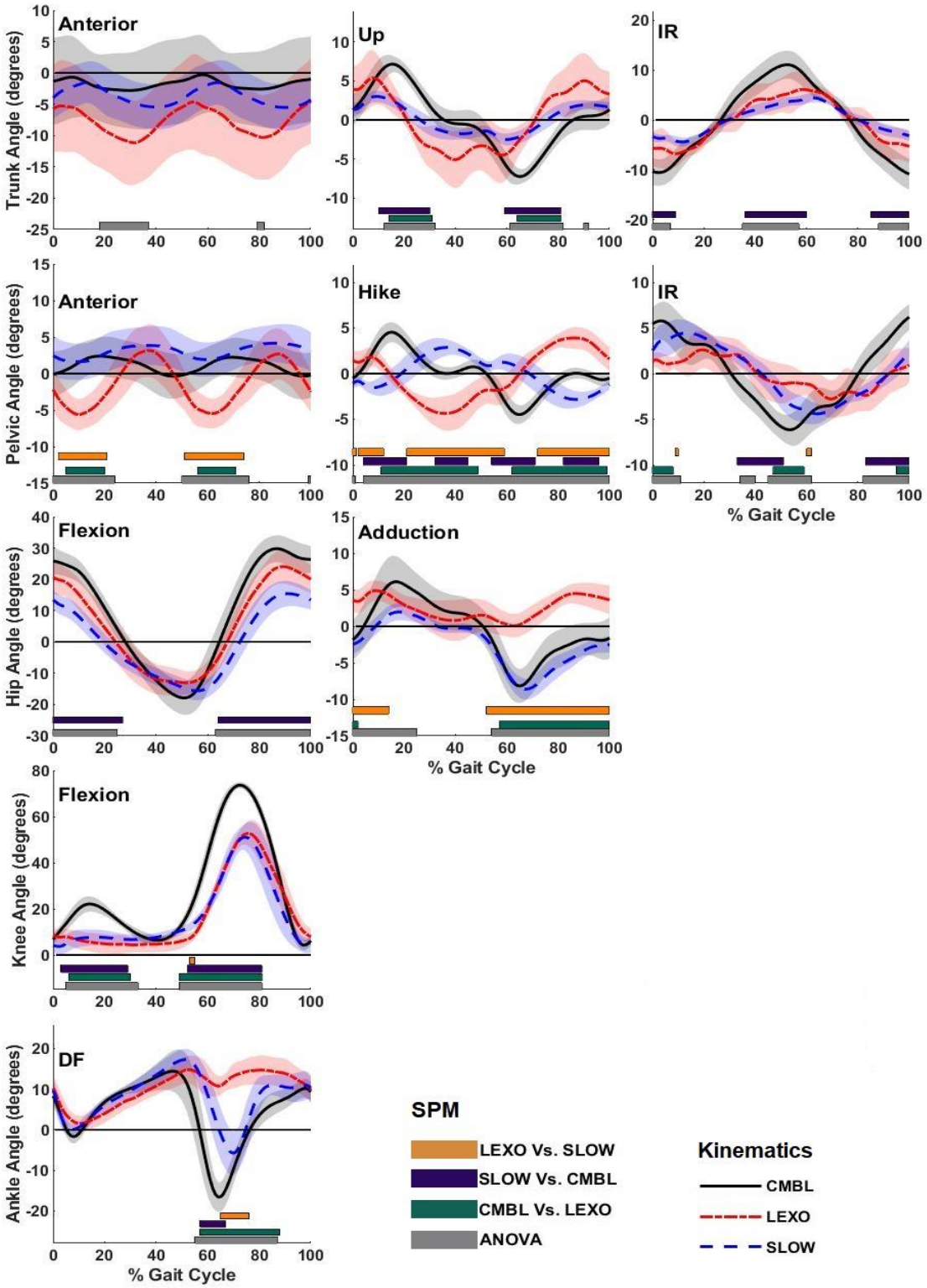
7.3.2. Joint kinematics

Multiple biomechanical differences were evident between the three conditions, as illustrated in Figure 7.2. The horizontal bars at the base of each graph represent the time (as a percentage of the gait cycle) when significant differences were evident. Table 7.2 displays the results of the one-way repeated measures ANOVA kinematic waveforms, showing significant differences in all ten variables assessed, with post-hoc comparison results presented in Table 7.3. Although significant differences were identified at the model level for trunk kinematics, no differences existed between LEXO and SLOW gait. The only differences observed between CMBL and LEXO gait were in the frontal plane between 14–31% and 64–81% of the gait cycle (%GC) (loading response and push-off/early swing, respectively); there was a greater ROM in the CMBL gait condition and a difference in the waveform shape. In hip motion, SLOW gait presented with significantly less flexion compared to CMBL gait. There were, however, no differences between any of the conditions for hip extension. One of the most striking differences was the complete absence of abduction at the hip during LEXO gait, contributing to significant differences in both the CMBL and SLOW conditions at initial contact, during the loading response and swing phase. See appendix 5 for full SPM output.

Table 7.2. SPM one-way repeated measures ANOVA results for CMBL, LEXO and SLOW gait kinematics (critical threshold was set at 95 % and is reported as the threshold F-statistic).

ANOVA	Cluster threshold F statistic	Number of clusters exceeding threshold	P Value and time of occurrence (% GC)		P Value and time of occurrence (% GC)		P Value and time of occurrence (% GC)		P Value and time of occurrence (% GC)	
Trunk (Sagittal)	6.596	2	*P* = 0.029	18 – 37	*P* = 0.049	79 – 82				
Trunk (Frontal)	9.148	2	*P* < 0.001	12 – 32	*P* < 0.001	61 – 82	*P* < 0.046	90 – 92		
Trunk (Transverse)	10.26	3	*P* < 0.001	0 – 7	*P* < 0.001	35 – 57	*P* < 0.001	88 – 100		
Pelvis (sagittal)	7.535	3	*P* < 0.001	0 – 24	*P* < 0.001	50 – 76	*P* = 0.050	99 – 100		
Pelvis (frontal)	8.992	2	*P* = 0.049	0 – 1	*P* < 0.001	4 – 100				
Pelvis (transverse)	9.043	4	*P* < 0.001	0 – 11	*P* = 0.023	34 – 40	*P* < 0.001	45 – 62	*P* < 0.001	82 - 100
Hip (sagittal)	7.591	2	*P* < 0.001	0 – 25	*P* < 0.001	63 – 100				
Hip (frontal)	7.581	2	*P* < 0.001	0 – 25	*P* < 0.001	54 – 100				
Knee (sagittal)	9.197	2	*P* < 0.001	5 – 33	*P* < 0.001	49 - 81				
Ankle(sagittal)	9.184	1	*P* < 0.001	55 – 87						

% GC = percentage of gait cycle



Anterior tilt, up, hike, internal rotation, flexion, dorsiflexion and adduction are positive.

Figure 7.2. Trunk, pelvis, hip, knee and ankle joint angles for CMBL, SLOW and LEXO gait in the three planes of motion. The horizontal bars along the bottom of each graph represent the time period where the differences between the waveforms were significant ($P \leq 0.05$) at the ANOVA (lowest bar) and post-hoc comparisons. 2nd bar = CMBL vs. LEXO, 3rd bar = CMBL vs. SLOW, and 4th bar = LEXO vs. SLOW, with bars described from bottom upwards.

Table 7.3. SPM post-hoc comparison t-tests of CMBL, LEXO and SLOW gait kinematics (critical threshold was set at 95 % and is reported as the threshold t-statistic).

Post-hoc analysis	Post hoc comparison t - test	Threshold t - statistic	Clusters exceeding threshold	P Value and time of occurrence (% GC)		P Value and time of occurrence (% GC)		P Value and time of occurrence (% GC)		P Value and time of occurrence (% GC)	
Trunk (Sagittal)	CMBL vs LEXO	3.545	0								
	CMBL vs SLOW	3.413	0								
	LEXO vs SLOW	3.587	0								
Trunk (Frontal)	CMBL vs LEXO	4.213	2	*P* < 0.001	14 – 31	*P* < 0.001	64 – 81				
	CMBL vs SLOW	4.132	2	*P* < 0.001	10 – 30	*P* < 0.001	59 – 81				
	LEXO vs SLOW	4.203	0								
Trunk (Transverse)	CMBL vs LEXO	5.085	0								
	CMBL vs SLOW	4.287	3	*P* = 0.001	0 – 9	*P* < 0.001	36 – 60	*P* < 0.001	85 – 100		
	LEXO vs SLOW	4.437	0								
Pelvis (sagittal)	CMBL vs LEXO	3.808	2	*P* = 0.006	5 – 20	*P* = 0.006	56 – 71				
	CMBL vs SLOW	3.576	0								
	LEXO vs Slow	3.817	2	*P* = 0.003	2 – 21	*P* = 0.001	51 – 74				
Pelvis (frontal)	CMBL vs LEXO	4.152	2	*P* < 0.001	11 – 49	*P* < 0.001	62 – 99				
	CMBL vs SLOW	4.139	4	*P* < 0.001	4 – 21	*P* = 0.001	32 – 45	*P* < 0.001	54 – 71	*P* < 0.001	82 – 96
	LEXO vs SLOW	4.099	4	*P* = 0.016	0 – 2	*P* < 0.004	2 – 12	*P* < 0.001	21 – 59	*P* < 0.001	72 – 100
Pelvis (transverse)	CMBL vs LEXO	4.165	3	*P* = 0.004	0 – 8	*P* < 0.001	47 – 59	*P* = 0.009	95 – 100		
	CMBL vs SLOW	4.100	2	*P* < 0.001	33 – 51	*P* < 0.001	83 – 100				
	LEXO vs SLOW	4.202	2	*P* = 0.017	9 – 10	*P* = 0.015	60 – 62				
Hip (sagittal)	CMBL vs LEXO	3.810	0								
	CMBL vs SLOW	3.834	2	*P* < 0.001	0 – 27	*P* < 0.001	64 – 100				
	LEXO vs SLOW	3.865	0								
Hip (frontal)	CMBL vs LEXO	3.890	2	*P* = 0.017	0 – 2	*P* < 0.001	57 – 100				
	CMBL vs SLOW	3.863	0								
	LEXO vs SLOW	3.989	2	*P* = 0.002	0 – 14	*P* < 0.001	52 – 100				
Knee (sagittal)	CMBL vs LEXO	4.195	2	*P* < 0.001	6 – 30	*P* < 0.001	49 – 81				
	CMBL vs SLOW	4.268	2	*P* < 0.001	3 – 29	*P* < 0.001	52 – 81				
	LEXO vs SLOW	4.179	1	*P* = 0.015	53 – 55						
Ankle (sagittal)	CMBL vs LEXO	4.154	1	*P* < 0.001	57 – 88						
	CMBL vs SLOW	4.233	1	*P* = 0.001	57 – 67						
	LEXO vs SLOW	4.175	1	*P* = 0.001	65 – 76						

% GC = percentage of gait cycle

7.3.3. Ground reaction forces

GRF SPM results are reported in Table 7.4, load and decay rates are reported in Table 7.5, and GRF profiles are presented in Figure 7.3. The vertical GRF profile presented in Figure 3 clearly shows that the reduced speed of SLOW and LEXO gait flattened the typical double hump curve, generated during CMBL gait, leading to significant differences between the CMBL condition and the other two conditions between 22 – 39 %GC. The only difference in the vGRF between the SLOW and LEXO conditions occurred during terminal stance/push-off (60-69 %GC) when a longer stance phase was observed in the SLOW condition. There was however no significant difference in decay rate between the LEXO and SLOW conditions (mean difference 0.16 N/kg/s, P = 1.000). Significantly greater braking and propulsive forces were evident during CMBL walking compared to the other two conditions.

Table 7.4. SPM one-way repeated measures ANOVA and post-hoc comparison t-test results for CMBL, LEXO and SLOW gait ground reaction forces (critical threshold was set at 95 % and is reported as threshold F-statistic and threshold t-statistic respectively).

ANOVA	Cluster threshold F statistic	Number of clusters exceeding threshold	P Value and time of occurrence (% GC)		P Value and time of occurrence (% GC)		P Value and time of occurrence (% GC)		P Value and time of occurrence (% GC)	
Medial – lateral GRF	13.763	4	*P* < 0.001	2 – 5	*P* < 0.001	11 – 12	*P* < 0.001	40 – 41	*P* < 0.001	53 – 63
Anterior – posterior GRF	13.763	3	*P* < 0.001	3 – 24	*P* < 0.001	36 – 56	*P* < 0.001	61 – 70		
Vertical GRF	13.763	4	*P* < 0.001	1 – 2	*P* < 0.001	4 – 13	*P* < 0.001	22 – 39	*P* < 0.001	55 – 70

Post-hoc analysis	**Post hoc comparison t - test**	**Cluster threshold t - statistic**	**Number of clusters exceeding threshold**	**P Value and time of occurrence (% GC)**		**P Value and time of occurrence (% GC)**		**P Value and time of occurrence (% GC)**		**P Value and time of occurrence (% GC)**	
Medial – lateral GRF	CMBL vs LEXO	5.080	2	*P* < 0.001	3 – 5	*P* < 0.001	55 – 57				
	CMBL vs SLOW	5.080	2	*P* < 0.001	11 – 13	*P* < 0.001	53 – 62				
	LEXO vs SLOW	5.080	0								
Anterior – posterior GRF	CMBL vs LEXO	5.080	4	*P* < 0.001	6 – 23	*P* < 0.001	36 – 38	*P* < 0.001	40 – 55	*P* < 0.001	64 – 65
	CMBL vs SLOW	5.080	3	*P* < 0.001	4 – 22	*P* < 0.001	41 – 55	*P* < 0.001	62 – 69		
	LEXO vs SLOW	5.080	2	*P* < 0.001	62 - 66	*P* < 0.001	66 - 70				
Vertical GRF	CMBL vs LEXO	5.080	2	*P* < 0.001	23 – 37	*P* < 0.001	63 - 65				
	CMBL vs SLOW	5.080	3	*P* < 0.001	5 – 12	*P* < 0.001	22 – 39	*P* < 0.001	56 – 70		
	LEXO vs SLOW	5.080	3	*P* < 0.001	60 – 64	*P* < 0.001	65 – 68	*P* < 0.001	68 - 69		

% GC = percentage of gait cycle

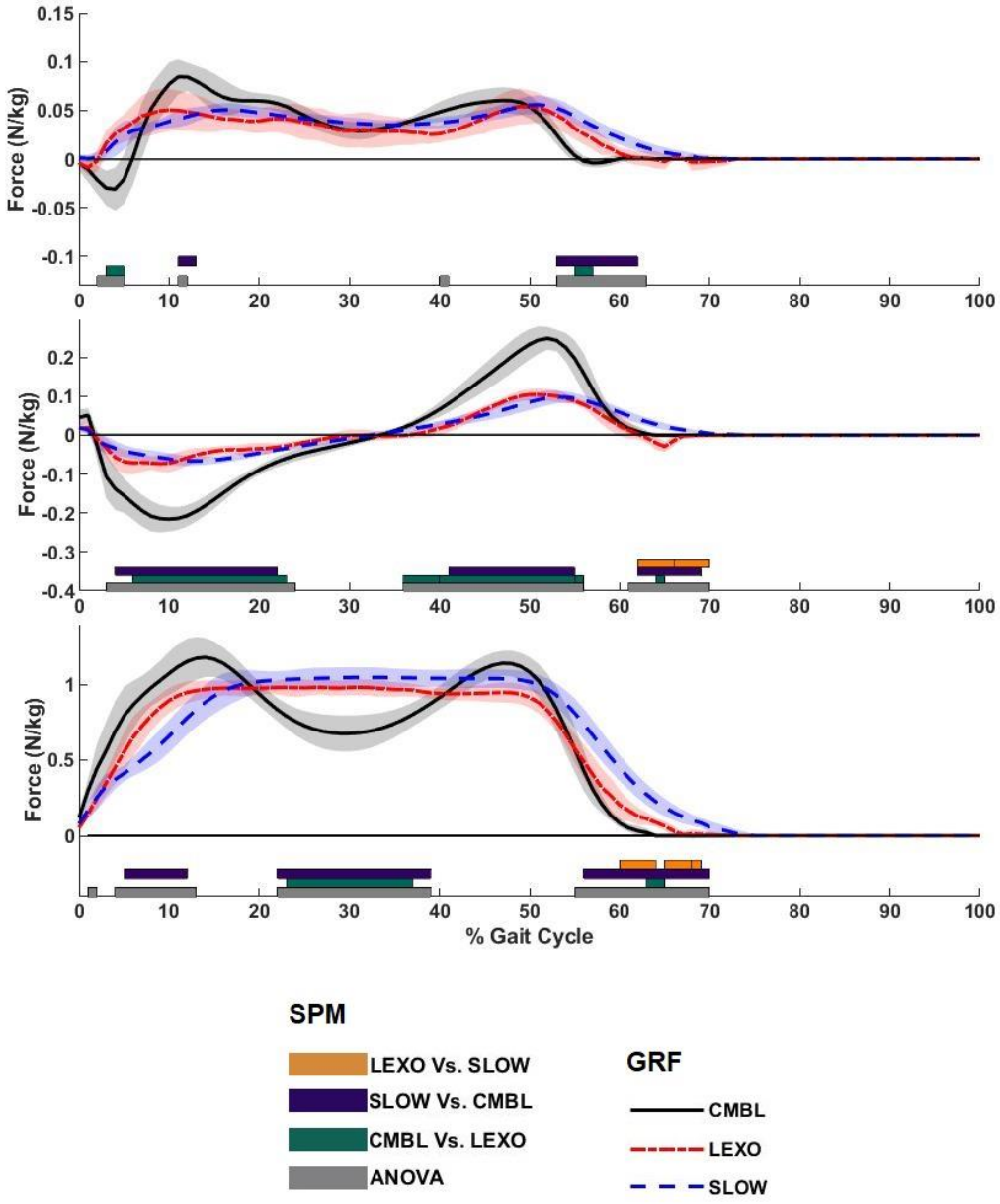
Table 7.5. Mean (standard deviation) vertical GRF load and decay rate data for CMBL, SLOW and LEXO gait (one-way repeated measures ANOVA, significance set at 95%, post-hoc test with Bonferroni correction 95% confidence intervals and Cohen's *d* effect sizes).

(N/Kg)	CMBL Gait	SLOW Gait	LEXO Gait	Significance	Effect Size (ω_p^2)
Load rate (N/kg/s)	8.22 (1.92)	1.62 (0.47)	1.83 (0.71)	F(2, 14) = 69.582,	***P* < 0.001**	0.851
Decay rate (N/kg/s)	-9.34 (1.38)	-1.57 (0.41)	-1.73 (0.74)	F(2, 14) = 139.461,	***P* < 0.001**	0.920

Post-Hoc Analysis	**CMBL Gait Vs. LEXO Gait**				**CMBL Gait Vs. SLOW Gait**				**LEXO Gait Vs. SLOW Gait**			
(N/Kg)	Mean Difference	Sig (*P*)	95% Confidence Intervals	Effect Size (*d*)	Mean Difference	Sig (*P*)	95% Confidence Intervals	Effect Size (*d*)	Mean Difference	Sig (*P*)	95% Confidence Intervals	Effect Size (*d*)
Load rate (N/kg/s)	6.38	**<0.001**	3.97 to 8.80	4.72	6.60	**<0.001**	4.38 to 8.81	5.05	0.21	1.000	-0.84 to 1.26	0.38
Decay rate (N/kg/s)	7.61	**<0.001**	5.55 to 9.67	7.32	7.77	**<0.001**	5.94 to 9.59	8.13	0.16	1.000	-0.68 to 1.00	0.29

* Assumption of sphericity not met – Greenhouse-Geisser correction used.

ω_p^2 = partial omega squared



Lateral and anterior propulsion are positive.

Figure 7.3. Medial-lateral, anterior-posterior and vertical ground reaction forces. Data were normalised to body mass or body mass and LEXO mass dependent upon condition. The gait cycle commences and terminates with ipsilateral foot contact. The horizontal bars along the bottom of each graph represent the time period where the differences between the waveforms are significant ($P \leq 0.05$) at the ANOVA (lowest bar) and post hoc comparisons. 2nd bar = CMBL vs. LEXO, 3rd bar = CMBL vs. SLOW, and 4th bar = LEXO vs. SLOW, with bars described from bottom upwards.

7.4. Discussion

Few studies (Ramanujam et al., 2017, Hidler et al., 2008 & Knaepen et al., 2014) have quantified the movement characteristics of the user inside a LEXO, limiting our understanding of how these devices impact the body. The aim of this study was to compare the gait parameters of able-bodied individuals walking with a LEXO, and at different speeds without a LEXO, to identify the differences in gait kinematics and kinetics independent of speed. Although other studies have provided information on the lower limb kinematic and GRF characteristics of LEXO use (Fineberg et al*.,* 2013; Arazpour et al., 2014; Ramanujam et al., 2017; Hidler et al., 2008; Knaepen et al., 2014), the current study is the first to focus on the user's whole body kinematics for an overground LEXO, and the first to compare LEXO gait to speed-matched able-bodied walking.

This and previous studies have reported slow walking speeds for able-bodied individuals using LEXOs: 0.40 m/s and 0.25–0.87 m/s respectively (Ramanujam et al., 2017; Arazpour et al., 2014; Hidler et al*.,* 2008). Speed influences a number of gait parameters during unaided walking, including swing and support times, joint kinematics and dynamic stability (Kerrigan et al*.,* 1998) as evidenced in this study. It was hypothesised that the temporal-spatial characteristics of LEXO gait would resemble those of SLOW gait, as this was speed-matched to the LEXO condition. The results in Table 7.2 clearly show the differences between CMBL and SLOW walking as all variables were significantly different. When comparing SLOW and LEXO gait, the most meaningful difference was the time in swing phase. Participants spent an average of 6 %GC longer in swing using the LEXO, more closely resembling the stance:swing ratio (60:40) seen at a CMBL gait

speed than the hypothesised similarity to speed-matched SLOW gait. The longer swing time with the LEXO led to a concomitant reduction in stance time, which although not significantly different to SLOW gait, presented with a large effect size (*d* = -1.38). The cumulative effect of decreased stance was reflected in the significantly shorter double support for LEXO gait relative to SLOW gait (-12 %GC) (Table 7.2).

Previous reports indicate that slow walking speeds enhance local dynamic stability despite increased kinematic variability when walking at preferred speeds (England and Granata, 2007; Dingwall and Marin, 2006). Reduced step length and increased double support time have been reported as common adaptations to produce a more stable gait pattern (Buzzi et al*.,* 2003), both have been identified as functions of slow walking (den Otter et al*.,* 2004; Sekiya and Nagasaki, 1998) and were evident in the SLOW condition in the current study. Reduced step length in the LEXO condition was a result of the pre-programmed ROM rather than a balance strategy as evidenced by Hayes et al. (2018). Furthermore, the temporal control of the LEXO appears to have removed the capacity for individuals to utilise increased double support time as a strategy to maintain local dynamic stability. Step time is a programmable feature of the ReWalk™ and controls the time spent in swing. Double support was user-controlled, as the ReWalk™ allows a period of time to be programmed after terminal swing in which the tilt sensor is unresponsive. By setting this latency to 0 ms, any temporal variations in stepping were a direct result of the user. Step initiation was triggered through the user's body orientation, and differences in the time taken to achieve appropriate positioning would have influenced this temporal component. Step initiation was triggered only once the tilt sensor interpreted a 7° anterior tilt orientation.

Recent work into the influence of proprioceptive feedback on neural plasticity and gait re-education after SCI has highlighted the importance of trunk control (Moraud et al., 2018). The head, arms and trunk (HAT) are typically described as a passenger unit during gait. Maintaining dynamic balance inflicts a continuous state of instability that can only be controlled by placing the swinging limb antero-laterally to the falling COM (Horak 2006; Winter et al., 1990). During stereotypical able-bodied gait, individuals are able to process environmental and afferent information, adjusting foot placement accordingly to maintain dynamic control. Use of a LEXO prevents this control strategy, even for able-bodied individuals. Although they are capable of processing the stimuli, they cannot influence the speed or position of the pre-programmed step of the LEXO. Consequently, alternative postural control strategies, using the freely moving upper body segments and walking aids (crutches), must be adopted with the LEXO, especially in light of the requirement to orientate the HAT to facilitate ongoing stepping.

Able-bodied individuals, with intact central nervous systems were used in this study to ensure any differences in gait between the conditions were relative to the condition and not the capacity of the individual to control their trunk orientation. In all three conditions the trunk maintained a posterior tilt (Figure 7.2). Leardini et al. (2013) suggested that a continuous backward lean of the trunk when walking reduces trunk motion during toe-off. At toe-off, the individual transfers their mass antero-laterally as body-weight moves from the trail foot onto the lead foot and into the more challenging single support phase. At the ANOVA level a significant difference was identified between the conditions in the sagittal plane (at 18–37 and 79–82 %GC). Although post-hoc comparisons revealed no differences between the conditions in the sagittal plane, frontal plane kinematics showed significant differences between both the SLOW and

LEXO conditions with respect to CMBL walking (Table 7.3).The difference in the frontal plane trunk kinematics between the SLOW and CMBL conditions was due to the reduced ROM in the SLOW condition. However, in the LEXO condition, it was evident that the trunk had already begun to shift laterally toward the contralateral lead leg, most likely due to the use of the ipsilateral crutch to lever the body towards the contralateral side and to facilitate toe clearance, leading to an altered upper body orientation relative to CMBL walking.

It was anticipated that a side-to-side motion (generated through the use of crutches) would elicit an increased frontal plane ROM of the trunk and pelvis during LEXO gait. Although the frontal plane trunk ROM during LEXO walking did not exceed that of the CMBL condition (Figure 7.2), the altered timing of directional changes is clearly evident for both the trunk and pelvis. No trunk obliquity differences were evident between the LEXO and SLOW conditions; however, multiple occurrences of differing obliquity are evident at the pelvis, as all three conditions presented with radically different waveforms (Figure 7.2). Several authors have reported reduced pelvic obliquity during slower walking as part of an overall reduction in pelvic movement (Romkes et al., 2017; Swinnen et al., 2013; Taylor et al., 1999). It is also possible that, to help maintain postural control during the SLOW and LEXO conditions, a wider stride width was adopted (Table 7.1), resulting in reduced hip adduction and pelvic hike (Bruijn and van Dieen, 2018). In the LEXO condition, pelvic drop during stance would have been as a consequence of contralateral pelvic hike during toe off, as described above. The pelvic hike during swing also explains the lack of hip abduction compared to the other conditions (52-100 %GC) (Figure 7.2 and Table 7.3), as the pelvis rises ipsilaterally and the weight of the limb falls medially, the hip joint adducts.

Swinnen et al. (2015) reported reductions in trunk and pelvic excursions of able-bodied users of the Lokomat®, but increased pelvic tilt ROM. The use of an overground LEXO system in this study produced augmented pelvic tilt profiles, similar to Swinnen et al. (2015). However, in the current study, the other kinematic components of the trunk and pelvis were not reduced compared to CMBL walking. The body-weight support system of the Lokomat® impedes HAT motion and prevents limb-to-limb weight transfer, a main component of dynamic postural control (Pennycote et al., 2012). Overground LEXO gait presents potentially important benefits for training dynamic postural control, that are not achieved through treadmill-based LEXO gait when the trunk is constrained by a body-weight support system.

The sagittal plane kinematics of the lower limbs were significantly reduced during SLOW vs. CMBL walking. Table 7.3 shows hip flexion to be significantly lower during early stance and throughout the swing phase (0-27 and 64-100 %GC). During LEXO use, the user's ankle was restricted by the spring-loaded mechanical joint, thereby preventing plantarflexion. The walking speed of the SLOW and LEXO conditions removed the need for knee flexion during loading. Furthermore, knee flexion during loading has been omitted from ReWalk™ gait and is not a programmable feature. It was hypothesised that LEXO lower limb kinematics would resemble those of SLOW walking, and it appears that only the ankle joint kinematics were significantly different to those of SLOW gait.

The kinematic data presented in Figure 7.2, and the significantly different variables identified in this discussion can all be accepted as representative of true differences between the conditions as the values identified all exceed the standard error of

measurement (SEM) values reported in chapter 6 (Table 6.2 and Figure 6.1). Although the sagittal plane trunk and hip, SEM values of 5.28^{o} and 4.37^{o} (respectively) were the two highest SEM measures reported they are both lower than the differences identified between the conditions for the appropriate periods reported in Table 7.2 (trunk: 18-37 and 79-82 %GC and hip: 0-27 and 64-100 %GC).

The reduced speed of SLOW and LEXO gait caused the significantly reduced GRF components compared to CMBL gait (Figure 3). Moreover, the significantly lower vGRFs seen in the SLOW and LEXO conditions differed from the results presented by Fineberg et al. (2013) who indicated that LEXO gait (with no external assistance from a therapist) generated similar vGRF for both discrete peak values and pattern. This is the first study to investigate the horizontal GRF components in LEXO gait. The significantly slower walking speed in the LEXO and SLOW conditions reduced the peak horizontal GRFs relative to the CMBL condition. No differences were found between the SLOW and LEXO gait for the medial-lateral GRF component, but both were significantly different to that of CMBL walking during weight acceptance and push-off (Table 7.4). The altered medio-lateral trunk obliquity seen in LEXO gait, relative to SLOW gait, may not have changed the GRF component for two reasons. Firstly, the use of non-instrumented crutches will have generated a GRF that was not recorded; and secondly, as seen in the work of Mundermaan et al. (2008), increased medio-lateral trunk sway of 10^{o} (± 5^{o}) did not present with any significant differences in lateral GRF for healthy able-bodied individuals.

The most notable vGRF differences for SLOW and LEXO gait were load and decay rates. Load rate in CMBL walking was on average 6.38 and 6.60 N/kg/s greater than in the LEXO and SLOW conditions, respectively. Similarly, the CMBL decay rate was on average -7.77 and -7.61 N/kg/s greater than the LEXO and SLOW conditions (Table 7.5). This suggests that, although the peak forces were comparable across the three conditions, the individuals experienced them very differently during two critical sub-phases in stance. The results presented in Table 7.5 indicate that walking speed may have been the predominant factor related to the load and decay rate differences, however, it is possible that the use of crutches in the LEXO condition may have influenced the GRF. Only through the use of instrumented crutches would it be possible to assess this.

It should be acknowledged that the current study used able-bodied participants who would normally not use a LEXO device. Although individuals with neurological movement disorders, who may use a LEXO, have varying levels of movement control, able-bodied participants were recruited as any differences identified between the conditions could then be attributed to the device and not the individual's capacity to walk. The results of the current study were also obtained from a small sample and the data were only specifically relevant to the ReWalk^{TM} (no other LEXO devices). Another limitation was that the GRFs from the LEXO condition were only representative of overground bipedal locomotion with walking aids. Although the elbow crutches were used predominantly for guidance, without force transducers embedded into the crutches, it was impossible to quantify how much weight was borne through the upper limbs. Nonetheless, the capacity of overground LEXO devices to provide postural control training has emerged as a finding of this research. Future work should investigate the

impact of crutches on the GRFs of LEXO walking. Understanding the interaction between the individual and the LEXO device, in both able-bodied and neurologically impaired populations, should also be undertaken to ascertain how closely the SCI user follows the prescribed movement patterns.

7.5. Conclusion

The current study is the first of its kind to quantify the movement characteristics of the whole-body inside a LEXO during overground LEXO walking. The findings highlight the significant temporal-spatial, kinematic and GRF differences between able-bodied gait with and without a LEXO at CMBL and SLOW speeds. The SLOW condition provided the opportunity to identify biomechanical differences between able-bodied and LEXO gait that were independent of speed. The complex upper body movement control needed to operate an overground LEXO may provide an important functional balance and postural control training environment for mobility impaired individuals that warrants further investigation. The use of SPM analysis allowed the comparison of the full waveform of both kinematic and kinetic data, facilitating an understanding of the movement characteristics of LEXO users. By appreciating the differences to able-bodied slow gait, rehabilitators may be able to identify other areas of motor control that are not targeted through LEXO use, and therefore require alternative therapies.

Chapter 8 - Biomechanical differences between able-bodied and spinal cord injured individuals walking in an overground robotic exoskeleton

8.1. Introduction

Spinal cord injury at any level can lead to limited function, deficiencies in health and ultimately reduced life satisfaction. Approximately 80% of SCI individuals are dependant upon a wheelchair for the rest of their life (Fliess-Douer et al., 2010) with said wheelchair becoming the platform from which they will perform activities of daily living, including home based and community mobility (Minkel, 2000). Unfortunately various comorbidities are associated with SCI and manual wheelchair use: reduced bone mineral density (Bauman et al., 2009), muscle contracture (Steeves et al., 2007), poor posture and the development of pressure sores (Masani et al., 2009) are a small sample of SCI sequelae. The impact of some of these conditions can be mitigated through appropriate rehabilitation such as standing (Alekna et al., 2008), stretching (Harvey & Herbert, 2002), strength training (Hicks et al., 2011) and walking (Hubli & Dietz, 2013; Mikolajewska & Mikolajewski, 2011).

Lower limb robotic exoskeletons (LEXO) have been designed as rehabilitative tools and mobility devices, to provide individuals with neuro-muscular deficits a method of upright ambulation. Regular LEXO use has the potential to maintain and even improve some of the benefits associated with traditional rehabilitation modalities for a number of SCI-related comorbidities (Ramanujam et al., 2017).However, several barriers currently exist related to the practical use of LEXOs as mobility devices: walking

independently can be dangerous for individuals with compromised balance control; the limited speed of walking is prohibitive (Louie et al., 2015); as is the requirement to use a walking aid such as elbow crutches, preventing users carrying anything around the home or work environment (Viteckova et al., 2013). Chapter 3 advocated the use of robotic exoskeletons in SCI rehabilitation as part of a multi-modality approach with clear recommendations that its use should not be at the cost of other therapies.

There is still however a limited understanding of how these devices affect the body of the user including the impact they have on the central nervous system (CNS) and the activation of latent central pattern generators (CPGs) located in the lower spinal cord through afferent feedback (Hubli & Dietz, 2013). The previous chapter compared able-bodied normal walking and speed-matched normal walking with LEXO gait and has shown the temporal components of LEXO gait to more closely resemble normal speed walking (e.g., ~1.54 m/s) as opposed to speed-matched walking (e.g., ~0.44 m/s) whereas the spatial components of LEXO gait resembled speed-matched gait. The design of the LEXO, and the fact that its movement parameters are programmable, should mean that these findings are applicable to any LEXO user as long as they are competent and can maintain steady gait. However, it is unclear how the user's body interacts with the device and how this differs from an able-bodied user.

In order to maximise the potential rehabilitation benefits of overground LEXOs, the interaction between the device and the user, as well as the effect the device has on the user, need to be better understood. Therefore, the overarching aim of this study was to assess whether biomechanical differences exist between able-bodied and SCI individuals

during overground LEXO walking. The first objective was to compare the temporal-spatial characteristics of the two groups. Work by Arazpour et al. (2014) suggests that able-bodied and SCI cohorts should generate different temporal-spatial parameters. However, their methods lack clarity about how the exoskeleton used in their study controlled movement and how step initiation was triggered. The ReWalk™ uses pre-programmed peak angles in the sagittal plane, which were set as follows in this thesis: hips (extension 8°, flexion 22°) and knees (flexion 46°), and ankles (fixed at 10° dorsiflexion). Based on the premise that the LEXO would prescribe the movement to the individual user, and that step length and width were normalised to leg length, it was hypothesised that there would be no significant difference in the temporal-spatial variables between the two groups.

The second objective was to identify any differences in range of motion (ROM) and peak joint angles of the lower limbs between the SCI and able-bodied users, and between the LEXO device itself and its user. It was hypothesised that the able-bodied users would generate larger ROM and peak angles (in the sagittal plane) than the SCI group, as the SCI individuals do not have the capacity to override the programmed device and would therefore move within the constraints set by the motors. However, it was anticipated that able-bodied individuals would generate movements that differed from the angles and ROM generated by the LEXO due to the unlikeliness they would behave passively and therefore follow the movement parameters of the device completely.

The third objective was to evaluate upper body movement of the individuals, in conjunction with whole body centre of mass movement (COM) in the vertical and

medio-lateral directions, as an indicator of postural control. It was hypothesised that the SCI group would have less COM control than the able-bodied group, which would result in greater trunk excursion angles in the sagittal and frontal planes.

The fourth and final objective was to compare the GRFs of the two groups. The previous chapter has demonstrated that the GRFs of able-bodied individuals during LEXO gait were significantly lower than normal walking, however that they resembled slow gait GRFs. As the walking speed of SCI and AB users should be the same, speed-related differences in GRF profiles were not anticipated.

8.2. Methods

8.2.1. Participants

Eight able-bodied (mean[SD]: age 28[6] years: height 1.72[0.04] m; mass 77[7] kg) and four complete SCI individuals (age 36[11] years; height 1.81[0.07] m; mass 66[9] kg) were recruited (as described in section 4.2). Healthy able-bodied adults aged 18-60 years, measuring between 160–190 cm in stature, with a mass of less than 100 kg, with no neurological or mobility impairing conditions, and with no musculoskeletal injury were included in the study. Individuals with an SCI were included if they met the same inclusion criteria except for having a lesion to their spinal cord. Spinal cord injured participants were also required to be motor-complete (ASIA A-B) injury level of T2 or below, and must have been classified as an experienced ReWalk™ user (defined as a user capable of completing the basic skill assessment established by ReWalk™ (ReWalk™, 2014) and had a minimum of 20 hours previous use). The ability to transfer

independently between two stable level surfaces, the use of their arms and some hand function, and the capacity to tolerate upright positioning for a minimum of 30 minutes without experiencing light headedness, a drop in blood pressure or other adverse reaction were pre-requisites for the safe use of the LEXO. Ethical approval was provided by the University of Hull's departmental review board (reference number 1415213). All participants gave their written informed consent prior to testing.

8.2.2. Protocol

Testing consisted of a single visit to the Human Performance laboratory. All participants were fitted for the ReWalk™ upon arrival. Standardised settings according to manufacturer specifications were programmed for all participants (ReWalk™, 2014) as described in sections 4.6.1 and 4.6.2. All participants ambulated with forearm crutches for balance and were followed closely by a certified ReWalk™ trainer during LEXO use. All participants were given a 30-minute re-familiarisation session in the ReWalk™ prior to preparation for the testing session. The data presented in this chapter for the able-bodied group is the same as the second set of data presented in Chapter 6, the time at which this group of individuals was most experienced in the LEXO. Individuals had experienced an initial familiarisation session, ReWalk™ session 1 and ReWalk™ session 2 (and up to 30 minutes of re-familiarisation prior to each session).

Participants wore form-fitting clothing for the testing but were provided with standardised trainers that fit their feet and the ReWalk™ footplate. A total of 105 retro-reflective markers (14 mm) were used to track the motion of the user and the LEXO, 73 of these markers were used to track the body and the remaining 32 were used to track

the LEXO and crutches (as in section 4.7.4). Body segments and LEXO segments were defined by an end point or joint centre based upon anatomical locations or ReWalk™ technical specifications and the calibrated anatomical systems technique (Cappozzo et al., 1995). Tracking marker clusters were affixed to each body segment and LEXO segment. Each segment was tracked using the six-degrees-of-freedom principles (Buczek et al., 2010). Three-dimensional kinematics were captured with ten Oqus 4.0 cameras (Gothenburg, Sweden) at 100 Hz and synchronised with two floor integrated Kistler (9286AA) force plates (Winterthur, Switzerland) sampling at 1000 Hz via Qualisys Track Manager software version 2.15 (Gothenburg, Sweden). Full details can be found in section 4.7.

Participants were asked to walk along a five-meter walkway ten times. The starting point of each walking trial was determined *a priori* to facilitate GRF data collection. This was because at least one step with each foot was required before and after contact with the force plates to ensure the data analysed were not representative of gait initiation or termination. Kinetic data were discarded if a complete foot contact was not made with the force plate.

8.2.3. Data Reduction

3D marker coordinate and GRF data were processed as explained in section 4.7. All variables were normalised to the gait cycle starting with initial contact; GRFs were normalised to combined body and ReWalk™ mass. The vertical GRF peaks, defined as vertical loading and vertical push-off, were identified based on percentage gait cycle relative to slow gait in the previous chapter (7.3.3.).

The following kinematics were identified for the user and the LEXO: ankle, knee and hip peak joint angles and ROM (degrees) and peak fontal plane hip angles; these variables were averaged across both the right and left limb for each individual (section 4.9.1). Trunk and pelvis segment excursions (degrees) were reported in all three planes for the user only. Peak vertical and anterior-posterior GRFs (N/kg) were compared between groups. Centre of mass medio-lateral and vertical displacements were normalised to body height (%). Medio-lateral COM was offset using a Euclidean distance correction factor as individuals did not walk along the x-axis of the laboratory co-ordinate system. The Euclidian distance correction factor was calculated by identifying the mean of all data points in the medio-lateral COM and subtracting this value from each data point.

8.2.4. Statistical analysis

All data were analysed using SPSS statistical package (V22, IBM statistics, Armonk, NY). Lower limb kinematic data were analysed using a Kruskall-Wallis H and Dunn's post-hoc analysis (Dunn, 1964). The distribution shapes were not similar for any of the 12 variables, as such interpretations were based on mean rank scores. The remaining data were all analysed using a Mann-Whitney U test, distribution shapes were not similar for any variables, mean rank scores were again used. Non-parametric Cliff's Delta effect sizes were calculated (Cliff, 2014). Established thresholds of small (0.147–0.33) medium (0.33–0.474) and large (>0.474) were used for interpretation (Romano et al., 2006).

8.3. Results

Temporal-spatial parameters for able-bodied and SCI LEXO gait are displayed in Table 8.1. Significant reductions in step length and cadence (P = 0.004 and P = 0.028, respectively) resulted in a significantly slower walking speed for the SCI group (P = 0.016, δ = 0.88), leading to a potentially, meaningful increase in time spent in double support (δ = -0.56, 95% CI -0.94 to 0.41).

Table 8.1. Median (IRQ) temporal-spatial data for able-bodied and SCI LEXO gait. (Mann Whitney U tests, significance set at 95%, Cliff's delta effect sizes and 95% confidence intervals).

Temporal-spatial parameters	AB Medians (IQR)		SCI Medians (IQR)		AB Mean Rank	SCI Mean Rank	U	Sig (*p*)	Effect size δ (95% CI)		
Walking speed (m/s)	0.39	(0.04)	0.32	(0.03)	8.25	3.00	2.00	0.016*	0.88	(0.99 to	0.19)
Double support time (%)	26	(4.6)	34	(5.5)	5.31	8.88	25.50	0.109	-0.56	(0.41 to	-0.94)
Cadence (steps/min)	48	(2)	46	(2)	8.13	3.25	3.00	0.028*	0.88	(0.99 to	0.19)
Stance time (%)	64	(2.0)	68	(2.6)	5.13	9.25	27.00	0.730	-0.69	(0.21 to	-0.96)
Swing time (%)	37	(2.3)	33	(2.7)	7.63	4.25	7.00	0.154	0.56	(0.94 to	-0.41)
Step length (% leg length)	52	(8.1)	45	(1.5)	8.50	2.50	0.00	0.004*		1	
Step width (% leg length)	18	(2.6)	15	(1.2)	8.50	2.50	0.00	0.004*		1	

Comparison of mean ranks, distribution shapes not similar

AB = Able-bodied, SCI = Spinal cord injured, IQR = interquartile range, Sig = Significance, U = Mann Whitney U statistic, GRF = Ground reaction force.

* = significant difference, alpha level 0.05

Using trigonometry based on a hip flexion angle of 22° and a hip extension angle of 8° (total of 30°), step length should be 52% leg length for every participant (Figure 8.1). The median step length of able-bodied individuals was 52% leg length, however in the SCI group the median step length was 45% leg length (Table 8.1) which was significantly shorter (P = 0.004).

$$\sin(\theta/2) = \frac{X}{leg\ length}$$

$$X = (\sin(\theta/2))\ leg\ length$$

$$step\ length = (\frac{X_2}{leg\ length})100$$

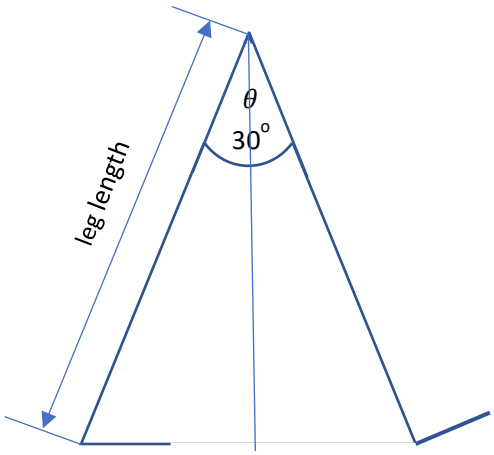
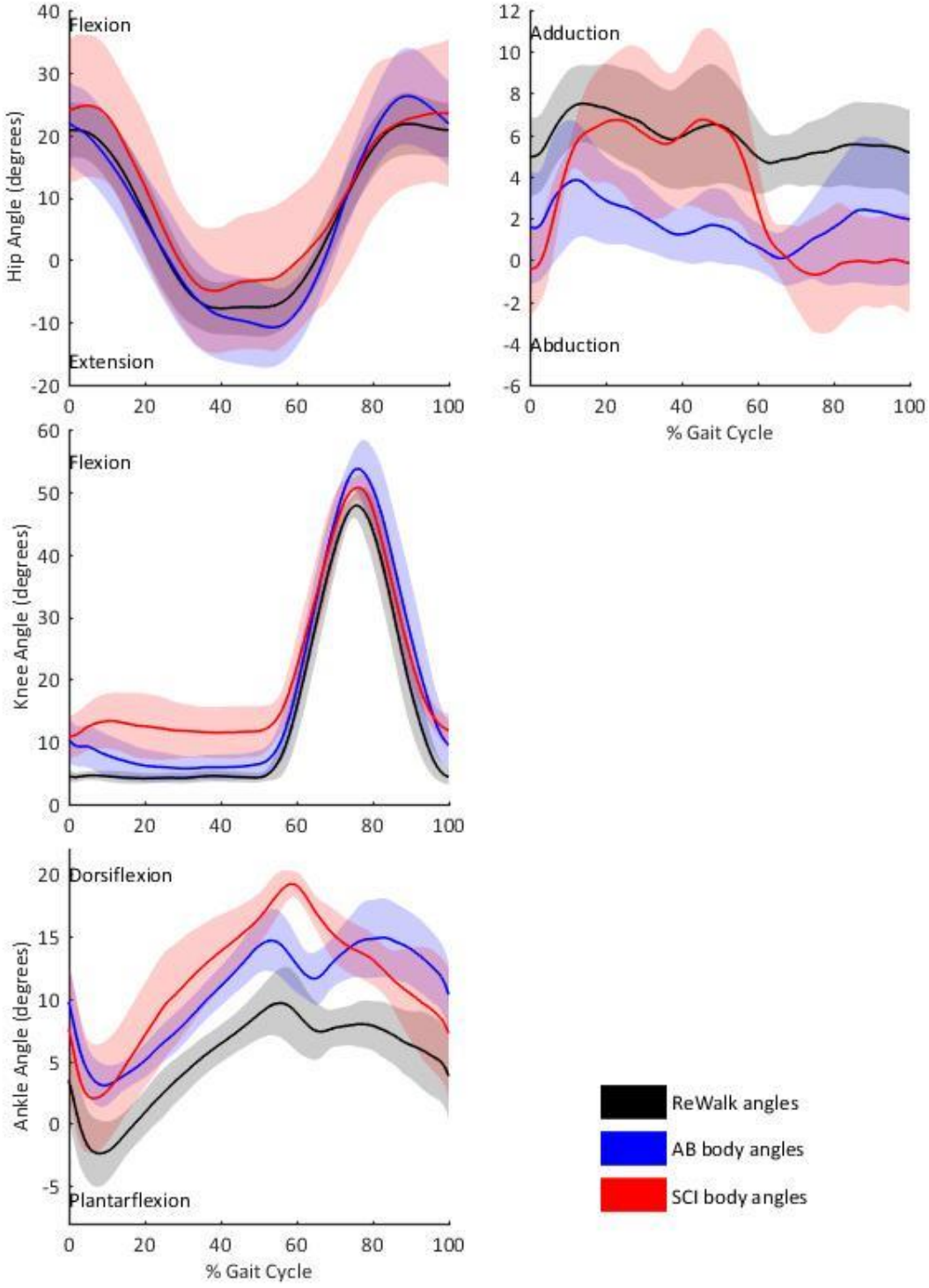


Figure 8.1. Calculation of step length

8.3.1. Lower limb kinematics

Lower-limb peak kinematic and ROM data are presented in Figure 8.2 and Table 8.2. Twelve lower-limb variables were analysed for the hip, knee and ankle joints. Significant differences were identified for nine of the twelve variables. Results from the post-hoc analysis revealed that the greatest differences in peak joint angles and ROM existed between the able-bodied users and the LEXO. Furthermore, large effect sizes were evident for all variables between the two groups. The frontal plane motion of the hip, knee flexion during swing and ankle dorsiflexion, for both the SCI and able-bodied groups, all presented with significant differences to the LEXO. During frontal plane

movement of the hip, the LEXO limb maintained an adducted position throughout the gait cycle, whereas the SCI and able-bodied users' hips abducted beyond neutral to ~1.5°. Able-bodied and SCI knee flexion during swing (SCI mean rank = 17.25, AB mean rank = 19.13, RW mean rank = 6.50, $p = 0.025$ and $p > 0.001$) and ankle dorsiflexion (SCI mean rank = 22.00, AB mean rank = 16.25, RW mean rank = 6.83, $p = 0.001$ and $p = 0.011$) were both significantly greater than the peak angles generated by the LEXO. The median differences between the able-bodied and SCI groups all exceeded the average SEM values reported in chapter 6 (Table 6.2) except for the hip abduction, knee flexion during swing and plantarflexion during swing. However, knee ROM was the only variable that was significantly different (~5.5°) between the able-bodied and SCI groups.



Flexion, dorsiflexion and adduction are positive.

Figure 8.2. Hip, knee and ankle joint angles of the ReWalk™, able-bodied and SCI individuals. Data are averaged across both limbs. The gait cycle commences and terminates with ipsilateral foot contact.

Table 8.2. Median (IRQ) lower limb peak kinematic values and joint range of motion (ROM) for able-bodied and SCI LEXO gait (°). (Kruskall-Wallis H test, significance set at 95%, Dunn's post-hoc test and Cliff's delta effect sizes and 95% confidence intervals).

	Median AB Angles (IQR)		Median SCI Angles (IQR)		Median RW Angles (IQR)		Mean Rank			$X^2(2)$	Sig (*p*)	Effect Size
							AB	SCI	RW			
Hip ROM (sagittal)	38.7	(2.1)	32.6	(4.4)	31.1	(2.0)	20.13	11.50	7.75	14.797	0.001*	0.64
Hip ROM (frontal)	5.7	(0.5)	8.3	(8.6)	4.1	(1.4)	15.88	16.50	8.92	6.184	0.045*	0.27
Hip flexion	28.0	(10.3)	30.4	(8.3)	21.6	(4.7)	14.88	15.25	10.00	3.007	0.222	0.13
Hip extension	-9.2	(9.1)	-1.4	(7.3)	-10.3	(4.6)	10.75	17.00	12.17	2.137	0.344	0.09
Hip adduction stance	5.0	(1.8)	7.2	(4.7)	7.8	(1.1)	6.75	14.75	15.58	7.977	0.019*	0.35
Hip abduction swing	-1.0	(2.5)	-1.5	(3.4)	3.7	(1.6)	8.25	7.00	17.17	10.537	0.005*	0.46
Knee ROM (sagittal)	51.9	(3.3)	46.4	(3.6)	47.4	(0.7)	20.50	6.25	9.25	15.9	0.000*	0.69
Knee flexion loading response	7.8	(1.9)	11.9	(3.0)	4.8	(1.3)	15.75	21.75	7.25	15.15	0.001*	0.66
Knee flexion swing	54.9	(3.7)	54.6	(2.2)	50.4	(0.9)	19.13	17.25	6.50	17.468	0.000*	0.76
Ankle ROM (sagittal)	13.6	(2.4)	18.4	(5.3)	12.8	(3.8)	12.38	18.00	10.75	3.158	0.206	0.14
Ankle dorsiflexion	14.5	(3.5)	20.6	(0.7)	10.0	(3.3)	16.25	22.00	6.83	17.177	0.000*	0.75
Ankle plantarflexion swing	1.6	(2.4)	1.3	(7.0)	-2.4	(3.7)	18.63	15.25	7.50	12.607	0.002*	0.55

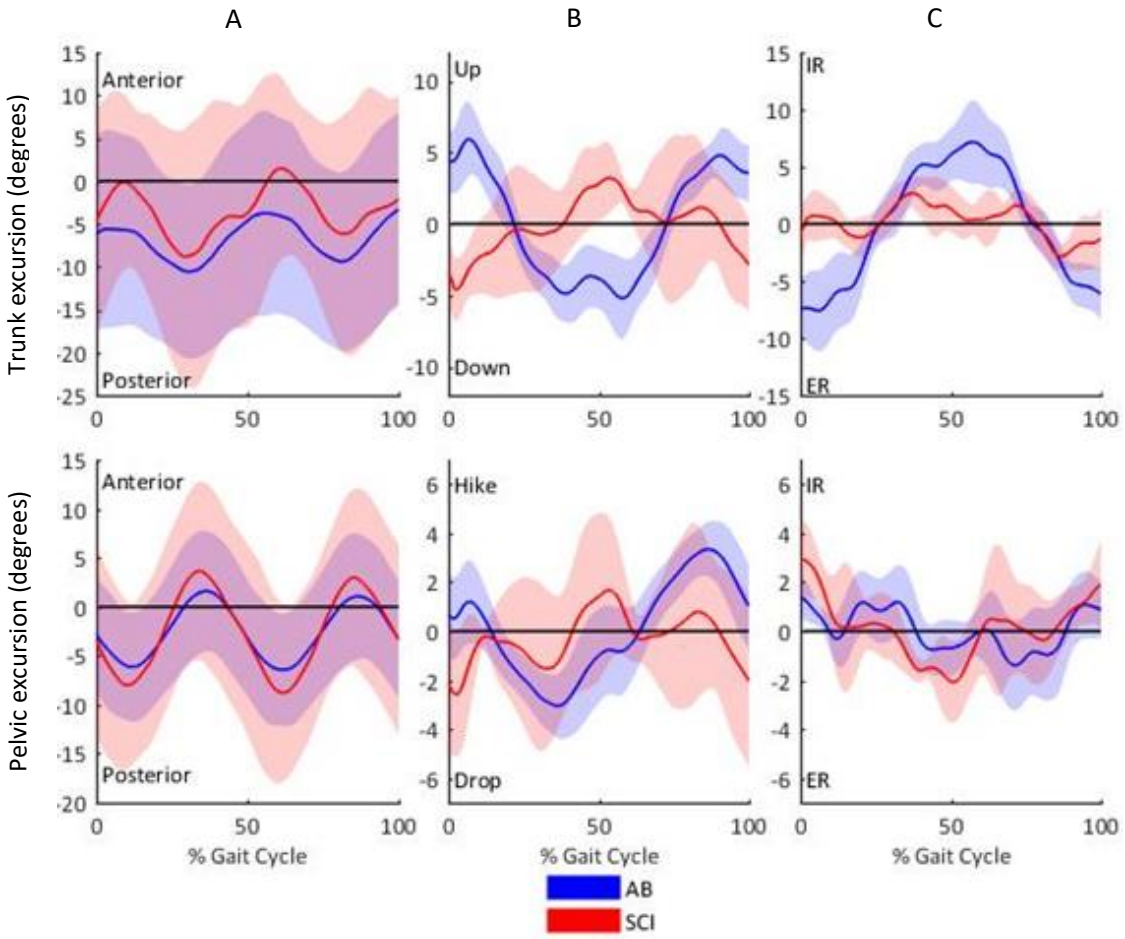
Post-Hoc Analysis	RW vs. SCI			RW vs. AB			SCI vs. AB		
	Mean Rank Difference	Sig (*p*)	Effect Size δ	Mean Rank Difference	Sig (*p*)	Effect Size δ	Mean Rank Difference	Sig (*p*)	Effect Size δ
Hip ROM (sagittal)	3.75	1.000	-0.38 (0.40 to -0.84)	12.38	0.000*	-1	8.63	0.139	-1
Hip ROM (frontal)	7.58	0.190	-0.67 (0.02 to -0.93)	6.96	0.093	-0.56 (0.01 to -0.86)	-0.63	1.000	0.00 (0.75 to -0.75)
Hip adduction stance	0.83	1.000	0.00 (0.70 to -0.70)	8.83	0.019*	0.77 (0.95 to 0.23)	8.00	0.194	0.56 (0.91 to -0.25)
Hip abduction swing	10.17	0.038*	0.83 (0.97 to 0.24)	8.92	0.017*	0.75 (0.94 to 0.22)	1.25	1.000	-0.13 (0.55 to -0.70)
Knee ROM (sagittal)	3.00	1.000	0.38 (0.87 to -0.51)	11.25	0.001*	-1	14.25	0.003*	-1
Knee flexion loading response	14.50	0.001	-1	8.50	0.025*	-0.81 (-0.34 to -0.96)	6.00	0.498	0.81 (0.97 to 0.09)
Knee flexion swing	10.75	0.025*	-1	12.63	0.000*	-1	1.88	1.000	-0.31 (0.41 to -0.79)
Ankle dorsiflexion	15.17	0.001*	-1	9.42	0.011*	-0.81 (-0.37 to -0.95)	5.75	0.553	0.88 (0.99 to 0.19)
Ankle plantarflexion swing	7.75	0.173	-0.50 (0.28 to -0.88)	11.13	0.002*	-1	3.38	1.000	-0.06 (0.71 to -0.77)

AB = Able-bodied, SCI = Spinal cord injured, RW = ReWalk™, IQR = interquartile range, Sig = Significance, $X^2(2)$ = Chi-squared statistic (degrees of freedom).
* = significant difference, alpha level 0.05

8.3.2. Centre of mass and postural control

Trunk and pelvic ROM and peak segment excursions are reported in Table 8.3 and displayed in Figure 8.3. Sagittal ROM for the trunk was ~8.6^{o} greater in SCI individuals (AB mean rank = 4.63, SCI mean rank = 10.25, U = 37.00, p = 0.008) and the pelvic sagittal ROM was ~5.4^{o} greater in SCI individuals (AB mean rank = 4.50, SCI mean rank = 10.50, U = 36.00, p = 0.004) compared to the able-bodied group. Although no significant differences were identified in the frontal and transverse planes for either the trunk or pevic kinematics, the waveforms presented in Figure 8.3 show opposing movement patterens between the two groups.

Frontal and vertical centre of mass displacement data are presented in Table 8.4. Although no significant differences were identified for COM displacement, the medio-lateral COM displacement variables all presented with large effect sizes (δ = > 0.474) suggesting that the medio-lateral COM movement may have been greater for SCI individuals. This can be seen more clearly in Figure 8.4 A.



Internal rotation is transverse rotation in an anterior direction with the side of the body defined by the lead limb at commencement of the gait cycle.

Figure 8.3. Trunk and pelvis segment excursions (A) sagittal, (B) frontal (C) transverse of able-bodied and SCI individuals. The gait cycle commences and terminates with ipsilateral foot contact.

Table 8.3. Median (IRQ) trunk and pelvis kinematic values and joint range of motion (ROM) for able-bodied and SCI LEXO gait (°). (Mann Whitney U tests, significance set at 95%, Cliff's delta effect sizes and 95% confidence intervals).

Upper body kinematics	AB Median Angle (IQR)		SCI Median Angle (IQR)		AB Mean Rank	SCI Mean Rank	U	Sig (*p*)	Effect size δ (95% CI)		
Trunk ROM (sagittal)	12.6	(2.1)	21.2	(4.1)	4.63	10.25	37.00	0.008*	-0.94	(-0.36 to	-0.10)
Trunk ROM (frontal)	14.5	(6.4)	16.5	(6.8)	6.13	7.25	49.00	0.683	-0.19	(0.55 to	-0.76)
Trunk ROM (transverse)	21.1	(8.0)	16.6	(9.3)	7.38	4.75	19.00	0.283	0.44	(0.85 to	-0.31)
Pelvis ROM (sagittal)	11.0	(2.6)	16.4	(1.8)	4.50	10.50	36.00	0.004*		-1	
Pelvis ROM (frontal)	8.0	(1.8)	11.0	(4.2)	5.50	8.50	44.00	0.214	-0.50	(0.35 to	-0.90)
Pelvis ROM (transverse)	7.9	(1.9)	9.0	(1.8)	5.63	8.25	45.00	0.283	-0.44	(0.32 to	-0.85)

Comparison of mean ranks, distribution shapes not similar

AB = Able-bodied, SCI = Spinal cord injured, IQR = interquartile range, Sig = Significance, U = Mann Whitney U statistic, COM = Centre of mass

* = significant difference, alpha level 0.05

Table 8.4. Median (IRQ) Centre of mass displacement values for able-bodied and SCI LEXO gait (% leg length). (Mann Whitney U tests, significance set at 95%, Cliff's delta effect sizes and 95% confidence intervals).

Centre of mass displacement	AB Median Displacement (IQR)		SCI Median Displacement (IQR)		AB Mean Rank	SCI Mean Rank	U	Sig (*p*)	Effect size δ (95% CI)		
COM medial-lateral max	4.75	(0.71)	5.27	(1.68)	5.38	8.75	25.00	0.154	-0.56	(0.18 to	-0.90)
COM medial-lateral min	-4.59	(0.74)	-5.77	(1.62)	7.75	4.00	6.00	0.109	0.63	(0.92 to	-0.14)
COM medial-lateral range	9.34	(1.44)	11.49	(3.30)	5.25	9.00	26.00	0.109	-0.63	(0.14 to	-0.92)
COM vertical max	1.56	(0.17)	1.44	(0.16)	7.25	5.00	10.00	0.154	0.38	(0.82 to	-0.35)
COM vertical min	-1.53	(0.31)	-1.38	(0.34)	5.88	7.75	21.00	0.214	-0.31	(0.41 to	-0.79)
COM vertical range	3.07	(0.46)	2.80	(0.52)	7.25	5.00	10.00	0.368	0.38	(0.82 to	-0.35)

Comparison of mean ranks, distribution shapes not similar

AB = Able-bodied, SCI = Spinal cord injured, IQR = interquartile range, Sig = Significance, U = Mann Whitney U statistic, COM = Centre of mass, Max = Maximum Min = Minimum.

* = significant difference, alpha level 0.05

A

B

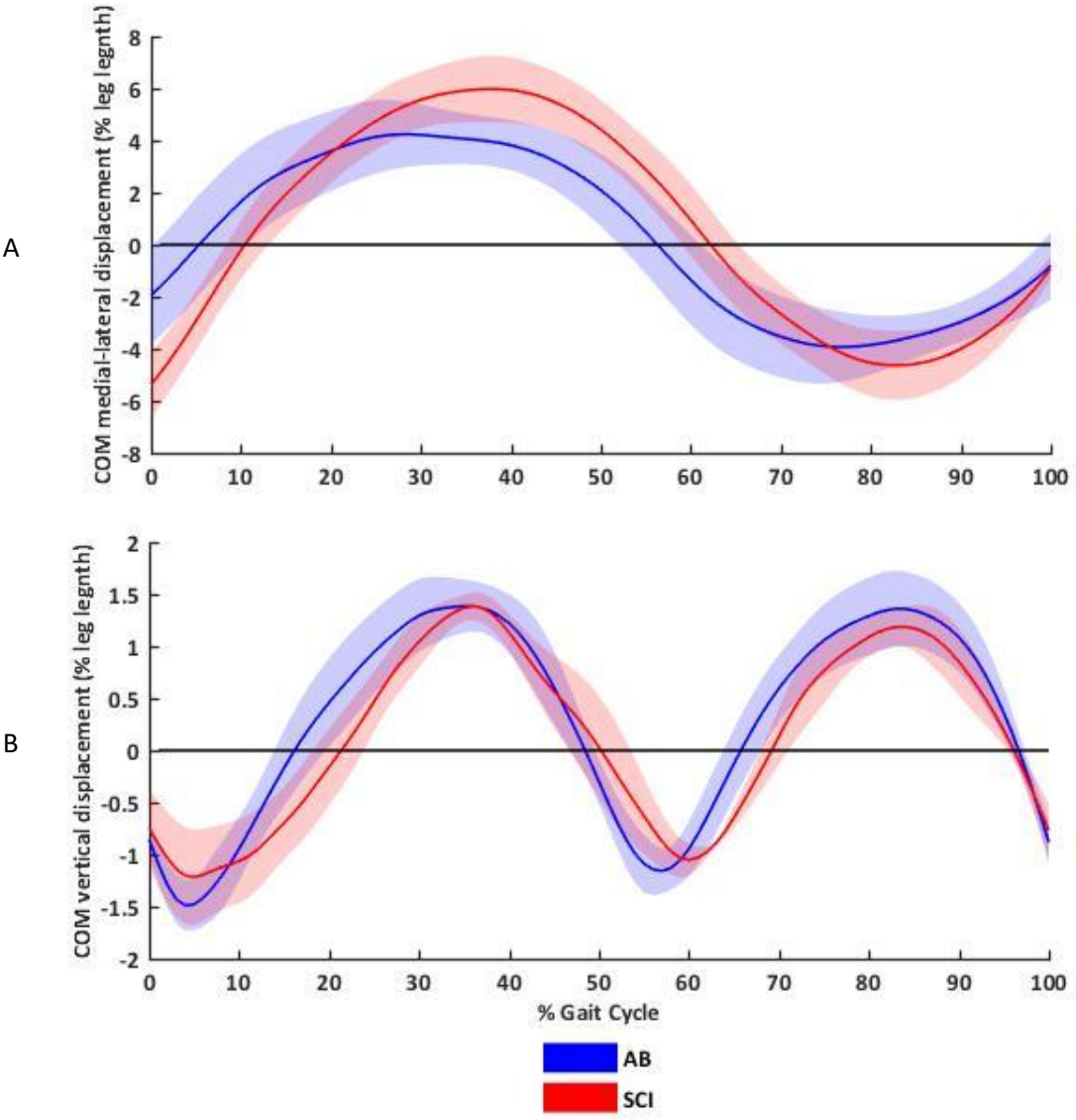
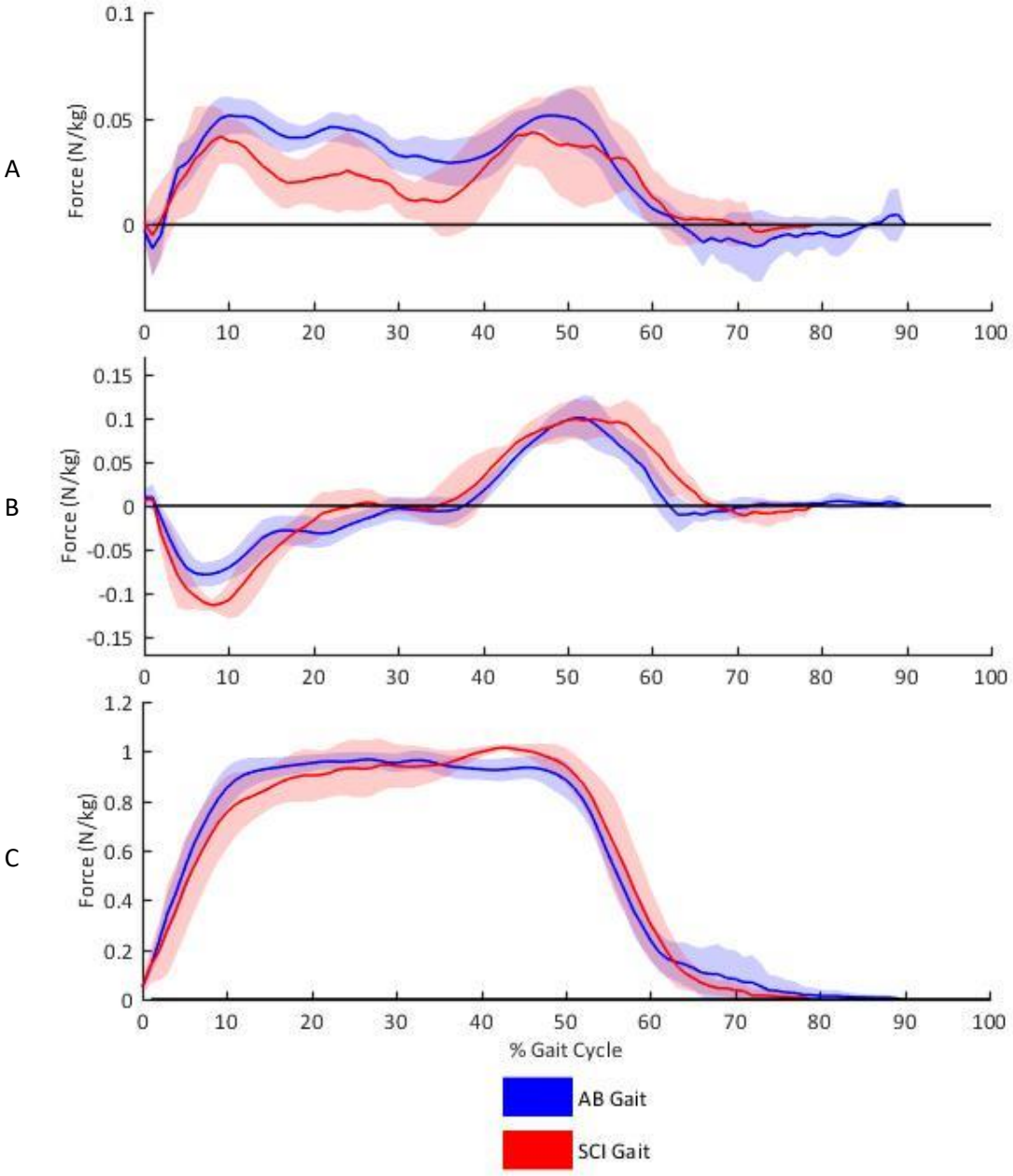


Figure 8.4. Centre of mass displacement of able-bodied and SCI individuals in the (A) medial-lateral and (B) vertical directions. Medial-lateral displacement data were exposed to a Euclidian correction factor to facilitate a change of sign as movement direction changed. The gait cycle commences and terminates with ipsilateral foot contact.

8.3.3. Ground reaction forces

Figure 8.5 illustrates the GRF profiles of able-bodied and SCI LEXO gait. Significantly greater forces were identified for the SCI group in loading in the anterior-posterior direction (AB mean rank = 8.60, SCI mean rank = 2.50, U = 0.00, p = 0.004) and in preparation for toe off (~45% of gait cycle) in the vertical direction (AB mean rank = 4.62, SCI mean rank = 10.25, U = 31.00, p = 0.008). Based on the large effect size, able-

bodied individuals presented with a greater load rate but this was not significantly different (δ = 0.56, 95% CI: 0.91 to -0.25) (Table 7.5).



(A) Lateral and (B) anterior propulsion forces are positive.

Figure 8.5. (A) Medial-lateral, (B) anterior-posterior and (C) vertical ground reaction forces of Able-bodied and SCI individuals. Data were normalised to body mass and LEXO mass. The gait cycle commences and terminates with ipsilateral foot contact.

Table 8.5. Median (IRQ) peak ground reaction forces (N/kg) and load/decay rates (N/kg/s) for able-bodied and SCI LEXO gait. (Mann Whitney U tests, significance set at 95%, Cliff's delta effect sizes and 95% confidence intervals).

Ground reaction forces	AB Median GRF (IQR)		SCI Median GRF (IQR)		AB Mean Rank	SCI Mean Rank	U	Sig (*p*)	Effect Sizes δ (95% CI)			
Lateral	0.07	(0.01)	0.07	(0.02)	6.38	6.75	17.00	1.000	0.06	(0.64	to	-0.71)
Anterior propulsion	0.13	(0.02)	0.14	(0.01)	6.12	7.25	19.00	0.683	-0.19	(0.47	to	-0.71)
Posterior braking	-0.10	(0.01)	-0.15	(0.02)	8.60	2.50	0.00	0.004*		-1		
Vertical loading	1.01	(0.02)	0.96	(0.16)	6.88	5.75	13.00	0.683	0.19	(0.80	to	-0.62)
Minimum vertical force in stance	0.87	(0.05)	0.83	(0.10)	7.25	5.00	10.00	0.368	0.38	(0.84	to	-0.40)
Vertical push-off	1.03	(0.03)	1.09	(0.04)	4.62	10.25	31.00	0.008*	-0.94	(-0.36	to	-1.00)
Load rate (N/kg/s)	1.39	(0.17)	1.21	(0.34)	7.63	4.25	7.00	0.154	0.56	(0.91	to	-0.25)
Decay rate (N/kg/s)	-1.44	(0.39)	-1.35	(0.28)	7.25	5.00	10.00	0.368	0.38	(0.84	to	-0.40)

Comparison of mean ranks, distribution shapes not similar

AB = Able-bodied, SCI = Spinal cord injured, IQR = interquartile range, Sig = Significance, U = Mann Whitney U statistic, GRF = Ground reaction force.

* = significant difference, alpha level 0.05

8.4. Discussion

The aim of the current study was to determine if there were any biomechanical differences between able-bodied and SCI overground LEXO users. Previous work has investigated temporal-spatial parameters and has measured the kinematics of overground LEXO devices rather than the user inside (Arazpour et al., 2014). The lower limb kinematics of SCI overground LEXO users and associated EMG (Ramanujam et al., 2017), lower-limb kinematics of able-bodied treadmill-based LEXO users (Hidler et al., 2008), and upper-body kinematics of treadmill based SCI LEXO gait (Swinnen et al., 2015) have also been studied. To date the only study that has investigated the GRF during LEXO walking was that of Fineberg et al. (2013) and, although their study compared LEXO use to a control group ("normal gait"), due to the in-shoe pressure system used to calculate the force variables, only vertical GRF was presented. The work completed in chapter 7 of this thesis demonstrated that significant differences were evident between able-bodied comfortable and LEXO gait in the anterior-posterior directions.

The multi-faceted, interconnected variables used in gait analysis are often examined in isolation. However, it is only when we combine the various elements that it is possible to determine the reasoning behind individual and/or group differences. It was hypothesised that there would be no significant differences between groups relating to the temporal-spatial gait parameters. Yet several significant differences were identified: reduced step length and cadence in the SCI group, contributing to their slower walking speeds. Whole-body movements should be considered to understand why these differences existed. The timing and magnitude of trunk movement during LEXO use

appeared to explain several biomechanical differences between able-bodied and SCI users. Specifically, the anterior orientation and timing of trunk movement influenced step length, horizontal GRF (braking) and subsequently walking speed.

Sagittal plane ROM of the trunk (Table 8.3) was significantly greater in SCI individuals and although the trunk maintained a predominantly posterior orientation for both groups, the SCI group displayed a generally more anterior position throughout the gait cycle (Figure 8.3). If the user's trunk rotated anteriorly too early or too far during ipsilateral swing this could lead to an anterior rotation of the whole body and insufficient ground clearance, leading to early contact and a shorter step length. In this instance the power of the motor would no longer drive the swinging limb forward and would push the rest of the body backwards. This could also account for the significantly larger posterior GRF in the SCI group (Table 8.5). Combined with the significant reduction in cadence of two steps per minute, these variables explain the significantly slower walking speed in the SCI group.

As the LEXO settings were identical for both groups, any temporal variation was ultimately a product of the user orientating the body differently to initiate step transition (the process of taking the next step in the cycle). During LEXO walking (specifically using the ReWalk^{TM}) step transition has to be triggered. Activation of step transition occurs through the orientation of a tilt sensor located on the left lateral portion of the pelvic bracket (Zeilig et al., 2012). The temporal differences between groups may be explained by differences in the time taken to orientate the body between steps. Although both groups needed to maintain postural control, the able-bodied

individuals could utilise their core muscles and neuromuscular feedback to achieve the specific body orientation to facilitate step transition more quickly, with greater positional control and a reduced trunk ROM compared to the SCI group (median difference -8.6^{o}, P = 0.008). The standard error of measurement (SEM) data reported in chapter 6 for sagittal plane trunk ROM was 5.28^{o}. Although this is a large value and would suggest the data need to be interpreted with caution (McGinley et al., 2009), the median difference between groups of -8.6^{o} exceeds the SEM suggesting that the difference was representative of a true difference rather than as a result of measurement error. Therefore, it can be assumed that the temporal variances leading to reduced cadence in the SCI group were independent of the LEXO because it was about how the individual was able to orientate themselves and how quickly they could achieve this.

It was hypothesised that SCI users would experience smaller lower limb ROM and reduced peak angles than able-bodied users whilst generating larger upper body ROM. Table 8.2 shows that significant differences were evident between the able-bodied individuals, SCI individuals and the LEXO itself at the hip, knee and ankle joints. Post-hoc analysis revealed that the decrease in sagittal knee ROM for SCI users was the only significant difference between able-bodied and SCI users. The graphical representation in Figure 8.2 illustrates that the knee joint in the SCI group experienced an increased level of flexion throughout stance phase. Practically, this was likely caused by the strapping system used to hold the user's limbs against the LEXO. The flexible webbing allowed the individual to drop ('sag') within the device, pushing the knee into approximately 10^{o} of flexion. Although not directly measured this would have changed

the alignment of the individuals' knee with the LEXO knee joint centre, which may also have impacted the alignment of the hip joints. Newer versions of the ReWalk™ have subsequently installed a physical stop immediately inferior to the knee to prevent the anterior drop of the tibia. The misalignment of the anatomical joint centres with the robotic joint centres may have different consequences. The capacity of any robot assisted gait training device to deliver prescribed movement patterns is based on the alignment of joint centres (Hidler et al., 2008). Hidler et al. (2008) however, identified joint misalignment in able-bodied individuals walking in the Lokomat, they concluded that said misalignment provided the capacity for variability within the gait cycle. The principles of motor learning include task specificity, training intensity and task variability (Hubli and Dietz, 2013), task variability has positive implications for learning (or re-learning) tasks (Wolpert and Flanagan, 2016) and can prevent the spinal cord from entering a state of learned helplessness, where a lack of capacity for exploration will result in poor skill acquisition (Cai, et al., 2005).

The concept of variability in motor learning and the triggering of locomotor CPGs has previously been explored with the negative implications of the patient not actively engaging with the movement and therefore remaining passive (Labruyère & van Hedel, 2014; Lam et al., 2011; Nooijen et al., 2009). Although joint centre misalignment was likely in both groups, the reasoning for each would be very different. The able-bodied group most likely demonstrated variability equivalent to and for the same reasons as those identified by Hidler et al. (2008) as they tried to operate beyond the mechanical constraints of the LEXO. As previously discussed, the SCI individuals appeared to have dropped within the device which will have altered their position relative to the LEXO,

leading to a limited yet, persistent change in the user kinematics. Essentially, SCI individuals may experience misalignment with the device joint centres but are unlikely to have altered the misalignment throughout the movement as they would not be able to try to exceed the LEXO parameters and would rest against the physical stop provided by the webbing straps. Evidence of the differences between the groups can be seen in Table 8.2. Three variables presented with significant differences between the SCI group and the LEXO itself, compared to eight of nine significant kinematic variables between the able-bodied group and the LEXO. This suggests that the SCI users more closely followed the movements of the LEXO trial after trial compared to the able-bodied group. The active involvement of the trunk to maintain balance and facilitate stepping may also provide sufficient engagement in the activity to prevent participant passivity.

In order to activate the CPGs residing in the lower spine and elicit a stepping response, appropriate afferent feedback must be sent from the muscle spindles of the hip flexors and the change in load under the ipsilateral foot. The average sagittal hip ROM for the able-bodied and the SCI groups were equivalent to the previously explored slow walking gait (without LEXO) depicted in chapter 7 (~32^{o}). Coupled with the vertical GRF data showing equal un-loading between the two groups (Figure 8.4 and Table 8.5), there is an argument to suggest that the afferent stimulation at the hip joint, and ipsilateral lower limb un-loading, may still provide sufficient stimulus to trigger stepping CPGs (Reier et al., 2017).

It was hypothesised that the SCI group would exhibit a greater displacement of whole-body COM in the medial lateral and vertical directions during LEXO walking than the

able-bodied group. The vertical component of the COM displayed no significant differences and small to moderate effect sizes (δ = -0.31 to 0.38) between the groups. Step length has been shown to directly impact the vertical displacement of the body COM with the peak height occurring during single support when the supporting leg is directly under the trunk and fully extended. The lowest vertical position is directly related to the angle generated between the hip joints based on step length during double support (Gard et al., 2004; Orendurff et al., 2004). Although vertical displacement of the body's COM has often been related to the energetic cost of walking, the robotic nature of the LEXO negates this as movement of the limbs is produced by the motors and not the individual. Although the SCI group presented with significantly shorter step-lengths compared to the able-bodied group, the lack of difference between the groups for the vertical displacement of the COM may be due to step length difference between the groups as being relatively small. The data from chapter 7 for the same group of able-bodied individuals revealed an average step length of 88% of leg length during comfortable walking opposed to the 52% of leg length displayed in Table 8.1, suggesting that the step length during LEXO walking was short enough that it limited the vertical displacement of the COM for all participants.

Discreet values based on lateral trunk displacement did not show any significant differences between the two groups. However, based on the waveform presented in Figure 8.3 it is clear that the two groups generated opposing movement patterns whilst maintaining equivalent ROM. This suggests that the frontal plane movement control differed between the two groups. There were no significant differences between the groups for the medial-lateral COM displacement, however large effect sizes were

evident (max δ = -0.56, min δ = 0.63 and range δ = -0.63) potentially suggesting greater medio-lateral displacement in the able-bodied group, in contrast to the hypothesis. Furthermore, Figure 8.4 demonstrates that the peak lateral displacements of the COM occurred at the same time as the maxima of the vertical displacement of COM in both the SCI and able-bodied groups and that these presented with the same waveform for both groups. In normal walking, the lateral position of the swinging limb's ground contact (i.e., step width) relative to the falling COM influences frontal plane stability (Rosenblatt & Grabiner, 2010). In order to maintain frontal stability, it would make sense for the LEXO to generate a larger step width to produce a sufficiently wide base of support within which the COM can be maintained (Hurt et al., 2010). The lack of robotic articulation in the frontal plane by the LEXO means that step width was predominantly controlled by the size of the pelvic bracket and the rigidity of the exoskeleton. Able-bodied individuals who presented with a significantly greater step width (p = 0.004) would have been able to engage their hip abductors to prevent the prolonged hip adduction seen in the SCI group throughout stance (Figure 8.2), thus preserving the greater step width.

The narrow base of support experienced by the SCI users may have CNS computational and metabolic energetic cost implications. Previous work has evidenced that step width in able-bodied walking is adjusted to account for head arm and trunk (HAT) kinematics (Hurt et al., 2010) but that HAT kinematics can also be influenced by constraints of step width (Arvin et al., 2016). Donelan et al. (2004) highlighted that reduced sensorimotor information available to the CNS, and associated with lateral stability, led to increased step width variability, which contributed to increased metabolic costs. The SCI group

could have used the movement of the trunk as a counterweight to the falling COM. Unlike the able-bodied participants, it is possible that this attempt to maintain stability was the most appropriate in terms of CNS computation and was a learned adaptation based on postural control strategies developed during sitting to avoid falling (Chisholm et al., 2017). Although only speculative, because force data could not be collected from the elbow crutches, it is also probable that the SCI users applied greater force through the walking aids compared to the able-bodied group as the medial-lateral force profile under the foot was not different across the groups and core control alone was unlikely to facilitate trunk change of direction in the SCI group. This requirement to use the trunk to control posture may be more energetically costly for the SCI group than for the able-bodied individuals; as such it is suggested that future work should investigate the energetic requirements of overground LEXO gait.

The primary limitations associated with the work in this study are related to the limited sample size of individuals who had experienced a SCI. Although previously discussed in chapter 4, that although the sample appears small it was approximately20% of the viable UK population of ReWalk™ active individuals at the time. It is also evident that the age span of the individuals and the differences in their injury level and severity as well as any differences in time since injury may all have impacted the capacity for the therapeutic effects of the ReWalk™ to activate the latent CPGs. The work undertaken in this chapter was however designed to identify the movement profiles of the different groups rather than to assess the impact said movement may have on the CPGs, as a result, it is acknowledged that these limitations in group homogeneity exist but that they would not negatively impact the outcome of the study. It is also noted that the

individuals with an SCI who were recruited for this study, were asked to complete the walking tasks how they were most comfortable and competent in relation to the use of crutches. Three of the four participants utilised a four-point gait pattern, advancing one crutch at a time followed by the contralateral leg and one participant used a three-point pattern, advancing both crutches between each step. It is possible that the differences in these movement may have increased the variability in the data between the participants with an SCI, however, median data were used in the analysis rather than mean limiting the effect of any variation due to outlying data points.

8.5. Conclusion

This study is the first to present kinematic analysis of the whole body with COM displacement data, together with GRF data, in overground LEXO gait between SCI and able-bodied users. The primary findings show that, although some significant differences were evident between the groups, the parameters that would most directly pertain to CPG activation (hip extension and ipsilateral lower limb loading) presented with no significant between-group differences. These findings suggest that for both groups appropriate afferent information was available to elicit a positive response of the CPGs in the lower spinal cord. Therefore, the ReWalk^{TM} can offer potential benefits for SCI individuals irrespective of injury severity. No differences were identified in the COM displacement data and limited differences were identified in trunk and pelvic kinematics. It is possible that the different trunk movement employed by the SCI group may have arisen from learned postural control adaptations during sitting, as well as being kinematically driven through reactions to upright ambulation within the LEXO. Finally, although overground LEXO devices use pre-defined movements, the active

requirement of the user to balance, facilitate forward movement using the trunk, and the capacity for joint angles to exceed those prescribed by the device suggest that the use of overground LEXOs produces very similar biomechanical profiles for different user groups. As such it is suggested that user-device interactions may vary between different user groups depending on their neuromuscular control, however the gait patterns are largely similar and representative of 'normal' slow walking.

Chapter 9. – General Discussion

9.1. Summary of main findings

The purpose of this thesis was to investigate the biomechanical characteristics associated with seated balance and upright mobility, using robotic exoskeleton technologies in spinal cord injured individuals. This thesis adds to the existing knowledge base through several novel contributions.

Chapter 3 provided a new perspective on existing data related to the use of RAGT systems with complete and incomplete SCI individuals. The paucity of data related to overground RAGT systems, and the low quality scores associated with said studies, made it difficult to answer the original questions. The different methods used to report the same outcome measures such as walking speed and distance walked also presented a challenge for making definitive conclusions. Of the 12 studies included in the review, eight studies (using treadmill-based systems) reported speed based on the 10-meter walk test, and three studies (using overground RAGT systems) reported speed based on walking as part of the main protocol (Arazpour et al., 2014, 2014; Fineberg et al., 2013). The different approaches used to measure walking speed made direct comparisons difficult as speeds calculated over different distances could potentially mask the impact of factors such as fatigue, furthermore, overground RAGT studies all completed the walking speed assessment with participants using the device whilst the treadmill based RAGT studies often measured speed overground without the device. In relation to walking distance, only Fineberg et al. (2013) reported distance walked by overground RAGT system users. Evidence of other temporal-spatial characteristics associated with

upright stepping in RAGT use was very limited as only three studies included any variables other than walking speed and distance. Furthermore, no studies included in the systematic review with a focus on overground RAGT recruited incomplete SCI individuals and the majority of research in this area considers overground RAGT as a functional mobility tool rather than as a rehabilitation device. A consensus on the most relevant outcome measures used in RAGT research (specifically speed and distance walked) would benefit future research. Moreover, such a consensus may even provide clinical practitioners useful information related to realistic goal setting for SCI individuals using RAGT systems. It is suggested that future work should consider the rehabilitative capacity of overground devices rather than just their safety and capacity to be used in the community. One of the functional outcomes from this systematic review identified upright stepping using overground RAGT devices unlike treadmill-based systems, to have positive implications for balance control. It is possible that improved balance under the demanding circumstances involved in overground RAGT use may transfer to the less challenging but more often experienced seated posture of SCI individuals.

Chapter 5 explored the existence of relationships between 1) stability performance, 2) control demand, and 3) postural angles with A) SCI disability level and B) fear of falling. A secondary objective was to investigate the use of an individualised limit of stability boundary as a method for detecting increased falls risk in SCI individuals. Although very few significant relationships were identified, the chapter provides evidence that an individualised limit of stability boundary is a useful tool for determining centre of mass control during static seated activities and that it can be a useful visual representation of stability performance and control demand in dynamic tasks. The capacity for several

participants to exceed their individual limit of stability boundary may be linked to task difficulty and pre-existing strategies. A learnt postural control strategy used in the completion of a common task, the forward sit and reach, compared to an unfamiliar task, the elliptical trace task, required to generate the limit of stability boundary, may explain the capacity to move beyond the boundary in a specific direction (Horak, 2006). In addition to the potential skill difference between tasks, it is possible that fear of falling may also have influenced both the circumference of the limit of stability boundary and the distance reached in the forward sit and reach task. A recent systematic review investigating the effectiveness of task specific balance interventions in SCI individuals indicated that clinical measures are unable to predict falls, whereas the use of COP measures have been useful in this area (Tse et al., 2018). The work undertaken in this chapter suggests that the use of a validated, self-reported fear of falling questionnaire should be used in conjunction with both clinical and biomechanical measures to help researchers and clinicians to appreciate falls risk.

Although being seated is where most SCI individuals will spend the majority of their time and complete most of the daily activities, upright standing and stepping are long term goals for many. As well as providing therapeutic benefits to counter the negative consequences of continuous sitting, stepping has the potential to preserve function of the nervous system below the level of the lesion which may have long term benefits as rehabilitation research and practices continue to develop. Chapter 6 presents the first of three empirical chapters focused on upright mobility with an overground RAGT; it was a repeatability study specifically designed to assess the agreement across testing sessions for marker placement by the researcher using a modified six degrees of

freedom model. Not only did it provide evidence of the acceptable level of agreement across sessions based on the agreement thresholds suggested by McGinley et al. (2009) for the lower limb kinematics (acceptable <2^{o}, reasonable 2-5^{o} and questionable >5^{o}), but the inclusion of standard error of measurement (SEM) values relative to the peak angle experienced at each joint in each plane as a percentage, provided confidence in the results of the following chapters. In similar fashion to 'normal' walking data presented by Schwartz et al. (2004), the frontal plane kinematics of the hip presented with a smaller SEM than either of the hip, knee or ankle sagittal plane measures. This, however, was offset by the substantially larger sagittal plane ROM resulting in the lowest relative error for all assessed variables. The use of ICCs in this chapter led to the hypothesis that the data collection procedures would be reliable, this hypothesis was rejected. As reliability testing assess the variability between participants relative to measurement error (de Vet et al., 2006), and variability between participants was not a characteristic that would determine the capacity of the investigator to effectively use the marker set. In this instance good agreement was deemed to be a more important factor to ensure accurate and repeatable data collection procedures.

The accurate marker set established in Chapter 6 was used with confidence in Chapter 7 and 8. Chapter 7 was the first study to investigate whole body kinematics, GRF data and temporal-spatial parameters of overground LEXO gait compared to comfortable and slow walking. A number of the findings were important, particularly in relation to the outcomes of the systematic review. Although the gait speeds of the slow and LEXO gait conditions were speed-matched, the time spent in swing and in double support in the LEXO condition resembled comfortable 'normal' walking speed more than the slow

speed. Increased time spent in double support and reduced step length are evidenced during slow gait to help maintain a stable gait pattern and ensure local dynamic stability (Buzzi et al., 2003; den Otter et al., 2004; Sekiya & Nagasaki, 1998). During LEXO gait, it is not possible to manipulate the different lower limb body segments as desired, due to the pre-programmed step length and swing to stance ratio. Consequently, other compensatory mechanisms must be employed by users to maintain local dynamic stability.

The above findings concur with the work of Moraud et al. (2018), who highlighted the importance of trunk control in their work on proprioceptive feedback and neural plasticity during gait re-education. The pre-programmed movements of the LEXO prohibit responsive stepping in individuals who possess the capacity to react to the falling COM associated with ambulation (Horak, 2006; Winter et al., 1990). The increase in pelvic ROM in the sagittal plane in LEXO gait relative to both comfortable slow walking and the increased ROM in the trunk during LEXO walking compared to comfortable walking are further evidence of the importance of upper body control during LEXO gait. Once combined with the significantly different frontal plane kinematic waveforms seen during LEXO gait for the trunk and pelvis, it is clear that even in able-bodied individuals with intact central nervous systems the upper body cannot simply act passively as a passenger, and must be actively involved in maintaining postural control to prevent falling. This finding is unique to overground exoskeletons as treadmill-based systems such as the Lokomat® rely on the use of a body-weight support harness which impedes upper body motion as well as limiting limb-to-limb weight transfer, an integral component of dynamic postural control (Pennycott et al., 2012).

The final component of chapter 7 that contributes to its novelty is the incorporation of full GRF data, using floor integrated force plates. The only other study identified that incorporated force data into investigations using overground LEXOs was that of Fineberg et al. (2013). Their work relied on the use of in-shoe pressure measurement insoles to calculate the vertical component of GRF. The current work was able to collect all three GRF components thereby illustrating the differences in the horizontal GRF components that clearly distinguish between comfortable speed walking and the other two conditions. These findings may have important consequences for the maintenance of bone mineral density in SCI individuals. Although investigating the osteogenic effects of LEXO gait is beyond the scope of this thesis, it may be an area of future research with potential benefits for LEXO users.

Chapter 8 is a progression from the work completed in the previous chapter, with the focus shifting to a comparison between SCI and able-bodied users of an overground LEXO device. Based on the findings in the previous chapter, COM displacement data were included in the analysis to try and identify characteristics related to postural control strategies employed by the two groups. Furthermore, the movement of the individual users' relative to the LEXO device was explored, as only limited previous work could be identified providing insight into this area (Hidler et al., 2008; Knaepen et al., 2014; Ramanujam et al., 2017). The limited understanding of how overground LEXO devices impact the body of the user was a finding directly related to the outcomes of the systematic review justifying the need for the work carried out in Chapter 8 of this thesis. The concept that repetitive, specific training with appropriate afferent feedback

can be used to stimulate central pattern generators (CPGs) in the lower spinal column below the level of the lesion is common in rehabilitative literature (Dimitrijevic et al., 1998; Duysens & Van de Crommert, 1998; Reier et al., 2017; van Hedel & Dietz, 2010) and is based on motor learning processes (Hallet, 2004; Reier et al., 2017; Wolpaw, 2010). For overground LEXO devices to be effective as gait rehabilitative devices rather than just mobility aids, they must be able to generate appropriate afferent feedback.

Chapter 8 presents data to show that despite numerous biomechanical differences between the two groups, the two primary stimuli for stepping CPG activation, hip extension and lower limb unloading (Hallet, 2004), were not significantly different. Although the decay rate only provides part of the information required for lower limb unloading, the peak vertical GRF at push-off was significantly greater in the SCI group compared to the able-bodied group ($P = 0.008$) further suggesting that in the SCI group an appropriate afferent stimulus is present, as previous work in Chapter 7 had already shown no differences between slow, comfortable walking and able-bodied LEXO gait.

One limitation related to the use of robotic exoskeletons of any kind in rehabilitation of motor control has been linked to the potential for the patient to remain passive and to not actively engage in the process (Labruyère & van Hedel, 2014; Nooijen et al., 2009; Ramanujam et al., 2017). A secondary limitation related to this passivity is the lack of variability introduced into the movement pattern (Hidler et al., 2008). Some attempt has been made to include periods of resistance or path control during the movement cycle in treadmill-based RAGT systems using the motors in the robotic limbs (Duschau-Wicke et al., 2010; Lam et al., 2011). It is only the use of body-weight support harnesses during

treadmill-based LEXO use which would prevent the individual from falling that make adaptive resistance during swing phase possible. Overground RAGT systems would not be able to safely implement adaptive resistance protocols as individuals would fall if unable to overcome the resistance. It appears, that the same safety feature that allows treadmill-based systems to prevent passivity in the lower body (the harness) may be introducing an inactive approach to upper body control. The requirement to actively maintain upper body postural control to facilitate stepping, as much as to prevent falling, and the significantly greater sagittal plane trunk ROM (median difference = 8.6^{o}, P = 0.008) plus the altered waveform seen in the frontal plane of the SCI group, suggest different control strategies were used to maintain dynamic stability. These findings imply a sufficient stimulus exists to ensure active participation of the individual during overground LEXO use.

The inclusion of COM displacement in the analysis was as a result of the significantly different movement characteristics of able-bodied individuals when using the LEXO compared to 'normal' walking. Even though significant differences were identified for trunk movement between the two groups no significant differences were identified for COM displacement. This supports the idea that different movement patterns were used to facilitate the same outcome in the different groups. These findings, along with the reduced walking speed, may have implications for different user groups relative to the energetic costs of walking.

9.2. Strengths and limitations

A number of strengths and limitations have been identified in particular chapters, some of these will be explored here. The systematic review identified a small number of studies using overground RAGT systems and even fewer focusing on the rehabilitative capacity of these devices rather than their use as a mobility aid. Chapters 7 and 8 were designed with these factors in mind and designed to address the paucity of research related to overground RAGT systems. It was also acknowledged in chapter 3 that the use of varied outcome measures made comparisons between studies challenging. Chapters 7 and 8 therefore measured speed in the same way as two of the three included overground RAGT studies did in the systematic review. Walking speed and distance walked were also measured during 10-meter walk trials and a 6-minute walk test, these data are reported in appendix 6 for comparison to other trials. To facilitate future research and enable study comparisons it is suggested that a consensus on walking speed assessment should be agreed upon. The 10-meter walk test would provide a simple test that could be used across a spectrum of studies ranging from in practice clinical assessments through more mechanistic motion capture studies and would not require substantial adjustments to standard procedures.

The use of the quality assessment tool in the systematic review highlighted the importance of using valid and reliable data collection protocol and constructs. As a result, validated testing procedures were used throughout this thesis, such as the Calibrated Anatomical System Technique during 3D motion capture (Cappozzo et al., 1995), the postural analysis methods of van Niekerk et al., (2008) as well as the quality of life questionnaires which were validated specifically for use with SCI cohorts (SCI-FI

basic mobility and self-care) (Jette et al., 2015). The chapters of this thesis provide a cumulative structure which was designed to build towards applied research that could help inform the complete rehabilitation of individuals with SCI.

One limitation relevant to all studies included in this thesis is the small sample sizes, despite the use of various advertising methods and the support of several clinics. Harvey et al. (2009) noted that poor statistical power in clinical trials involving SCI participants is a continuing problem and that although every effort should be made to ensure trials are appropriately powered, where this is not possible future meta-analyses may be able to provide the evidence required to quantify the effectiveness of particular interventions. This potential reliance on future meta-analysis is another reason that a consensus on outcome measures and reporting is so vital for future research in this area. Although not a limitation, it was decided that the involvement of NHS rehabilitation centres would not have benefitted the recruitment of participants for this thesis as LEXOs were not in regular use within NHS facilities at the time. Furthermore, individuals were recruited if they were an experienced user of the overground LEXO and had no other co-morbidities, which would have been unlikely for individuals under NHS care. The relationships developed with private clinics unfortunately did not yield the numbers of participants originally planned for leading to the small sample sizes evident in this thesis. With regard to the number of participants with a SCI recruited for LEXO chapter, it is acknowledged that the sample size appears to be small. However, based on the number of UK based individuals with an SCI, and those in the local and surrounding regions, ~20% of the (known) UK population were recruited for this study.

The second and potentially most obvious limitation of the work in the final two empirical studies is related to the GRF data and the use of elbow crutches. Due to the inability to obtain or build instrumented crutches, it was not possible to include any force borne or generated by the arms and crutches during the walking trials in the analysis. It is recommended that such devices are used in future work.

9.3. Future directions

The future directions of this work should follow several strands. Firstly, in both LEXO studies, the upper body movement profile suggests that overground LEXO walking has the potential to provide a dynamic postural control training environment. The investigation into postural control should include EMG analysis of upper body muscles including those identified as compensatory muscles (latissimus dorsi, trapezius, serratus anterior and pectoralis major (Seelen et al., 1998)) in individuals with SCI as the control of core stabilisers such as the erector spinae and rectus abdominus is limited at best. Furthermore, the use of instrumented crutches would further our understanding of how much force is being generated / absorbed by the arms during step-to-step transitions. These data may provide information about the underlying mechanisms of individual postural control strategies. Secondly, the concept of metabolic cost during overground LEXO walking should be considered. Although previous work has investigated the energetic cost of walking with a robotic device compared with manually powered reciprocating gait orthoses (Arazpour et al., 2013) and acute cardiorespiratory and metabolic costs of complete SCI individuals walking in an overground robotic

exoskeleton (Evans et al., 2015), understanding of upper body mechanical power and energy costs are currently unknown. Furthermore, both studies only included complete SCI individuals as did the work in this thesis. Future work should include a more heterogenous sample to ensure the results can be applied to a broader spectrum of SCI patients.

Finally, this thesis has shown that active participation of the user to maintain trunk control during overground LEXO use provides a training environment for upper body postural control. Future work should explore the extent to which this training may transfer to seated postural control and whether continued LEXO use leads to longitudinal postural control improvements to assist with the completion of activities of daily living.

Chapter 10. Conclusions

The current UK clinical guidelines, related to treatment following spinal cord injury, provided by the Clinical Advisory Group (NHS) and the National Spinal Cord Injury Strategy Board only cover pre-admission through acute rehabilitation. Various clinical bodies provide other guidelines such as pressure ulcer management and manual handling. Although there are other common forms of treatment (eg. postural control improvements and LEXOs) there are no clinical guidelines related to their rehabilitation use. What guidance there is about the use of LEXOs as a rehabilitation tool is specific to individuals suffering from stroke. The findings of this thesis contribute to a growing body of knowledge related to the use of technology in SCI rehabilitation. The systematic review identified a paucity of scientific literature related to the biomechanical implications of overground robotic exoskeleton use as rehabilitative devices in SCI individuals. It was however able to report several findings including that the use of robotic assisted gait training did not lead to increases in walking speed more than other conventional gait training methods and that no reviewed studies enabled large enough improvements in speed or walking distance to facilitate community ambulation. The systematic review demonstrated that, although the use of robotic exoskeletons should not replace other therapies, they can complement a multi-modality rehabilitation approach. Although more literature has been published since the commencement of this thesis in 2013, there are still areas to be explored and this thesis has contributed novel material to the literature which may inform to use of overground exoskeletons in SCI individuals.

Postural control is a challenge for people following SCI. It is required for daily tasks, performed either in seated or upright positions, yet control demand is rarely measured/assessed in clinical practice. This thesis has demonstrated that the use of an individualised limit of stability boundary can be used as a visual support alongside numerical data to support postural control data interpretation. However, it must be noted that fear of falling may play a significant role in an individuals' capacity to complete postural control tasks. Clinicians should therefore include fear of falling assessments into their postural control training and rehabilitation protocols.

This thesis has provided evidence that overground robotic exoskeleton use delivers appropriate lower limb stimulation to be used as a rehabilitation tool for upright stepping in SCI individuals. Furthermore, it clearly demonstrates the requirement for any user of overground robotic exoskeletons to actively control upper body orientation to prevent falling and to facilitate step-to-step transitions. The necessity to maintain trunk control generates a postural control training environment that may transfer to improved seated postural stability and subsequently a greater capacity to complete activities of daily living more easily.

The use of overground LEXOs has often been reserved for individuals with complete spinal lesions, minimal potential to regain ambulatory capacity and as novel mobility aids rather than as a rehabilitative apparatus. Although the interaction between the user and the device may vary depending on injury level, severity and neuromuscular control, the gait profiles will be largely representative of normal walking and therefore follow the principles of motor learning: high specificity and high repetition. The findings of this

thesis indicate that these devices have the capacity to be used as rehabilitative tools as part of a multi-modality rehabilitative approach for SCI individuals.

Several implications for clinical rehabilitation can be identified, based on these findings. Firstly, fear of falling should be considered during physical rehabilitation for individuals with an SCI, especially when new or unfamiliar tasks are to be completed. Secondly, that the use of overground LEXO devices should not (as has typically been identified from literature) be restricted to individuals with complete SCI. The requirement to maintain orientation of the upper body in order to control the motion of the LEXO devices provides an environment where the user must play an active part in the movement unlike in treadmill based LEXOs where the user can become a passenger. Finally, the evidence that able-bodied users were able to move within the device, beyond the pre-defined limits of movement, allows for variability of movement. Therefore, any individual with an SCI that may have some lower body motor function should be able to achieve a similar response, enabling motor variation alongside the high dose of specific and repeatable cyclic movement required for CPG activation.

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Appendices

Appendix 1

Department of Sport, Health & Exercise Science

UNIVERSITY OF Hull
Faculty of Science

Participant Letter of Invitation

Project title	A cross-sectional study to determine the lower-limb biomechanical profiles when ambulating with a powered exoskeleton: A comparison between able-bodied and spinal cord injured users.
Principal investigator	Name: Dr Natalie Vanicek Email address: N.Vanicek@Hull.ac.uk Contact telephone number: 01482 463607
Student investigator (if applicable)	Name: Stephen Hayes Email address: S.Hayes@Hull.ac.uk Contact telephone number: 01482 465510

Dear Sir or Madam

This is a letter of invitation to enquire if you would like to take part in a research project at the Biomechanics Laboratory on the University of Hull Campus.

Before you decide if you would like to take part it is important for you to understand why the project is being done and what it will involve. Please take time to carefully read the Participant Information Sheet on the following pages and discuss it with others if you wish. Ask me if there is anything that is not clear, or if you would like more information.

If you would like to take part, please complete and return the Informed Consent Declaration form.

Please do not hesitate to contact me if you have any questions.

Yours faithfully,

Stephen Hayes

Participant Information Sheet

Project title	A cross-sectional study to determine the lower-limb biomechanical profiles when ambulating with a powered exoskeleton: A comparison between able-bodied and spinal cord injured users.
Principal investigator	Name: Dr Natalie Vanicek Email address: N.Vanicek@Hull.ac.uk Contact telephone number: 01482 463607
Student investigator (if applicable)	Name: Stephen Hayes Email address: S.Hayes@Hull.ac.uk Contact telephone number: 01482 465510

What is the purpose of this project?

The purpose of this project is to quantify the biomechanical movement characteristics of individuals walking unaided with a powered exoskeleton system, such as the ReWalk™. This will be measured with able-bodied and experienced powered exoskeleton SCI users. Their profiles will compared with the movement characteristics of the ReWalk itself, a commercially-available powered exoskeleton system. Our aim is to gain an understanding of how a powered exoskeleton affects the kinematic and kinetic gait profiles of the user inside the suit during common activities of daily living, such as sit-to-stand, stand-to-sit and walking tasks.

Why have I been chosen?

You have been chosen as we believe you may fit the inclusion / exclusion criteria for safe use of the ReWalk™. We are looking for 2 groups of participants to take part in this study: a group of able-bodied individuals and a group of incomplete SCI individuals who are experienced ReWalk™ users. Participants in both groups will need to be aged 18-50 years, be less that 100kg and between 155cm and 190cm tall. You will need to be generally healthy and have no muscular or skeletal injuries (except spinal cord injury in the SCI user group).

Spinal cord injured individuals must also be able to tolerate 30 minutes in an upright position without experiencing light headedness or a drop in blood pressure; you will need to be able to perform transfers between stable level surfaces and you will need to be an experienced ReWalk™ user. You will need to obtain medical clearance from your GP and / or consultant in order to use the ReWalk™.

What happens if I volunteer to take part in this project?

First, it is up to you to decide whether or not to take part. If you decide to take part you will be given this Participant Information Sheet to keep and asked to complete the Informed Consent Declaration at the back. You should give the Informed Consent Declaration to the

investigator at the earliest opportunity. You will also have the opportunity to ask any questions you may have about the project. If you decide to take part, you are still free to withdraw at any time and without needing to give a reason.

What will I have to do?

Able-bodied participants will be asked to attend the laboratory on 3-4 occasions; 1 or 2 ReWalk™ training sessions and 2 testing sessions. SCI participants will be asked to attend the laboratory for a single testing session.

Upon giving informed consent able-bodied participants will be invited into the laboratory for a familiarisation session with the ReWalk. You will be asked to wear shorts or trousers and you will need socks (shoes will be provided for ReWalk™ use). Your height and body mass will be measured as will your leg lengths and hip size. This information will be used to set up the ReWalk™ to fit the physical parameters of your body. The investigator will help you don the ReWalk™ and hand you a pair of elbow crutches. You will then with the assistance of the investigator learn to stand, sit, balance and walk in the exoskeleton. It is anticipated this initial familiarisation session will take approximately 2-3 hours. If you are unable to reach a suitably safe and proficient level of ReWalk™ use after two sessions, you will unfortunately be excluded from the rest of the study.

The able-bodied participants will be asked to return to the laboratory for a second visit approximately 1 week later wearing tight fitting shorts (e.g. cycling shorts), a t-shirt and comfortable flat shoes. A number of light reflecting markers that can be tracked by our camera system will be placed onto the surface of your skin of your lower limbs. When ready you will be asked to perform a number of common daily tasks in the view of the camera system (the cameras will only track the movement of the markers you are wearing, video footage of you will not be collected). This will constitute your baseline gait data.

SCI participants will start the testing session at this point. All participants will then be asked to don the ReWalk™ and you will be given a short re-familiarisation session. Blood pressure and heart rate measurements will be recorded for all participants prior to any activity taking place and after the re-familiarisation to ensure that BP has remained within normal limits. Reflective markers will be placed onto your lower limbs and also onto the ReWalk™ itself. You will be asked to stand still in the ReWalk so we can collect a static marker file. You will then be asked to perform up to 10 sit-to-stand and stand-to-sit trials with your feet on a force plate (a device embedded into the floor enabling us to measure the ground reaction force exerted onto you). You will also be asked to complete up to 10 walking trials over 12 metres. Adequate rest will be given in between the trials. At this stage you will be asked to complete a 6 minute walk test around a distance marked walkway, you will be asked to walk as far as you can in the 6 minute period, you will be able to rest as often and for as long as you need. Your heart rate and self perceived exertion will be measured each minute and the distance covered will be recorded at the end of the test.

Each testing session will last approximately 3 hours.

SCI participants will be asked to report your height and mass. You will be asked to wear tight fitting shorts (e.g. cycling shorts) and a t-shirt for the purpose of motion data capture. Before transferring into the ReWalk™ the investigator will perform muscle spasticity and range of motion tests as well as some passive stretching to help you warm up. Before and after each ReWalk™ session all participants will be asked to submit to some basic skin assessment checks on your lower limbs to determine any adverse pressure effects from the ReWalk suit.

Padding will be used to minimise the risk of skin damage but areas of contact with the ReWalk™ will be checked such as the bones around the ankle (malleoli) and Just below the knee on the outside of your leg (head of the fibular).

You will then be asked to transfer into the ReWalk™ with the assistance of the investigator and you will then follow the same protocol as the able-bodied participants.

At the end of the session you will be asked to transfer back into your wheelchair with the aid of the researcher and all reflective markers will be removed. The entire session should last 3-4 hours.

Will I receive any financial reward or travel expenses for taking part?
No financial reward or travel expenses are available

Are there any other benefits of taking part?
Some basic information out your walking movement patterns will be available and you will be able to experience the use of a novel and innovative piece of technology.

Will participation involve any physical discomfort or harm?
The chances of harm are minimal during the testing sessions however some mild discomfort from the wearing of the ReWalk™ may be experienced. Due to the nature of the ReWalk™ the straps that support the wearer must be quite tight. There is also a requirement to use crutches which may cause slight discomfort or fatigue in the arms if this is not something you are used to. A ReWalk™ Trainer will be with you the entire time for support and you will be able to rest at any time if you need to. For spinal cord injured participants the risk of damage to your skin through use of the ReWalk™ is a possibility as is the use of any equipment that may cause rubbing or pressure. Protective pads will be used to prevent this and pre and post use skin assessments will be carried out in each sessions.

Will I have to provide any bodily samples (e.g. blood or saliva)?
No

Will participation involve any embarrassment or other psychological stress?
The application of the reflective markers to your body will require us to touch your skin and feel for prominent/obvious bony/skeletal landmarks on your lower limbs and you will need to wear tight fitting clothing so we can ensure the markers are representative of the underlying anatomical structures of your body. Able bodied participants will be asked to wear shorts during the un-assisted walking testing session. You will not be asked to perform any tasks that you would not perform in everyday life or during use of the ReWalk™ and access to the laboratory will be restricted during the times of your testing.

What will happen once I have completed all that is asked of me?
Once you have completed all the testing sessions the data will need to be processed and analysed before any feedback can be given. You are free to ask any questions before, during or after testing and any findings or outcomes will be relayed to you in your preferred manner (email or post) if requested. Verbal explanations can be provided in person if you can return to the laboratory or by phone if you wish.

How will my taking part in this project be kept confidential?
On entry into the study you will be assigned a participant code that will be used to ensure that no names or identifiable information will be associated with your data. All data will be kept secure on a password protected PC in a lockable room and only the research team will have access to this information. Your signed consent forms will be stored in a lockable cabinet in a lockable room separately from your testing data.

How will my data be used?
Data obtained from your participation in this study will be analysed and used to form part of a PhD thesis at the University of Hull. If sufficient findings are present then the results may be submitted to a scientific journal for publication or presented at a scientific conference.

Who has reviewed this study?
This project has undergone full ethical scrutiny and all procedures have been risk assessed and approved by the Department of Sport, Health and Exercise Science Ethics Committee at the University of Hull.

What if I am unhappy during my participation in the project?
You are free to withdraw from the project at any time. During the study itself, if you decide that you do not wish to take any further part then please inform the person named in Section 18 and they will facilitate your withdrawal. You do not have to give a reason for your withdrawal. Any personal information or data that you have provided (both paper and electronic) will be destroyed or deleted as soon as possible after your withdrawal. After you have completed the research you can still withdraw your personal information and data by contacting the person named in Section 18. If you are concerned that regulations are being infringed, or that your interests are otherwise being ignored, neglected or denied, you should inform Dr Andrew Garrett, Chair of the Department of Sport, Health and Exercise Research Ethics Committee, who will investigate your complaint (Tel: 01482 463866; Email: a.garrett@hull.ac.uk

Participant Letter of Invitation

Project title	Cross – sectional study to assess the seated postural control in spinal cord injured individuals
Principal investigator	Name: Dr Natalie Vanicek Email address: N.Vanicek@Hull.ac.uk Contact telephone number: 01482 463607
Student investigator (if applicable)	Name: Stephen Hayes Email address: S.Hayes@Hull.ac.uk Contact telephone number: 01482 465510

Dear Sir or Madam

This is a letter of invitation to enquire if you would like to take part in a research project at the Biomechanics Laboratory on the University of Hull Campus or at the Cyclone Technologies clinic in Hull.

Before you decide if you would like to take part it is important for you to understand why the project is being done and what it will involve. Please take time to carefully read the Participant Information Sheet on the following pages and discuss it with others if you wish. Ask me if there is anything that is not clear, or if you would like more information.

If you would like to take part, please complete and return the Informed Consent Declaration form.

Please do not hesitate to contact me if you have any questions.

Yours faithfully,

Stephen Hayes

Department of Sport, Health & Exercise Science

UNIVERSITY OF Hull
Faculty of Science

Participant Information Sheet

Project title	Cross – sectional study to assess the seated postural stability and seated posture of spinal cord injured individuals
Principal investigator	Name: Dr Natalie Vanicek Email address: N.Vanicek@Hull.ac.uk Contact telephone number: 01482 463607
Student investigator (if applicable)	Name: Stephen Hayes Email address: S.Hayes@Hull.ac.uk Contact telephone number: 01482 465510

What is the purpose of this project?

The purpose of this study is to identify and quantify any postural and balance differences between two groups of spinal cord injured individuals; individuals who have used a robotic exoskeleton in the past 12 months and non-users. Our aim is to determine if the use of robotic exoskeletons has a transferable effect on posture and balance in sitting.

Why have I been chosen?

You have been chosen as we believe you fit the inclusion and exclusion criteria for this study and will fit into one of the 2 groups detailed above. Participants in both groups will be aged 18-60 years and will need to be generally healthy with no muscular or skeletal injuries (except spinal cord injury) and have no diagnosed inner ear or balance disorder. To be included in the study your injury level must be T2 or below AISA A-D and you must be able to perform independent transfers between stable level surfaces.

You must also be able to tolerate 30 minutes in an upright position without experiencing light headedness or a drop in blood pressure. You will also need to be able to perform transfers between stable level surfaces.

What happens if I volunteer to take part in this project?

First, it is up to you to decide whether or not to take part. If you decide to take part you will be given this Participant Information Sheet to keep and asked to complete the Informed Consent Declaration at the back. You should give the Informed Consent Declaration to the investigator at the earliest opportunity. You will also have the opportunity to ask any questions you may have about the project. If you decide to take part you are still free to withdraw at any time and without needing to give a reason.

What will I have to do?

You will be required to attend a single testing session that will last approximately 1 hour and no longer the 2 hours.

Upon giving informed consent you will be asked to perform a number of tasks whilst seated on a custom built seat containing a force plate (a device that allows us to measure the force exerted by you on the plate). You will be asked to wear a form fitting t-shirt for the testing procedure, no other clothing restrictions will apply.

You will be asked to transfer to the test seat at the start of the testing session with the aid of the researcher. Once in this position you will be asked to complete 3 tasks.

- The first is quiet sitting (sitting still with your arms by you sides) for 60 seconds while the force plate is actively sampling data and a standard digital video camera is used to take still photographs of your posture.

- The second task is a variation on the quiet sitting test where you will be asked to move your upper body from your hips and waist to trace a circular pattern by leaning forwards, diagonally, sideways and backwards, for 30 seconds. You will be asked to lean as far as possible in each direction without losing your balance. The force plate will be collecting data over this time period.

- The final task is a forward leaning reach task. You will be asked to raise your dominant arm in front of you so that your hand is level with your shoulder and to place your other hand on your stomach. You will then be asked to lean as far forwards as possible and to return to the start position, all the while keeping your head and shoulders square to the forward direction. Data will be recorded using the force plate once again and the movement will be recorded from the side using the digital video camera.

The researcher will be on hand throughout the testing session to provide support should you need it.

At the end of the session you will be asked to transfer back to your wheelchair with the aid of the researcher.

Between trials the force plate will need to be reset. In order to achieve this all weight will need to be removed from the surface of the plate. As such a Rota Stand will be used to help you stand until the force plate is ready for you to sit down again.

Will I receive any financial reward or travel expenses for taking part?

No financial reward or travel expenses are available

Are there any other benefits of taking part?

Some basic information related to your posture and balance will be available to you after the testing has been completed.

Will participation involve any physical discomfort or harm?

The chances of harm are minimal during the testing sessions. The greatest risk would be from falling during any of the testing procedures. The researcher will be present at all times to

provide support if you need it and only one of the tests will require you to reach beyond your base of support.

Will I have to provide any bodily samples (e.g. blood or saliva)?
No

Will participation involve any embarrassment or other psychological stress?
You will not be asked to perform any tasks that you would not perform in everyday life and access to the laboratory will be restricted during the times of your testing. A tight fitting t-shirt will be required during the testing to ensure that the photographs taken allow us to see the body landmarks required to measure the angles for the posture assessment. Some of the testing session will be recorded on a digital video camera but only members of the research team will see the footage.

What will happen once I have completed all that is asked of me?
Once you have completed all the testing sessions the data will need to be processed and analysed before any feedback can be given. You are free to ask any questions before, during or after testing and any findings or outcomes will be relayed to you in your preferred manner (email or post) if requested. Verbal explanations can be provided in person if you can return to the laboratory or by phone if you wish.

How will my taking part in this project be kept confidential?
On entry into the study you will be assigned a participant code that will be used to ensure that no names or identifiable information will be associated with your data. All data will be kept secure on a password protected PC in a lockable room and only the research team will have access to this information. Your signed consent forms will be stored in a lockable cabinet in a lockable room separately from your testing data.

How will my data be used?
Data obtained from your participation in this study will be analysed and used to form part of a PhD thesis at the University of Hull. If sufficient findings are present then the results may be submitted to a scientific journal for publication or presented at a scientific conference.

Who has reviewed this study?
This project has undergone full ethical scrutiny and all procedures have been risk assessed and approved by the Department of Sport, Health and Exercise Science Ethics Committee at the University of Hull.

What if I am unhappy during my participation in the project?
You are free to withdraw from the project at any time. During the study itself, if you decide that you do not wish to take any further part then please inform the person named in Section

18 and they will facilitate your withdrawal. You do not have to give a reason for your withdrawal. Any personal information or data that you have provided (both paper and electronic) will be destroyed or deleted as soon as possible after your withdrawal. After you have completed the research you can still withdraw your personal information and data by contacting the person named in Section 18. If you are concerned that regulations are being infringed, or that your interests are otherwise being ignored, neglected or denied, you should inform Dr Andrew Garrett, Chair of the Department of Sport, Health and Exercise Research Ethics Committee, who will investigate your complaint (Tel: 01482 463866; Email: a.garrett@hull.ac.uk

Department of Sport, Health & Exercise Science

UNIVERSITY OF Hull
Faculty of Science

Informed Consent Declaration

Project title	
Principal investigator	Name: Dr Natalie Vanicek Email address: N.Vanicek@Hull.ac.uk Contact telephone number: 01482 463607
Student investigator (if applicable)	Name: Stephen Hayes Email address: S.Hayes@Hull.ac.uk Contact telephone number: 01482 465510

Please Initial

☐ I confirm that I have read and understood all the information provided in the Informed Consent Form (EC2) relating to the above project and I have had the opportunity to ask questions.

☐ I understand this project is designed to further scientific knowledge and that all procedures have been risk assessed and approved by the Department of Sport, Health and Exercise Science Research Ethics Committee at the University of Hull. Any questions I have about my participation in this project have been answered to my satisfaction.

☐ I fully understand my participation is voluntary and that I am free to withdraw from this project at any time and at any stage, without giving any reason. I have read and fully understand this consent form.

☐ I agree to take part in this project.

.....	.....	.....
Name of participant	Date	Signature
.....	.....	.....
Person taking consent	Date	Signature

Appendix 2

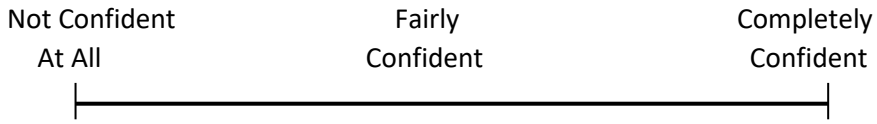
Modified Falls Efficacy Scale

Instructions

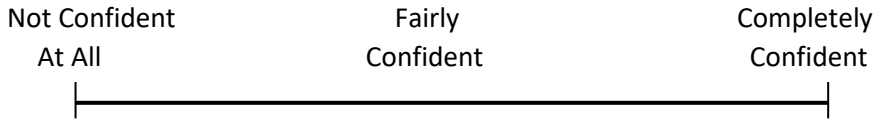
As you read each statement, remember there is no right or wrong answer. Just think about how confident you are to execute each activity without falling. Do this by making a mark through the line anywhere along the line from 'not-confident / not sure at all' (score of 0) to 'completely confident / completely sure' (score of 10).

How confident/sure are you that you do each of the activities without falling:

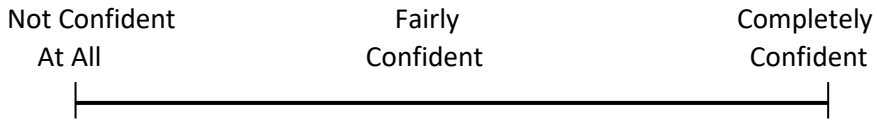
(1) Get dressed and undressed



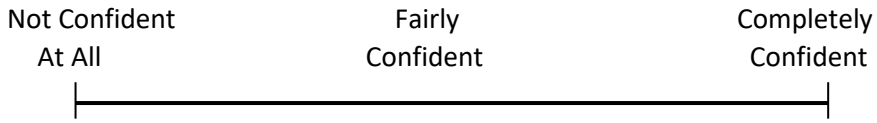
(2) Prepare a simple meal



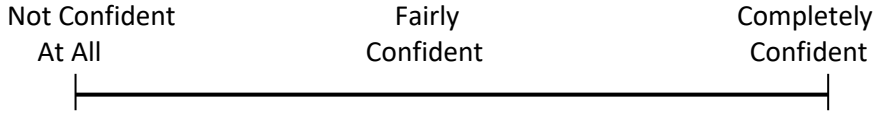
(3) Take a bath or a shower



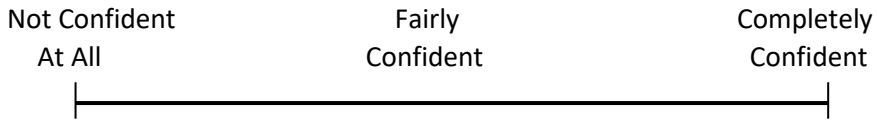
(4) Get in/out of a chair



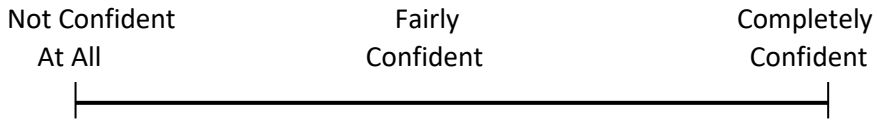
(5) Get in/out of bed



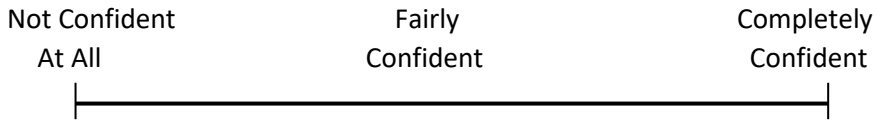
(6) Answer the door or the telephone



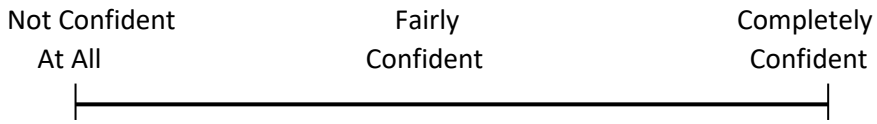
(7) Walk around the inside of your house



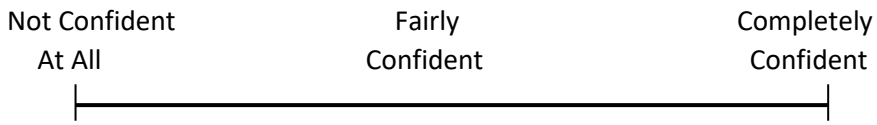
(8) Reach into cabinets or closet



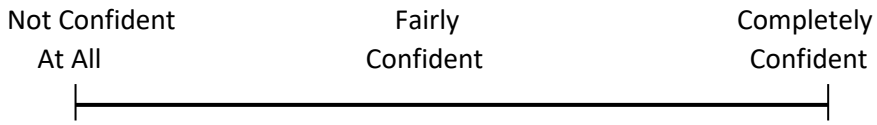
(9) Light housekeeping



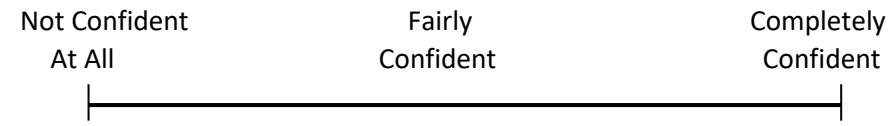
(10)Simple shopping



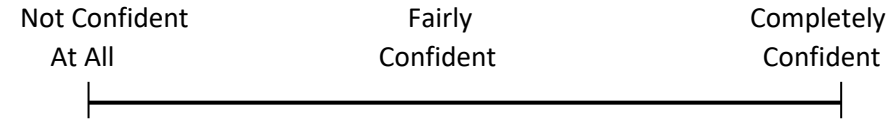
(11)Using public transport



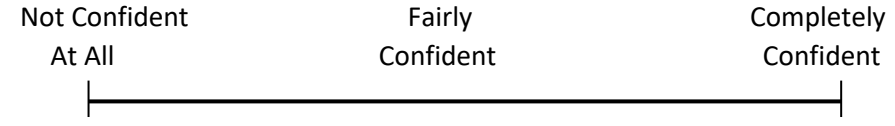
(12)Crossing roads



(13)Light gardening or hanging out the washing (rate most commonly performed of these activities)



(14)Using front or rear steps at home



Appendix 3

Basic Mobility – Short Form 11a

Please select the response that best describes your ability to do each activity without special devices, equipment, or help from another person, unless specifically stated in the item.

		Without Any Difficulty	With a Little Difficulty	With Some Difficulty	With Much Difficulty	Unable to Do
CMob4	Once in bed, I can pull up my sheets and blankets…	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
CMob8	When you are in bed, are you able to turn your body for pressure relief?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
CMob13	Are you able to reach for a book on a table when sitting in a chair with a firm seat and a back?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
CMob20	Are you able to sit in a chair with a firm seat and a back when you can use your arms for support?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC45	Are you able to get on and off the toilet?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
CMob29	Are you able to get down on the floor (e.g., to play with a child or pet)?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA45	Are you able to get out of bed into a chair?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
CMob31	When transferring into bed, are you able to get your legs onto the bed?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA56	Are you able to get in and out of a car?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		No Difficulty	A little Difficulty	Some Difficulty	A Lot of Difficulty	Can't Do
NQMOB18	How much difficulty do you currently have getting into and out of a kneeling position?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		None	A little	A lot	Total
Help2	How much help from another person do you currently need to push open a heavy door?	☐ 4	☐ 3	☐ 2	☐ 1

Scoring Information

SCI-QOL, SCI-FI, and TBI-QOL Short-Form

1. After a participant has answered all of the questions on the short-form, sum the responses on the form to create a raw score. The participant should answer all of the questions.

2. Convert that raw score to an IRT-based *T*-score using the appropriate lookup table. The *T*-score value for a raw score on the short-form will be directly comparable to the *T*-scores that are obtained through the Computer Adapted Test (CAT) administration.

The lookup table for the scale you requested follows this page.

If you have questions, contact SCI-QOL@udel.edu

11/2015

SCI-FI v1.0 Basic Mobility SF11a		
Raw Score	*T*-Score	SE
11	30.21	5.06
12	34.36	3.93
13	35.56	3.89
14	36.84	3.74
15	37.97	3.58
16	39.31	3.18
17	40.29	3.02
18	41.23	2.84
19	42.09	2.67
20	42.91	2.51
21	43.67	2.36
22	44.39	2.22
23	45.07	2.08
24	45.72	1.95
25	46.33	1.84
26	46.90	1.74
27	47.44	1.66
28	47.95	1.60
29	48.42	1.54
30	48.88	1.50
31	49.32	1.48
32	49.74	1.46
33	50.17	1.45
34	50.58	1.44
35	51.00	1.43
36	51.41	1.44
37	51.83	1.45
38	52.26	1.47
39	52.70	1.48
40	53.15	1.51
41	53.62	1.54
42	54.10	1.59
43	54.62	1.64
44	55.17	1.70
45	55.77	1.79
46	56.42	1.91
47	57.10	2.01
48	57.88	2.15
49	58.77	2.33
50	60.08	2.82
51	61.02	2.93
52	62.31	3.14
53	64.10	3.44
54	68.47	4.96

11 included items are as follows:
CMob4
CMob8
CMob13
CMob20
PFC45
CMob29
PFA45
CMob31
PFA56
NQMOB18
Help2

The **higher the score**, more of the construct of basic mobility is being measured.

A **higher score** represents more basic mobility (better functioning).

Appendix 4

Self-Care – Short Form 11a

Please select the response that best describes your ability to do each activity without special devices, equipment, or help from another person, unless specifically stated in the item.

		Without Any Difficulty	With a Little Difficulty	With Some Difficulty	With Much Difficulty	Unable to Do
PTB26	Are you able to shampoo your hair?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Csc9	I can scratch my face…	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PTA46	Are you able to cut your toe nails?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PTA50	Are you able to brush your teeth?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Csc25	Are you able to dress your upper body?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PTA55	Are you able to wash and dry your body?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Csc39	I can put on my socks…	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Csc57	Are you able to drink liquids from a cup with a handle?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA52	Are you able to tie your shoelaces?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		No Difficulty	A little Difficulty	Some Difficulty	A Lot of Difficulty	Can't Do
Csc45	How much difficulty do you currently have opening previously opened jars?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQUEX17	How much difficulty do you currently have pulling up and fastening your pants after a bowel movement?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Scoring Information

SCI-QOL, SCI-FI, and TBI-QOL Short-Form

1. After a participant has answered all of the questions on the short-form, sum the responses on the form to create a raw score. The participant should answer all of the questions.

2. Convert that raw score to an IRT-based *T*-score using the appropriate lookup table. The *T*-score value for a raw score on the short-form will be directly comparable to the *T*-scores that are obtained through the Computer Adapted Test (CAT) administration.

The lookup table for the scale you requested follows this page.

If you have questions, contact SCI-QOL@udel.edu

11/2015

SCI-FI v1.0 Self Care SF11a		
Raw Score	*T*-Score	SE
11	29.74	4.64
12	33.80	3.26
13	34.64	3.20
14	35.29	3.17
15	36.23	3.00
16	37.80	2.43
17	38.53	2.34
18	39.35	2.21
19	40.11	2.09
20	40.83	1.97
21	41.47	1.89
22	42.10	1.82
23	42.69	1.75
24	43.26	1.70
25	43.80	1.66
26	44.32	1.62
27	44.82	1.58
28	45.30	1.55
29	45.78	1.53
30	46.24	1.51
31	46.70	1.48
32	47.15	1.46
33	47.59	1.45
34	48.03	1.44
35	48.46	1.42
36	48.89	1.41
37	49.32	1.41
38	49.74	1.41
39	50.17	1.41
40	50.60	1.41
41	51.03	1.42
42	51.46	1.43
43	51.90	1.46
44	52.36	1.48
45	52.83	1.51
46	53.32	1.55
47	53.84	1.60
48	54.39	1.66
49	55.00	1.74
50	55.69	1.86
51	56.58	2.19
52	57.24	2.17
53	58.31	2.37
54	59.72	2.59
55	65.01	4.94

11 included items are as follows:

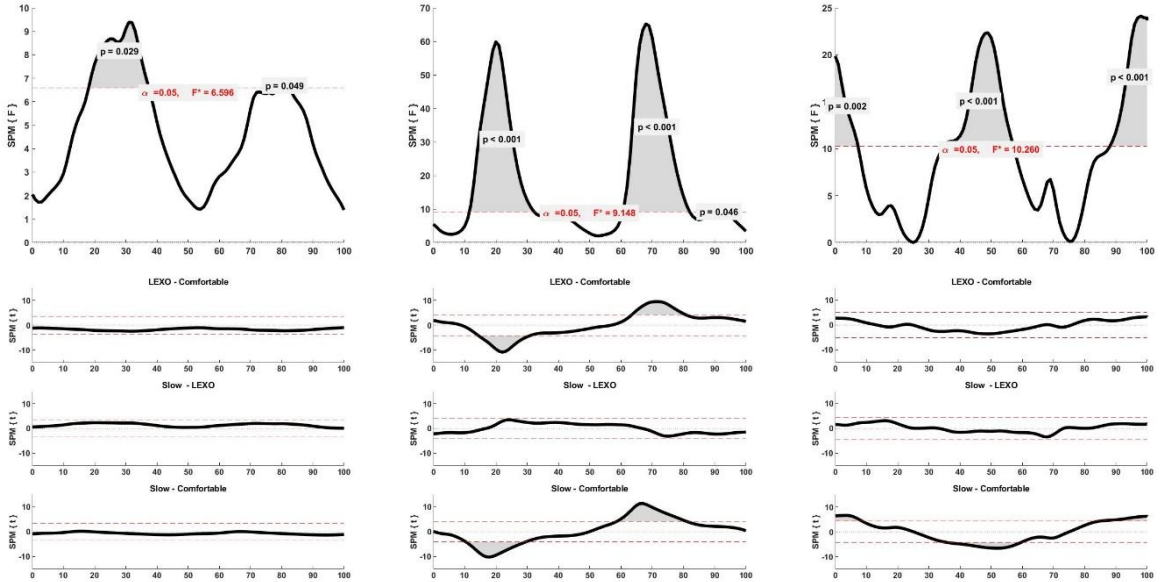
PFB26
Csc9
PFA46
PFA50
Csc25
PFA55
Csc39
Csc57
PFA52
Csc45
NQUEX17

The **higher the score**, more of the construct of self-care is being measured.

A **higher score** represents more self-care (better functioning).

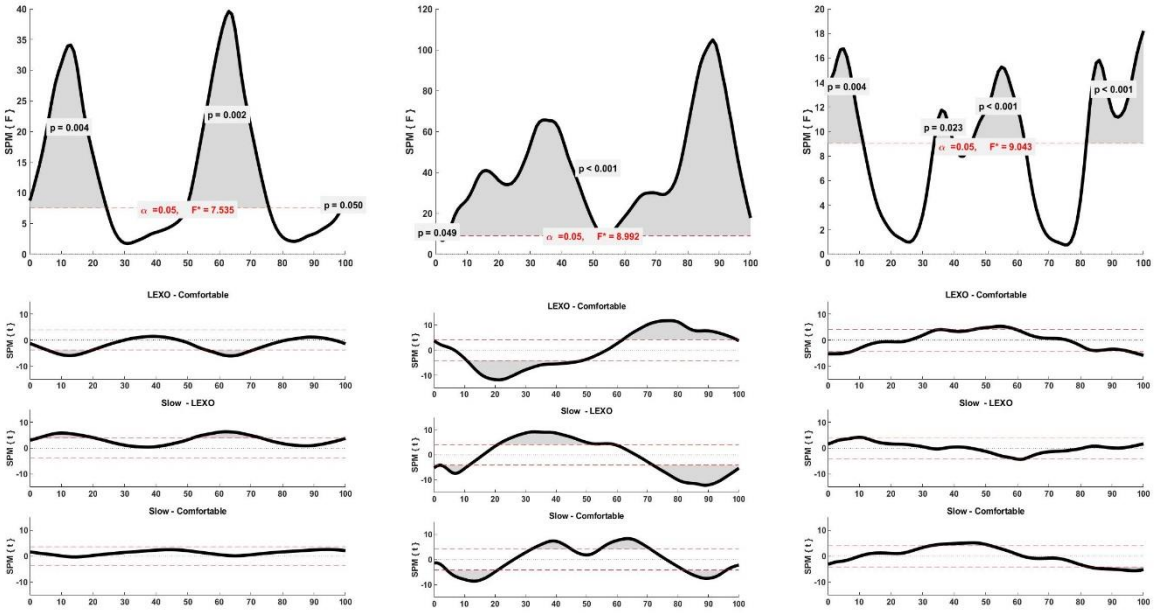
Appendix 5

SPM output



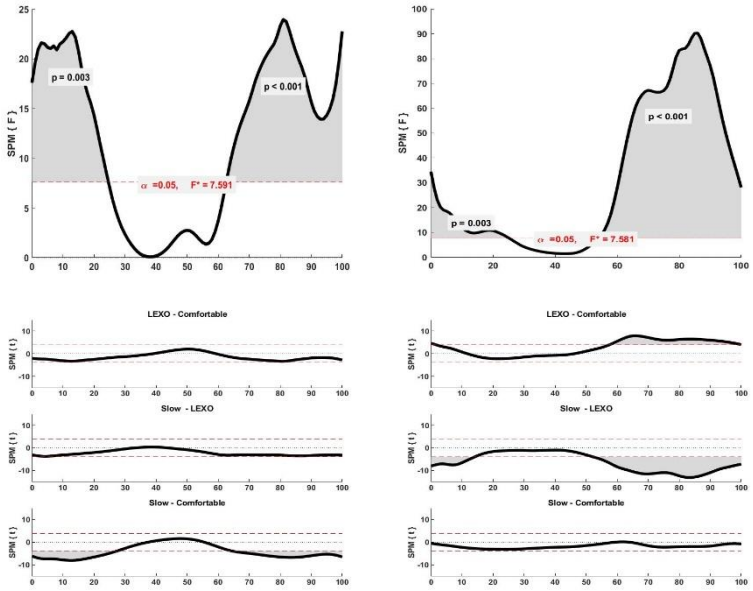
A B C

Figure 1. SPM one-way repeated measures ANOVA output for trunk kinematics in the A) sagittal, B) frontal and C) transverse planes with associated post hoc comparisons below.



A B C

Figure 2. SPM one-way repeated measures ANOVA output for pelvis kinematics in the A) sagittal, B) frontal and C) transverse planes with associated post hoc comparisons below.



A B

Figure 3. SPM one-way repeated measures ANOVA output for hip kinematics in the A) sagittal and B) frontal planes with associated post hoc comparisons below.

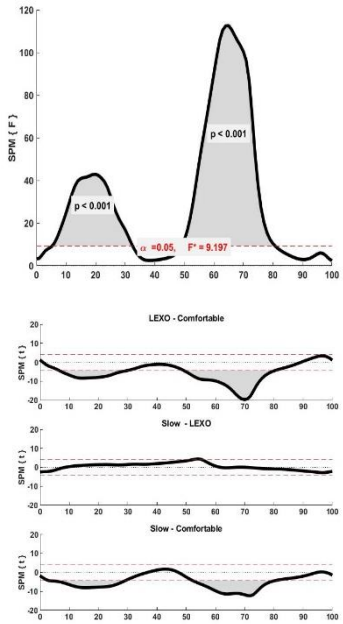


Figure 4. SPM one-way repeated measures ANOVA output for knee kinematics in the sagittal plane with associated post hoc comparisons below.

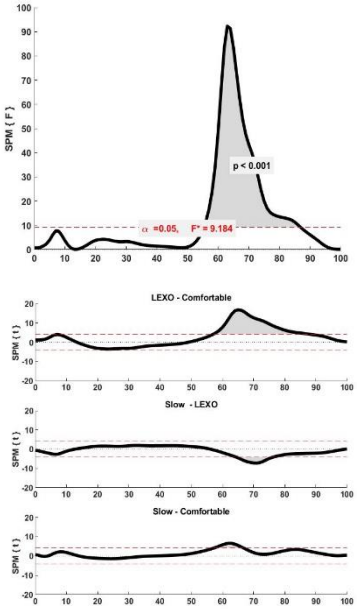


Figure 5. SPM one-way repeated measures ANOVA output for ankle kinematics in the sagittal plane with associated post hoc comparisons below.

Appendix 6

10-meter walk times and associated speeds

Participant	Time (s)	SD	Speed (m/s)
AB 1	25.59	0.28	0.39
AB 2	27.42	0.78	0.36
AB 3	25.00	0.18	0.40
AB 4	22.44	0.20	0.45
AB 5	21.08	0.24	0.47
AB 6	22.79	3.82	0.44
AB 7	24.38	0.19	0.41
AB 8	26.40	0.45	0.38
Average	24.39	0.77	**0.41**
Participant	Time (s)	SD	Speed (m/s)
SCI 1	32.05	0.49	0.31
SCI 2	32.37	0.33	0.31
SCI 3	29.37	0.46	0.34
SCI 4	28.50	0.39	0.35
Average	30.57	0.42	**0.33**

AB = able-bodied, SCI = Spinal cord injury, s = seconds, m/s = meters per second, SD = standard deviation

6-minute walk distances and associated heart rate and self-reported rate of perceived exertion (6-20)

Participant	Resting	Minute 1		Minute 2		Minute 3		Minute 4		Minute 5		Minute 6		Total Distance	Support
	HR	HR	RPE	HR	RPE	HR	RPE	HR	RPE	HR	RPE	HR	RPE	(m)	
AB 1	80	130	10	123	10	122	10	128	11	132	11	125	12	**134**	minimal
AB 2	58	85	6	79	6	79	7	79	7	87	7	85	7	**115**	minimal
AB 3	92	115	7	114	8	115	8	120	8	113	9	112	9	**136**	minimal
AB 4	95	138	8	147	9	150	10	154	11	151	11	155	13	**150**	minimal
AB 5	84	112	8	119	8	125	9	125	10	126	11	129	13	**168**	minimal
AB 6	96	113	6	113	6	115	6	113	6	110	6	113	6	**129**	moderate
AB 7	66	111	9	103	11	112	11	114	11	109	11	103	11	**133**	minimal
AB 8	85	122	6	120	8	119	9	114	9	120	9	110	10	**149**	minimal
SCI 1	100	113	9	113	9	118	9	110	11	114	11	107	11	**119**	moderate
SCI 2	91	86	8	103	9	103	8	104	9	101	9	105	10	**107**	assisted
SCI 3	80	NR	9	NR	9	NR	9	NR	11	NR	11	NR	11	**116**	assisted
SCI 4	89	110	7	107	9	119	10	117	12	118	13	122	14	**120**	moderate

AB = Able-bodied, SCI = Spinal cord injured, NR = Not recorded, HR = Heart rate, RPE = Rate of perceived exertion, m = meters