Pia Wedege

Reliability of three-dimensional gait analysis in adults with acquired incomplete spinal cord injury

Master thesis in Sports Physiotherapy
Department of Sports Medicine
Norwegian School of Sport Sciences, 2013

Contents

Acknowledgement

This master thesis was written under the supervision of Arve Opheim, Kathrin Steffen and Vegard Strøm. Their guidance and support throughout the process have been invaluable and much appreciated.

I would also like to thank the following persons for their assistance and support during this study:

- The Motion Analysis Laboratory staff at Sunnaas Rehabilitation Hospital, in particular Sandra L Hansen, who patiently assisted me when I was afraid "to wipe the internet"
- My dedicated colleagues at PVO4 at Sunnaas Rehabilitation Hospital, and especially all the physiotherapists and the physicians, Ingebjørg Irgens and Jelena Simic
- My beloved family who encouraged and assisted me throughout the Master Degree
- Subject 1-15, who kindly volunteered for this study. I hope this study in some way will be of benefit to you.

May 29th, 2013

Pia Wedege

Summary

Background: Incomplete spinal cord injury (SCI) results in varying degrees of gait impairments. Three-dimensional (3D) gait analysis has been recommended as part of a standardised gait assessment for individuals with incomplete SCI. However, reliability of 3D gait analysis has not been established for this population. The aim of the present study was to investigate intra- and inter-session reliability of gait kinematics in a group of individuals with incomplete SCI. We also sought to estimate the changes required to exceed measurement errors for the kinematic variables used in evaluation of gait impairments for this study group.

Methods: Fifteen adults with acquired SCI (American Spinal Injury Association Impairment Scale - D) were consecutively recruited from an in-patient hospital ward. 3D gait analyses were conducted on two separate days, one or two days apart. Six infrared cameras, 16 reflective markers and the Plug-in-Gait model (Vicon Motion System, Oxford, UK) were employed for the gait analyses. For each subject, five trials from each session were included in the analysis. Gait Profile Scores and Gait Variable Scores were used as outcome measures. Reliability was assessed with Intraclass correlation coefficient (ICC), Standard Error of Measurement (SEM), Bland-Altman 95% limits of agreement and Minimal Detectable Change.

Results: Inter-session results demonstrated very high reliability with ICCs for Gait Profile Scores and Gait Variable Scores above 0.90 and SEM values below 1°, except for left and right hip rotation (ICC=0.50 and 0.64, and SEM=3.7° and 2.7°, respectively) and left knee flexion/extension (ICC=0.83 and SEM=1.7°). Intra-session results demonstrated slightly higher reliability than inter-session. Minimal Detectable Changes for all Gait Profile Scores were below 2.3° and for Gait Variable Scores below 5.0°, except for hip rotation, which was below 10.2°.

Conclusion: In general, the results exhibited very high intra- and inter-session reliability, indicating only a small trial-to-trial and day-to-day gait variation in this study group. The results also showed that, except for hip rotation, only small changes were required to exceed measurement errors for kinematic variables. These results can be used to interpret future 3D gait analysis results when evaluating gait impairments in individuals with SCI. The results suggested that 3D gait analysis is a reliable measure

for adults with acquired SCI (AIS-D) both for clinical and research purposes. However, caution is recommended when evaluating hip rotation.

1. Introduction

Walking is of high priority for individuals recovering from spinal cord injury (SCI). The proportion of individuals with SCI, who regain their walking function, will probably increase in the future, mainly due to improved medical interventions. Furthermore, these individuals will strive to preserve the walking function throughout their lives. These facts impose new demands on the management of this patient group with respect to better understanding and evaluation of gait impairments.

Three-dimensional (3D) gait analysis is commonly used to evaluate gait for both clinical and research purposes, and the method is recommended also for individuals with SCI (Patrick, 2003). Despite several reliability studies of 3D gait analysis, there is limited cohesive information of the reliability of this measure (McGinley, Baker, Wolfe, & Morris, 2009). The reasons may be that reliability is population-dependent and that each clinical population has its own reliability characteristics (Bruton, Conway, & Holgate, 2000). It is recommended that each motion analysis laboratory should establish reliability for individuals without gait pathology and for different groups with pathology to improve the quality of data collection and interpretation (Yavuzer, Öken, Elhan, & Stam, 2008). At Sunnaas Rehabilitation Hospital, where this study was performed, reliability has previously been established for adults without gait pathology and for adults with traumatic brain injury and cerebral palsy. Reliability has not yet been established for individuals with incomplete SCI there or elsewhere. The SCI unit at Sunnaas Rehabilitation Hospital is the largest of its kind in Norway, and the Motion Analysis Laboratory at this hospital is therefore a key location to conduct such a study.

The aim of the present study was to investigate intra- and inter-session reliability of 3D gait analysis in adults with acquired incomplete spinal cord injury. In addition, we sought to estimate the minimal change required to exceed measurement errors, so that the results may be used in clinical evaluation of 3D gait analyses in individuals with incomplete SCI. For this purpose, 15 subjects with acquired incomplete SCI were recruited to conduct 3D gait analyses on two separate days.

2. Theory

2.1. Spinal Cord Injury

2.1.1. Prevalence and incidence

Spinal cord injury (SCI) affects conduction of motor and sensory signals between the central nervous system and spinal cord. About 4 500-5 000 individuals are diagnosed with SCI in Norway (Landsforeningen for Ryggmargsskadde, 2012b). In industrialized nations, the annual incidence rate of traumatic SCI is 15 to 40 individuals per million (Sekhon & Fehlings, 2001; Pickett, Campos-Benitez, Keller, & Duggal, 2006; Albert & Ravaud, 2005; Mehrholz, Kugler, & Pohl, 2012). In Norway the annual incidence rate is between 10 and 20 individuals per million inhabitants, implying 50 to 100 new incidences every year (Landsforeningen for Ryggmargsskadde, 2012a). In addition to this number of individuals with traumatic SCI, an equal number is suffering from a non-traumatic SCI every year (Landsforeningen for Ryggmargsskadde, 2012a). According to Hagen et al. (2010), the incidence of traumatic SCIs is rising due to an increased number of falls among the elderly population.

2.1.2. Classification

The lesion to the spinal cord is classified as either traumatic or non-traumatic, depending on the cause of SCI. Traumatic injuries are caused by a mechanical impact, i.e. traffic accident, fall or violence. A non-traumatic injury can be caused by infections or diseases (Hjeltnes, 2009; Harvey, 2008).

The neurological level of injury refers to “the most caudal segment of the spinal cord with normal sensory and antigravity motor function on both sides of the body, provided that there is normal sensory and motor function superiorly” (American Spinal Injury Association, 2011). The neurological level is broadly classified as tetraplegic or paraplegic. Tetraplegia refers to impairment or loss of motor and/or sensory function in the cervical segments of the spinal cord, resulting in impairment of function of the arms, trunk, pelvic organs and legs (American Spinal Injury Association, 2011). The injury is termed paraplegia if arm function is intact and refers to an impairment or loss of motor and/or sensory function in the thoracic, lumbar or sacral segments of the spinal cord (American Spinal Injury Association, 2011). SCI is also classified as either complete or

incomplete. The American Spinal Injury Association (ASIA) has introduced a classification system, the ASIA Impairment Scale (AIS), which delineates the completeness of the SCI. Both the neurological level and the completeness of the injury are assessed with the International Standard Neurological Classification of SCI assessment form (Appendix 1). The sensory function is graded as either absent, altered or normal. The strength of the muscle is scored on a six-point (0-5) manual muscle testing scale, where a higher score indicates a better muscle functioning (Harvey, 2008). The AIS is as follows (American Spinal Injury Association, 2011):

- AIS-A – Complete: no sensory or motor function is preserved in the sacral segments S4-S5
- AIS-B – Incomplete: sensory, but not motor function is preserved below the neurological level and includes the sacral segments S4-S5
- AIS-C – Incomplete: motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3 (grades 0-2)
- AIS-D – Incomplete: motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a muscle grade greater than or equal to 3
- AIS-E – Normal: sensory and motor function are normal

The cross-sectional extent of damage of the spinal cord is equally important as the level of injury for the degree of functioning after SCI (Hjeltnes, 2009). Epidemiological studies have shown that a larger proportion of new traumatic cases are presented as incomplete lesions and are therefore more likely to regain walking function (Barbeau, Ladouceur, Norman, Pepin, & Leroux, 1999; DeVivo & Chen, 2011). The reasons for the increased proportion of individuals with incomplete SCI are improved medical interventions, better paramedical retrieval, changes in vehicle design and usage, as well as greater public awareness and knowledge of the dangers of moving an injured person (Paddison & Middleton, 2004).

2.2. Gait

2.2.1. Definition

Normal human walking can be defined as "a method of locomotion involving the use of the two legs, alternately, to provide support and propulsion with at least one foot being in contact with the ground at all times" (Whittle, 2003c). The words walking and gait tend to be used interchangeably. However, Whittle (2003) points out that there is a difference in the terminology, and that the word gait describes "the manner or style of walking" rather than the walking process itself (Whittle, 2003c).

The World Health Organization's (WHO) International Classification of Functioning, Disability and Health (ICF) is a classification of health and health-related domains. The domains are: body function and structure, activity and participation, and environmental factors (World Health Organization, 2013). According to ICF, walking can be defined both in the context of activities and participation, as a form of moving, and in the context of body functions.

In this thesis, walking will be discussed under the context of body functions, hence defined according to the ICF as: "movement functions – gait pattern functions: functions of movement patterns associated with walking, running or other whole body movements. Inclusions: walking patterns and running patterns; impairments such as spastic gait, hemiplegic gait, paraplegic gait, asymmetric gait, limping and stiff gait pattern" (World Health Organization, 2001).

2.2.2. Gait cycle

A gait cycle is the same as a stride. It consists of a single sequence of limb motions by one limb, starting at the moment of floor contact and ending with the following floor contact by the same limb (Perry & Burnfield, 2010d). A gait cycle can be divided into a stance phase and a swing phase. In normal walking, the stance phase represents approximately 60% of the cycle and the swing phase 40% (Whittle, 2003c). The stance phase can be subdivided into initial contact, loading response, mid stance, terminal stance and pre-swing. The swing phase can be subdivided into initial swing, mid swing and terminal swing (Perry & Burnfield, 2010j). These different subdivisions can be grouped into three basic tasks by the functions to which they contribute. Hence, the task

involved in initial contact and loading response is weight acceptance, the task involved in mid and terminal stance is single limb support, and the task involved in all four different phases of swing is limb advancement (Perry & Burnfield, 2010j).
Gait can be quantified into different variables such as kinematic, kinetic, and spatiotemporal variables. Only kinematic and certain spatiotemporal variables will be discussed in this thesis. Kinematics describes motion without reference to the forces involved (kinetics) (Whittle, 2003a), and describes the gait in terms of the angles, positions (displacements), velocities and acceleration of body segments and joints (Kirtly, 2006). Spatiotemporal variables of gait are variables belonging to both time and space, such as gait speed and step length. Such variables are of clinical relevance in the assessment of motor pathologies (Macellari, Giacomozzi, & Saggini, 1999). Gait speed affects joint kinematics, both in a healthy population and in populations with gait pathology (Bejek, Paróczai, Illyés, & Kiss, 2006; Røislien et al., 2009), with the main effects found in the knee and ankle (Kirtley, 2006). The relationship between gait speed and kinematic variables is non-linear and hence not predictive (Lelas, Merriman, Riley, & Kerrigan, 2003).

2.3. Gait analysis

Whittle (2003d) describes gait analysis as the systematic study of human walking. Clinical gait analysis seeks to discriminate between normal and abnormal gait and to assess change in walking over time (Baker, 2006). Repeated gait analyses can be used to evaluate the response to therapeutic interventions such as physiotherapy, surgery, medications, and assisted walking devices (McGinley et al., 2009). Gait analysis can be performed in many different ways ranging from methods not requiring technological aids, such as visual gait analysis, to methods using expensive and complicated equipment (Whittle, 2003b). The more advanced analyses are performed in a gait laboratory with three-dimensional (3D) motion capture systems combined with force platforms that measure ground reaction forces. In general, the quality of the data collected is better the more elaborate and expensive the system is. However, it might be inappropriate to use high quality systems in a clinical setting due to its high cost, and because the clinical problem can be managed with a simpler technique (Whittle, 2003b).

When using a simpler technique, it is important to be aware of its limitations. For instance, the limitations of a visual gait analysis are the lack of permanent records, the difficulties of the eye to observe high speed and forces and the dependence of the skill of the observer (Whittle, 2003b).

2.3.1. 3D gait analysis

By using sophisticated hardware and software, 3D gait analysis acquires and converts images of a walking person into quantifiable data describing the motions and forces involved (Perry & Burnfield, 2010a). 3D gait analysis utilizes either passive (video based) systems or active (optoelectrical) systems (Perry & Burnfield, 2010a). In this thesis, only the passive system will be discussed as this was used in the data collection.

To perform the analysis, passive reflective markers are placed on the surface of the subject's skin and aligned with specific bony landmarks and joint axes. When the subject walks along the central walkway in the laboratory, the location of these markers are monitored with a 3D motion data capture system (Davis, 2004). The system usually consists of at least six specialized video cameras arrayed around the walkway and interfaced to a central computer. Each camera is equipped with a cluster of light-emitting diodes that strobe the pathway and the markers on the subject with infrared or visible light. Light reflected from the markers to the cameras is then processed by the computer program to determine the 3D locations of the markers (Davis, 2004). The systems collect data at different frequencies; usually frequencies of 50 Hz, 60 Hz or 200 Hz are used (Whittle, 2003b). The marker position data allow for modeling of the subject, and for calculations of kinematic, kinetic and spatiotemporal variables (Davis, 2004).

To achieve reasonable accuracy in kinematic measurements it is necessary to use a calibrated 3D system (Whittle, 2003b). Most of the commercial kinematic systems employ a 3D calibration object which is viewed by all cameras (Whittle, 2003b). Computer software calculates the relationship between the known 3D positions of the markers on the calibration object and the two-dimensional positions of those markers in the field of view of the different cameras. Thereafter, markers anywhere in this space can be tracked in 3D as long as at least two cameras can observe them (Kirtley, 2006). The 3D position of a marker cannot be calculated if the marker is only captured by one

camera. However, the position can be estimated with data from earlier or later picture frames (Whittle, 2003b).

2.3.2. Conventional gait model

"Biomechanical modelling is the process of taking the full complexity of human movement and making a series of assumptions to render this into simple concepts that both modern computers and the human mind can handle" (Baker & Rodda, 2003). The vast majority of motion analysis laboratories around the world use one of a variety of implementations of the same underlying biomechanical model, known by several names, such as Modified Helen Hayes (MHH), Kadaba, Newington, Gage or Davis (Kirtley, 2006; Baker & Rodda, 2003). The model is also referred to through manufacturer-specific implementations such as Vicon's clinical manager (VCM) or its further development, the Plug-in gait (PiG) model (Baker, 2013). This biomechanical modelling is based on the assumption that movements of the lower limbs can be represented by movement of seven rigid segments: the pelvis, two thighs, two lower legs and two feet (Baker & Rodda, 2003). These rigid segments are considered to be connected by joints that are assumed to be ball and socket joints (three degrees of freedom) (Schwartz, 2004; Baker, 2013). The movements that are assumed to take place in each joint are: flexion/extension, adduction/abduction, internal and external rotation. Hence, translational motions are not accounted for in this model.

Markers are used to define the segments. The segments are defined by three points (triangular shape), with a position and an orientation in space (Baker & Rodda, 2003).

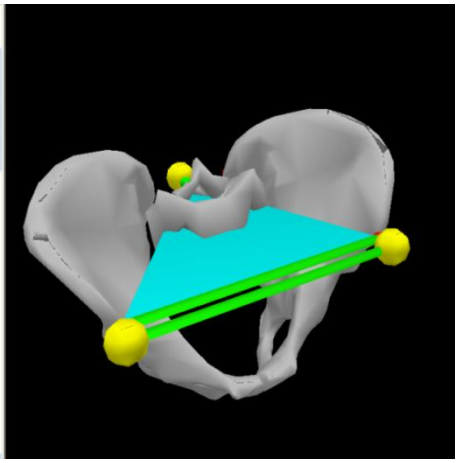


Figure 1. *Defining the pelvic segment (Baker & Rodda, 2003, with permission)*

The segment of the pelvis is represented by a triangle formed by a line joining the two anterior superior iliac spines and the mid-point between the posterior superior iliac spines (Figure 1) (Baker & Rodda, 2003).

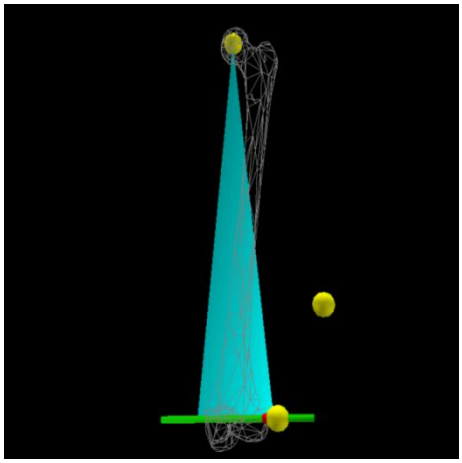


Figure 2. *Defining the femoral segment (Baker & Rodda, 2003, with permission)*

The femoral segment is represented by a line through the knee joint axis and a fixed point at the hip joint centre. The model assumes that the knee joint axis is in a fixed position in relation to the femur and passing through the medial and lateral condyle (Baker & Rodda, 2003). One marker is therefore placed on the lateral condyle, and the second marker is a virtual marker, calculated to be placed on what is assumed to be the hip joint centre. The third marker is used to define the transverse plane of which the segment lies, i.e. internal and external rotation. This marker is placed on a wand lateral to the thigh (Figure 2) (Baker & Rodda, 2003).

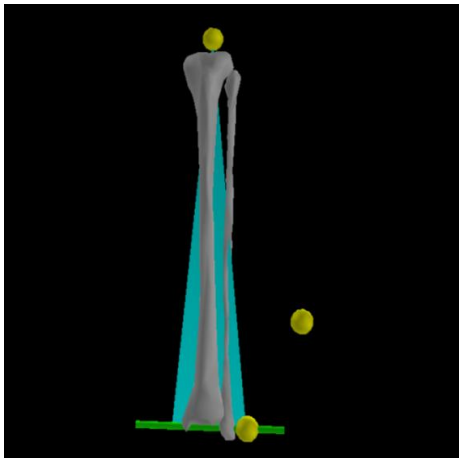
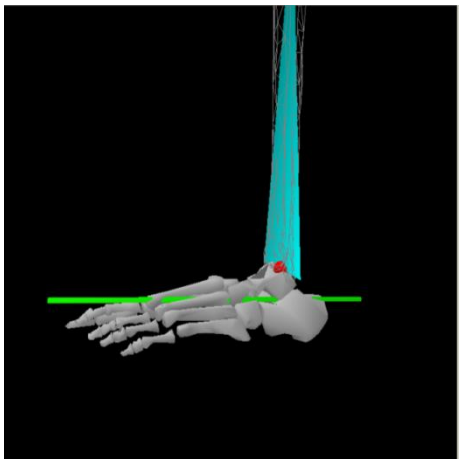


Figure 3. *Defining the tibial segment (Baker & Rodda, 2003, with permission)*

The tibial segment is represented in a similar way as the femoral segment, with a line through the ankle joint axis. Hence the first marker is placed at the fixed point at the ankle joint centre. The second marker is a virtual marker placed at a fixed point at the knee joint centre. The third maker is used to define the plane of the segment and is placed on a wand lateral to the tibia (Figure 3) (Baker & Rodda, 2003).



The foot is represented not as a 3D segment but as a one-dimensional vector. The reference points are at the ankle joint centre and at the middle of the forefoot (Baker & Rodda, 2003). The vector is aligned with the plantar surface of the foot (Figure 4).

Figure 4. *Defining the foot vector (Baker & Rodda, 2003, with permission)*

The biomechanical model is hierarchical, which means that proximal segments have to be detected by the cameras in order to define the distal segments (Schwartz, Trost, & Wervey, 2004; Baker, 2006; Baker, 2013).

2.3.3. Description of the kinematics of normal gait

Throughout the gait cycle, the joints of the limbs move through a range of motions. The motions can be visualised in graphs for each joint in three separate planes; sagittal, frontal and transverse (Figure 5).

Pelvis

The pelvis moves as one object, implying that when one side moves in one direction, the other side moves in the opposite direction. All of the motion arcs are small; the sagittal and frontal plane of motion is around 4°, and that of the transverse plane 10° (Perry & Burnfield, 2010e). In the sagittal plane, the pelvis tilts posteriorly early in the stance phase, then anteriorly at the end of stance phase, posteriorly again at the first part of the swing phase before moving anteriorly again at the last part of the swing phase. In the frontal plane, the pelvis drops down by approximately 4° at pre-swing before moving up again. In the transverse plane, the pelvis moves to maximum forward rotation at the terminal swing and initial contact and thereafter to maximum backwards rotation at terminal stance. At mid stance and mid swing the pelvis rotates through neutral position (Perry & Burnfield, 2010e).

Hip

Motion of the hip in normal gait occurs in all three planes with the largest motion in the sagittal plane. At initial contact, the hip is in 20° of flexion to optimise forward progression and stability (Perry & Burnfield, 2010f). The flexed position of the hip is maintained at loading response, but by the end of the loading response, the hip moves towards extension. There is also an internal rotation of the hip in this phase (Perry & Burnfield, 2010f). At mid stance, the hip extends to neutral to allow for forward progression of the head, arms and trunk. At terminal stance, the hip extension continues to about 20° hyperextension in addition to a passive abduction (Perry & Burnfield, 2010f). At pre-swing, hyperextension is reduced to 10° to prepare the limb to move forward (Perry & Burnfield, 2010f). At the initial swing, the hip is brought into 15° of flexion, which increases to 25° of flexion at mid swing to allow for foot clearance. At terminal swing, the flexion is slightly decreased by 5°, so that the limb can be positioned for a stable first initial contact (Perry & Burnfield, 2010f).

Knee

During normal gait, the knee has a large range of motion in the sagittal plane (0-60°) and a small range of motion in the frontal and transverse plane (Perry & Burnfield, 2010h). Throughout the stance phase, the knee is the major key to stability. At initial contact, the knee has a slight flexion of about 5°, which increases to 20° at loading response. The function in this phase is shock absorption. At mid stance, the knee is extended, and in terminal stance it reaches maximum extension before going into flexion again (Perry & Burnfield, 2010h). At pre-swing, the knee passively flexes to around 40 ° to prepare for the swing. At initial swing phase, the knee continues its flexing motion to around 60° to allow for foot clearance (Perry & Burnfield, 2010h). At mid and terminal swing, the knee passively extends (Perry & Burnfield, 2010h).

Ankle

The ankle alternates between plantarflexion and dorsiflexion, and the total range of ankle motion is around 30° (Whittle, 2003c). At initial contact, the ankle is held in a neutral position, before it plantarflexes at the loading response to reduces the impact of heel contact (Perry & Burnfield, 2010b). At mid stance, the ankle joint dorsiflexes. At terminal stance, the heel rises from the ground and the ankle held in a dorsiflexed position. The prolonged arc of dorsiflexion, from late loading response to the end of

terminal stance, assists the progression of body weight across the foot. This, in a combination with heel rise, causes forward progression during the stance phase (Perry & Burnfield, 2010b). At pre-swing, the ankle plantarflexes a second time, and the limb is moved forward over the toes to prepare for swing (Perry & Burnfield, 2010b). At initial swing, the ankle dorsiflexes to allow floor clearance for limb advancement, and this position is continued in the mid swing phase before the ankle returns to neutral position as it prepares for initial contact (Perry & Burnfield, 2010b).

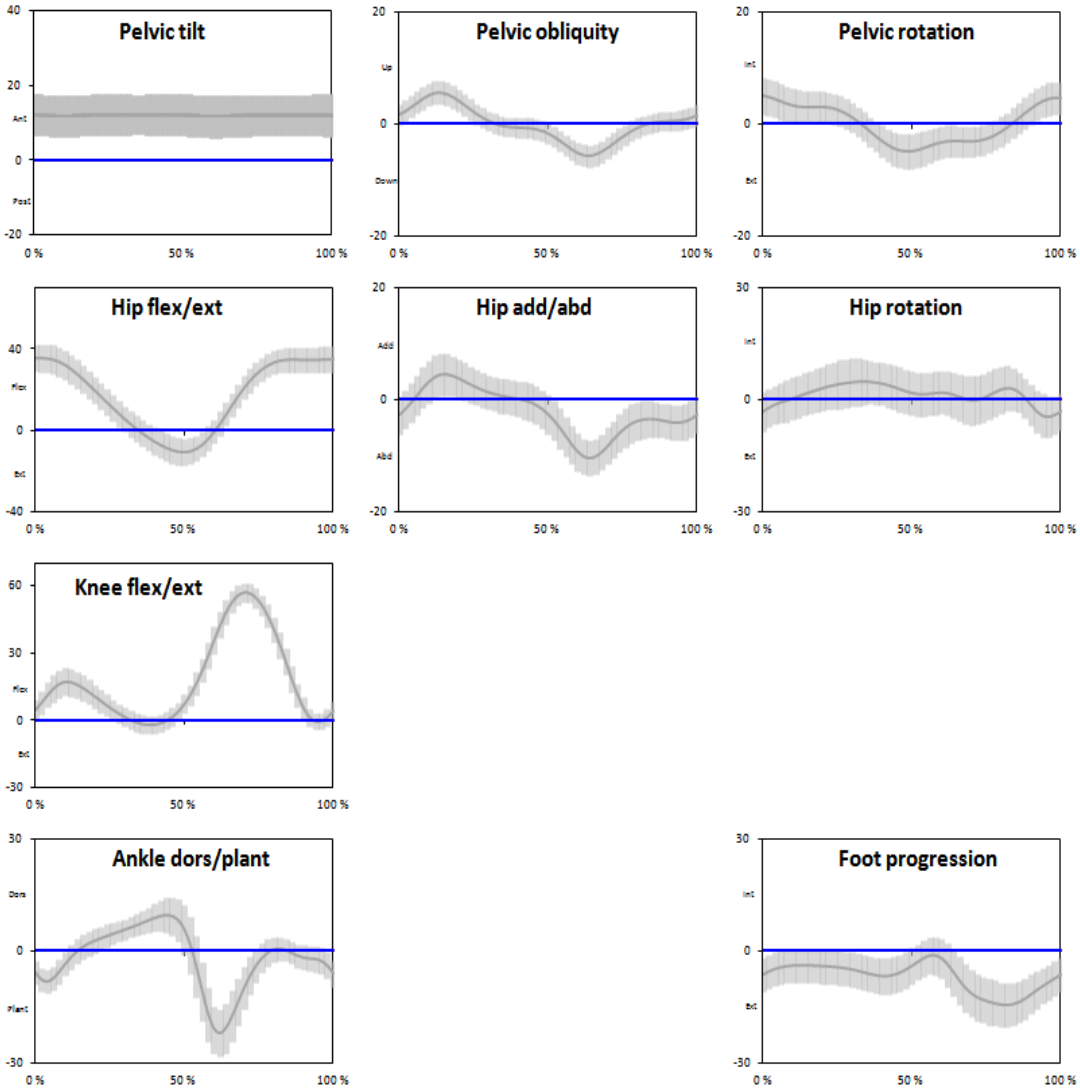


Figure 5. *Graphic view of the gait pattern from a reference group without gait impairment (mean ±1 SD). The horizontal axis of the graphs represents 0-100% of the gait cycle, the vertical axis represents joint angles in degrees. Left column shows sagittal plane, middle frontal plane, and right transverse plane. First row shows pelvis, second hip, third knee, and fourth ankle/foot. Abbreviations: flex=flexion, ext=extension, add=adduction, abd=abduction, dors=dorsiflexion, plant=plantarflexion.*

2.3.4. Gait in individuals with SCI

Exquisite, seamless interchange of information between the sensory and motor systems are needed for efficient walking (Perry & Burnfield, 2010c). Altered motor control can be caused by disruption of neurological pathways, either due to trauma or disease (Perry & Burnfield, 2010c), such as SCI. Strength, balance, spasticity, reduced coordination and age are strictly correlated with walking performance in individuals with SCI (Scivoletto et al., 2008; Hubli & Dietz, 2013; Pepin, Norman, & Barbeau, 2003; Pepin, Ladouceur, & Barbeau, 2003). Because of the wide variety of functional impairments after SCI, it is reasonable to assume a wide variation of the gait pattern between such individuals (Leroux, Fung, & Barbeau, 1999). The gait pattern in incomplete SCI has been reported to consist of inadequate hip extension during stance phase, limited hip and knee flexion at swing phase, either limited or increased plantarflexion of the ankle at end of stance and swing phase, and impaired foot contact at initial contact (Perry & Burnfield, 2010c; Van Der Salm et al., 2005; Pepin et al., 2003; Pepin et al., 2003). Decreased step length and walking speed have also been observed in individuals with SCI (Wang, Low, McGregor, & Tow, 2013; Barbeau et al., 1999).

2.3.5. Gait Profile Score

3D gait analysis produces a vast amount of detailed data on gait dynamics, and clinicians have to make decisions based on interpretation of this complex information (Baker et al., 2009). Attention has therefore been drawn to data reduction techniques, such as different gait summary measures (Kark, Vickers, McIntosh, & Simmons, 2012). These measures are based on the assumption that a single measure of the quality of a particular gait pattern can be useful (Baker et al., 2009). Examples of such measures are the Gillette Gait Index (Schutte et al., 2000), the Gait Deviation Index (Schwartz & Rozumalski, 2008) and the Gait Profile Score (GPS) (Baker et al., 2009). Only GPS will be discussed further in this thesis, as it was used as outcome measure in the present study.

GPS is a single index measure which summarises the overall quality of a subject's kinematic gait by quantifying its deviation relative to a reference population without gait pathology (Beynon, McGinley, Dobson, & Baker, 2010). To provide more information about which variable(s) that contribute(s) to an elevated GPS, the GPS can

be broken down into nine key relevant kinematic variables to provide the Gait Variable Score (GVS). The GVS includes pelvic and hip motion in the sagittal, frontal and transverse plane, knee and ankle motion in the sagittal plane, and foot motion in the transverse plane (foot progression angle). The GPS is presented together with the nine Gait Variable Scores in a bar chart, which creates the Movement Analysis Profile (MAP) (Figure 6) (Baker et al., 2009; Beynon et al., 2010). The root mean square average of all individual Gait Variable Scores equals the GPS (Baker et al., 2009).

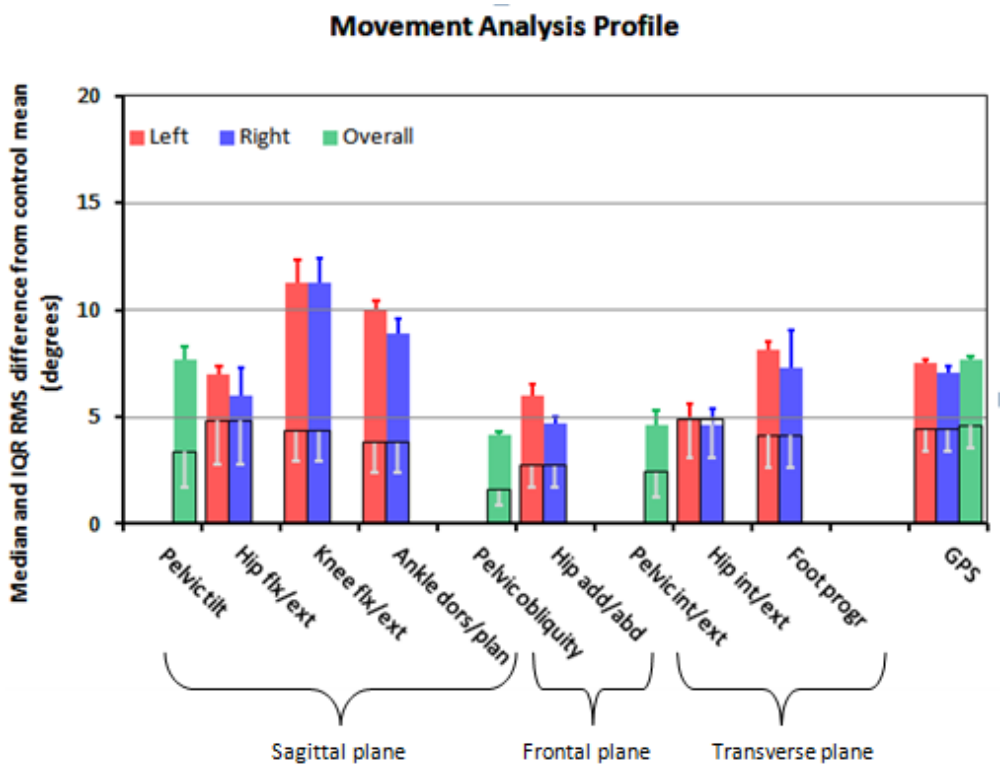


Figure 6. *Movement Analysis Profile (MAP) based on Gait Variable Scores (GVS) and Gait Profile Scores (GPSs). Red GPS represents the median of all GVS for the left leg, blue GPS the median of all GVS for the right leg and green GPS the median of all GVS for the left leg, right leg and pelvis. Black squares on top of the GVSs and GPSs represent the variation in the reference group without gait pathology. Abbreviations: IQR=interquartile range, RMS=root mean square, flx=flexion, ext=extension, add=adduction, abd=abduction, int=internal rotation, ext=external rotation, dors=dorsiflexion, plan=plantarflexion, foot progr=foot progression angle.*

2.4. Reliability

2.4.1. General definition

High quality is an essential requirement for all outcome measures (Scholtes, Terwee, & Poolman, 2011). To determine if an instrument is of high quality, reliability needs to be

assessed (Karanicolas et al., 2009). Reliability is defined as the degree to which a measurement is free from measurement errors, and as the extent to which scores for subjects who have not changed, are the same for repeated measurements under several conditions (Mokkink et al., 2010; Weir, 2005).

The term 'error' refers to the variation found across repeated measurements (McGinley et al., 2009) and is defined as the difference between the observed score and the true score (Thomas, Nelson, & Silverman, 2011; Bruton et al., 2000). Error is thought to occur during each measurement (Scholtes et al., 2011), it is usually unknown and can only be estimated. This estimate is the measure of reliability (Bruton et al., 2000). The general idea of reliability is that the lower the measurement error, the higher the reliability and thus the quality of the instrument (Scholtes et al., 2011). However, it is very rare to find a clinical measurement instrument that is perfectly reliable (Bruton et al., 2000). Measurement errors may be systematic or random. Systematic errors are predictable, occurs in one direction only, are constant and biased (Bruton et al., 2000). Random errors are due to chance, are unpredictable and are the basic concern of reliability (Bruton et al., 2000).

Reliability can be divided into several components which can be examined: internal consistency, instrument, intra-assessor, inter-assessor and intra-subject reliability (Domholdt, 2005a; Karanicolas et al., 2009). Intra-subject reliability is associated with actual changes in subjects' performance from time to time (Domholdt, 2005a) and is the focus of our study. Intra-subject reliability depends on the stability of the outcome to daily or weekly fluctuations, and can be evaluated with a test-retest design (Scholtes et al., 2011). The timing of the second test (retest) is essential as no real change is assumed to have occurred in-between the two tests. The interval will depend on the instrument tested (Scholtes et al., 2011).

2.4.2. Quantification of reliability

Relative reliability

Reliability can be quantified as either relative or absolute (Domholdt, 2005a). Relative reliability examines the relationship between two or more sets of repeated measurements (Domholdt, 2005a), and it describes how well subjects can be distinguished from each other despite measurement errors (de Vet, Terwee, Knol, &

Bouter, 2006; de Vet, Terwee, & Bouter, 2003). The concept is based on the assumption that a measure is reliable if the individual measurements within a group maintain their position within the group on repeated measurements (Domholdt, 2005a). This form of reliability is a characteristic of the performance of an instrument in a certain population sample. It is therefore highly dependent on the variation in the population sample and can only be generalized to samples with similar variations (de Vet et al., 2006). Relative reliability is measured with some form of correlation coefficient, i.e. intraclass correlation coefficient (ICC) (Domholdt, 2005a; Karanicolas et al., 2009). Measures, that are perfectly reliable, have a correlation coefficient equal '1', and measures with no true score have a correlation coefficient equal '0' (Scholtes et al., 2011). Although some reports have attempted to describe different levels of the ICC, such as poor, medium and good, there seems to be no consensus as to what constitutes a good correlation coefficient (Weir, 2005).

Absolute reliability

To make a meaningful statement about whether a subject's condition has changed, one must know the levels of variability in the scores that can be expected from the measurement errors (Domholdt, 2005a). Absolute reliability indicates the degree of variation of a score on repeated measurements (Domholdt, 2005a; Bruton et al., 2000). The standard error of measurement (SEM) is the preferred statistic to measure absolute reliability (Scholtes et al., 2011; Domholdt, 2005a). SEM has the same units as the measurement of interest, and it is largely independent of the population from which it was determined (Weir, 2005). It is recommended that studies reporting reliability of 3D gait analysis data should include absolute measures such as SEM (McGinley et al., 2009).

Minimal detectable change

It is recommended that consideration should be given to the investigation and development of minimum levels of detectable change in studies reporting reliability of 3D gait analysis (McGinley et al., 2009). Minimal Detectable Change (MDC) provides an indication of the smallest change that can be considered greater than the measurement error within a certain level of confidence for subjects who are truly unchanged (Stratford & Riddle, 2012; Gatchel, Lurie, & Mayer, 2010). MDC is regarded as one of the more common distribution-based methods to express change

scores in terms of an underlying sampling distribution and is based on SEM (Haley & Fragala-Pinkham, 2006). The percentage of confidence interval (CI) is selected depending on the precision needed for the score estimate (Haley & Fragala-Pinkham, 2006; Stratford & Riddle, 2012). A CI of 90% or 95% is typically reported (Stratford & Riddle, 2012).

2.4.3. Reliability of 3D gait analysis

Most of the reliability studies of 3D gait analysis conducted to date have evaluated healthy individuals (Faude, Donath, Roth, Fricker, & Zahner, 2012; Baker, 2006; Monaghan, Delahunt, & Caulfield, 2007; Maynard, Bakheit, Oldham, & Freeman, 2003; Diss, 2001; McGinley et al., 2009; Kadaba et al., 1989). Reliability has also been established for populations with gait pathology, such as:

- Children with cerebral palsy (Steinwender et al., 2000; Mackey, Walt, Lobb, & Stott, 2005; Klejman, Andrysek, Dupuis, & Wright, 2010; Redekop, Andrysek, & Wright, 2008)
- Adults with stroke (Yavuzer et al., 2008; Caty, Detrembleur, Bleyenheuft, & Lejeune, 2009)
- Adolescents with idiopathic scoliosis (Fortin, Nadeau, & Labelle, 2008)
- Adults with osteoarthritis (Robbins, Astephen Wilson, Rutherford, & Hubley-Kozey, 2013; Laroche et al., 2011)
- Adults with traumatic brain injury (Weider, 2010)
- Adults with cervical spondylotic myelopathy (McDermott, Bolger, Keating, McEvoy, & Meldrum, 2010)

Measurement errors and variability in 3D gait analysis can arise from at least three different sources: the subject, the measurement system and the assessor (Gorton III, Hebert, & Gannotti, 2009). Variability is defined by the sum of variance from each of these sources (Portney & Watkins, 2009a). For 3D gait analysis, Monaghan et al. (2007) summarise the potential sources of variability in test-retest experimental procedures as follows:

- Subject
    - Natural variation of gait

    - Natural variation of gait velocity
    - Variation of gait velocity in trials
    - Wearing different footwear
    - In response to the laboratory setting (short runway)
    - Real difference due to pathological change
- System
    - Calibration
    - Precision of computation algorithms
    - Uncertainty in construction of an embedded co-ordinate system
    - Downstream errors in non-frontal plane movements
    - Number of cameras and resolutions
    - Digitising of video analysis
    - Alignment procedures
    - Relative skin/marker movement error
    - Force plate drift/noise
- Assessor
    - Marker placement
    - Identification of anatomical landmarks
    - Wand alignment
    - Anthropometric measurement
    - Data processing
    - Choice of statistical analysis
    - Different rater measurements

Variability in 3D gait analysis can be divided into intrinsic and extrinsic variations (Schwartz et al., 2004). Intrinsic variations, which are the variations of interest in this study, arise naturally, either through subject-to-subject or trial-to-trial variability (Schwartz et al., 2004). The intrinsic variability cannot be reduced. However, if measured, the intrinsic variation can serve as an important baseline for comparison (Schwartz et al., 2004). The extrinsic variations derive from experimental errors and can be reduced or controlled for (Schwartz et al., 2004; Baker et al., 2009; McGinley et al., 2009). Natural variability should not be confused with experimental error (Schwartz et al., 2004).

In their systematic review of 23 studies on inter-session and/or inter-assessor reliability of 3D kinematic gait measurements, McGinley et al. (2009) concluded that the highest relative reliability indices occur in the sagittal and frontal plane (excluding pelvic tilt) and the lowest reliability in the transverse plane (excluding pelvic rotation). Their study also demonstrated that the magnitude of the absolute reliability measure is lowest, in general, in the frontal (around 2°) and in the sagittal plane (<4°). The lowest errors are observed for pelvis in the transverse and frontal plane, whereas rotation of the hip and knees show the highest errors. More recent studies also report high measurement errors in the transverse plane and low measurement errors in the frontal and sagittal plane (Klejman et al., 2010; Robbins et al., 2013; McDermott et al., 2010). Even though low relative reliability indices are observed in the transverse plane, as well (Caty et al., 2009; Laroche et al., 2011), the results seem less conclusive for relative reliability measures than absolute reliability measures (Klejman et al., 2010; Robbins et al., 2013; McDermott et al., 2010).

2.5. Summary

3D gait analysis is commonly used to document pathological gait for treatment planning, evaluation and research. It has been suggested that gait analysis laboratories should be utilized as part of the standard assessment of gait to supplement routine clinical examination, also for individuals with SCI (Patrick, 2003). Assessment of reliability of such quantitative measures is important as lack of precision can result in biased inferences (Luiz & Szklo, 2005). For a measure to be used appropriately, the measurement error should be known, and 3D gait analysis is only likely to receive wider acceptance in clinical practice if its reliability can be demonstrated (Maynard et al., 2003).

Despite several reliability studies of 3D gait analysis, there is limited cohesive information about the reliability of kinematic gait measurements (McGinley et al., 2009). One of the reasons may be that reliability is population-dependent (de Vet et al., 2003). Estimates from one population cannot be transferred to another population, because each clinical population has its own reliability characteristics (Bruton et al.,

2000). In addition, differences in gait kinematics may exist in subjects with gait pathology due to fatigue and the underlying musculoskeletal or neurologic conditions (Gorton III et al., 2009; Steinwender et al., 2000). Hence, one should be careful to generalize findings from studies of a population without gait pathology to one with gait pathology (Gorton III et al., 2009). It has been recommended that every motion analysis laboratory should determine measurement errors for subjects both with and without gait pathology to improve the quality of data collection and interpretation (Yavuzer et al., 2008). This was also the focus of the present study.

Walking is of high priority for recovery among individuals with SCI, irrespective of the severity of injury or age at time of injury (Ditunno, Patrick, Stineman, & Ditunno, 2008; El Masri & Kumar, 2011). According to Waters et al. (1993), more than 75% of those with initially incomplete SCI will regain some form of ambulatory function, and this proportion will probably increase in the future (Barbeau et al., 1999; DeVivo & Chen, 2011). Furthermore, these individuals will strive to preserve this function throughout their lives, which imposes new demands on the management of this patient group with regard to better understanding and evaluation of gait impairments.

2.6. Aims of the study

This is the first reliability study of gait kinematics in 3D gait analysis, with emphasis on intrinsic variation within a group of subjects with different levels and severities of SCI. The aim of our study was two-fold. First, we wanted to investigate intra- and inter-session reliability of kinematic variables in 3D gait analysis in adults with acquired incomplete SCI. Secondly, and for clinical purposes, we sought to estimate the change required to exceed measurement errors in kinematic variables in 3D gait analysis in adults with incomplete SCI.

3. Methods

3.1. Design

The present study was a laboratory study with two test sessions (test-retest), one or two days apart. The reason for the short time interval between the two test sessions was to ensure that the subjects' real physical condition were unchanged.

3.2. Study group

The subjects were consecutively recruited at Sunnaas Rehabilitation Hospital, Nesoddtangen, Norway, between July 2012 and September 2012. Initially, medical records of subjects with SCI, planned for an inpatient program at the hospital during the inclusion period, were scanned for eligibility with the following criteria:

Inclusion criteria

- Diagnosed with an acquired SCI (AIS-D), traumatic or non-traumatic
- A minimum of one year post injury
- Able to walk reciprocally 10 meters without assistance from another person
- Between 18 and 65 years of age
- Able to read and understand Norwegian
- Able to give informed consent and cooperate during the testing procedures

Exclusion criteria

- Severe respiratory or cardiac disease that prevented safe mobilization
- Symptomatic musculoskeletal problems affecting gait
- Botulinum toxin A injections in the lower limbs within the last three months
- Any orthopaedic or neurosurgery in the lower limbs in the previous six months
- Unstable level of physical function due to a diagnosed syringomyelia
- Other neurologic conditions in addition to SCI

Subjects, who were found eligible, received information about the study by post prior to their planned stay at the hospital (Appendix 2). One to two weeks before admittance,

the subjects were contacted by phone about participation in the study to allow for coordination of the test sessions with other scheduled assessments and treatment sessions during the hospital stay. Upon admittance, written informed consent was obtained (Appendix 3). If participation was accepted, the subjects were assessed for eligibility by an experienced physician in the field of SCI and the research coordinator (Pia Wedege, physiotherapist). All subjects, who were asked to take part in the study, accepted the invitation.

The initial eligibility check of the medical records led to exclusion of eight subjects with acquired incomplete SCI due to age restrictions (n=2), additional neurological or medical diagnosis (n=4), less than one year since injury (n=1) or not being able to walk independently for 10 meters (n=1). One subject was regarded as suitable, but was not included due to an already fully booked schedule.

3.3. Collection of study group characteristics

Data collection of the study group's characteristics followed recommendations by the Executive Committee for the International SCI Data Sets Committees (DeVivo et al., 2006). Data were collected from the subjects' medical record (age, time and cause of injury, spinal surgery) and from clinical assessments. The first clinical assessment to determine the neurological level of injury and motor function, was performed on admittance to the hospital and was part of the eligibility check. During the other clinical assessment, muscle tone, passive range of motion, walking ability and the need for walking device/brace were assessed by the subjects' regular physiotherapists at Sunnaas Rehabilitation Hospital. In total, six experienced physiotherapists in the field of neurology were involved in these assessments.

3.3.1. Neurological level of injury

Neurological level of injury was examined with the International Standard Neurological Classification of Spinal Cord Injury form (Appendix 1) and guidelines (American Spinal Injury Association, 2011). The International Standard for Neurological

Classification motor and sensory examinations are regarded as reliable measures (Marino, Jones, Kirshblum, Tal, & Dasgupta, 2008).

3.3.2. Motor function

Motor function was assessed with the AIS motor examination (Appendix 1), which involves strength testing of ten key muscles (elbow flexors, wrist extensors, elbow extensors, finger flexors, small finger abductors, hip flexors, knee extensors, ankle dorsi- and plantarflexors and long toe extensors). The strength of each muscle was graded on a six point scale ranging from 0-5, where '0' is total paralysis and '5' normal active movement, defined as full range of motion against sufficient resistance to be considered normal (American Spinal Injury Association, 2011). The motor score refers to the numerical summary score of motor function with a score ranging from 0-25 for each extremity (American Spinal Injury Association, 2011).

3.3.3. Muscle tone

Increased muscle tone can lead to decreased coordination of muscle action and reduced functional limb movement (Steeves et al., 2006) and is a common complication of SCI (Priebe, 2005). Muscle tone was assessed with the Modified Ashworth Scale (MAS), which intends to assess resistance to passive range of motion (Esquenazi, 2011). MAS is a six point scale (the range 0-5 was used in this study), where higher scores indicate higher muscle tone (Bohannon & Smith, 1987). MAS is one of the most commonly used methods to assess muscle tone in individuals with SCI and has good clinical utility (Hsieh, Wolfe, Miller, & Curt, 2007). Validity has only been partially established, and shows limited intra- and inter-assessor reliability for lower limb muscle tone assessment, as well as poor correlation with self-rated assessment of spasticity (Hsieh et al., 2007; Pandyan et al., 1999; Lechner, Frotzler, & Eser, 2006; Sköld, Levi, & Seiger, 1999). In our study, MAS was used for hip and knee flexors and extensors, as well as for ankle plantar flexors and hip adductors. For each subject, a median MAS score with interquartile range (IQR) for each joint (including left and right leg, as well as all movements tested in that joint) was calculated.

3.3.4. Passive range of motion

Passive range of motion was assessed with a goniometer for hip, knee and ankle flexion and extension, as well as for hip abduction/adduction and rotation. The inter-assessor variation for joint range of motion is found to be approximately 10° (McDowell, Hewitt, Nurse, Weston, & Baker, 2000). In our study, joints exhibiting reduced passive range of motion of ≥20° compared to 'normal' passive range of motion (Reese & Bandy, 2010; Esquenazi, 2011) were noted.

3.3.5. Walking ability

The subjects' walking ability was assessed with the Walking Index for Spinal Cord Injury II (WISCI II) and Timed Up & Go (TUG). WISCI II assesses the need for physical assistance, braces or devices when walking. It is an ordinal scale with a range of 0-20, where a higher score indicates better physical function (Appendix 4) (Ditunno & Ditunno, Jr., 2001). WISCI II, specifically developed for the SCI population in clinical trials (Jackson et al., 2008), represents a valid and reliable outcome measure for this population (Burns, Delparte, Patrick, Marino, & Ditunno, 2011). It is recommended that WISCI II is used in a combination with a more quantitative timed walking test, such as TUG (Steeves et al., 2006).

TUG is a timed walking test, measured in seconds, where the subject stands up from a chair, walks three meters, returns to the chair and sits down. TUG, originally developed as a functional balance test for elderly subjects (Mathias, Nayak, & Isaacs, 1986), is a reliable and valid outcome measure in ambulatory subjects with SCI (Poncumhak, Saengsuwan, Kamruecha, & Amatachaya, 2013). With this test, the fastest time from a maximum of three trials for each subject was noted. The subjects walked with the braces/devices they normally used.

3.4. Outcome measures

In the present study, the outcome measures were Gait Profile Scores (GPSs) (Overall, Left and Right) and the nine individual Gait Variable Scores (GVSs) (2.3.5).

The quantity of the GPS is the root mean square difference between the gait vector of the subject investigated and the average gait vector for a reference group without gait pathology (Baker et al., 2009). The value from every 2% of the gait cycle curves (0-100%), altogether 51 points, for each of the nine GVS, were used to calculate GPS. The calculations involved a log transformation (Baker et al., 2009). GPS is defined as a raw score and reported in degrees. Because it is assumed to have a chi-distribution GPS was reported as a median value with an IQR (Baker et al., 2009). Pelvic kinematics were included from the left side only as the pelvic is common to both segments. In our study, the reference group for the GPS template was 50 healthy adults (mean age 39.7±11.7 years, both sexes) collected previously with an identical protocol at Sunnaas Rehabilitation Hospital (Røislien et al., 2009). GPS has been validated against Gait Deviation Index and general measures of mobility in children with gait pathology (Baker et al., 2009).

Because gait speed is not correlated with GPS, it is recommended to report this in addition to GPS in clinical studies (Baker et al., 2012). Hence, gait speed and step length were measured and reported in our study.

3.5. 3D gait analysis experimental protocol

3.5.1. Assessors

Four assessors (three physiotherapists and one human movement scientist), working in pairs, were involved in the gait analysis assessments. They were all employed at the Motion Analysis Laboratory at the hospital. All physiotherapists had seven years of experience in gait analysis, and the human movement scientist had six months of experience. Each subject was assessed by the same pair of assessors in both sessions. When the human movement scientist was part of the assessment pair, the more experienced physiotherapist was in charge of marker placements and anthropometrical measurements.

3.5.2. 3D gait analysis measuring instruments

Figure 7. Motion Analysis Laboratory at Sunnaas Rehabilitation Hospital

The 3D gait analysis recordings were performed at the Motion Analysis Laboratory at Sunnaas Rehabilitation Hospital (Figure 7). The laboratory holds a 10 x 1 meter walkway, of which the middle 4-5 meters were included in the capture volume. The equipment consisted of six infrared MX 13 cameras (Figure 8) working at 100 Hz (Vicon Motion Systems, Oxford, UK), two AMTI OR6-7 force plates embedded in the walkway (Advanced Mechanical Technology Inc., Watertown, USA) and two digital video cameras (JVC Kenwood Corp., Kanagawa, Japan) (Figure 9). The video cameras recorded the gait in the frontal and sagittal plane, but not simultaneously.

Figure 8. Infrared camera

Figure 9. Digital camera

3.5.3. 3D gait analysis procedure

For each subject, the two test sessions were performed at the same time of the day and fitted into the subject's previously planned schedule at the hospital. The time of the day varied between the subjects. The first session was scheduled to last about one and a half

hours and the second session up to one hour. The subjects were asked to wear shorts and, if possible, to walk bare-footed. They were advised to walk in their own, comfortable speed and were allowed to use walking devices, braces or shoes if needed. Moreover, they were asked to refrain from strenuous exercise and not to alter their medication between the two sessions to reduce experimental errors. All subjects were allowed a few practice trials before the recordings started to limit the learning effect bias.

The gait assessments followed a standardised test procedure, developed by the Nordic Vicon User Group (Nordic Vicon User Group, 2013), based on the recommendations from the marker set-up for the Plug-in gait (PiG) model (Vicon Motion Systems, 2012). Each test day, the assessors calibrated the six infrared and the two digital cameras with a five marker wand L-frame. At the start of the first session, the assessors collected the following anthropometric data for each subject:

- Weight (measured with a digital scale)
- Height (measured with a measuring tape)
- Bilateral leg length (distance between anterior superior iliac spine and the ipsilateral medial malleolus with the knee extended, measured with a measuring tape)
- Pelvic width (distance between anterior superior iliac spines measured with a dial calliper)
- Knee width (distance between lateral and medial femoral condyle measured with a dial calliper)
- Ankle width (distance between lateral and medial malleolus measured with a dial calliper)

The anthropometric data were exported to the software programme Vicon Nexus 1.7.1 (Vicon Motion Systems, Oxford, UK). The data from the first session were used in the second session to reduce experimental errors.

Sixteen reflective markers (each of 14 mm diameter) (Vicon Motion Systems, Oxford, UK) were attached to the anatomical landmarks according to the PiG model (Vicon Motion Systems, 2012) and guidelines from the Nordic Vicon User Group (2013). The landmarks were: anterior superior iliac spines, posterior superior iliac spines, lateral

thighs (wand markers), lateral femoral condyles, lateral shins (wand markers), heels, lateral ankle malleolus and forefoot (between 2nd and 3rd metatarsal head) (Figure 10 and Figure 11). Heel markers were aligned with the height of the forefoot markers using horizontal laser measurement equipment, designed especially for this task. The wand markers, which identified the femoral and tibial segments, were positioned by two thin metal pins as visualisation device (Nordic Vicon User Group, 2013). The markers were attached with double sided tape, cut into squares of 2.5 x 2.5 cm. To ensure consistent marker placement between the two sessions, the skin was marked with a water resistant pen, but the wand markers had to be repositioned before each session.

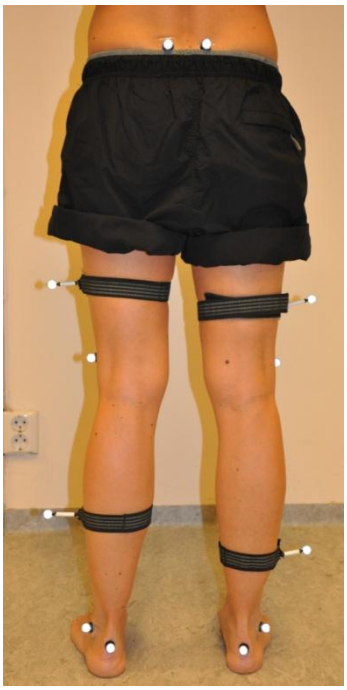


Figure 10. *Subject with markers - posterior view*

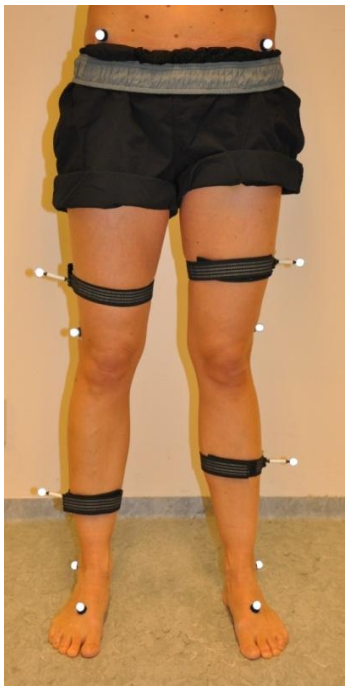


Figure 11. *Subject with markers - anterior view*

One static trial was performed before the gait trials. Based on anthropometric data and the static recording, a model of the subject was created using the PiG model software (Vicon Motion Systems, Oxford, UK). As mentioned above, the conventional gait model is the model most frequently used in clinical 3D gait analysis. Despite this, evidence of its validity reported in the literature is not strong, but it is stronger than what is reported for any other models (Baker, 2013).

For each subject and each test session, we captured at least five trials with one complete gait cycle with clean force plate strikes, preferably with both feet hitting the force plates consecutively, and adequate picture quality. To achieve this, the number of trials for

each subject in one session varied between 13 and 36 with an average of 24 trials. The subjects were allowed to rest between the trials if necessary. Reliability of the kinetic variables was not investigated in this study, and the force plate strikes were used only to determine the foot strike and toe-off events of the gait cycle. The subjects were not informed about the force plates and their function.

3.5.4. Data processing

For each subject, five trials from each session were analysed because kinematic variables show greater variability than both kinetic and spatiotemporal variables, and this variability decreases with increasing number of trials (Monaghan et al., 2007). If more than five trials qualified for inclusion, five were randomly chosen by drawing lots. The quality of all gait cycle recordings was checked initially with a combination of '3D perspective' and 'graph' (trajectory count). A trial was considered to have sufficient quality to be included in the analysis if the marker trajectory gap was smaller than 20 picture frames, and if a satisfactory reconstruction of the gap could be achieved. Trials with the least gaps were prioritised. The preferred gait cycle to be included started with initial contact on the force plate. If the quality of this recording was unacceptable, the cycle ending with initial contact at the force plate was included. Several trials were excluded due to lack of clean force plate strikes or too large marker trajectory gaps.

For the chosen five trials, the process was as follows:

- The name of the markers were checked and renamed if necessary
- The recordings were reduced to consist of as many gait cycles as possible with acceptable quality. However, a sequence of at least one full gait cycle of each leg had to be included.

To obtain and calculate kinematic and spatiotemporal variables, the following procedures were applied in Vicon Nexus 1.7.1.:

1. 'Fill gaps (Woltering) and Detect Gait Cycle Events.' Gaps in the marker path less than 20 frames were filled using either the 'spline fill' or 'pattern fill' function, depending on which method that gave the best reconstruction pattern. Gaps of 10 and less picture frames were filled by the research coordinator, and

gaps between 10 and 20 were filled by a more senior member of the Motion Analysis Laboratory staff.

2. 'Apply Woltering Filter and Auto correlate Events.' The kinematic and kinetic data were filtered with a Woltering filtering routine. Heel strike and toe-off were identified by aid of the force plate information and an autocorrelation function in the software programme. These events were controlled and if necessary adjusted according to visual assessment of the different marker trajectories. The setting of the events was always done in the same order, starting with left heel strike, left toe-off, right heel strike and right toe-off.
3. 'Generate Gait Cycle Parameters and Run Dynamic Model.' The PiG model was used to compute lower extremity joint kinematics and spatiotemporal variables. The mean of all complete gait cycles in each trial was calculated for both kinematic and spatiotemporal variables.

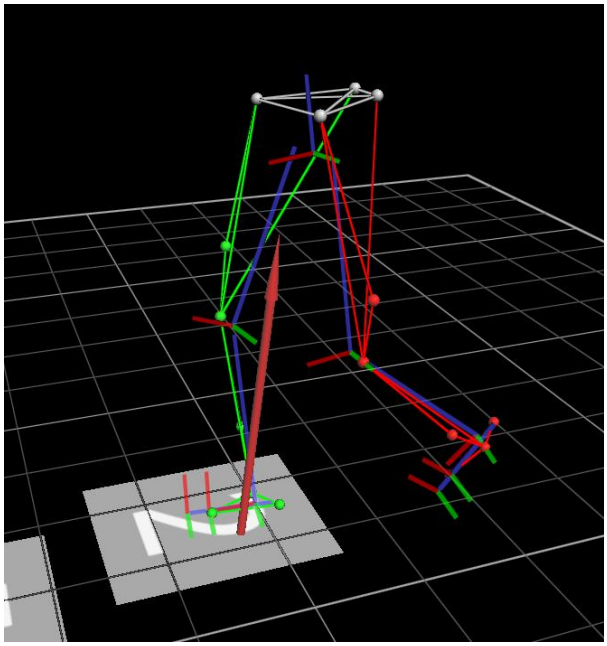


Figure 12. *Plug-in gait (PiG) model as shown in Nexus*

The research coordinator performed all data processing with the integrated software programmes Nexus 1.7.1 and Polygon 3.5.1 (Vicon Motion Systems, Oxford, UK). Event settings were checked by a member of the Motion Analysis Laboratory staff. If they disagreed in the event setting of more than ±1 frame (Mickelborough, van der

Linden, Richards, & Ennos, 2000), the trial was evaluated in unison by these two persons, and the event setting changed according to the agreement reached.

The data from Nexus 1.7.1 were transferred to a report template in the software programme Vicon Polygon 3.5.1, where the spatiotemporal variables (gait speed and step length) were calculated and thereafter exported to an Excel spreadsheet (Excel 2007, Microsoft). To calculate GPSs and GVSs, the kinematic data were transferred to another Excel template (©Richard Baker).

3.6. Pilot testing

One subject, meeting the inclusion criteria, was used for pilot testing. A complete test procedure was performed, including collection of both characteristics and 3D gait analysis experimental protocol. Two of the four assessors participated in the pilot testing. The experience from this test was implemented in the final test procedure protocol before initiation of the main study. One experience, gained from the pilot testing, was cutting of double-sided tape into squares of 2.5 x 2.5 cm, instead of random squares, and placing the markers in the centre of these. This ensured more consistent marker placement between the two sessions. The results from the pilot testing were not included in the present study.

3.7. Sample size

According to Weir (2005), there is no consensus as to the number of subjects required to obtain adequate stability for the ICC and SEM calculations. However, assuming an intraclass correlation coefficient (ICC) of 0.8 with 95% confidence interval (CI) of ± 0.1, a sample size of 52 subjects was needed. Assuming an ICC of 0.9 with 95% CI of ± 0.1, a sample size of 15 was needed (Shoukri, Asyali, & Donner, 2004). We expected ICC for the kinematic variables in our study to be around 0.8-0.9, based on a reliability study in a study group of similar gait pathology (McDermott et al., 2010). Recruiting 52

subjects, fitting the criteria for the aim of the study, was not realistic due to the time available for this study. Therefore, we decided to include 15 subjects. The decision about the sample size was based on the report by Bruton et al. (2000), stating that the number of subjects multiplied by the number of measurements should at least be 25. Based on the interest of inter-session reliability, a minimum for this study would therefore be 13 subjects as each subject was measured twice.

3.8. Statistical analysis

The statistical analysis was done in PASW Statistics 18 and in Excel (2007, Microsoft). All statistical tests were performed at a 0.05 significance level. Data were analysed with mean and standard deviation (SD), controlled for normality with Shapiro-Wilk test, and for outliers with box-plots. If non-normal distribution or outliers were found, the data were presented with median and IQR, as was also used for ordinal data. For intra-session calculations, five random trials from each subject were included. For inter-session calculations the mean of the five trials from each subject was included.

To assess for differences between trials in each session, repeated measures Analysis of Variance (ANOVA) were used, and both the ratio value, F (F= average variance between groups/average variance within group) and p-values were reported for these analyses. A paired t-test was used to assess differences between the two sessions, and the p-value was reported for these analyses. When calculating repeated measures ANOVA for intra-session reliability, the assumption of sphericity was controlled with Mauchley's test. If this test was significant, Greenhouse-Geisser adjustment was employed (Vincent, 2005).

The relative reliability for intra-session was measured with ICC (2,1) and for inter-session with ICC (2,k). Model 2 was chosen as each subject was assessed by the same pair of assessors, and so that the results could be generalized to other assessors with similar characteristics (Weir, 2005; Portney & Watkins, 2009b). ICC form '1' was chosen for intra-session reliability because single measurements were used for these calculations (Weir, 2005; Portney & Watkins, 2009b). As the mean of the five trials in each session was employed in the calculations for inter-session ICC, form 'k' was

chosen (Weir, 2005; Portney & Watkins, 2009b). 95% CI for each of the ICCs was also computed. All data were controlled for normality with the Shapiro-Wilk test. If a normal distribution was not present, ICC was calculated using log transformed data. ICCs were interpreted according to Domholdt (2005b), where ICCs of 0.90-1.00 represent very high correlation, 0.70-0.89 high correlation, 0.50-0.69 moderate correlation, 0.26-0.49 low correlation and ICCs of 0.00-0.25 represent little, if any correlation.

Absolute reliability for both intra- and inter-session was estimated with Standard Error of Measurement (SEM), where SEM was estimated as the root of the mean square error term from the ANOVA (Weir, 2005; Eliasziw, Young, Woodbury, & Fryday-Field, 1994). This SEM formula has been recommended by Atkinson and Nevill (1998), because it is unaffected by the extent of variation of the sample. For clinical interpretation purposes, Minimal Detectable Change (MDC) was reported only for inter-session results and was calculated from the formula MDC=SEM x 1.96 x √2 (de Vet et al., 2006; Haley & Fragala-Pinkham, 2006).

To illustrate reliability and agreement between test sessions and estimate measurement bias, Bland-Altman plots with 95% limits of agreement (LOA) were used (Bland & Altman, 1986). Bland-Altman 95% LOA was calculated as D±SD (D) x 2, where 'D' represents the mean difference between all 15 subjects for a variable measured in session 1 and 2 and 'SD (D)' represents the SD for the difference measured in session 1 and 2 (Monaghan et al., 2007; Bland & Altman, 1986). The plots were constructed by plotting the mean difference of the two sessions for each subject on the vertical axis and the mean of the two sessions on the horizontal axis. Three reference lines were placed on the scatter plots; one at the mean difference between sessions (Session 1-Session 2) and two dotted lines for the upper and lower bounds of the 95% LOA.

3.9. Approval

The study protocol was approved by both the Regional Ethical Committee (Appendix 5) and the Commissionaire for the Protection of Privacy in Research (Appendix 6) before initiation of the study.

4. Results

4.1. Descriptive

4.1.1. Study group characteristics

Fifteen subjects (eleven males and four females), diagnosed with acquired SCI (AIS-D), were included in the study. An overview of the study group characteristics is shown in Table 1. Eight subjects were diagnosed with traumatic SCI and seven with non-traumatic SCI. The traumatic injuries were caused by transport activities (n=3), falls (n=3), assault (n=1) and hit by a heavy falling object (n=1). The non-traumatic injuries were due to stenosis (n=1), prolapse (n=2), ischaemic lesion (n=1), abcess (n=2) and tumor (n=1). Eleven of the 15 subjects had spinal surgery. The subjects were divided almost equally between tetraplegia (n=7) and paraplegia (n=8). Five subjects had full AIS motor score (Table 1) in one of the legs. Seven subjects were assessed to have some degree of increased muscle tone, with muscles around the ankle being most affected. Four subjects showed reduced passive range of motion in at least one joint (Table 1). The 3D gait analysis was performed bare-footed and without any walking devices or braces by ten of the subjects. One of the 15 subjects used shoes only, four subjects a form of walking device and two subjects also an ankle-foot orthosis.

Table 1. *Overview of study group characteristics*

Subject	Gender	Age	BMI	NLI	Time since injury	AIS Motor Score			MAS[1]			PROM	TUG	WISCI II[2]	Walking devices/braces
		Years	Kg/m²		Years	LL left (0-25)	LL right (0-25)	Total (0-100)	Hip (0-5)	Knee (0-5)	Ankle (0-5)		Sec	(0-20)	
1	M	58	24.70	T11	6.0	24	22	96	0 (0)	0 (0)	0 (0)	Normal	16	19	Shoes+stick
2	M	53	26.6	C5	3.9	20	23	90	0 (0)	0 (0)	0 (0)	Normal	7	20	No
3	M	26	21.3	T9	4.7	19	3	72	0.5 (1.0)	1.5 (1.5)	3.0 (0)	Normal	15	12	Shoes+AFO R+crutches
4	F	25	20	L2	1.6	24	8	82	0 (0)	1.0 (2.0)	3.0 (0)	Normal	17	16	Crutches
5	F	61	28.5	C3	13.0	7	23	70	0 (0)	0.5 (1.3)	0.5 (0.5)	Normal	14	15	Shoes+crutch+AFO Le
6	M	60	32.8	C4	3.5	25	22	97	0 (0)	0 (0.3)	0.5 (0.5)	NT hip+knee flx/ext ↓hip int/ext rot	12	20	No
7	M	41	26.6	L1	16.9	18	17	85	0 (0)	0 (0)	0 (0)	↓hip int/ext rot	7	20	No
8	F	45	31.7	C5	3.3	24	20	93	0 (0)	0 (0)	0 (0)	↓hip abd/add	6	20	No
9	M	57	22.8	T11	3.2	25	21	96	0 (0.8)	0.5 (1.0)	3.5 (0.5)	Normal	5	20	No
10	M	59	26.2	C2	2.3	25	21	95	0 (0)	0.5 (1.0)	1.0 (0)	Normal	6	20	No
11	M	39	37.2	C3	2.0	22	25	92	0 (0)	0 (0)	0 (0)	Normal	6	20	No
12	M	62	30.1	C4	3.3	22	23	90	0 (0)	0 (0)	0 (0)	Normal	6	20	No
13	M	50	24.1	T9	1.8	20	22	92	4.0 (0)	4.0 (0)	4.0 (0)	↓hip+knee flx/ext	13	20	Shoes
14	M	38	32.6	L2	2.6	22	25	97	0 (0)	0 (0)	0 (0)	Normal	5	20	No
15	F	35	21.9	L2	4.0	24	15	89	0 (0)	0 (0)	0 (0)	Normal	6	20	No
Summary		**46.3 (12.7)**	**27.1 (4.9)**		***3.3 (2.7)**	***22 (4)**	***22 (6)**	***92 (8.5)**	***0 (0)**	***0 (0.5)**	***0 (1.5)**		***7 (8)**	***20 (1)**	

Summary values given as: mean (SD) or *median (IQR). Abbreviations: SD=standard deviation, IQR=interquartile range, M=male, F=female, BMI=body mass index, NLI=Neurological level of injury, T=thoracic, C=cervical, L=lumbar, AIS=ASIA Impairment Scale, LL=lower limb, MAS=Modified Ashworth Scale, PROM=passive range of motion, TUG=timed up & go, WISCI II=Walking Index for Spinal Cord Injury II, NA=not applicable, ↓=reduced, NT=not tested, flx=flexion, ext=extension, rot=rotation, abd=abduction, add=adduction, AFO=ankle-foot-orthosis, R=right, Le=left, Sec=seconds

[1] For each subject, median MAS score with IQR for each joint was calculated. Scores for hip include: flx, ext, add, for left + right leg. Scores for knee include: flx, ext for left + right leg. Scores for ankle include plantarflexors, for left + right leg. Higher scores indicate higher muscle tone.

[2] Minimum score of WISCI II is '0' which indicates unable to walk. Maximum score is '20' which indicates ability to walk 10 m without assistance or devices/braces

4.1.2. Gait characteristics

The study group's kinematic deviations from the reference group without gait pathology are visualised both in graphs (Figure 13) and in the Movement Analysis Profile (MAP) (Figure 14), and the findings can be summarised as follows:

- Sagittal plane
    - Increased anterior pelvic tilt at mid stance
    - Increased hip flexion throughout the stance phase, and lack of hyperextension of the hip at the last part of stance phase
    - Increased knee flexion throughout the stance phase with a wider variation in the right leg
    - Reduced and delayed maximum knee flexion at swing phase, being more pronounced in the right leg
    - Increased ankle dorsiflexion throughout the gait cycle and lack of ankle plantarflexion at the end of stance and initial swing phase
- Frontal plane
    - Increased hip abduction at the first part of stance phase
    - Reduced and delayed hip abduction at terminal stance phase
- Transverse plane
    - Decreased internal rotation of the left hip at stance phase and increased internal rotation of the right hip throughout the gait cycle, specifically at the second half of the cycle
    - Increased external foot progression angle of both feet throughout the gait cycle, being more pronounced at stance and first part of swing phase

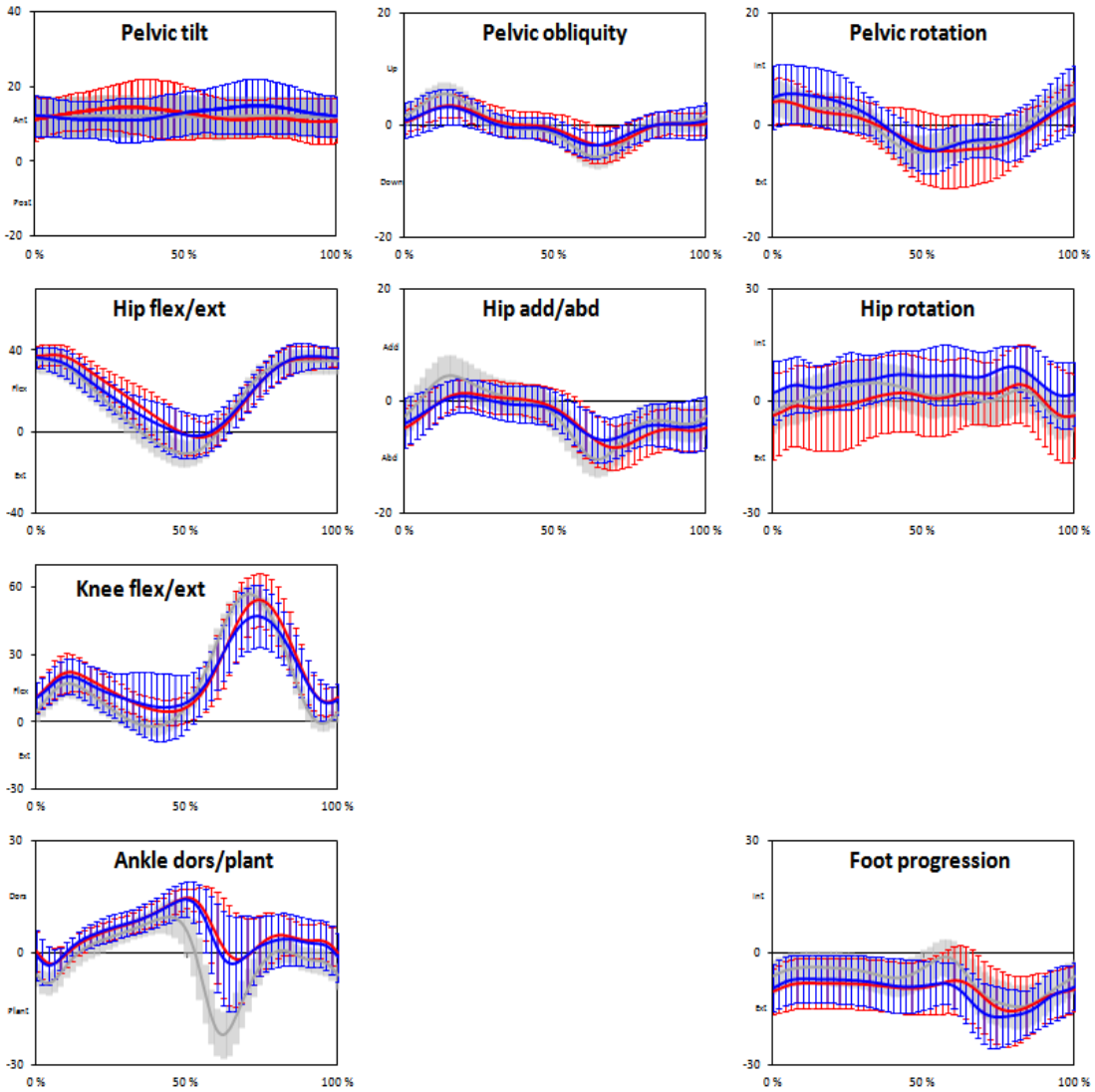


Figure 13. *Graphic view of the kinematics of the study group from Session 1 based on five trials of 15 subjects with incomplete spinal cord injury. The horizontal axis of the graphs represents 0-100% of the gait cycle, the vertical axis represents joint angle in degrees. Left column shows sagittal, middle frontal and right transverse plane. First row shows pelvis, second hip, third knee and fourth ankle/foot. Red colour=left leg (mean±1 SD), blue=right leg (mean±1SD), grey= reference group without gait pathology (mean±1SD). Abbreviations: ant=anterior, post=posterior, int=internal, ext=external, flex=flexion, ext=extension, add=adduction, abd=abduction, dors=dorsiflexion, plant=plantarflexion.*

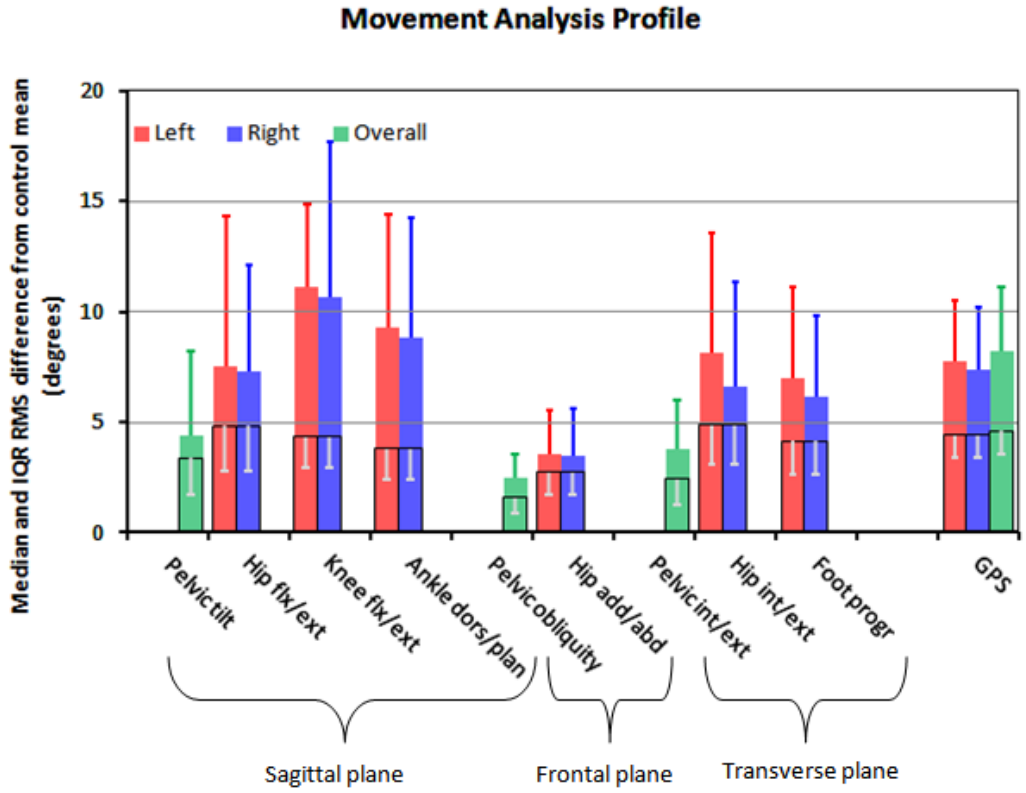


Figure 14. *Movement Analysis Profile (MAP) from Session 1 based on Gait Variable Scores (GVS) and Gait Profile Scores (GPS) of five trials in 15 subjects with incomplete spinal cord injury. For GPS, red column represents the median of all GVS for the left leg, blue column the median of all GVS for the right leg and green column the median of GVS for left leg, right leg, and pelvis. Black squares on top of the GVS and GPS columns represent the variation in the reference group without gait pathology. Abbreviations: IQR=interquartile range, RMS=root mean square, control mean=reference group mean, flx=flexion, ext=extension, add=adduction, abd=abduction, int=internal rotation, ext=external rotation, dors=dorsiflexion, plan=plantarflexion, Foot progr=foot progression angle.*

4.1.3. Spatiotemporal variables

Descriptive results from session 1 and 2 are observed in Table 2. No statistically significant differences between the two sessions were obtained for any of the spatiotemporal variables.

Table 2. *Descriptive results for spatiotemporal variables in the two sessions based on 15 subjects with incomplete spinal cord injury.*

Spatiotemporal variables	**Session 1** Mean (SD)	**Session 2** Mean (SD)	**Difference**	**p-value**
Gait speed (m/sec)	1.029 (0.31)	1.033 (0.30)	0.003	0.82
Step length, left (m)	0.589 (0.11)	0.594 (0.11)	0.005	0.52
Step length, right (m)	0.595 (0.11)	0.596 (0.11)	0.001	0.94

P-value from paired t-test. m=meter, sec=second, SD=standard deviation. Difference=Session 2-Session 1. Calculations of mean (SD), difference, and p-value are based on the mean of five trials in the two sessions

Within each session, a statistically significant difference between the five trials was observed for gait speed (Session 1: F=2.92, p=0.029, Session 2: F=5.24, p=0.001). The analysis revealed that gait speed increased from the first to the last trial with 0.05 m/sec in Session 1 and 0.04 m/sec in Session 2.

Within Session 1, a statistically significant difference was obtained for step length of the left leg (F=3.761, p=0.009), which increased 3 cm from the first to the last trial. However, an increased step length from the first to the last trial was observed also within Session 2, but the difference was less than 3 cm and not statistically significant.

4.2. Reliability

4.2.1. Intra-session

Gait Profile Scores (GPSs)

No statistically significant differences were found between the five trials for any of the GPSs (Overall, Left and Right) in either of the sessions (p>0.48).

Intra-session reliability results from Session 1 are shown in Table 3. All ICCs for GPS intra-session reliability were very high (≥0.96), with a 95% confidence interval (CI) widths ≤0.06 (Table 3). All SEM values for GPS intra-session reliability were ≤0.5° (Table 3). Similar results were found for Session 2 (Appendix 7, Table 9).

Table 3. *Intra-session reliability for Gait Profile Score (GPS) in Session 1 based on five trials in 15 subjects with incomplete spinal cord injury*

GPS	ICC(2,1)			SEM (°)
	ICC	95% CI		
Overall	**0.98**	0.96	0.99	**0.4**
Left	**0.96**	0.92	0.98	**0.5**
Right	**0.98**	0.96	0.99	**0.4**

ICC (2,1)= intraclass correlation coefficient (2,1), 95% CI= 95% confidence intervals for ICCs, SEM=standard error of measurement

Gait Variable Scores (GVSs)

No statistically significant differences were found between the five trials for any of the GVSs in either of the sessions (p>0.15).

Intra-session reliability results from Session 1 are shown in Table 4. ICCs were, for most variables, very high (>0.90) with 95% CI widths <0.15. High ICCs (≥0.78) were observed for pelvic rotation, foot progression, and left knee flexion/extension. SEM for all variables was <1.5°, with the majority <1°. Variables with SEM values >1° were knee flexion/extension, foot progression and left hip rotation (Table 4). ICCs in Session 2 were similar to those in Session 1, as was the case for SEM, the exception being left hip rotation with SEM of 0.7° (Appendix 7, Table 10).

Table 4. *Intra-session reliability for Gait Variable Score in Session 1 based on five trials in 15 subjects with incomplete spinal cord injury*

Plane	**Gait Variable Score**	**ICC(2,1)**			**SEM (°)**
		ICC	95% CI		
Sagittal	Pelvic tilt	**0.97**	0.94	0.99	**0.5**
	Hip flexion/extension, left	**0.97**	0.95	0.99	**0.8**
	Hip flexion/extension, right*	**0.97**	0.94	0.99	**0.7**
	Knee flexion/extension, left	**0.83**	0.69	0.93	**1.4**
	Knee flexion/extension, right*	**0.95**	0.89	0.98	**1.2**
	Ankle dorsiflexion/plantarflexion, left	**0.98**	0.97	0.99	**0.5**
	Ankle dorsiflexion/plantarflexion, right	**0.97**	0.94	0.99	**0.8**
Frontal	Pelvic obliquity	**0.91**	0.82	0.96	**0.3**
	Hip adduction/abduction, left	**0.91**	0.82	0.96	**0.4**
	Hip adduction/abduction, right	**0.94**	0.88	0.98	**0.4**
Transverse	Pelvic internal/external rotation*	**0.78**	0.62	0.91	**0.7**
	Hip internal/external rotation, left*	**0.96**	0.92	0.99	**1.2**
	Hip internal/external rotation, right*	**0.94**	0.87	0.98	**0.8**
	Foot progression, left*	**0.83**	0.68	0.93	**1.2**
	Foot progression, right*	**0.82**	0.68	0.93	**1.3**

ICC (2,1)= intraclass correlation coefficient (2,1), 95% CI= 95% confidence intervals for ICCs, SEM=standard error of measurement, *= ICC calculated from log transform data

These results showed that intra-session reliability was high for all GPSs and GVSs.

4.2.2. Inter-session

Gait Profile Scores (GPSs)

Descriptive results from Session 1 and 2 are presented in Table 5. No statistically significant differences were obtained for any of the GPSs (Overall, Left and Right) between the two sessions.

Table 5. Inter-session descriptive results for Gait Profile Score (GPS) based on five trials from each of the two sessions in 15 subjects with incomplete spinal cord injury

GPS	Session 1(°) Mean (SD)	Session 2(°) Mean (SD)	Diff(°)	p-value
Overall	8.6 (2.5)	8.8 (2.4)	0.2	0.34
Left	8.1 (2.2)	8.2 (2.1)	0.1	0.74
Right†	7.7 (2.7)	8.0 (2.6)	0.3	0.12

P-value from paired t-test, †non-normal distribution: p-value calculated from log transformed data. Diff=Difference=Session 2-Session 1. SD=standard deviation

Inter-session reliability results are presented in Table 6. All ICCs for GPS were very high (≥0.93), with 95% CI widths ≤0.18. All SEM values were ≤0.8° and Minimal Detectable Changes (MDC) ≤2.2° (Table 6).

Table 6. Inter-session reliability results for Gait Profile Score (GPS) based on five trials from each of the two sessions in 15 subjects with incomplete spinal cord injury

GPS	ICC (2,k)			SEM (°)	MDC (°)
	ICC	95% CI			
Overall	**0.97**	0.92	0.99	**0.6**	**1.6**
Left	**0.93**	0.80	0.98	**0.8**	**2.2**
Right*	**0.97**	0.92	0.99	**0.4**	**1.1**

ICC (2,k)= intraclass correlation coefficient (2,k), 95% CI= 95% confidence intervals for ICCs, SEM=standard error of measurement, MDC=minimal detectable change,
*=ICC calculated from log transformed data

Bland-Altman plots with 95% limits of agreement (LOA) showed that the difference between the two sessions for all GPSs were <0.3° with small SD of the differences (<1.2°) (Appendix 8, Table 11). The 95% LOAs range were all <4.2°. The lowest range was observed for GPS Right (-1.4° to 0.9°) and the highest for GPS Left (-2.3° to 2.1°) (Appendix 8, Table 11). No obvious systematic errors were observed in the plots (Appendix 8, Figure16).

Gait Variable Scores (GVSs)

For GVSs, a statistically significant difference between the two sessions was obtained only for pelvic rotation (95% CI: 0.003-0.139, p=0.04) (Table 7).

Table 7. *Inter-session descriptive results for Gait Variable Score based on five trials from each of the two sessions in 15 subjects with incomplete spinal cord injury*

Plane	Gait Variable Score	Session 1(°) Mean (SD)	Session 2(°) Mean (SD)	Diff(°)	p-value
Sagittal	Pelvic tilt†	5.2 (3.2)	5.0 (3.2)	-0.2	0.68
	Hip flexion/extension, left	8.8 (4.6)	8.7 (4.4)	-0.1	0.75
	Hip flexion/extension, right†	8.2 (4.5)	8.5 (5.2)	0.3	0.33
	Knee flexion/extension, left	11.5 (3.1)	11.5 (3.0)	0.0	0.98
	Knee flexion/extension, right†	12.0 (6.3)	12.6 (6.9)	0.6	0.12
	Ankle dorsiflexion/plantarflexion, left	10.2 (4.3)	10.4 (4.0)	0.2	0.43
	Ankle dorsiflexion/plantarflexion, right	9.7 (4.4)	10.1 (4.1)	0.4	0.28
Frontal	Pelvic obliquity	2.6 (0.9)	2.7 (1.0)	0.1	0.54
	Hip adduction/abduction, left	3.8 (1.4)	4.1 (1.4)	0.3	0.25
	Hip adduction/abduction, right	3.8 (1.7)	3.8 (1.8)	0.0	1.00
Transverse	Pelvic internal/external rotation†	4.2 (2.2)	4.0 (2.5)	0.0	0.04
	Hip internal/external rotation, left†	9.3 (5.5)	10.0 (5.0)	0.7	0.46
	Hip internal/external rotation, right†	7.5 (4.2)	7.4 (3.4)	-0.1	0.77
	Foot progression, left	7.6 (3.2)	7.6 (3.3)	0.0	0.90
	Foot progression, right†	6.8 (3.2)	6.9 (3.7)	0.1	0.90

P-value from paired t-test, †non-normal distribution: p-value calculated from log transformed data. Diff=Difference=Session 2-Session 1. SD=standard deviation

Inter-session reliability results are presented in Table 8. ICCs for most GVSs were very high (≥0.90), with 95% CI widths ≤0.25, except for left knee flexion/extension (high correlation) and hip rotation (moderate correlation). All SEM values were <3.8°, with the majority being <1°, except for left knee flexion/extension and hip rotation (Table 8). MDCs were <2.6° with the exception of left knee flexion/extension and hip rotation (Table 8).

Table 8. *Inter-session reliability results for Gait Variable Score based on five trials from each of the two sessions in 15 subjects with incomplete spinal cord injury*

Plane	**Gait Variable Score**	**ICC (2,k)**			**SEM (°)**	**MDC (°)**
		ICC	95% CI			
Sagittal	Pelvic tilt*	**0.95**	0.84	0.98	**0.6**	**1.6**
	Hip flexion/extension, left	**0.99**	0.98	1.00	**0.6**	**1.6**
	Hip flexion/extension, right*	**0.99**	0.96	1.00	**0.9**	**2.5**
	Knee flexion/extension, left	**0.83**	0.48	0.94	**1.7**	**4.6**
	Knee flexion/extension, right*	**0.99**	0.95	1.00	**0.8**	**2.3**
	Ankle dorsiflexion/plantarflexion, left	**0.98**	0.93	0.99	**0.9**	**2.6**
	Ankle dorsiflexion/plantarflexion, right	**0.98**	0.95	1.00	**0.8**	**2.1**
Frontal	Pelvic obliquity	**0.93**	0.79	0.98	**0.3**	**1.0**
	Hip adduction/abduction, left	**0.90**	0.72	0.97	**0.6**	**1.6**
	Hip adduction/abduction, right	**0.97**	0.92	0.99	**0.4**	**1.2**
Transverse	Pelvic internal/external rotation*	**0.98**	0.92	0.99	**0.4**	**1.0**
	Hip internal/external rotation, left*	**0.64**	-0.08	0.88	**3.7**	**10.2**
	Hip internal/external rotation, right*	**0.50**	-0.59	0.84	**2.7**	**7.4**
	Foot progression, left	**0.98**	0.94	0.99	**0.7**	**1.9**
	Foot progression, right*	**0.96**	0.89	0.99	**0.8**	**2.3**

ICC (2,k)= intraclass correlation coefficient (2,k), 95% CI= 95% confidence intervals for ICCs, SEM=standard error of measurement, MDC=minimal detectable change, *=ICC calculated from log transformed data

Bland-Altman plots with 95% LOA for knee flexion/extension and hip rotation are shown in Figure 15. The remaining plots are presented in Appendix 9, Figure 17, Figure 18 and Figure 19. Bland-Altman 95% LOA demonstrated that the mean difference between the two sessions were ≤0.7°, and the SD of the differences were <5.3°, except for left knee flexion/extension and hip rotation (Figure 15). The lowest 95% LOA range was -1.1° to 0.9° (pelvic obliquity), and the highest range was -11.0° to 9.7° (left hip rotation) (Appendix 9, Table 12). No obvious systematic errors could be observed in the Bland-Altman plots (Figure 15 and Appendix 9). For pelvic rotation and right hip flexion/extension, the plots showed a tendency toward an increased difference between the two sessions with an increasing mean (Appendix 9, Figure 19 and Figure 17, respectively). In contrast, a tendency toward a decreased difference between the two sessions with an increasing mean was observed for pelvic tilt (Appendix 9, Figure 17).

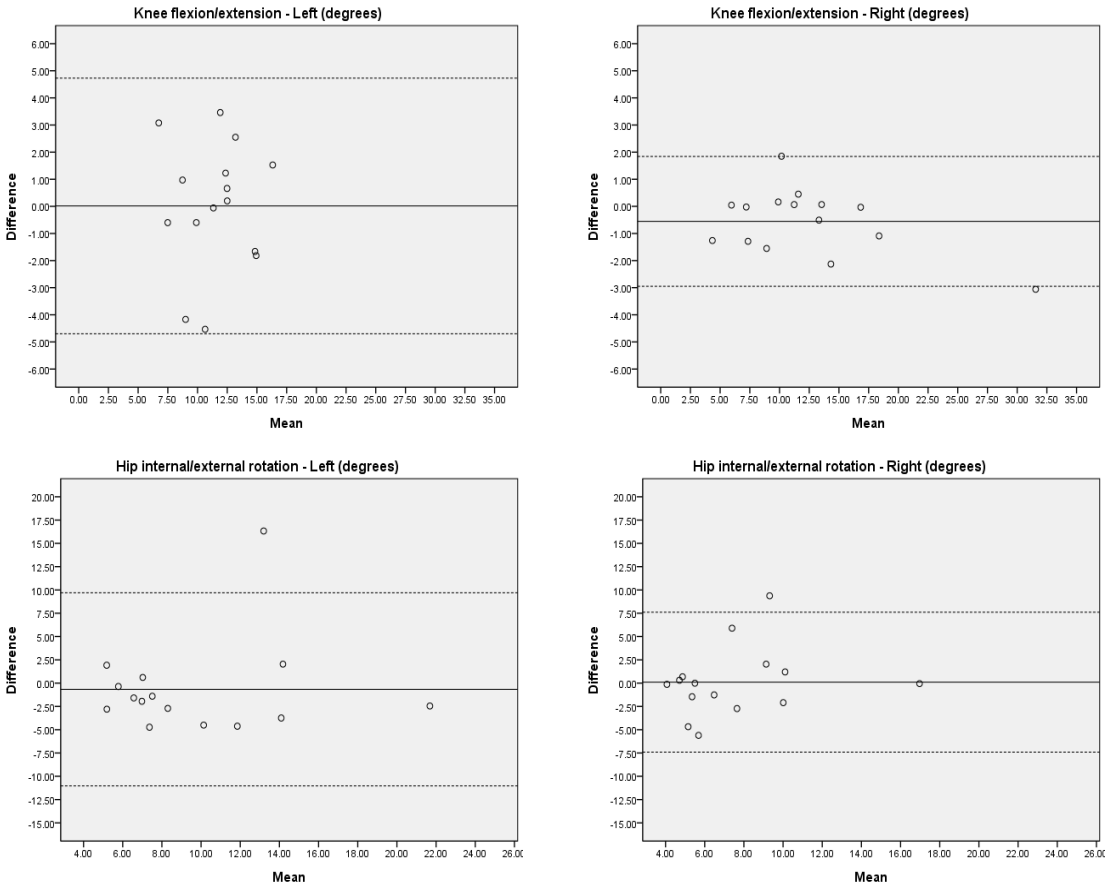


Figure 15. *Bland-Altman plots with 95% limits of agreement (dotted lines) based on 15 subjects with incomplete spinal cord injury. The first row represents knee in sagittal plane, the second row the hip in transverse plane. Solid line=mean difference between Session 1 and 2*

To summarize, inter-session reliability was high for both GPSs and GVSs, except for left and right hip rotation, which demonstrated moderate reliability.

5. Discussion

The aims of the present study were to investigate intra- and inter-session reliability of kinematic variables in 3D gait analysis in adults with acquired incomplete SCI (AIS-D), and to estimate the changes required to exceed measurement errors for kinematic variables in this study group. A total of 15 subjects participated in 3D gait analyses on two separate days. Five trials from each session were included in the analysis.

In general, the results demonstrated high or very high inter- and intra-session reliability for the Gait Profile Scores (GPSs) and Gait Variable Scores (GVSs) with Intraclass correlation coefficients (ICCs) above 0.77, and Standard Error of Measurement (SEM) values below 1.4° (Table 3, Table 4, Table 6 and Table 8). The exceptions were left and right hip rotation showing moderate ICCs and SEM values ≤ 3.7°. Minimal Detectable Change (MDC) provides an indication of the smallest change that can be considered greater than the measurement error and were estimated for clinical purposes. Values obtained for this measure were below 4.7° for GPSs and GVSs, except for left and right hip rotation (Table 8). These findings indicated only a small trial-to-trial and day-to-day variations of gait kinematics in the study group, and except for hip rotation, only small changes were required to exceed measurement errors.

5.1. Reliability of 3D gait analysis

5.1.1. Inter-session

Hip

In the present study, inter-session reliability for hip rotation in the transverse plane exhibited moderate ICCs and relatively high SEM values (Table 8). These results are supported by several other studies investigating reliability of 3D gait analysis in populations with and without gait pathology. ICCs and SEM values in our study were similar to those for hip rotation in a population with cervical spondylotic myelopathy (McDermott et al., 2010). Although Klejman et al. (2010), examining reliability of discrete gait parameters in children with cerebral palsy, observed a higher mean ICC (0.88) for hip rotation than in the present study, their SEM values were high (≤7°) for hip rotation in the transverse plane. The same moderate ICC (0.62) for hip rotation was

also observed by Cathy et al. (2009) in adults with stroke and in the review by McGinley et al. (2009).

According to Monaghan et al. (2007), two of the recognised errors in 3D gait analyses are marker placement and relative skin/marker movement error. The moderate reliability for hip rotation in the present study was probably due to placement of the thigh wand markers. Because of the wands, these markers had to be realigned in the second session. Subjective palpation to position the thigh wand markers was difficult, but necessary, when using the Plug-in gait (PiG) model (Stief, Böhm, Michel, Schwirtz, & Döderlein, 2013). The assessors were dependent on defining the hip joint centre and the flexion/extension axis of the knee joint before adjusting the wand marker to find the plane of the thigh segment. Baker and Rodda (2003) investigated the consequences of misplacing markers in the conventional gait model by 5 to 15 mm. Misplacing of the thigh marker, either forwards or backwards with 5 mm, affected hip rotation with 2.8°.

The mean body mass index (BMI) among our subjects was >25 (Table 1), which implied that the group was overweight according to World Health Organization (2011a). Adipose tissue may present difficulties in palpating the anatomical landmarks for the marker placements. In addition, excessive motions of the skin-mounted markers relative to the underlying bone may cause errors in determination of the segment coordinate system axes (Growney, Meglan, Johnson, Cahalan, & An, 1997).

Muscle tone is known to be a changing phenomenon (Domholdt, 2005a), and a possible explanation for the moderate inter-session reliability for hip rotation was that changes in muscle tone may induce changes in hip rotation (Perry & Burnfield, 2010g). Based on the study group characteristics (Table 1), only three subjects (20%) showed increased muscle tone around the hips. However, muscle tone may appear different in walking than tested passively in a supine position.

One may also assume that the thigh wand markers were more easily exposed to touch from the subjects leading to changes in the positions between trials. However, this would also have caused a low intra-session reliability result for this variable, which was not the case in our study (Table 4).

Knee

Variables in the sagittal plane demonstrated very high reliability, except for left knee flexion/extension with moderate ICC (0.83) and SEM of 1.7° (Table 8). Whereas the SEM value was lower, the ICC was within the range obtained in previous studies reporting reliability of knee flexion/extension in the sagittal plane (Klejman et al., 2010; McDermott et al., 2010; Robbins et al., 2013; Weider, 2010; Fortin et al., 2008; Laroche et al., 2011; Caty et al., 2009; McGinley et al., 2009). Interestingly, we found a difference in the kinematics and reliability between the left and the right knee (Table 8, Figure 13 and Figure 14). This was possibly due to a random variation in our study group and would not be expected in a larger study group. Except for a slightly larger range of AIS motor scores in the right leg compared to the left (Table 1), no obvious reason for the difference between the two legs could be observed from the study group characteristics.

Marker misplacement of both the thigh and knee markers can affect the motion observed in knee flexion/extension (Baker & Rodda, 2003). However, this possibility did not explain the difference in reliability between the two legs. Similar to inter-session variation observed for hip rotation, the variation observed for the knee could be caused by intrinsic changes in the subjects' gait, either due to natural or pathological causes, such as increased muscle tone, muscle weakness or impaired balance. For instance, increased muscle tone in the hamstring muscle will affect knee extension at stance phase (Perry & Burnfield, 2010i). Increased muscle tone was more pronounced around the knee than around the hip among our subjects (Table 1). Similar to the description of the SCI gait pattern in the literature (section 2.3.4), our study group showed increased knee flexion throughout the stance phase and decreased knee flexion at swing phase, being more pronounced in the right leg (Figure 14). In individuals with SCI, providing weight support and balance during walking will significantly reduce the amount of knee flexion at foot contact and for most of the stance phase (Visintin & Barbeau, 1989). Thus, keeping the knee in a more flexed position may be part of a strategy to enhance their balance during stance.

The right knee flexion/extension showed greater deviation than the left knee compared to the reference group without gait pathology (Figure 13), suggesting a higher degree of pathology in the right knee than in the left. It may be noted that pathological gait not necessarily leads to lower reliability, as pathology caused by SCI could induce

stereotypical movements and hence less variability. Somatosensory information is important for the production of a stable inter-segmental coordination pattern (Buchanan & Horak, 2001). Possibly, a higher degree of somatosensory pathology causes the central nervous system to suppress the degrees of freedom in the knee joint, thus making the knee more stable to maintain the subject's balance when walking (Buchanan & Horak, 2001; Di Giulio, Baltzopoulos, Managanaris, & Loram, 2013).

Pelvic

Compared with previous reliability studies (McGinley et al., 2009; Laroche et al., 2011; Klejman et al., 2010; McDermott et al., 2010; Caty et al., 2009), our inter-session reliability results for pelvic variables were higher (Table 4 and Table 8). The reason for this was probably due to precise positioning of the markers between the two sessions. However, it may also be due to a more stereotypical movement pattern as discussed above.

Gait speed

Gait speed is known to influence kinematic variables (Shimada et al., 2006; Bejek et al., 2006; Røislien et al., 2009). No statistically significant difference was found between the two sessions, either for gait speed or step length (Table 2). Hence, inter-session kinematic variations obtained for hip rotations and left knee flexion/extension cannot be attributed to changes in gait speed or step length.

5.1.2. Intra-session

All GPSs and most of the GVSs demonstrated very high ICCs and SEM values below 1° (Table 3 and Table 4). The remaining GVSs for left knee flexion/extension, pelvic rotation, left hip rotation and foot progression showed high ICCs (≥0.78) with SEM values ≤1.4°. As different marker positioning are less likely to affect intra-session results, the small variations obtained were probably due to intrinsic variation in the subjects' gait, for example fatigue due to many trials in one session, or pathology, such as changes in muscle tone, muscle weakness or impaired balance (Perry & Burnfield, 2010g; Perry & Burnfield, 2010i), discussed in section 5.1.1. Exact conclusions cannot be drawn from the study group characteristics, as these factors were not investigated in detail or not at all, e.g. balance.

Another reason for the intra-session variation the knee flexion/extension, may occur from the possible contact of the subjects with their thigh marker between the trials, as discussed in section 5.1.1., but this would probably also have affected the intra-session results for hip rotation, which was not apparent (Table 4).

Gait Speed

Statistically significant differences between trials were obtained for both gait speed (Session 1: F=2.92, p=0.029, Session 2: F=5.24, p=0.001) and step length of the left leg (Session 1: F=3.761, p=0.009). However, the difference between the trials was no more than 5 cm/sec for gait speed and 3 cm for step length. It may also be questioned whether these changes, although statistically significant, were of clinical relevance and had an impact on the kinematic variables.

5.1.3. Intra-session versus inter-session

It was expected that intra-session reliability should be better than inter-session reliability as differences in marker placement within a session were less likely to be an issue (Gorton III et al., 2009). In our study, intra- and inter-session reliability were almost similar (Table 3 versus Table 6, and Table 4 versus Table 8), probably due to the fact that we tried to reduce the experimental errors as much as possible in order to investigate the true variation of gait among the SCI subjects. Although marker placement was controlled for by using permanent ink and tapes of equal size, minor differences in the alignment between the two days were still possible. This was definitely true for the wand markers, which had to be repositioned in the second session for all subjects.

5.1.4. Clinical interpretation

In the present study, SEM values were not interpreted according to predefined levels of reliability. The reason for this was that each joint and plane of motion had to be considered separately, because the level of measurement error must be compared to the total range of movement (Monaghan et al., 2007).

In their systematic review, McGinley et al. (2009) noted that a measurement error of 2° or less is acceptable in most common clinical situations, and that such errors are too small to require explicit consideration in interpretation of the data. They also stated that errors between 2° and 5° are reasonable, but may require consideration in the data interpretation, and that errors above 5° may be large enough to mislead clinical interpretation and should raise concern. Our error estimates for intra- and inter-session results of GPS and GVS were well below 2°, except for inter-session reliability of left and right hip rotation, which were below 3.8° (Table 8). This was also reflected in the MDC values, which were based on SEM (section 2.4.2). The MDC values were below 5°, except for rotation of left and right hip, which were high (≤10.2°) (Table 8). Thus, our results suggested that hip rotation should be evaluated with caution.

5.2. Methodological considerations

5.2.1. Study design

According to Scholtes et al. (2011), the test-retest reliability evaluates reliability across different times, and the timing of the second test (retest) is therefore essential. The time interval should be small enough so that the subject has had no real change in-between, but should also be so far apart to minimise bias effects such as recollection and fatigue (Scholtes et al., 2011). The time interval in 3D gait analysis reliability studies, similar to the present study, varies from two hours to several months (Robbins et al., 2013; Noonan et al., 2003; Yavuzer et al., 2008). The test-retest in our study was performed one or two days apart. Ideally, the same time interval should be used for all subjects, but this was not possible due to the subjects' planned schedule at the hospital. The test sessions for each subject, however, were performed at the same time of the day.

Evidence suggests that increasing the number of trials analysed improves reliability (Monaghan et al., 2007; Diss, 2001). For each subject, five trials from each session were included in our study. The high number of trials performed by some of the subjects in order to achieve five qualified trials, may possibly have affected the results. However, the subjects with the highest number of trials did not seem to show more variations of the different variables between the sessions than the others.

Fritz and Wainner (2001) claim that the best method to ensure a representative sample and avoid spectrum bias, is to utilize a prospective cohort design with a consecutive group of subjects from a clinical population. In our study, subjects, who fulfilled the study criteria, were consecutively recruited at Sunnaas Rehabilitation Hospital.

5.2.2. Study group

A comparison of reliability results between studies is not possible, regardless of the reliability tests selected, unless the size and characteristics of the study groups are virtually identical (Rankin & Stokes, 1998). McGinley et al. (2009) claim that adequate description of the subjects and sampling method are necessary, as it allows insight into generalisation to other populations and ensures that the range of characteristics of interest in a clinical population is represented in the study group. The subjects in our study were described by gender, age, BMI, neurological level and completeness of injury, time since injury, cause of injury and functional abilities, such as AIS motor score, muscle tone, reduced range of motion and walking abilities (TUG and WISCI II) (Table 1). Therefore, one of the strengths of our study was the possibility to evaluate the representativeness of the subjects, and thus the ability to generalize the results.

SCI

It has been recommended that the study population should include subjects who are representative of the population for whom the test is used clinically, and that the subjects should reflect a continuum of severity from mild to severe (Fritz & Wainner, 2001; Lijmer JG, 1999). To be certain that all subjects were able to complete the testing protocol, only subjects diagnosed with SCI AIS-D were included. Hence, subjects diagnosed with AIS-C were not included, even though they may be able to walk (section 2.1.2) and therefore candidates for 3D gait analysis. However, our group of AIS-D subjects showed a fairly wide range of walking and functional abilities, thus both mild and more severely impaired subjects were represented (Table 1). For example, WISCI II results ranged from 12 to 20, indicating that one subject walked with two crutches and a brace and others walked without devices or braces.

Seven of the 15 subjects (47%) had a cervical injury (Table 1), which is consistent with slightly more than 50% of the SCI population in previous studies (Jackson, Dijkers,

DeVivo, & Poczatek, 2004; Hagen, Eide, Rekand, Gilhus, & Gronning, 2010). Eight subjects (56%) suffered from traumatic SCI, which corresponded roughly to the proportion of traumatic and non-traumatic injuries in the SCI population in Norway (Landsforeningen for Ryggmargsskadde, 2012a). The causes of injury also seemed to be representative of the SCI population, with falls and transport activities being the major causes (Hagen et al., 2010; Jackson et al., 2004).

Gender

Four of the 15 subjects (27%) in our study were females (Table 1), which was similar to the female/male ratio reported for individuals with SCI, being approximately 1:4 (Helsedirektoratet, 2009; Jackson et al., 2004). In addition, the ratio in our study represented the ratio for in-patients with SCI at Sunnaas Rehabilitation Hospital over the last few years (personal communication – Siv Anita Horn, Quality Advisor, Sunnaas Rehabilitation Hospital).

Age

The age range in our study was 18 to 65 years. The lower limit was set to avoid variability in the 3D gait analysis data which can arise when testing children (Stolze, Kuhtz-Buschbeck, Mondwurf, Jöhnk, & Friege, 1998). The upper age limit was set to reduce additional injuries and/or diseases that might arise in an elderly population. The mean age of our subjects was 46 years, and the median time since injury was three years (Table 1), which corresponded to the average age at time of injury (43 years) of individuals with SCI admitted to Sunnaas Rehabilitation Hospital (personal communication – Siv Anita Horn, Quality Advisor, Sunnaas Rehabilitation Hospital).

BMI

The mean BMI was 27.1 (SD±4.9), and nine of the subjects (60%) had a BMI >25 (Table 1). These data implied that the study group represented the Norwegian population of whom 42% have a BMI ≥ 25 (World Health Organization, 2011b). However, these data also suggested possible difficulties in palpating the anatomical landmarks used for marker placement because of adipose tissue as discussed previously in section 5.1.1.

Muscle tone

Seven of the 15 subjects (47%) were assessed by the Modified Ashworth Scale (MAS) to have increased muscle tone in the lower limbs (Table 1). The prevalence of increased muscle tone in individuals with SCI shows a range from 65% to 78% (Sköld et al., 1999; Maynard, Karunas, & Waring, III, 1990). Although MAS is a commonly used method to assess muscle tone in individuals with SCI, and of good clinical utility (Hsieh et al., 2007), it is not recommended as a single outcome measure for muscle tone (Fleuren et al., 2010). A single clinical assessment will not necessarily reflect a subject's overall level of muscle tone in an accurate manner, because the level of muscle tone varies over time (Steeves et al., 2006). Another restriction is that MAS only addresses the velocity-dependent aspect of muscle tone across a single joint (Hsieh et al., 2007) in a supine position. In addition, biomechanical changes in muscles and joints are hard to differentiate from changes in muscle tone (Fleuren et al., 2010). Therefore, a limitation of our study was the use of only one measure of muscle tone.

Passive range of motion

Passive range of joint motion (Table 1) was assessed with a goniometer, which was part of the assessment of individuals with SCI at the hospital. However, the procedure was not standardized in our study, e.g. the level of pressure applied to the limbs and the position of the subject during assessment. These factors also set a limitation to our study. In addition, inter-assessor reliability for passive range of motion in the lower limbs is generally low (van Trijffel, van de Pol, Oostendorp, & Lucas, 2010), and there is, to our knowledge, not a specific definition in SCI individuals, as the level of restriction in one joint before a reduced range of motion is specified. The limit of 20°, used in our study, may have different impacts depending on the joint and motion assessed. For instance, a 20° reduction of dorsiflexion of the ankle was likely to have more impact on walking than a 20° reduction of knee flexion, because of the total range of motion needed for normal walking.

Walking ability

As noted in section 3.5.3 and Table 1, five subjects (33%) used walking devices, shoes or braces, which may have affected the gait. To reduce experimental errors, the markers were placed according to the NVUG guidelines for marker placement when braces or shoes are used (Nordic Vicon User Group, 2013). Although the same type of

device/brace and shoes were used in both sessions with the same marker placement on the shoes/braces, differences in lacing/securing the shoes/braces between the sessions may have occurred. In addition, some movement of the leg/foot inside the brace/shoe may have taken place which was not analyzed. When markers are placed on a brace/shoe rather than on the skin, it is the motion of the brace/shoe in relation to the joint proximal to it that is captured, and not the motion of the limb (Nordic Vicon User Group, 2013). Many individuals with SCI are in need of walking devices, braces and/or shoes to walk, and it is recommended that reliability of 3D gait analysis should be investigated also for subjects using braces (McGinley et al., 2009). It was therefore decided to include such individuals in our sample. A closer examination of the Bland-Altman plots revealed that the two subjects walking with shoes, brace and crutch(es) often showed up as outliers in the plots. However, the study was not powered to investigate differences of subgroups such as with or without walking devices.

5.2.3. Outcome measures

GPS and GVS were selected as outcome measures because they capture the whole gait cycle, instead of discrete gait variables which may be less informative. The benefit of GPS, compared with other gait indices, is that it readily provides an overview of individual gait variables in the Movement Analysis Profile (MAP) (Beynon et al., 2010) and is reported in degrees, making it easy to interpret.

GPS and GVS correspond well with clinicians' rating of kinematic gait deviations (Beynon et al., 2010). However, the outcome measures have some limitations, as individual gait scores do not indicate timing or direction of the gait deviation, and the scores are not scaled (Beynon et al., 2010). For instance, a 10° deviation in the hip does not have the same clinical significance as a 10° deviation in the knee (Beynon et al., 2010).

GPS was recently developed (Baker et al., 2009) and has since been used as an outcome measure in studies of different populations with gait pathology, such as in children and adults with cerebral palsy (Rutz, Passmore, Baker, & Graham, 2012; Rutz, Donath, Tirosh, Graham, & Baker, 2013; Rutz et al., 2011; Opheim, McGinley, Olsson, Stanghelle, & Jahnsen, 2013; Thomason, Selber, & Graham, 2013) and in adults with amputation (Kark et al., 2012). It has not yet been used as an outcome measure in a SCI

population, nor has it been used in reliability studies of 3D gait analysis. Therefore, it is difficult to compare the results of the present study with other similar studies.

5.2.4. Assessors

Differences in marker placement are recognised as the major source of error in 3D gait analysis (Gorton III et al., 2009; Chambers & Goode, 1996; Kadaba et al., 1989; McGinley et al., 2009). The use of landmark specific models, such as the PiG model, requires specialised skills of the staff, including accurate and consistent placement of markers, and expert knowledge of the underlying biomechanical model (McGinley et al., 2009). Description of the assessors is therefore important, e.g. how were they recruited, their professional background and experience (McGinley et al., 2009).

In our study, the four assessors, working in pairs, were selected for practical reasons and their profession and experience were described in section 3.5.1. In similar studies the number of assessors varied from one to three (Robbins et al., 2013; Klejman et al., 2010).

The three experienced assessors in our study had previously participated in a 3D gait analysis study of inter-assessor reliability in adults with no gait pathology, which showed good reliability (Rennie, 2008). The assessors were not blinded in our study, because the emphasis was to investigate subject variation. The possible influence of the assessors on the results was minimised as they did not take part in the data processing, which was performed by the research coordinator. The research coordinator was present at all the test sessions but had little to no influence on the subjects' performance.

In addition, six other assessors, who were the subjects' regular physiotherapists at the hospital, participated in the collection of study group characteristics in order to minimise the number of tests performed on the subjects during their hospital stay. In hindsight, it was obvious that this number of physiotherapists led to increased variation in some assessments despite both oral and written information to the physiotherapists prior to the study.

5.2.5. 3D gait analysis instruments

Description of the protocol and the model used are essential factors in reporting 3D gait analysis reliability studies (McGinley et al., 2009), and from our descriptions it should be possible to replicate the study. The protocol was similar to the one normally used at the Motion Analysis Laboratory at the hospital, and developed on the basis of recommendations from NVUG (Nordic Vicon User Group, 2013) and from the manufacturer (Vicon Motion Systems, Oxford, UK).

Measurement errors in 3D gait analysis can also occur from the system itself, and they are affected by number of cameras and resolution, data collection frequencies and calibration procedures, to name a few. However, in previous studies, only minimal variability (around 2%) has been attributed to the system accuracy (Chambers & Goode, 1996; Gorton III et al., 2009). This accuracy is generally limited by the accuracy of determining the marker positions which is estimated to be in the order of 1 mm (Baker, 2006). In our study, the position of the infrared cameras and the force plates were calibrated before each test session, following the strict quality control guidelines from the manufacturer.

The conventional gait model (PiG), is commonly used in 3D gait analysis (Kirtley, 2006) and is based on several assumptions and simplifications of the human body and its movements (Kirtley, 2006; Schwartz et al., 2004; Davis III, Õunpuu, Tyburski, & Gage, 1991; Baker & Rodda, 2003). Only a few and the most relevant ones are discussed in this thesis. First, determination of joint centres, especially the hip joint centre, was difficult and based on some assumptions. The joint centre was calculated relative to the position of the anterior superior iliac spines and the width of the pelvis. Secondly, the motion of the knee joint was simplified as the position between the thigh and the lower leg segments is assumed to be fixed (section 2.3.2). Hence, the anterior/posterior glide of the femur on the tibial plateau was not accounted for in the model (Baker & Rodda, 2003). Thirdly, the foot was only represented with a vector line in the PiG model (section 2.3.2). Pronation and supination of the foot were not analysed, and information about foot kinematics may be lost. Fourthly, rotation of the femoral and tibial segments depended on the thigh and tibial wand markers. Their position were based on subjective decisions by the assessors using palpation and visual assessment to define the joint centres and the axis of motion as noted previously (section 5.1.1). Fifthly, the model is hierarchical, implying that errors propagated from

proximal to distal (Schwartz et al., 2004), i.e. errors in the pelvic angles may have generated errors in the hip, knee and ankles angles. In addition, pelvic and foot progression angles were absolute angles with reference to the fixed laboratory coordinate system, whereas the angles of hip, knee and ankle were relative angles with reference to the more proximal joint (Davis III et al., 1991). All these assumptions and simplifications of the conventional gait model were likely to affect the accuracy of the 3D gait analysis.

5.2.6. Data processing

3D gait analysis produces a vast amount of data. As only the research coordinator was involved in the data processing, the data may possibly have been processed wrongly by mistake. In an attempt to reduce this risk, all data were checked twice by the research coordinator, whereas the gait cycle events were checked by a member of the Motion Analysis Laboratory staff as noted in section 3.5.4.

5.2.7. Sample size

The number of subjects included in similar studies varies from 10 to 40 (Mackey et al., 2005; Steinwender et al., 2000). The reason behind our sample size of 15 subjects is previously described in section 3.7.

The sample size in our study was small and the results should be regarded as trends rather than strictly conclusive. It was not possible to estimate reliability for subgroups, such as tetraplegia versus paraplegia, males versus females or those with braces versus those without because of the small sample size. It was also too small to allow for accurate calculations of Bland-Altman 95% limits of agreement (LOA) (Rankin & Stokes, 1998).

5.2.8. Statistical analyses

ICC is frequently used when reporting reliability of 3D gait analysis (McGinley et al., 2009). There are at least six different equations for calculating the ICC (Atkinson & Nevill, 1998; Portney & Watkins, 2009b; Weir, 2005). The equations are differentiated

by the type of measurement, the study design and the purpose of the reliability study (Portney & Watkins, 2009b). It is recommended that researchers should describe the ICC equation used in detail and the reasons behind the choice (Atkinson & Nevill, 1998). As there is no consensus of a 'cut-off' point of ICC to which a measurement has good reliability or not, it is also recommended to calculate CI for a given ICC (Atkinson & Nevill, 1998; Morrow, Jr. & Jackson, 1993; Atkinson & Nevill, 1998). In our study, intra-session and inter-session reliability were calculated by equation ICC (2,1) and ICC (2,k), respectively, as described in section 3.8. Model 2, a random effect model, was used as both subjects and assessors were considered to be randomly chosen from a larger population. Rankin and Stokes (1998) and Weir (2005) state that if the aim is general application in clinical practice or research trials, this model is appropriate. It was desirable to be able to generalise the results beyond the confines of this study.

The ICC were interpreted according to Domholdt (2005b). It has been suggested that for many clinical measures, reliability should exceed 0.90 (Portney & Watkins, 2009b). Even with this level of correlation, our results showed high reliability with the exception of hip rotation and left knee flexion/extension (Table 8).

The advantage of ICC is that a single reliability coefficient is easily understood (Rankin & Stokes, 1998). One of the disadvantages of ICC is the effect by the magnitude of between-subject variation (Rankin & Stokes, 1998). If subjects differ little from each other, ICC will be small, even if trial-to-trial variability is small and vice versa (Weir, 2005; Rankin & Stokes, 1998). Thus, ICC is closely related to the context. Other disadvantages are the potential to oversimplify the results if ICC is quoted without context, the selection of the wrong equation, the lack of actual measurement values or ranges, bias in the measurements and that ICC cannot be interpreted clinically (Rankin & Stokes, 1998).

Because ICC is difficult to interpret clinically, it is recommended that ICC should be complemented by calculations of SEM or Bland-Altman 95% limits of agreement (LOA) (Rankin & Stokes, 1998). Thus, we used a combination of relative (ICC) and absolute (SEM and Bland-Altman 95% LOA) reliability measures.

Measures of ICC depend on the homogeneity of the study population, but not so for measures of SEM. Thus, in a homogeneous population, ICCs might be low and SEM high, whereas in a heterogeneous population, the ICC and SEM values may correlate

better (De Vet, 2005). For inter-session results in our study the ICCs corresponded well with the SEM values for all variables (Table 6 and Table 8). The intra-session results, in contrast, showed a disparity between the ICC and SEM values for right knee flexion/extension, pelvic rotation, and left hip rotation (Table 4). Right knee flexion/extension and left hip rotation demonstrated very high ICCs, but also relatively high SEM values. In each session, SD for these variables was relatively high compared with the other variables. This could be due to a greater variation, making it easier to distinguish the subjects from each other (heterogeneous group), and resulting in a higher ICC. For pelvic rotation, the opposite may be true. A small range of pelvic rotation during walking (section 2.3.3) could make it difficult to distinguish between subjects, thus causing a lower ICC.

The advantage of the Bland-Altman plot is its visual interpretation. It is easy to see size and range of differences in measurements, any bias or outliers, or relation between the size of differences with the size of the mean (Rankin & Stokes, 1998; De Vet, 2005). Other benefits are that the errors are expressed in terms of the measurement scale, which enable direct clinical interpretation of the results (De Vet, 2005), and that the plot is independent of between-subject variation (Rankin & Stokes, 1998). The disadvantage of the Bland-Altman 95% LOA, used in our study, was the recommendation of a sample size of at least 50 subjects to avoid very wide limits (Rankin & Stokes, 1998). Bland-Altman 95% LOA was reported for all variables in our study, but the values were all greater than the corresponding SEM values (Appendix 8 and Appendix 9, and Table 6 and Table 8). A number of outliers, observed for some of the variables, may have contributed to a large SD of the difference and a wider 95% LOA. The effect of the outliers may probably be reduced in a larger study group.

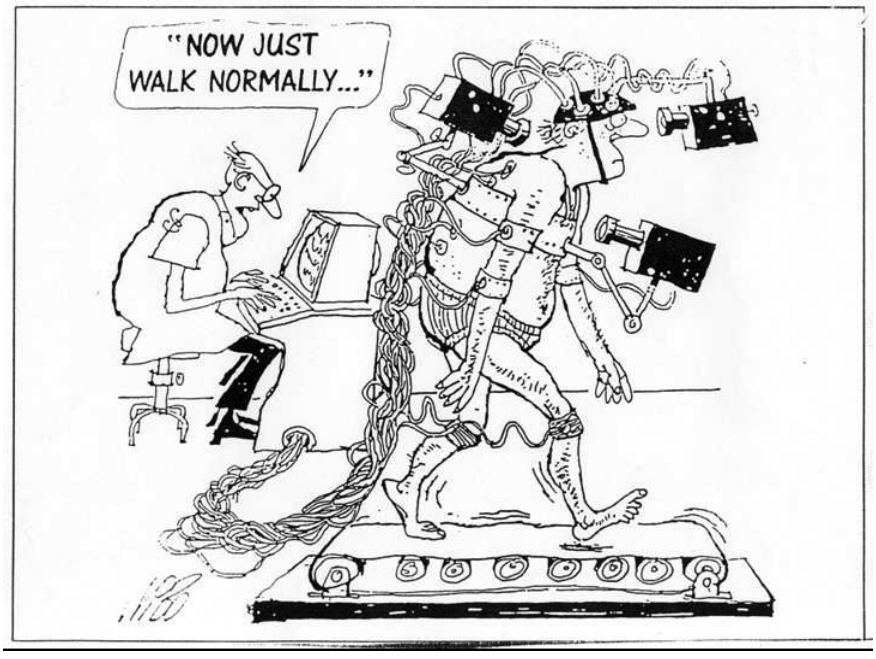
MDC is easy to generate because it requires no additional data other than SEM. In addition, it can serve as an important adjunct for estimating reliable changes in a wide variety of tests and measures (Haley & Fragala-Pinkham, 2006). However, its interpretation is limited because it assumes that detectable changes are uniform at any point along the scale (Haley & Fragala-Pinkham, 2006). MDC does not provide a good indication of the importance of the observed change (De Vet et al., 2006; Gatchel et al., 2010). Our results indicated that a relatively small change ($\leq 4.7°$) was necessary to exceed measurement errors for both GPSs and GVSs, except for hip rotation which demonstrated a larger MDC value (Table 6 and Table 8).

6. Conclusion

This study investigated intra- and inter-session reliability of kinematic variables in 3D gait analysis in 15 adults with acquired incomplete SCI (AIS-D). We also sought to estimate the changes required to exceed measurement errors for the kinematic variables. Except for inter-session reliability of hip rotation, the results showed very high or high intra- and inter-session reliability. The demonstration of only a small trial-to-trial and day-to-day variability of gait in this study group suggested that 3D gait analysis is a reliable measure for adults with SCI (AIS-D). However, caution is recommended for hip rotation evaluation. With the exception of hip rotation, the results also showed that only small changes were required to exceed measurement error for the kinematic variables. These findings may be clinically relevant for the evaluation of gait impairment in these individuals.

Estimates from a reliability study will generally underestimate variability in a routine clinical assessment. The sample size in this study was also small and rather than drawing strict conclusions, the results should be regarded as trends.

Only kinematic variables were investigated, and future studies should aim to analyse also kinetic variables in SCI individuals, responsiveness and sensitivity to change, and subgroups of the SCI population, such as different levels of injury, AIS-C versus AIS-D, and males versus females.



Reference list

Albert, T. & Ravaud, J. F. (2005). Rehabilitation of spinal cord injury in France: a nationwide multicentre study of incidence and regional disparities. *Spinal Cord, 43,* 357-365.

American Spinal Injury Association (2011). *International Standars for Neurological Classification of Spinal Cord Injury*. Atlanta: American Spinal Injury Association.

Atkinson, G. & Nevill, A. M. (1998). Statistical Methods For Assessing Measurement Error (Reliability) in Variables Relevant to Sports Medicine. *Sports Medicine, 26*.

Baker, R. (2006). Gait analysis methods in rehabilitation. *Journal of NeuroEngineering and Rehabilitation, 3,* 4.

Baker, R. (2013). The conventional gait model. In R.Baker (Ed.), *Measuring Walking: A Handbook of Clinical Gait Analysis* (1st ed., pp. 29-49). London: Mac Keith Press.

Baker, R., McGinley, J. L., Schwartz, M. H., Beynon, S., Rozumalski, A., Graham, H. K. et al. (2009). The Gait Profile Score and Movement Analysis Profile. *Gait & posture, 30,* 265-269.

Baker, R., McGinley, J. L., Schwartz, M., Thomason, P., Rodda, J., & Graham, H. K. (2012). The minimal clinically important difference for the Gait Profile Score. *Gait & posture, 35,* 612-615.

Baker, R. & Rodda, J. All you ever wanted to know about the Conventional Gait Model but were afraid to ask (CD-ROM). 2003.

Barbeau, H., Ladouceur, M., Norman, K. E., Pepin, A., & Leroux, A. (1999). Walking after spinal cord injury: Evaluation, treatment, and functional recovery. *Archives of Physical Medicine and Rehabilitation, 80,* 225-235.

Bejek, Z., Paróczai, R., Illyés, Á., & Kiss, R. (2006). The influence of walking speed on gait parameters in healthy people and in patients with osteoarthritis. *Knee Surg Sports Traumatol Arthr, 14,* 612-622.

Beynon, S., McGinley, J. L., Dobson, F., & Baker, R. (2010). Correlations of the Gait Profile Score and the Movement Analysis Profile relative to clinical judgments. *Gait & posture, 32,* 129-132.

Bland, J. M. & Altman, D. G. (1986). Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet, 1,* 307-310.

Bohannon, R. W. & Smith, M. B. (1987). Interrater Reliability of a Modified Ashworth Scale of Muscle Spasticity. *Physical Therapy, 67,* 206-207.

Bruton, A., Conway, J. H., & Holgate, S. T. (2000). Reliability: What is it, and how is it measured? *Physiotherapy, 86,* 94-99.

Buchanan, J. J. & Horak, F. B. (2001). Transitions in a postural task: do the recruitment and suppression of degrees of freedom stabilize posture? *Exp Brain Res, 139,* 482-494.

Burns, A. S., Delparte, J. J., Patrick, M., Marino, R. J., & Ditunno, J. F. (2011). The Reproducibility and Convergent Validity of the Walking Index for Spinal Cord Injury (WISCI) in Chronic Spinal Cord Injury. *Neurorehabilitation and Neural Repair, 25,* 149-157.

Caty, G. D., Detrembleur, C., Bleyenheuft, C., & Lejeune, T. M. (2009). Reliability of lower limb kinematics, mechanics and energetics during gait in patients after stroke. *J Rehabil Med, 41,* 588-590.

Chambers, C. & Goode, B. (1996). Variability in gait measurements across multiple sites. *Gait & posture, 4,* 167.

Davis III, R. B., Õunpuu, S., Tyburski, D., & Gage, J. R. (1991). A gait analysis data collection and reduction technique. *Human Movement Science, 10,* 575-587.

Davis, R. B. (2004). The motion analysis laboratory. In J.R.Gage (Ed.), *The Treatment of Gait Problems in Cerebral Palsy* (pp. 90-98). London: Mac Keith Press.

De Vet, H. (2005). Observer Reliability and Agreement. In *Encyclopedia of Biostatistics* (John Wiley & Sons, Ltd.

De Vet, H. C., Terwee, C. B., Ostelo, R. W., Beckerman, H., Knol, D. L., & Bouter, L. M. (2006). Minimal changes in health status questionnaires: distinction between minimally detectable change and minimally important change. *Health Qual Life Outcomes., 4,* 54.

de Vet, H. C. W., Terwee, C. B., & Bouter, L. M. (2003). Current challenges in clinimetrics. *Journal of Clinical Epidemiology, 56,* 1137-1141.

de Vet, H. C. W., Terwee, C. B., Knol, D. L., & Bouter, L. M. (2006). When to use agreement versus reliability measures. *Journal of Clinical Epidemiology, 59,* 1033-1039.

DeVivo, M., Biering-Sorensen, F., Charlifue, S., Noonan, V., Post, M., Stripling, T. et al. (2006). International Spinal Cord Injury Core Data Set. *Spinal Cord, 44,* 535-540.

DeVivo, M. J. & Chen, Y. (2011). Trends in New Injuries, Prevalent Cases, and Aging With Spinal Cord Injury. *Archives of Physical Medicine and Rehabilitation, 92,* 332-338.

Di Giulio, I., Baltzopoulos, V., Managanaris, C. N., & Loram, I. D. (2013). Human standing: does the control strategy pre-program a rigid knee? *Journal of Applied Physiology*.

Diss, C. E. (2001). The reliability of kinetic and kinematic variables used to analyse normal running gait. *Gait & posture, 14,* 98-103.

Ditunno, P. L. & Ditunno, J. F., Jr. (2001). Walking index for spinal cord injury (WISCI II): scale revision. *Spinal Cord, 39,* 654-656.

Ditunno, P. L., Patrick, M., Stineman, M., & Ditunno, J. F. (2008). Who wants to walk? Preferences for recovery after SCI: a longitudinal and cross-sectional study. *Spinal Cord, 46,* 500-506.

Domholdt, E. (2005a). Measurement Theory. In *Rehabilitation Research: Principles and Applications* (3rd ed., pp. 245-264). St. Louis: Elsevier Saunders.

Domholdt, E. (2005b). Statistical Analysis of Relationships: The Basics. In *Rehabilitation Research: Principles and Applications* (3rd ed., pp. 351-363). St Louis: Elsevier Saunders.

El Masri, W. & Kumar, N. (2011). Traumatic spinal cord injuries. *The Lancet, 377,* 972-974.

Eliasziw, M., Young, S. L., Woodbury, M. G., & Fryday-Field, K. (1994). Statistical Methodology for the Concurrent Assessment of Interrater and Intrarater Reliability: Using Goniometric Measurements as an Example. *Physical Therapy, 74,* 777-788.

Esquenazi, A. (2011). Assessment of Spasticity and Other Consequences of the Upper Motor Neuron Syndrome Affecting the Lower Limb. In A.Brashear & E. Elovic (Eds.), *Spasticity: Diagnosis and Management* (1st ed., pp. 81-90). New York: Demos Medical Publishing LLC.

Faude, O., Donath, L., Roth, R., Fricker, L., & Zahner, L. (2012). Reliability of gait parameters during treadmill walking in community-dwelling healthy seniors. *Gait & posture, 36,* 444-448.

Fleuren, J. F. M., Voerman, G. E., Erren-Wolters, C. V., Snoek, G. J., Rietman, J. S., Hermens, H. J. et al. (2010). Stop using the Ashworth Scale for the assessment of spasticity. *Journal of Neurology, Neurosurgery & Psychiatry, 81,* 46-52.

Fortin, C., Nadeau, S., & Labelle, H. (2008). Inter-trial and test-retest reliability of kinematic and kinetic gait parameters among subjects with adolescent idiopathic scoliosis. *Eur Spine J, 17,* 204-216.

Fritz, J. M. & Wainner, R. S. (2001). Examining Diagnostic Tests: An Evidence-Based Perspective. *Physical Therapy, 81,* 1546-1564.

Gatchel, R. J., Lurie, J. D., & Mayer, T. G. (2010). Minimal clinically important difference. *Spine (Phila Pa 1976.), 35,* 1739-1743.

Gorton III, G. E., Hebert, D. A., & Gannotti, M. E. (2009). Assessment of the kinematic variability among 12 motion analysis laboratories. *Gait & posture, 29,* 398-402.

Growney, E., Meglan, D., Johnson, M., Cahalan, T., & An, K. N. (1997). Repeated measures of adult normal walking using a video tracking system. *Gait & posture, 6,* 147-162.

Hagen, E. M., Eide, G. E., Rekand, T., Gilhus, N. E., & Gronning, M. (2010). A 50-year follow-up of the incidence of traumatic spinal cord injuries in Western Norway. *Spinal Cord, 48,* 313-318.

Haley, S. M. & Fragala-Pinkham, M. A. (2006). Interpreting Change Scores of Tests and Measures Used in Physical Therapy. *Physical Therapy, 86,* 735-743.

Harvey, L. A. (2008). Background information. In *Management of Spinal Cord Injuries: A guide for physiotherapists* (1st ed., pp. 4-33). London: Butterworth-Heinemann Elsevier.

Helsedirektoratet (2009). Aktivitetshåndboken - fysisk aktivitet i forebygging og behandling. http://www.helsedirektoratet.no/publikasjoner/aktivitetshandboken-fysisk-aktivitet-i-forebygging-og-behandling/Sider/default.aspx

Hjeltnes, N. (2009). Ryggmargsskade. In R.Bahr (Ed.), *Aktivitetshåndboken* (pp. 523-536). Helsedirektoratet.

Hsieh, J. T. C., Wolfe, D. L., Miller, W. C., & Curt, A. (2007). Spasticity outcome measures in spinal cord injury: psychometric properties and clinical utility. *Spinal Cord, 46,* 86-95.

Hubli, M. & Dietz, V. (2013). The physiological basis of neurorehabilitation - locomotor training after spinal cord injury. *Journal of NeuroEngineering and Rehabilitation, 10,* 5.

Jackson, A. B., Carnel, C. T., Ditunno, J. F., Read, M. S., Boninger, M. L., Schmeler, M. R. et al. (2008). Outcome measures for gait and ambulation in the spinal cord injury population. *J Spinal Cord Med, 31,* 487-499.

Jackson, A. B., Dijkers, M., DeVivo, M. J., & Poczatek, R. B. (2004). A demographic profile of new traumatic spinal cord injuries: Change and stability over 30 years. *Archives of Physical Medicine and Rehabilitation, 85,* 1740-1748.

Kadaba, M. P., Ramakrishnan, H. K., Wootten, M. E., Gainey, J., Gorton, G., & Cochran, G. V. (1989). Repeatability of kinematic, kinetic, and electromyographic data in normal adult gait. *J Orthop Res, 7,* 849-860.

Karanicolas, P. J., Bhandari, M., Kreder, H., Moroni, A., Richardson, M., Walter, S. D. et al. (2009). Evaluating agreement: conducting a reliability study. *J Bone Joint Surg Am, 91 Suppl 3,* 99-106.

Kark, L., Vickers, D., McIntosh, A., & Simmons, A. (2012). Use of gait summary measures with lower limb amputees. *Gait & posture, 35,* 238-243.

Kirtley, C. (2006). Three-dimensional gait analysis. In *Clinical Gait Analysis: Theory and Practice* (pp. 53-71). London: Churchill Livingstone, Elsevier.

Kirtly, C. (2006). Measurement of gait kinematics. In *Clinical Gait Analysis: Theory and Practice* (pp. 39-51). London: Elsevier/Churchill Livingstone.

Klejman, S., Andrysek, J., Dupuis, A., & Wright, V. (2010). Test-Retest Reliability of Discrete Gait Parameters in Children With Cerebral Palsy. *Archives of Physical Medicine and Rehabilitation, 91,* 781-787.

Landsforeningen for Ryggmargsskadde (2012a). ABC om ryggmargsskader for helsepersonell. http://www.regioner.nhf.no/novus/upload/file/LARS/ABC%20om%20ryggmargsskade%20for%20helsepersonell.pdf

Landsforeningen for Ryggmargsskadde (2012b). Hva er en ryggmargsskade. Retrieved 3-5-2012b, from http://www.regioner.nhf.no/index.asp?id=55065&te=55065

Laroche, D., Duval, A., Morisset, C., Beis, J. N., d'Athis, P., Maillefert, J. F. et al. (2011). Test–retest reliability of 3D kinematic gait variables in hip osteoarthritis patients. *Osteoarthritis and Cartilage, 19,* 194-199.

Lechner, H. E., Frotzler, A., & Eser, P. (2006). Relationship Between Self- and Clinically Rated Spasticity in Spinal Cord Injury. *Archives of Physical Medicine and Rehabilitation, 87,* 15-19.

Lelas, J. L., Merriman, G. J., Riley, P. O., & Kerrigan, D. C. (2003). Predicting peak kinematic and kinetic parameters from gait speed. *Gait & posture, 17,* 106-112.

Leroux, A., Fung, J., & Barbeau, H. (1999). Adaptation of the walking pattern to uphill walking in normal and spinal-cord injured subjects. *Experimental Brain Research, 126,* 359-368.

Lijmer JG, M. B. (1999). Empirical evidence of design-related bias in studies of diagnostic tests. *JAMA: The Journal of the American Medical Association, 282,* 1061-1066.

Luiz, R. R. & Szklo, M. (2005). More than one statistical strategy to assess agreement of quantitative measurements may usefully be reported. *Journal of Clinical Epidemiology, 58,* 215-216.

Macellari, V., Giacomozzi, C., & Saggini, R. (1999). Spatial-temporal parameters of gait: reference data and a statistical method for normality assessment. *Gait & posture, 10,* 171-181.

Mackey, A. H., Walt, S. E., Lobb, G. A., & Stott, N. S. (2005). Reliability of upper and lower limb three-dimensional kinematics in children with hemiplegia. *Gait & posture, 22,* 1-9.

Marino, R. J., Jones, L., Kirshblum, S., Tal, J., & Dasgupta, A. (2008). Reliability and repeatability of the motor and sensory examination of the international standards for neurological classification of spinal cord injury. *J Spinal Cord Med, 31,* 166-170.

Mathias, S., Nayak, U. S., & Isaacs, B. (1986). Balance in elderly patients: the "get-up and go" test. *Arch Phys Med Rehabil, 67,* 387-389.

Maynard, F. M., Karunas, R. S., & Waring, W. P., III. (1990). Epidemiology of spasticity following traumatic spinal cord injury. Arch Phys Med Rehabil 71[8], 566-569.
Ref Type: Abstract

Maynard, V., Bakheit, A. M. O., Oldham, J., & Freeman, J. (2003). Intra-rater and inter-rater reliability of gait measurements with CODA mpx30 motion analysis system. *Gait & posture, 17,* 59-67.

McDermott, A., Bolger, C., Keating, L., McEvoy, L., & Meldrum, D. (2010). Reliability of three-dimensional gait analysis in cervical spondylotic myelopathy. *Gait & posture, 32,* 552-558.

McDowell, B. C., Hewitt, V., Nurse, A., Weston, T., & Baker, R. (2000). The variability of goniometric measurements in ambulatory children with spastic cerebral palsy. *Gait & posture, 12,* 114-121.

McGinley, J. L., Baker, R., Wolfe, R., & Morris, M. E. (2009). The reliability of three-dimensional kinematic gait measurements: A systematic review. *Gait & posture, 29,* 360-369.

Mehrholz, J., Kugler, J., & Pohl, M. (2012). Locomotor training for walking after spinal cord injury. *Cochrane.Database.Syst.Rev, 11,* CD006676.

Mickelborough, J., van der Linden, M. L., Richards, J., & Ennos, A. R. (2000). Validity and reliability of a kinematic protocol for determining foot contact events. *Gait & posture, 11,* 32-37.

Monaghan, K., Delahunt, E., & Caulfield, B. (2007). Increasing the number of gait trial recordings maximises intra-rater reliability of the CODA motion analysis system. *Gait & posture, 25,* 303-315.

Morrow, J. R., Jr. & Jackson, A. W. (1993). How "significant" is your reliability? *Res Q.Exerc.Sport, 64,* 352-355.

Noonan, K. J., Halliday, S., Browne, R., O'Brien, S., Kayes, K., & Feinberg, J. (2003). Interobserver Variability of Gait Analysis in Patients With Cerebral Palsy. *Journal of Pediatric Orthopaedics, 23*.

Nordic Vicon User Group (2013). Rørelseslaboratoriet. http://www.motionlab.se/nordicvicon.htm

Opheim, A., McGinley, J. L., Olsson, E., Stanghelle, J. K., & Jahnsen, R. (2013). Walking deterioration and gait analysis in adults with spastic bilateral cerebral palsy. *Gait & posture, 37,* 165-171.

Paddison, S. & Middleton, F. (2004). Spinal Cord Injury. In M.Stokes (Ed.), *Physical Management in Neurological Rehabilitation* (2nd ed., pp. 125-152). London: Elsevier Ltd.

Pandyan, A. D., Johnson, G. R., Price, C. I. M., Curless, R. H., Barnes, M. P., & Rodgers, H. (1999). A review of the properties and limitations of the Ashworth and modified Ashworth Scales as measures of spasticity. *Clinical Rehabilitation, 13,* 373-383.

Patrick, J. H. (2003). The Case for gait analysis as part of the management of incomplete spinal cord injury. *Spinal Cord, 41,* 479-482.

Pepin, A., Ladouceur, M., & Barbeau, H. (2003). Treadmill walking in incomplete spinal-cord-injured subjects: 2. Factors limiting the maximal speed. *Spinal Cord, 41,* 271-279.

Pepin, A., Norman, K. E., & Barbeau, H. (2003). Treadmill walking in incomplete spinal-cord-injured subjects: 1. Adaptation to changes in speed. *Spinal Cord, 41,* 257-270.

Perry, J. & Burnfield, J. (2010a). Motion Analysis. In *Gait Analysis: Normal and Pathological Function* (2nd ed., pp. 407-424). Thorofare, NJ: SLACK Incorporated.

Perry, J. & Burnfield, J. M. (2010b). Ankle-Foot Complex. In *Gait Analysis: Normal and Pathological Function* (2nd ed., pp. 51-82). Thorofare: SLACK Inc.

Perry, J. & Burnfield, J. M. (2010c). Examples of Pathological Gait. In *Gait Analysis: Normal and Pathological Function* (2nd ed., pp. 281-339). Thorofare: SLACK Inc.

Perry, J. & Burnfield, J. M. (2010d). Gait Cycle. In *Gait Analysis: Normal and Pathological Function* (2nd ed., pp. 3-6). Thorofare: SLACK Inc.

Perry, J. & Burnfield, J. M. (2010e). Head, Trunk, and Pelvis. In *Gait Analysis: Normal and Pathological Function* (2nd ed., pp. 121-128). Thorofare: SLACK Inc.

Perry, J. & Burnfield, J. M. (2010f). Hip. In *Gait Analysis: Normal and Pathological Function* (2nd ed., pp. 103-119). Thorofare: SLACK Inc.

Perry, J. & Burnfield, J. M. (2010g). Hip Gait Deviations. In *Gait Analysis: Normal and Pathological Function* (2nd ed., pp. 237-256). Thorofare: SLACK Inc.

Perry, J. & Burnfield, J. M. (2010h). Knee. In *Gait Analysis: Normal and Pathological Function* (2nd ed., pp. 85-100). Thorofare: SLACK Inc.

Perry, J. & Burnfield, J. M. (2010i). Knee Gait Deviations. In *Gait Analysis: Normal and Pathological Function* (2nd ed., pp. 213-235). Thorofare: SLACK Inc.

Perry, J. & Burnfield, J. M. (2010j). Phases of Gait. In *Gait Analysis: Normal and Pathological Function* (2nd ed., pp. 9-16). Thorofare: SLACK Inc.

Pickett, G. E., Campos-Benitez, M., Keller, J. L., & Duggal, N. (2006). Epidemiology of traumatic spinal cord injury in Canada. *Spine (Phila Pa 1976.), 31,* 799-805.

Poncumhak, P., Saengsuwan, J., Kamruecha, W., & Amatachaya, S. (2013). Reliability and validity of three functional tests in ambulatory patients with spinal cord injury. *Spinal Cord, 51,* 214-217.

Portney, L. G. & Watkins, M. P. (2009a). Reliability og Measurements. In M.Cohen & M. Kerina (Eds.), *Foundations of Clinical Research: Application to Practice* (3rd ed., pp. 77-96). London: Pearson Education Ltd.

Portney, L. G. & Watkins, M. P. (2009b). Statistical Measures of Reliability. In *Foundation of clinical research: Application to practice* (3rd ed., pp. 585-618). London: Pearson Education Ltd.

Priebe, M. M. (2005). Assessment of Spinal Cord Injury Spasticity in Clinical Trials. *Topics in Spinal Cord Injury Rehabilitation, 11,* 69-77.

Rankin, G. & Stokes, M. (1998). Reliability of assessment tools in rehabilitation: an illustration of appropriate statistical analyses. *Clinical Rehabilitation, 12,* 187-199.

Redekop, S., Andrysek, J., & Wright, V. (2008). Single-session reliability of discrete gait parameters in ambulatory children with cerebral palsy based on GMFCS level. *Gait & posture, 28,* 627-633.

Reese, N. B. & Bandy, W. D. (2010). Measurement of Range of Motion and Muscle Length: Clinical Relevance. In *Joint Range of Motion and Muscle Length Testing* (2nd ed., pp. 31-44). St Louis: Saunders Elsevier.

Rennie, L. (2008). *Reliability in three dimensional gait analysis.* Master Degree Section of Physiotherapy Science, University of Bergen.

Robbins, S. M., Astephen Wilson, J. L., Rutherford, D. J., & Hubley-Kozey, C. L. Reliability of principal components and discrete parameters of knee angle and moment gait waveforms in individuals with moderate knee osteoarthritis. *Gait & posture,* (in press).

Røislien, J., Skare, Ø., Gustavsen, M., Broch, N. L., Rennie, L., & Opheim, A. (2009). Simultaneous estimation of effects of gender, age and walking speed on kinematic gait data. *Gait & posture, 30,* 441-445.

Rutz, E., Baker, R., Tirosh, O., Romkes, J., Haase, C., & Brunner, R. (2011). Tibialis anterior tendon shortening in combination with Achilles tendon lengthening in spastic equinus in cerebral palsy. *Gait & posture, 33,* 152-157.

Rutz, E., Donath, S., Tirosh, O., Graham, H. K., & Baker, R. Explaining the variability improvements in gait quality as a result of single event multi-level surgery in cerebral palsy. *Gait & posture,* (in press).

Rutz, E., Passmore, E., Baker, R., & Graham, H. K. (2012). Multilevel Surgery Improves Gait in Spastic Hemiplegia But Does Not Resolve Hip Dysplasia. *Clin Orthop Relat Res, 470,* 1294-1302.

Scholtes, V. A., Terwee, C. B., & Poolman, R. W. (2011). What makes a measurement instrument valid and reliable? *Injury, 42,* 236-240.

Schutte, L. M., Narayanan, U., Stout, J. L., Selber, P., Gage, J. R., & Schwartz, M. H. (2000). An index for quantifying deviations from normal gait. *Gait & posture, 11,* 25-31.

Schwartz, M. (2004). Kinematics of normal gait. In J.R.Gage (Ed.), *The Treatment of Gait Problems in Cerebral Palsy* (pp. 99-119). London: Mac Keith Press.

Schwartz, M. H. & Rozumalski, A. (2008). The gait deviation index: A new comprehensive index of gait pathology. *Gait & posture, 28,* 351-357.

Schwartz, M. H., Trost, J. P., & Wervey, R. A. (2004). Measurement and management of errors in quantitative gait data. *Gait & posture, 20,* 196-203.

Scivoletto, G., Romanelli, A., Mariotti, A., Marinucci, D., Tamburella, F., Mammone, A. et al. (2008). Clinical factors that affect walking level and performance in chronic spinal cord lesion patients. *Spine (Phila Pa 1976.), 33,* 259-264.

Sekhon, L. H. & Fehlings, M. G. (2001). Epidemiology, demographics, and pathophysiology of acute spinal cord injury. *Spine (Phila Pa 1976.), 26,* S2-12.

Shimada, S., Kobayashi, S., Wada, M., Sasaki, S., Kawahara, H., Uchida, K. et al. (2006). Effect of compensation procedures for velocity on repeatability and variability of gait parameters in normal subjects. *Clinical Rehabilitation, 20,* 239-245.

Shoukri, M. M., Asyali, M. H., & Donner, A. (2004). Sample size requirements for the design of reliability study: review and new results. *Statistical Methods in Medical Research, 13,* 251-271.

Sköld, C., Levi, R., & Seiger, Å. (1999). Spasticity after traumatic spinal cord injury: Nature, severity, and location. *Archives of Physical Medicine and Rehabilitation, 80,* 1548-1557.

Steeves, J. D., Lammertse, D., Curt, A., Fawcett, J. W., Tuszynski, M. H., Ditunno, J. F. et al. (2006). Guidelines for the conduct of clinical trials for spinal cord injury (SCI) as developed by the ICCP panel: clinical trial outcome measures. *Spinal Cord, 45,* 206-221.

Steinwender, G., Saraph, V., Scheiber, S., Zwick, E. B., Uitz, C., & Hackl, K. (2000). Intrasubject repeatability of gait analysis data in normal and spastic children. *Clinical Biomechanics, 15,* 134-139.

Stief, F., Böhm, H., Michel, K., Schwirtz, A., & Döderlein, L. (2013). Reliability and Accuracy in Three-Dimensional Gait Analysis: A Comparison of Two Lower Body Protocols. *Journal of Applied Biomechanics, 29,* 105-111.

Stolze, H., Kuhtz-Buschbeck, J. P., Mondwurf, C., Jöhnk, K., & Friege, L. (1998). Retest reliability of spatiotemporal gait parameters in children and adults. *Gait & posture, 7,* 125-130.

Stratford, P. W. & Riddle, D. L. (2012). When Minimal Detectable Change Exceeds a Diagnostic Test–Based Threshold Change Value for an Outcome Measure: Resolving the Conflict. *Physical Therapy, 92,* 1338-1347.

Thomas, J. R., Nelson, J. K., & Silverman, S. J. (2011). Measureing Research Variables. In J.R.Thomas, J. K. Nelson, & S. J. Silverman (Eds.), *Research Methods in Physical Activity* (6th ed., pp. 193-213). Leeds: Human Kinetics.

Thomason, P., Selber, P., & Graham, H. K. (2013). Single Event Multilevel Surgery in children with bilateral spastic cerebral palsy: A 5 year prospective cohort study. *Gait & posture, 37,* 23-28.

Van Der Salm, A., Nene, A. V., Maxwell, D. J., Veltink, P. H., Hermens, H. J., & IJzerman, M. J. (2005). Gait Impairments in a Group of Patients With Incomplete Spinal Cord Injury and Their Relevance Regarding Therapeutic Approaches Using Functional Electrical Stimulation. *Artificial Organs, 29,* 8-14.

van Trijffel, E., van de Pol, R. J., Oostendorp, R. A., & Lucas, C. (2010). Inter-rater reliability for measurement of passive physiological movements in lower extremity joints is generally low: a systematic review. *J Physiother., 56,* 223-235.

Vicon Motion Systems (2012). Plug-in gait User manual. http://www.irc-web.co.jp/vicon_web/news_bn/PIGManualver1.pdf

Vincent, W. J. (2005). Analysis of Variance With Repeated Measures. In *Statistics in Kinesiology* (3rd ed., pp. 183-200). Leeds, UK: Human Kinetics.

Visintin, M. & Barbeau, H. (1989). The effects of body weight support on the locomotor pattern of spastic paretic patients. Can.J Neurol Sci 16[3], 315-325.
Ref Type: Abstract

Wang, P., Low, K. H., McGregor, A. H., & Tow, A. (2013). Detection of abnormal muscle activations during walking following spinal cord injury (SCI). *Research in Developmental Disabilities, 34,* 1226-1235.

Waters, R. L., Adkins, R. H., Yakura, J. S., & Sie, I. (1993). Motor and sensory recovery following complete tetraplegia. *Arch Phys Med Rehabil, 74,* 242-247.

Weider, T. S. (2010). *Reliabilitet av tredimensjonal ganganalye for personer med traumatisk hjerneskade.* Master i helsefag Universitetet i Bergen.

Weir, J. P. (2005). Quantifying test-retest reliability using the intraclass correlation coefficient and the SEM. *Journal of Strength and Conditioning Research, 19,* 231-240.

Whittle, M. W. (2003a). Basic Sciences. In *Gait Analysis: An introduction* (3rd ed., pp. 1-41). London: Butterworth Heinemann.

Whittle, M. W. (2003b). Methods of gait analysis. In *Gait Analysis: An introduction* (3rd ed., pp. 127-161). London: Butterworth-Heinemann.

Whittle, M. W. (2003c). Normal gait. In *Gait analysis: An introduction* (3rd ed., pp. 42-88). London: Butterworth-Heinemann.

Whittle, M. W. (2003d). Preface to third edition. In *Gait Analysis: An introduction* (3rd ed., London: Butterworth Heinemann.

World Health Organization (2001). *ICF: International Classification of Functioning, Disability and Health*. Geneva: World Health Organization.

World Health Organization (2011a). Obesity and overweight. Retrieved 20-3-2012a, from http://www.who.int/mediacentre/factsheets/fs311/en/#

World Health Organization (2011b). WHO Global Infobase. https://apps.who.int/infobase/Indicators.aspx

World Health Organization (2013). International Classification of Functioning, Disability and Health (ICF). http://www.who.int/classifications/icf/en/

Yavuzer, G., Öken, Ö., Elhan, A., & Stam, H. J. (2008). Repeatability of lower limb three-dimensional kinematics in patients with stroke. *Gait & posture, 27,* 31-35.

List of tables

List of figures

Abbreviations

AIS	American Spinal Injury Association Impairment Scale
ANOVA	Analysis of Variance
ASIA	American Spinal Injury Association
BMI	Body Mass Index
CI	Confidence interval
GPS	Gait Profile Score
GVS	Gait Variable Score
Hz	Hertz
ICC	Intraclass correlation coefficient
ICF	International Classification of Functioning, Disability and Health
IQR	Interquartile range
LOA	Limits of agreement
MAP	Movement Analysis Profile
MAS	Modified Ashworth Scale
MDC	Minimal Detectable Change
PiG	Plug-in gait model
PROM	Passive range of motion
RMS	Root mean square
SCI	Spinal cord injury
SD	Standard deviation
SEM	Standard error of measurement
TUG	Timed Up & Go
WHO	World Health Organization
WISCI II	Walking Index for Spinal Cord Injury II
3D	Three-dimensional

Appendices

Appendix 1 – International Standard Neurological Classification of Spinal Cord Injury assessment form

Patient Name _____

Examiner Name _____ Date/Time of Exam_____

INTERNATIONAL STANDARDS FOR NEUROLOGICAL CLASSIFICATION OF SPINAL CORD INJURY

ASIA American Spinal Injury Association — ISCOS

MOTOR

KEY MUSCLES (scoring on reverse side)

	R	L	
C5	☐	☐	Elbow flexors
C6	☐	☐	Wrist extensors
C7	☐	☐	Elbow extensors
C8	☐	☐	Finger flexors (distal phalanx of middle finger)
T1	☐	☐	Finger abductors (little finger)

UPPER LIMB TOTAL (MAXIMUM) ☐ + ☐ = ☐ (25) (25) (50)

Comments:

L2	☐	☐	Hip flexors
L3	☐	☐	Knee extensors
L4	☐	☐	Ankle dorsiflexors
L5	☐	☐	Long toe extensors
S1	☐	☐	Ankle plantar flexors

(VAC) Voluntary anal contraction (Yes/No) ☐

LOWER LIMB TOTAL (MAXIMUM) ☐ + ☐ = ☐ (25) (25) (50)

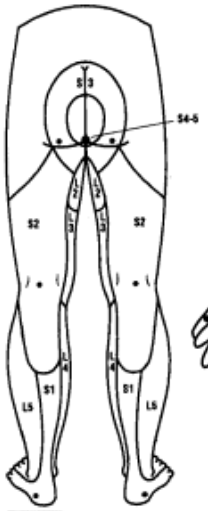
LIGHT TOUCH / PIN PRICK

	LIGHT TOUCH R	LIGHT TOUCH L	PIN PRICK R	PIN PRICK L
C2				
C3				
C4				
C5				
C6				
C7				
C8				
T1				
T2				
T3				
T4				
T5				
T6				
T7				
T8				
T9				
T10				
T11				
T12				
L1				
L2				
L3				
L4				
L5				
S1				
S2				
S3				
S4-5				
TOTALS (MAXIMUM)	☐ (56)	☐ (56)	☐ (56)	☐ (56)

SENSORY

KEY SENSORY POINTS

0 = absent
1 = altered
2 = normal
NT = not testable



• Key Sensory Points

(DAP) Deep anal pressure (yes/No) ☐

PIN PRICK SCORE (max: 112) ☐ + ☐ =

LIGHT TOUCH SCORE (max: 112) ☐ + ☐ =

NEUROLOGICAL LEVEL (The most caudal segment with normal function)		R	L	SINGLE NEUROLOGICAL LEVEL	COMPLETE OR INCOMPLETE? (Incomplete = Any sensory or motor function in S4-S5)	(In complete injuries only) ZONE OF PARTIAL PRESERVATION (Most caudal level with any innervation)		R	L
	SENSORY	☐	☐	☐	☐		SENSORY	☐	☐
	MOTOR	☐	☐		ASIA IMPAIRMENT SCALE (AIS) ☐		MOTOR	☐	☐

REV 04/11

Appendix 2 – Study information

Hei!

Vedlagt følger et informasjonsskriv angående en studie, som gjennomføres på Sunnaas sykehus HF i perioden juni-oktober 2012.

Vi håper du tar deg tid til å lese igjennom informasjonen, og at du vil ha interesse av å delta i studien.

I forkant av ditt opphold på Sunnaas vil du bli kontaktet per telefon av en prosjektmedarbeider, for å høre om du kunne tenke deg å delta på studien, og for eventuelt å kunne planlegge ditt opphold i forhold til de testene du da vil delta på.

Med vennlig hilsen

Pia Wedege

Fysioterapeut
Sunnaas Sykehus HF
Mastergradsstudent
Norges idrettshøgskole

Arve Opheim

Fysioterapeut PhD
Sunnaas sykehus HF
Hovedveileder

– en vei videre

Sunnaas sykehus HF

Forespørsel om deltakelse i forskningsprosjektet

"Reliabilitet av 3-dimensjonal ganganalyse hos voksne med ryggmargsskade"

Vil du være med på en studie for å undersøke påliteligheten av målinger ved gjentatte gangundersøkelser?

Bakgrunn

Hos personer med ryggmargsskade benyttes i økende grad databasert 3-dimensjonal ganganalyse for å vurdere gangfunksjonen og tiltak for å forbedre denne. Studier har vist at målemetoden er pålitelig hos friske personer og for noen andre pasientgrupper, men det foreligger ingen publikasjoner som har undersøkt dette hos voksne med ryggmargsskade. Grunnen til at det er viktig å vite noe om måleinstrumentets pålitelighet, et at vi da med større sikkerhet kan si at evt. endringer i gangmønsteret er et resultat av for eksempel iverksatte behandlingstiltak, og ikke kun en del av en naturlig variasjon. Du som innlegges ved Sunnaas sykehus HF med ryggmargsskade og er gående blir forespurt om å delta i dette prosjektet.

De som kan delta:

- Diagnosen ryggmargsskade, og hatt skaden i minimum 1 år
- Mellom 18 og 65 år
- Kunne forstå instruksjonene og gi informert samtykke
- Kunne gå minst 10 meter sammenhengende uten støtte av en annen person
- Være villig til å gjennomføre to undersøkelser i løpet av oppholdet

Sunnaas Sykehus HF i samarbeid med Norges idrettshøgskole er ansvarlig for studien. Studien er godkjent av Regional etisk komité og personvernombudet ved Sunnaas sykehus HF.

Hva innebærer studien?

Dersom du takker ja til å delta i prosjektet, vil du bli bedt om å gjennomføre to gangundersøkelser med 1-4 dagers mellomrom ved sykehusets databaserte 3-dimensjonale bevegelseslaboratorium. Rent praktisk innebærer dette at vi plasserer små, runde refleksmarkører med tape foran og bak på beina og bekkenet, og at du har på deg shorts og t-skjorte. Du må deretter gå barbent (hvis mulig) fram og tilbake en strekning på 8-10 meter, inntil vi har tilstrekkelig med gode opptak fra våre kamera i bevegelseslaboratoriet. Det vil være mulig å ta pauser underveis. Inkludert en kort klinisk undersøkelse (blant annet måling av høyde, vekt, og beinlengde) samt markørpåsetting og selve ganganalysen, vil undersøkelsen ta maksimalt 1-1,5 time. Det er ønskelig at du ikke trener hardt eller endrer medisinering mellom testene. Vi vil i tillegg til ganganalysen innhente informasjon fra din pasientjournal om ditt skadenivå, -tidspunkt og -årsak, samt resultater fra de ordinære målingene av styrke, bevegelighet og spastisitet i beina.

Det vil ikke bli utarbeidet noen egen rapport for deg av denne undersøkelsen, men dersom det er ønske om dette og/eller at undersøkelsen avdekker behov for videre utredning eller behandling, vil prosjektleder sørge for at du og den pasientansvarlige lege blir informert om dette under oppholdet. Det skal ikke medføre ulempe for deg å delta i dette prosjektet samtidig med oppholdet her på Sunnaas sykehus HF, og tidspunktene for undersøkelsen vil tilpasses din timeplan under oppholdet.

Mulige fordeler og ulemper

Du vil kanskje ikke ha noen umiddelbare fordeler av studien, bortsett fra det som er beskrevet i avsnittet over, og at ganganalysen av deg kan benyttes som sammenlikningsgrunnlag ved eventuelle senere utredninger av din gangfunksjon. Men erfaringer fra denne studien vil senere kunne hjelpe deg og andre med samme diagnose, ved at vi vil vite mer om hvor mye man kan stole på resultatene av slike ganganalyser.

Hva skjer med informasjonen om deg?

Informasjonen som registreres om deg skal kun brukes slik som det er beskrevet i formålet med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller direkte gjenkjennende opplysninger. Datamaterialet fra undersøkelsen vil bli lagret på forskningsavdelingens server, og er kun tilgjengelig for prosjektets medarbeidere. En kode knytter deg til dine opplysninger gjennom en navneliste. Navnelisten oppbevares innelåst i et brannsikkert skap. Det er kun autorisert personell tilknyttet prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når den publiseres.

Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger. Opplysningene blir senest slettet 01.08.2023.

Frivillig deltakelse

Det er frivillig å delta i studien. Dersom du ikke ønsker å delta, trenger du ikke å oppgi noen grunn, og det får ingen konsekvenser for den videre behandlingen du får ved sykehuset.

Dersom du ønsker å delta, undertegner du samtykkeerklæringen på den neste siden. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling på sykehuset.

Dersom du senere ønsker å trekke deg, kan du kontakte Pia Wedege, tlf.: 905 29 891.

Med vennlig hilsen

Pia Wedege	Arve Opheim	Kathrin Steffen
Fysioterapeut	Fysioterapeut PhD	Dr scient
Sunnaas sykehus HF	Sunnaas sykehus HF	Seksjon for idrettsmedisinske fag, Norges idrettshøgskole
Mastergradsstudent Norges idrettshøgskole	Hovedveileder	Biveileder

Appendix 3 – Informed consent form

Samtykke til deltakelse i studien

”Reliabilitet av 3-dimensjonal ganganalyse hos voksne med ryggmargsskade”

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Appendix 4 – Walking Index for Spinal Cord Injury II

Instructions for the Use of the Walking Index for Spinal Cord Injury II (WISCI II) – March 2005

Scoring Sheet for the Walking Index for Spinal Cord Injury (WISCI II)

Name_____ Date_____

Check descriptors that apply to current walking performance, and then assign the highest level of walking performance. (In scoring a level, one should choose the level at which the patient is safe as judged by the therapist, with patient's comfort level described. If devices other than those stated in the standard definitions are used, they should be documented as descriptors. If there is a discrepancy between two observers, the higher level should be chosen.)

Gait: reciprocal _____; swing through _____

Descriptors

Devices	Braces	Assistance	Patient reported Comfort level
//bars < 10 meters	Long Leg Braces- Uses 2 Uses 1	Max Assist x 2 people	Very comfortable
//bars 10 meters	Short Leg Braces- Uses 2 Uses 1	Min/Mod assist x 2 people	Slightly comfortable
Walker- Standard Rolling Platform	Locked at knee _____ Unlocked at knee _____	Min/mod assist x 1 person	Neither comfortable nor uncomfortable
Crutches- Uses 2 Uses 1	Other: _____		Slightly uncomfortable
Canes- Quad Uses 2 Uses 1			Very uncomfortable
No devices	No braces	No assistance	

WISCI Levels

Level	Devices	Braces	Assistance	Distance
0				Unable
1	Parallel bars	Braces	2 persons	Less than 10 meters
2	Parallel bars	Braces	2 persons	10 meters
3	Parallel bars	Braces	1 person	10 meters
4	Parallel bars	No braces	1 person	10 meters
5	Parallel bars	Braces	No assistance	10 meters
6	Walker	Braces	1 person	10 meters
7	Two crutches	Braces	1 person	10 meters
8	Walker	No braces	1 person	10 meters
9	Walker	Braces	No assistance	10 meters
10	One cane/crutch	Braces	1 person	10 meters
11	Two crutches	No braces	1 person	10 meters
12	Two crutches	Braces	No assistance	10 meters
13	Walker	No braces	No assistance	10 meters
14	One cane/crutch	No braces	1 person	10 meters
15	One cane/crutch	Braces	No assistance	10 meters
16	Two crutches	No braces	No assistance	10 meters
17	No devices	No braces	1 person	10 meters
18	No devices	Braces	No assistance	10 meters
19	One cane/crutch	No braces	No assistance	10 meters
20	No devices	No braces	No assistance	10 meters

Level assigned_____

Revised 3/19/2002

Copy Freely – Do Not Alter

Walking Index for Spinal Cord Injury (WISCI II) Descriptors

Physical Limitation for walking secondary to impairment is defined at the person level and indicates the ability of a person to walk after spinal cord injury. The development of this assessment index required a rank ordering along a dimension of impairment, from the level of most severe impairment (0) to least severe impairment (20) based on the use of devices, braces and physical assistance of one or more persons. The order of the levels suggests each successive level is a less impaired level than the former. The ranking of severity is based on the severity or the impairment and not on functional independence in the environment. The following definitions standardize the terms used in each item:

Physical assistance: 'Physical assistance of two persons' is moderate to maximum assistance.
'Physical assistance of one person' is minimal to moderate assistance.

Braces: 'Braces' means one or two braces, either short or long leg.
(Splinting of lower extremities for standing is considered long leg bracing).
'No braces' means no braces on either leg.

Walker: 'Walker' is a conventional rigid walker without wheels.

Crutches: 'Crutches' can be Lofstrand (Canadian) or axillary.

Cane: 'Cane' is a conventional straight cane.

Level	Description
0	Client is unable to stand and/or participate in assisted walking.
1	Ambulates in parallel bars, with braces and physical assistance of two persons, less than 10 meters
2	Ambulates in parallel bars, with braces and physical assistance of two persons, 10 meters.
3	Ambulates in parallel bars, with braces and physical assistance of one person, 10 meters.
4	Ambulates in parallel bars, no braces and physical assistance of one person, 10 meters
5	Ambulates in parallel bars, with no braces and no physical assistance, 10 meters.
6	Ambulates with walker, with braces and physical assistance of one person, 10 meters.
7	Ambulates with two crutches, with braces and physical assistance of one person, 10 meters.
8	Ambulates with walker, no braces and physical assistance of one person, 10 meters.
9	Ambulates with walker, with braces and no physical assistance, 10 meters.
10	Ambulates with one cane/crutch, with braces and physical assistance of one person, 10 meters.
11	Ambulates with two crutches, no braces and physical assistance of one person, 10 meters.
12	Ambulates with two crutches, with braces and no physical assistance, 10 meters.
13	Ambulates with walker, no braces and no physical assistance, 10 meters.
14	Ambulates with one cane/crutch, no braces and physical assistance of one person, 10 meters.
15	Ambulates with one cane/crutch, with braces and no physical assistance, 10 meters.
16	Ambulates with two crutches, no braces and no physical assistance, 10 meters.
17	Ambulates with on devices, no braces and physical assistance of one person, 10 meters.
18	Ambulates with on devices, with braces and no physical assistance, 10 meters.
19	Ambulates with one cane/crutch, no braces and no physical assistance, 10 meters.
20	Ambulates with no devices, no braces and no physical assistance, 10 meters.

Appendix 5 – Letter of approval from Regional Ethical Committee

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Katrine Ore	22845512	28.06.2012	2012/972/REK sør-øst A
			Deres dato:	**Deres referanse:**
			22.05.2012	

Vår referanse må oppgis ved alle henvendelser

Arve Opheim
Bjørnemyrveien

2012/972 Reliabilitet av 3-dimensjonal ganganalyse hos voksne med en ryggmargsskade

Forskningsansvarlig: Sunnaas sykehus HF ved øverste ledelse
Prosjektleder: Arve Opheim

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst) i møtet 14.06.2012. Vurderingen er gjort med hjemmel i helseforskningsloven § 10, jf. forskningsetikklovens § 4.

Prosjektomtale
Reliabilitetsundersøkelse av 3-dimensjonal ganganalyse er tidligere gjort på friske personer og personer med cerebral parese. I denne masteroppgaven skal reliabiliteten av 3-dimensjonal ganganalyse undersøkes hos 15 voksne med ryggmargsskade. Det skal registreres opplysninger om gangmønster, nevrologisk status, muskelstyrke, leddbevegelighet og spastisitet i beina. Resultatene fra to ganganalyser skal sammenliknes. Som ulempe anføres at pasientene må gjennomgå to ganganalyser i løpet av 2-4 dager. Studien er samtykkebasert.

Vurdering

Komiteen har ingen forskningsetiske innvendinger til at studien gjennomføres slik den er beskrevet i søknaden med vedlegg.

Vedtak
Prosjektet godkjennes prosjektet med hjemmel i helseforskningsloven § 9 jf. § 33.

Godkjenningen gjelder til 31.07.2013.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren». Opplysningene skal ikke oppbevares lenger enn det som er nødvendig for å gjennomføre prosjektet, deretter skal opplysningene anonymiseres eller slettes.

Besøksadresse:
Gullhaug torg 4A, Nydalen,
0484 Oslo

Telefon: 22845511
E-post: post@helseforskning.etikkom.no
Web: http://helseforskning.etikkom.no/

Dersom det skal gjøres endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK.

Prosjektet skal sende sluttmelding på eget skjema, jf helseforskningsloven § 12, senest et halvt år etter prosjektslutt.

Komiteens vedtak kan påklages til Den nasjonale forskningsetiske komité for medisin og helsefag, jf. helseforskningsloven § 10, 3 ledd og forvaltningsloven § 28. En eventuell klage sendes til REK Sørøst A. Klagefristen er tre uker fra mottak av dette brevet, jf. forvaltningsloven § 29.

Komiteens avgjørelse var enstemmig

Med vennlig hilsen

Gunnar Nicolaysen
Professor dr med
Komiteens leder

Katrine Ore
Rådgiver

Kopi til: johan.stanghelle@sunnaas.no

Appendix 6 – Letter of approval from the Commissionaire for the Protection of Privacy in Research

Personvernombudet for forskning og kvalitetssikring
Kompetansesenter for personvern og informasjonssikkerhet

Oslo universitetssykehus HF

PERSONVERNOMBUDETS TILRÅDING

Til:	Arve Opheim, prosjektleder Pia Wedege, prosjektmedarbeider
Kopi:	
Fra:	Personvernombudet for forskning og kvalitetssikring
Saksbehandler:	Helge Grimnes
Dato:	15.05.12
Offentlighet:	Ikke unntatt offentlighet
Sak:	Personvernombudets tilråding til innsamling og behandling av personopplysninger
Saksnummer/ Personvernnummer:	2012/8440

Personvernombudets tilråding til innsamling og behandling av personopplysninger for prosjektet "*Reliabilitet av 3-dimensjonal ganganalyse hos voksne med ryggmargsskade*"

Viser til innsendt melding om behandling av personopplysninger / helseopplysninger. Det følgende er personvernombudets tilråding av prosjektet.

Med hjemmel i Personopplysningsforskriftens § 7-12 jf. Helseregisterlovens § 36 har Datatilsynet, ved oppnevning av personvernombud, fritatt sykehuset fra meldeplikten til Datatilsynet. Behandling og utlevering av person-/helseopplysninger meldes derfor til sykehusets personvernombud.

Databehandlingen tilfredsstiller forutsetningene for melding gitt i personopplysningsforskriften § 7-27 og er derfor unntatt konsesjon.

Personvernombudet tilrår at prosjektet gjennomføres under forutsetning av følgende:

1. Databehandlingsansvarlig er Sunnaas sykehus HF ved adm. dir.
2. Behandling av personopplysningene / helseopplysninger i prosjektet skjer i samsvar med og innenfor det formål som er oppgitt i meldingen.
3. Data lagres som oppgitt i meldingen. Annen lagringsform forutsetter gjennomføring av en risikovurdering som må godkjennes av Personvernombudet.
4. Vedlagte samtykke benyttes, inklusive markerte tillegg og endringer foretatt av personvernombudet. Eventuelle fremtidige endringer som berører formålet, utvalget inkluderte eller databehandlingen må forevises personvernombudet før de tas i bruk.
5. Kryssliste som kobler avidentifiserte data med personopplysninger lagres på papir som angitt i meldingen og oppbevares separat på prosjektleders avlåste kontor.
6. Dersom formålet eller databehandlingen endres må personvernombudet informeres om dette.
7. Kontaktperson for prosjektet skal hvert tredje år sende personvernombudet ny melding som bekrefter at databehandlingen skjer i overensstemmelse med opprinnelig formål og helseregisterlovens regler.
8. Data slettes eller anonymiseres ved prosjektslutt **01.08.2023** ved at krysslisten slettes og eventuelle andre identifikasjonsmuligheter i databasen fjernes. Når formålet med registeret er oppfylt sendes melding om bekreftet sletting til personvernombudet.

Prosjektet er registrert i oversikten over tilrådinger og uttalelser til forskning som Personvernombudet fører for sykehuset. Oversikten er offentlig tilgjengelig.

Lykke til med prosjektet!

Med vennlig hilsen
for Personvernombudet for forskning og kvalitetssikring

Helge Grimnes
Personvernrådgiver
Kompetansesenter for personvern og informasjonssikkerhet
Stab fag & pasientsikkerhet
Oslo universitetssykehus HF

Epost: personvern@oslo-universitetssykehus.no
Web: www.oslo-universitetssykehus.no/personvern

Appendix 7 – Reliability results: intra-session 2

Table 9. *Intra-session reliability for Gait Profile Score (GPS) in Session 2 based on five trials in 15 subjects with incomplete spinal cord injury*

GPS	ICC (2,1)			SEM (°)
	ICC	95% CI		
Overall	**0.99**	0.97	0.99	**0.3**
Left	**0.98**	0.96	0.99	**0.3**
Right*	**0.96**	0.93	0.99	**0.4**

ICC (2,1)= intraclass correlation coefficient (2,1), 95% CI= 95% confidence intervals for ICCs, SEM=standard error of measurement, *= ICC calculated from log transform data

Table 10. *Intra-session reliability for Gait Variable Score in Session 2 based on five trials in 15 subjects with incomplete spinal cord injury*

Plane	Gait Variable Score	ICC (2,1)			SEM (°)
		ICC	95% CI		
Sagittal	Pelvic tilt*	**0.93**	0.86	0.97	**0.6**
	Hip flexion/extension, left	**0.98**	0.96	0.99	**0.7**
	Hip flexion/extension, right*	**0.96**	0.93	0.99	**0.8**
	Knee flexion/extension, left	**0.90**	0.80	0.96	**1.0**
	Knee flexion/extension, right*	**0.97**	0.93	0.99	**1.1**
	Ankle dorsiflexion/plantarflexion, left	**0.98**	0.96	0.99	**0.5**
	Ankle dorsiflexion/plantarflexion, right	**0.97**	0.94	0.99	**0.7**
Frontal	Pelvic obliquity	**0.92**	0.84	0.97	**0.3**
	Hip adduction/abduction, left	**0.89**	0.80	0.96	**0.5**
	Hip adduction/abduction, right*	**0.95**	0.89	0.98	**0.4**
Transverse	Pelvic internal/external rotation*	**0.81**	0.66	0.92	**0.8**
	Hip internal/external, left*	**0.97**	0.95	0.99	**0.7**
	Hip internal/external, right*	**0.94**	0.88	0.98	**0.7**
	Foot progression, left	**0.85**	0.72	0.94	**1.4**
	Foot progression, right*	**0.86**	0.74	0.94	**1.3**

ICC (2,1)= intraclass correlation coefficient (2,1), 95% CI= 95% confidence intervals for ICCs, SEM=standard error of measurement, *= ICC calculated from log transformed data

Appendix 8 – Bland-Altman 95% LOA: Gait Profile Score

Table 11. *Inter-session reliability results for Gait Profile Score (GPS). Calculations of Bland-Altman 95% LOA are based on 15 subjects with incomplete spinal cord injury from two sessions*

GPS	Bland-Altman 95% LOA (°)			
	D	SD(D)	95% LOA	
Overall	-0.2	0.8	**-1.8**	**1.4**
Left	-0.1	1.1	**-2.3**	**2.1**
Right	-0.2	0.6	**-1.4**	**0.9**

Bland-Altman 95% LOA=Bland and Altman 95% limits of agreement, D=mean difference, SD (D) =standard deviation of the difference, 95% LOA=D±2 x SD (D)

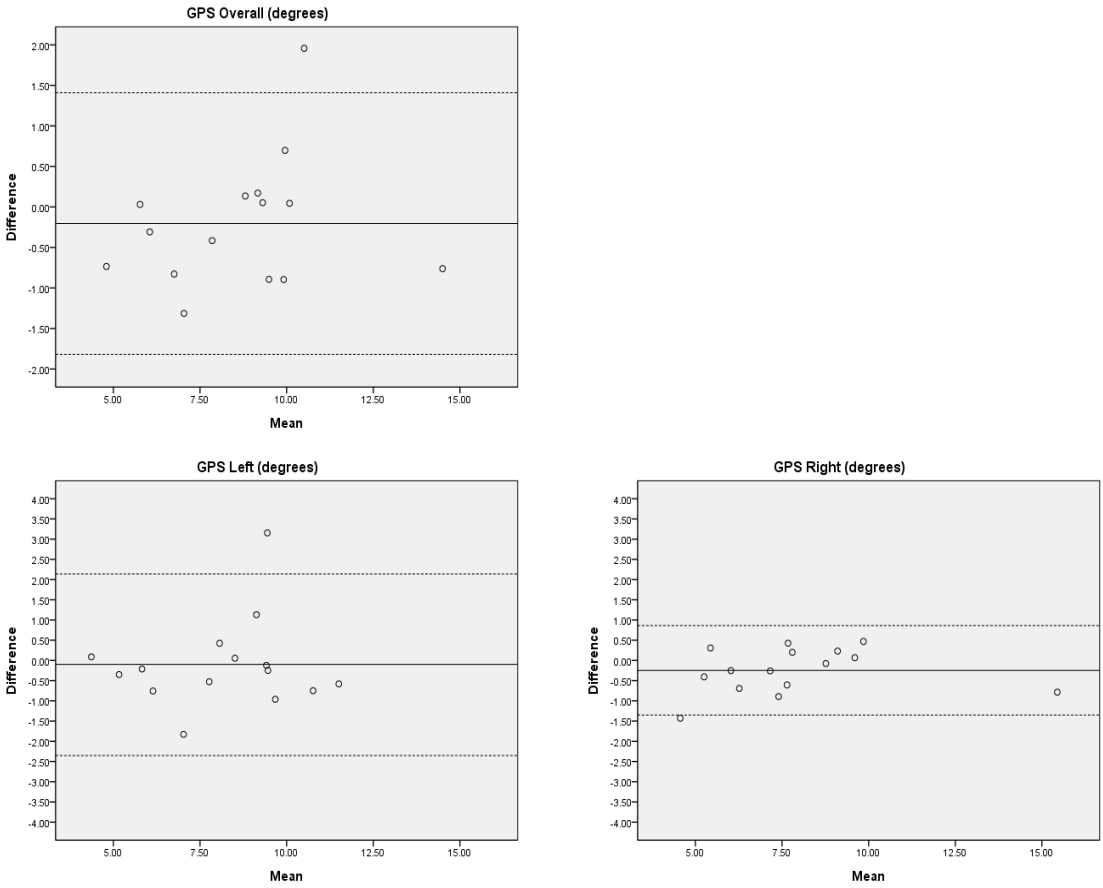


Figure16. *Bland-Altman plots with 95% limits of agreement (dotted lines) for Gait Profile Score Overall, Left and Right, based on 15 subjects with incomplete spinal cord injury. Solid line=mean difference between Session 1 and 2.*

Appendix 9 – Bland-Altman 95% LOA: Gait Variable Score

Table 12. *Inter-session reliability results for Gait Variable Score. Calculations of Bland-Altman 95% LOA are based on 15 subjects with incomplete spinal cord injury from two sessions*

Plane	**Gait Variable Score**	**Bland-Altman 95% LOA (°)**			
		D	SD(D)	95% LOA	
Sagittal	Pelvic tilt	0.2	0.8	**-1.4**	**1.8**
	Hip flexion/extension, left	0.1	0.8	**-1.6**	**1.7**
	Hip flexion/extension, right	-0.3	1.3	**-2.8**	**2.3**
	Knee flexion/extension, left	0.0	2.4	**-4.7**	**4.7**
	Knee flexion/extension, right	-0.6	1.2	**-2.9**	**1.8**
	Ankle dorsiflexion/plantarflexion, left	-0.3	1.3	**-2.9**	**2.3**
	Ankle dorsiflexion/plantarflexion, right	-0.3	1.1	**-2.4**	**1.8**
Frontal	Pelvic obliquity	-0.1	0.5	**-1.1**	**0.9**
	Hip adduction/abduction, left	-0.3	0.8	**-1.9**	**1.4**
	Hip adduction/abduction, right	0.0	0.6	**-1.2**	**1.2**
Transverse	Pelvic internal/external rotation	0.2	0.5	**-0.9**	**1.2**
	Hip internal/external rotation, left	-0.7	5.2	**-11.0**	**9.7**
	Hip internal/external rotation, right	0.1	3.8	**-7.4**	**7.6**
	Foot progression, left	0.0	1.0	**-2.0**	**1.9**
	Foot progression, right	-0.1	1.2	**-2.5**	**2.2**

Bland-Altman 95% LOA=Bland and Altman 95% limits of agreement, D=mean difference, SD(D)=standard deviation of the difference, 95% LOA=D±2 x SD(D)

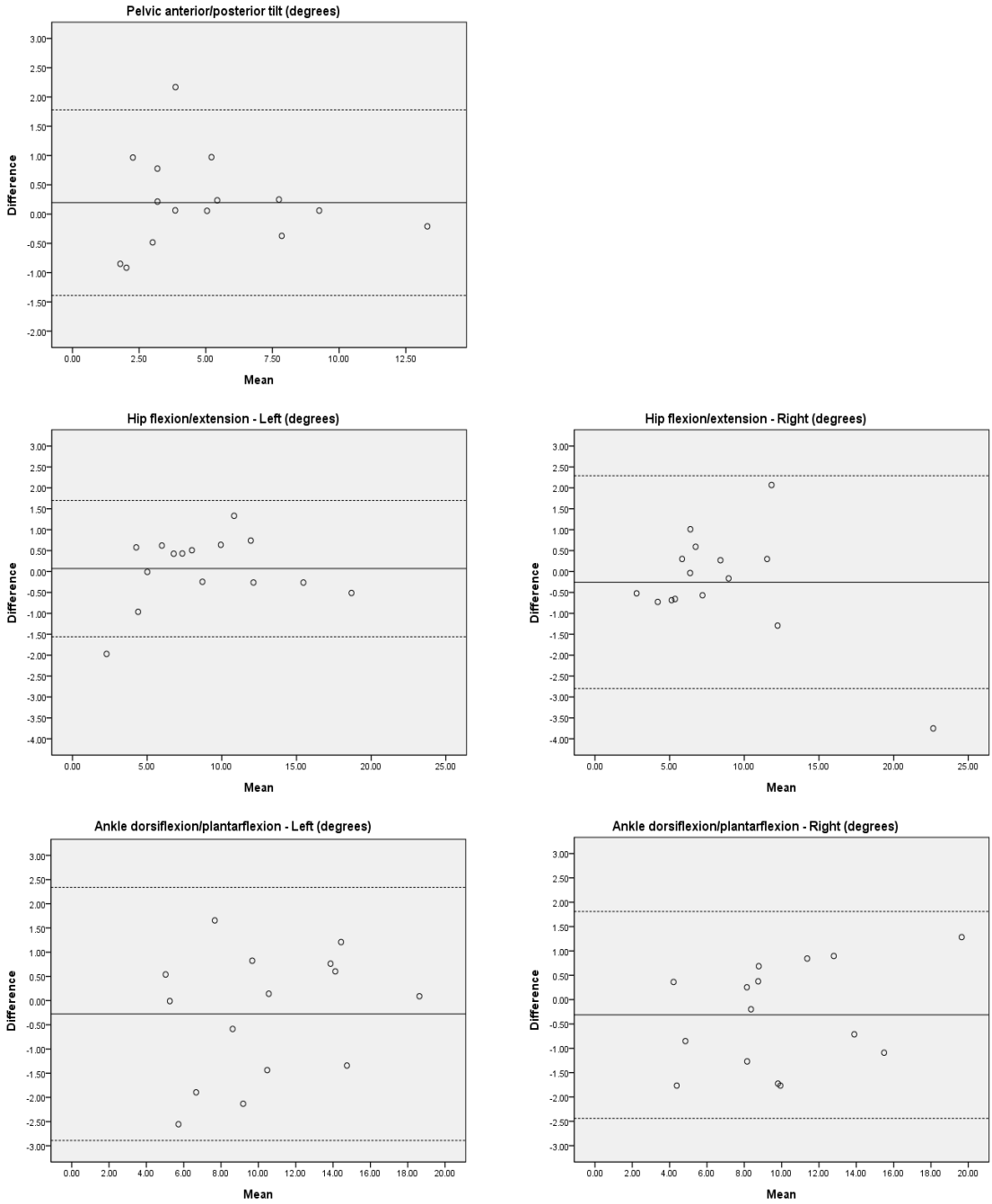


Figure 17. *Bland-Altman plots with 95% limits of agreement (dotted lines) for Gait Variable Scores in sagittal plane, based on 15 subjects with incomplete spinal cord injury. Solid line=mean difference between Session 1 and 2.*

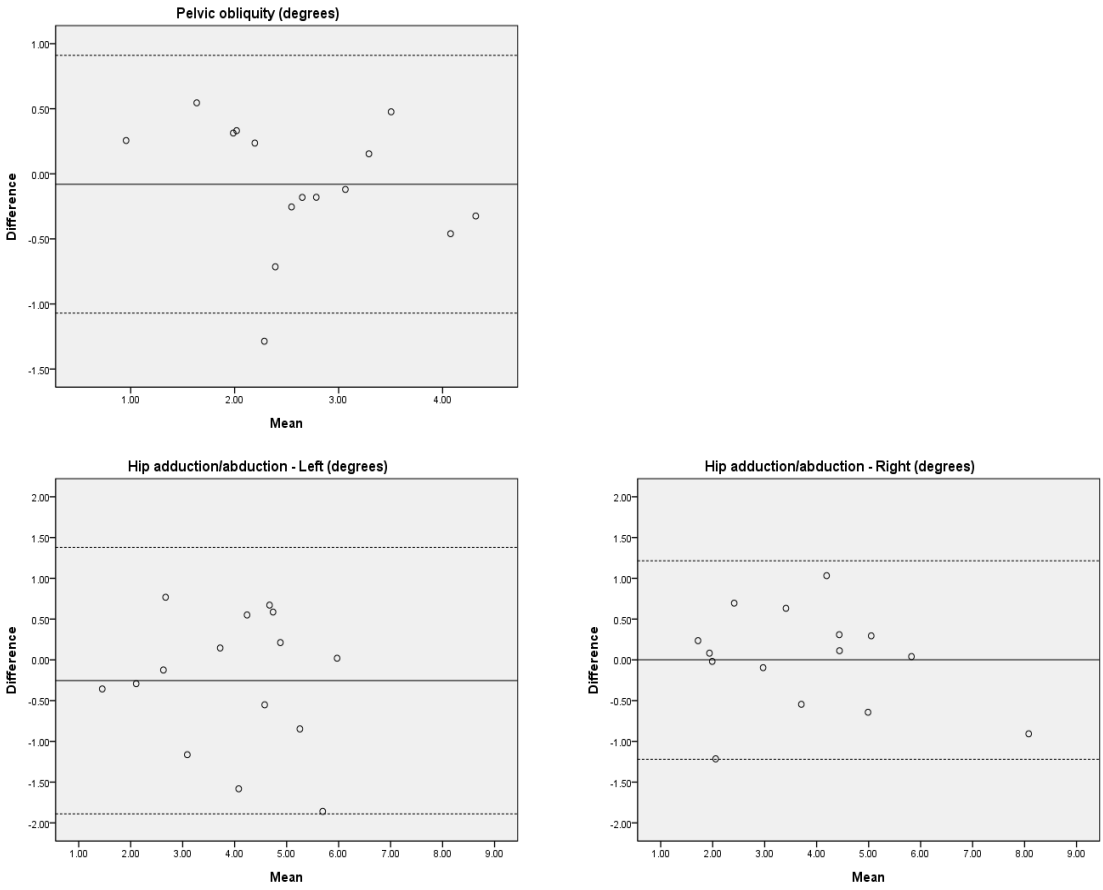


Figure 18. *Bland-Altman plots with 95% limits of agreement (dotted lines) for Gait Variable Scores in frontal plane, based on 15 subjects with incomplete spinal cord injury. Solid line=mean difference between Session 1 and 2.*

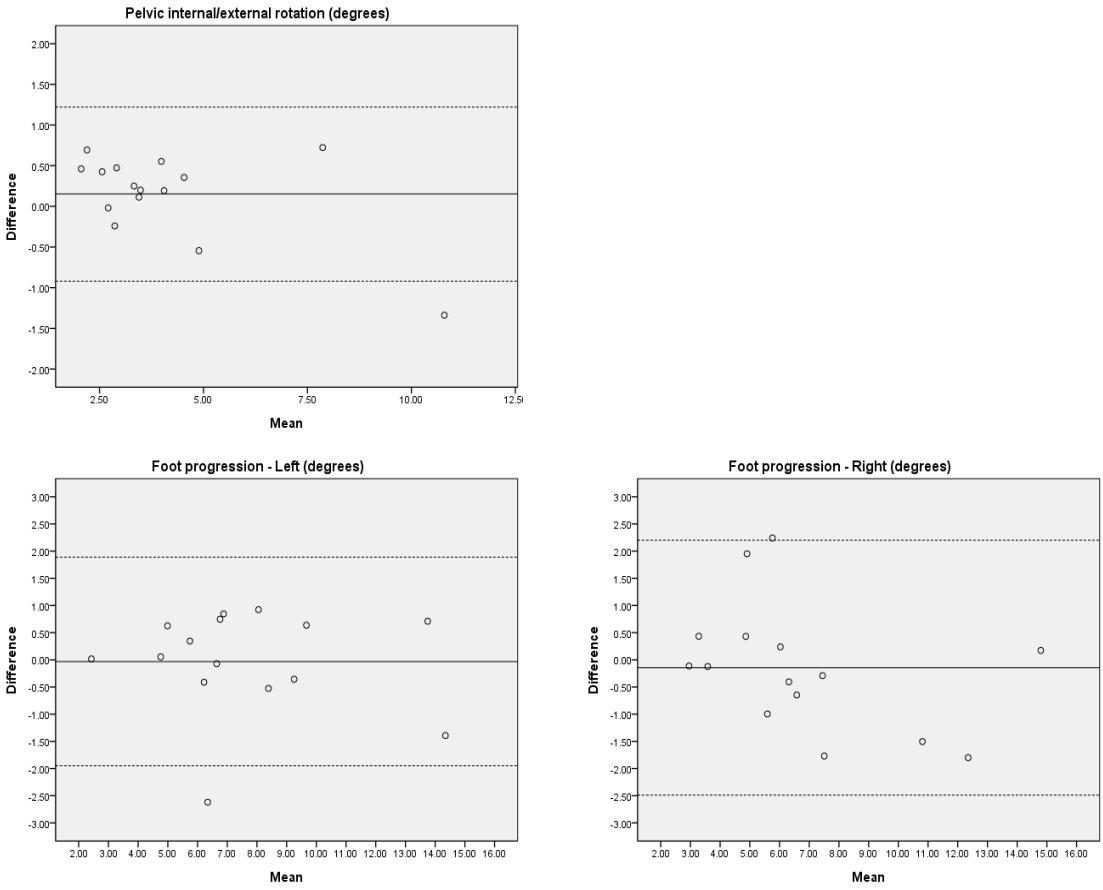


Figure 19. *Bland-Altman plots with 95% limits of agreement (dotted lines) for Gait Variable Scores in transverse plane, based on 15 subjects with incomplete spinal cord injury. Solid line=mean difference between Session 1 and 2.*

Appendix 10 – Communication with Richard Baker

From: R.J.Baker@salford.ac.uk
To: piawedege@hotmail.com
Subject: RE: Reliability of 3DGA in adults with an incomplete spinal cord injury
Date: Mon, 29 Apr 2013 08:22:47 +0000

Pia,

Really good to hear that this has proved useful. Please feel free to use whatever images you want in your PhD.

Richard

Richard Baker PhD CEng
Professor of Clinical Gait Analysis | School of Healthcare Science
C710, Allerton Building, University of Salford, Salford M6 6PU
t: +44 (0) 161 295 2465
r.j.baker@salford.ac.uk | www.salford.ac.uk | **blog:** www.wwRichard.net | profile

From: Pia Wedege [mailto:piawedege@hotmail.com]
Sent: 28 April 2013 20:31
To: Baker Richard
Subject: RE: Reliability of 3DGA in adults with an incomplete spinal cord injury

Dear Mr Baker.

Some of the illustrations in 'All you ever wanted to know about the Conventional Gait Model but were afraid to ask' would be ideally suited for my master thesis. I would appreciate your permission to reprint these with the appropriate reference source.

Best regards
Pia Wedege
