

**Title: Test-retest reliability and minimal detectable change of ankle kinematics and spatiotemporal parameters in MS population.**

**Abstract (295 words)**

*Background*

Many people with multiple sclerosis (pwMS) experience walking impairments often including foot drop, evident as either reduced dorsiflexion at initial contact and/or at the swing phase of the gait cycle. To measure even subtle differences in ankle kinematics 3D gait analysis is considered a 'gold' standard. However, the psychometric properties of ankle kinematics in the MS population have not yet been examined.

*Objective*

The aim of the study was to examine test-retest relative and absolute reliability of sagittal ankle kinematics and spatiotemporal parameters in two groups of pwMS with different levels of walking impairment.

*Methods*

Two groups of pwMS underwent 3D gait analysis on two occasions 7 to 14 days apart. Group A consisted of 21 (14 female) people with Expanded Disability Status Scale (EDSS) 1-3.5 and group B consisted of 28 participants (14 female) with EDSS 4-6. The Intraclass Correlation Coefficient (ICC<sub>2,2</sub>), standard error of measurement (SEM) and minimal detectable change (MDC<sub>95%</sub>) were calculated for peak dorsiflexion (DF) in swing, ankle angle at initial contact (IC), gait profile score (GPS), walking speed, cadence and step length.

*Results*

Both groups presented ‘excellent’ ICC values ( $>0.75$ ) for DF in swing, IC and step length of most and least affected limbs, walking speed and cadence, with GPS for both limbs exhibiting ‘fair’ to ‘good’ ICCs (0.489-0.698). The  $MDC_{95\%}$  values for all ankle kinematic parameters in group A were lower ( $1.9^\circ - 4.2^\circ$ ) than those in group B ( $2.2^\circ - 7.7^\circ$ ).

### *Conclusion*

The present results suggest that ankle kinematic and spatiotemporal parameters derived from 3D gait analysis are reliable outcome measures to be used in the MS population. Further, this study provides indices of reliability that can be applied to both clinical decision making and in the design of studies aimed at treating foot drop in people with MS.

### **Keywords**

reliability, ankle kinematics, multiple sclerosis, minimal detectable change

## **Introduction**

Gait impairment is a common problem in people with multiple sclerosis (pwMS) and this may negatively affect participation and quality of life. The typical gait pattern in most pwMS is to walk slowly, with associated shorter stride length and prolonged double support phase [1-4]. Moreover, studies examining kinematic changes in minimally impaired pwMS reported that there is a decrease of the ankle angle at initial contact and decrease in peak dorsiflexion in swing compared to healthy individuals [1,3,5]. Three-dimensional gait analysis (3DGA) through motion capture systems is an established method to quantify and reveal even minimal gait disorders in a variety of populations and has been considered the 'gold' standard in terms of quantitative gait analysis [6-7]. A recent systematic review reported that 3DGA is one of the most common outcome measures used to evaluate walking performance in MS population [8]. In recent years, there has been an increasing focus on the characterisation of gait pattern in pwMS through 3D kinematics [9-10]. More specifically, studies have reported on ankle kinematics to assess the effect of interventions such as Functional Electrical Stimulation (FES) and Ankle Foot Orthosis (AFO) on the treatment of foot drop [4, 11-12].

Gait kinematic outcome measures, need to exhibit the psychometric characteristics of reliability and responsiveness to changes. This is required in order that they may be used to assess meaningful change after clinical practice or research interventions [13]. Variability in 3D kinematics between sessions can be attributed to 'intrinsic' factors, such as age and pathology or due to 'extrinsic' factors such as marker placement, data processing or assessors' experience. Consequently, it is important to identify the measurement error for these outcomes in order to avoid misinterpretation of the results, e.g. either meaningful changes to be missed or small changes to be considered meaningful [14-15].

The psychometric properties of 3D gait kinematics are well established in healthy and other clinical populations such as stroke patients and people with cerebral palsy (CP) [16-21].

Interestingly, despite 3D ankle kinematics being one of the most frequently used outcome measures to assess the effects of assistive technology on foot drop, no studies reporting on its psychometric properties were identified for the MS population [8] even though it is considered a 'gold standard' for the assessment of walking performance [6].

In line with the definitions by de Vet et al. [22], we examined two aspects of reliability, namely relative reliability (or relative consistency), which is assessed by the ICC and absolute reliability (or measurement error), which is reported by measures like standard error of measurement (SEM), minimal detectable change (MDC) and the Limits of Agreement (LoA). Therefore, the purpose of this study was to examine relative and absolute reliability of the ankle kinematics and spatiotemporal parameters in pwMS when walking. As reliability assessment of walking impairment may be influenced by disease progression, this study included two groups of pwMS. One group included pwMS judged to have no walking impairment according to Expanded Disability Status Scale (EDSS range 0-3.5) and a second group classified by EDSS (range 4-6) as exhibiting mild to moderate walking impairment and using FES to treat foot drop or judged to be suitable to use FES.

## **Methods**

### ***Participants***

Forty-nine participants were recruited for the present study from National Health Services (NHS) in Edinburgh, UK. The cohort consisted of two groups according to their EDSS assigned level of walking impairment. The eligibility criteria for both groups were clinically definite diagnosis of MS according to the revised McDonald criteria and aged above 18. Participants in group A did not report any walking difficulties in their activities of daily life (EDSS<3.5). Participants in group B experienced foot drop during walking and were using or judged to be suitable for FES to treat foot drop (EDSS 4-6). The exclusion criteria for both groups were pregnancy or breast-feeding and any relapse in the past three months. The protocol was given a favourable opinion by the appropriate NHS Research Ethics Committee (REC number: 15/SS/0088) and Queen Margaret University Ethics Committee and all procedures were in accordance with the declaration of Helsinki regarding human experimentation. All participants who were eligible and agreed to take part in the study signed an informed consent form prior to commencing with the protocol.

### ***Experimental protocol***

Participants visited the motion analysis laboratory and underwent 3D gait analysis on two occasions 7 to 14 days apart. This period was assumed to be both practical for participants who may not wish to travel to the university twice within one week and too short for clinically important changes to occur. The two testing sessions were performed at the same time of the day. Data collection for each group was performed by two different raters, i.e. one rater was responsible for the data collection for both visits in Group A and the other rater for all data

collection in group B. Both raters used the same marker placement protocol and had undergone training and quality assurance by the same senior gait analyst. The gait analysis was undertaken using an eight infra-red camera (100Hz) Vicon Nexus computerized 3D motion capture system (Vicon Motion Systems, Oxford, UK). Passive reflective sphere markers of 9mm were placed on the lower limbs and pelvis of the participants according the Helen Hayes marker system [23]. A static trial was conducted first using a knee alignment device (KAD) to derive the orientation of the knee flexion/extension axis. Participants completed six trials by walking barefoot over a distance of 7m across the laboratory. To avoid fatigability, participants were instructed to walk in their preferred speed and were allowed to sit down/rest in between each trial.

### ***Kinematic data processing***

Kinematic data for each of the six trials in each visit were derived using the Vicon Plug-in-Gait software, which includes filtering and were time normalised so that every trial included one gait cycle (i.e. between two consecutive foot strikes) consisting of 51 data points. Foot contact events i.e. foot strike, foot-off and foot strike for each leg were manually selected from the stick figure in the Vicon Workstation environment. Through Polygon (version 3.5.2) (Oxford Metrics Group, Oxford, UK), kinematic and spatiotemporal data were extracted to Microsoft Excel files. The following parameters were derived for each trial: peak dorsiflexion (DF) in the swing phase, dorsiflexion at initial contact (IC) and step length of most and least affected limbs, walking speed and cadence. A custom written Matlab (R2014b, Mathworks, Natrick, USA) script was used to derive the peak DF in swing and dorsiflexion at initial contact from the processed data derived from Plug-In-Gait. This script allowed manual selection of the appropriate points on the ankle angle time curve for each trial for both limbs.

The Gait Profile Score (GPS) was also calculated for each walking trial for both visits and for the most and least affected limb separately. The GPS is an index of overall gait pathology and is derived from the pelvis, hip, knee and ankle kinematics. The higher the GPS score, the higher the deviation from a normal gait pattern [24].

### *Statistical analysis*

The relative reliability for peak DF in swing, dorsiflexion at IC, GPS and spatiotemporal parameters was calculated with the ICC (model 2, 2) using a two-way mixed effects type of average measures for absolute agreement [25]. As a guide for interpretation, intraclass correlation coefficient values  $\geq 0.75$  were regarded as excellent level of practical and clinical significance for test-retest reliability, while ‘good’ was between 0.60-0.74 and ‘fair’ between 0.40-0.59 [26].

The absolute reliability for the aforementioned variables was determined by reporting standard error of measurement (SEM) and minimal detectable change ( $MDC_{95\%}$ ) values. The SEM is related to an outcome’s reliability, because it provides an indication of the variability among measurements [22]. It was determined with the following equation:

$$SEM = SD \times \sqrt{(1 - ICC)} \quad (1)$$

where SD is the standard deviation from the first testing session.

Minimal detectable change is important information for an evaluative instrument to provide to clinicians and researchers because it gives information of the cut-off point above which it is likely that the change is not solely due to measurement error or normal variation [22] and was calculated using the equation:

$$MDC_{95\%} = 1.96 \times SEM \times \sqrt{2} \quad (2)$$

All ICC and 95% Confidence Interval (CI) values were calculated using SPSS 23 (IBM, Armonk, USA).

## Results

Group A consisted of 21 pwMS with no walking impairments and group B consisted of 28 pwMS who presented with foot drop. The demographic characteristics of the participants in both groups are provided in Table 1.

**Table 1** Participant characteristics.

	<b>Group A</b>	<b>Group B</b>	<b>p-value</b>
Female/Male, n	14/7	14/14	0.12
Age, years	43.8 (10.9)	52.2 (10.1)	<b>0.004</b>
EDSS range	1-3.5	4-6	-
Height, m	1.71 (0.08)	1.69 (0.07)	0.27
Body mass, kg	72.6 (14.4)	78.2 (16.7)	0.10
BMI, kg/m <sup>2</sup>	24.7 (4.4)	26.9 (4.3)	<b>0.04</b>
Walking aid (none/ walking stick/stroller), n	0/0/0	16/11/1	-

Abbreviations: BMI: Body Mass Index; EDSS: Expanded Disability Status Scale; NA: not available

Table 2 and Table 3 present the mean and standard deviation values from both visits of both groups respectively, ICCs (95% CI) between the two visits, and the SEM and MDC<sub>95%</sub> for all ankle kinematic and spatiotemporal parameters. There were no statistically significant differences ( $p > 0.05$ ) in any of the parameters between the two visits in either group. For group A, DF in swing, dorsiflexion at IC, walking speed, step length and cadence all exhibited ‘excellent’ ICC values of  $\geq 0.75$ . ‘Good’ reliability in this group was shown by the ICC values for the GPS of the most affected (ICC=0.698) and least affected (ICC=0.621) legs. For group B a similar pattern was observed, with peak DF in swing, dorsiflexion at IC, step length of the most affected leg, walking speed and cadence presenting ‘excellent’ ICC values. The ICC values for the GPS for both legs and step length of the least affected leg were ‘fair’ to ‘good’.

Absolute agreement analysis showed that the outcome measures in group B (SEM=0.8°-2.8°) had somewhat higher SEM values than those in group A (SEM=0.7°-1.5°) and higher MDC<sub>95%</sub> values by between ≈1°-5°. Group A also had lower SEM and MDC<sub>95%</sub> values for walking speed, step length and cadence (Table 2 & 3).

The Bland & Altman plots for both groups separately are presented as supplementary material.

Similar to the MDC values, they show that, in general, values indicating a higher walking impairment (i.e. those in Group B) are associated with a higher measurement error.

**Table 2** Test-retest reliability with mean (SD), ICC (95%CI), SEM and MDC for group A (unimpaired) kinematic and spatiotemporal parameters.

	<b>Session 1</b>	<b>Session 2</b>	<b>ICC (95% CI)</b>	<b>SEM</b>	<b>MDC</b>
	<b>Mean (SD)</b>	<b>Mean (SD)</b>			
Peak DF in swing MA (°)	7.9 (2.3)	8.1 (3.0)	0.862 (0.660-0.944)	0.85	2.4
Peak DF in swing LA (°)	9.0 (2.5)	8.9 (2.8)	0.862 (0.657-0.944)	0.9	2.5
AAIC MA (°)	0.9 (4.2)	1.7 (4.6)	0.919 (0.800-0.967)	1.21	3.4
AAIC LA (°)	2.5 (3.9)	2.1 (5.2)	0.852 (0.635-0.940)	1.5	4.2
GPS MA (°)	9.0 (1.4)	8.7 (1.1)	0.698 (0.274-0.876)	0.75	2.1
GPS LA (°)	9.0 (1.1)	8.9 (1.6)	0.621 (0.039-0.848)	0.7	1.9
Walking speed (m/s)	1.25 (0.14)	1.26 (0.18)	0.833 (0.585-0.932)	0.06	0.16
Step length MA (m)	0.64 (0.07)	0.64 (0.08)	0.931 (0.830-0.972)	0.02	0.05
Step length LA(m)	0.64 (0.07)	0.63 (0.07)	0.909 (0.777-0.963)	0.02	0.06
Cadence (steps/min)	117 (7)	119 (9)	0.877 (0.698-0.950)	2	6

Abbreviations: AAIC: Ankle Angle at Initial Contact; DF: Dorsiflexion; LA: Least Affected; MA: Most Affected

**Table 3** Test-retest reliability with mean (SD), ICC (95% CI), SEM and MDC for group B (mild-moderate walking impairment) kinematic and spatiotemporal parameters.

	<b>Session 1</b> <b>Mean (SD)</b>	<b>Session 2</b> <b>Mean (SD)</b>	<b>ICC (95% CI)</b>	<b>SEM</b>	<b>MDC</b>
Peak DF in swing MA (°)	2.9 (6.7)	1.9 (6.5)	0.891 (0.761-0.951)	2.2	6.1
Peak DF in swing LA (°)	7.5 (4.2)	6.4 (3.6)	0.823 (0.606-0.920)	1.8	4.9
AAIC MA (°)*	-3.7 (6.9)	-4.5 (5.6)	0.840 (0.647-0.928)	2.8	7.7
AAIC LA (°)*	1.8 (5.6)	1.1 (5.0)	0.773 (0.495-0.898)	2.7	7.4
GPS MA(°)	9.1 (1.3)	8.8 (1.0)	0.636 (0.192-0.836)	0.8	2.2
GPS LA (°)	9.5 (1.1)	9.2 (0.8)	0.489 (-0.105-0.767)	0.8	2.2
Walking speed (m/s)	0.77 (0.21)	0.81 (0.2)	0.831 (0.629-0.924)	0.08	0.23
Step length MA(m)	0.49 (0.09)	0.51 (0.09)	0.848 (0.666-0.931)	0.04	0.1
Step length LA (m)	0.47 (0.08)	0.49 (0.10)	0.742 (0.431-0.884)	0.04	0.1
Cadence (steps/min)	93 (16)	96 (14)	0.927 (0.835-0.968)	4	12

Abbreviations: AAIC: Ankle Angle at Initial Contact; DF: Dorsiflexion; LA: Least Affected; MA: Most Affected

\*a negative sign indicates plantarflexion.

## Discussion

An accurate measurement of ankle kinematics is an important outcome when evaluating the impact of an intervention aimed at the treatment of foot drop such as Functional Electrical Stimulation. Three-dimensional gait analysis which is considered a ‘gold’ standard for movement analysis provides this accurate method of recording ankle kinematics which is not possible through visual observation and most inertial sensors. Therefore, this study set out with the aim of reporting on the relative and absolute reliability of 3D ankle kinematics and spatiotemporal parameters in two groups of pwMS with different levels of walking impairment. Reliability indices were derived through a test-retest design with a period of seven to fourteen days between the two visits. The results indicated good to excellent ICC values for ankle kinematics, walking speed, step length and cadence in both groups. Fair to good ICC values ( $\approx 0.48-0.69$ ) were found for the GPS in both groups. Another important finding was that the  $MDC_{95\%}$  values of peak DF in swing and dorsiflexion at IC were lower ( $\approx 2.5^\circ$ ) for the low EDSS

group (unimpaired group A) compared to the high EDSS group (mild-moderately impaired group B) with  $MDC_{95\%}$  values ranging from  $4.9^\circ$ - $7.7^\circ$ .

Similar to our findings, studies with healthy, stroke and CP populations have shown good to excellent ICC values ranging from 0.77-0.93 for ankle kinematics [16, 18-21, 27-28]. In addition, excellent ICC values were observed for the GPS in both stroke and CP populations [18,29]. However, in contrast to our findings, one study in healthy and one in stroke populations have shown low ICCs for ankle kinematics and a possible explanation of this might be the small sample size that was used in these two studies ( $n=10$ ) [30-31]. Interestingly, the  $MDC_{95\%}$  values for our low EDSS group were similar to values reported for the healthy population with  $MDC_{95\%}$  values of  $\approx 3.8^\circ$  for peak DF in swing [16-17, 28]. In contrast, the  $MDC_{95\%}$  values reported for our higher EDSS group B are consistent with data obtained in stroke and CP populations. For example,  $MDC_{95\%}$  values have been reported to be  $4.9^\circ$  for peak DF in swing and  $7^\circ$  for initial contact in a study including participants after stroke [19]. The  $MDC_{95\%}$  of 6 degrees for the most affected leg in group B is higher than the mean orthotic effect of FES of 4 degrees reported by Scott et al [11]. However, in this and the few other papers that reported on the ankle kinematics in people with MS [4, 11-12], the individual data are not included. This means that we cannot comment on the number of participants of whom the orthotic effect of FES exceeded the  $MDC_{95\%}$  derived from this reliability study. Further, future studies should examine the Minimal Clinically Important Differences (MCID) for outcomes of ankle kinematics related to foot drop as these are currently lacking. Knowledge of these MCID values would assist in the clinical interpretation of the indices for the measurement error found in this study. In accordance with the present results, previous studies have demonstrated that spatiotemporal parameters are reliable and highly repeatable in the healthy population [32], along with cadence and walking speed (ICC

range 0.76-0.95) for children with CP [20, 33]. Although estimates of reliability for gait kinematics have not been reported in the MS population, a study by Sosnoff et al. [34] examined the reliability of walking speed, cadence and step length. They reported that in a group of pwMS with a varied disability level [Patient Determined Disease Steps (PDSS) range 0-6] there were excellent ICC values (0.91) for the spatiotemporal parameters similar to our findings for both groups.

Our results seem to indicate, unsurprisingly, that those pwMS whose walking ability is more impaired have a less reproducible gait pattern than those with no or little walking impairment. This trend was also shown by Redekop et al. [20] who reported that relative reliability in all kinematic variables were highest for children with Gross Motor Function Classification System (GMFCS) Level I (least impaired walking ability) compared to those with GMFCS Level II and III.

Similarly, several studies, exploring the association between gait variability and clinical walking indices in the MS population, concluded that, in comparison with people characterized with lower EDSS, people with higher EDSS (>4.5) and those using assistive devices had great variability in spatiotemporal parameters (i.e. step length, step time, etc.) [35-39].

### *Limitations*

This study has some limitations that should be addressed in the future. Firstly, both groups, but especially group A, had small sample sizes. According to the COSMIN criteria, the methodological quality of this study would be considered poor as the sample size is less than 30. Furthermore, in the present study, we were interested in ankle kinematics specifically, since it is an objective measure for the quantification and monitoring of foot drop in pwMS. However,

future studies should address the reliability of kinematics of other joints such as pelvis, hip and knee.

## **Conclusion**

The main objective of the present study was to determine relative and absolute reliability of 3D ankle kinematics and spatiotemporal parameters in two groups of pwMS with different levels of walking impairment.

The results showed good to excellent ICC values of peak DF in swing, dorsiflexion at IC, GPS, walking speed, step length and cadence. The SEM and  $MDC_{95\%}$  values for each of the parameters were lower for the group with lower EDSS compared to the group with higher EDSS and possibly suggesting the higher walking impairments are associated with higher within participant variability and thus lower the inter-session reliability.

The findings of this study provide clinicians and researchers with the indices of relative and absolute reliability for ankle kinematics in pwMS that can be applied to both clinical decision making and in the design of studies aimed at treating foot drop in people with MS. Future studies should consider investigating the responsiveness of ankle kinematics and spatiotemporal parameters.

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