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Clinical assessment of gait in individuals with multiple sclerosis using wearable inertial sensors: Comparison with patient-based measure

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ABSTRACT

Background: This study aims to verify the feasibility of use of wearable accelerometers in an ambulatory environment to assess spatiotemporal parameters of gait in people with Multiple Sclerosis (pwMS), as well as the correlation of objective data with patient-reported outcomes.

Methods: One hundred and five pwMS (Expanded Disability Status Scale, EDSS in the range 0–6.5) classified in three sub-groups (EDSS 0–1.5, EDSS 2–4, EDSS 4.5–6.5) and 47 healthy controls (HC) participated in the study. All the subjects were evaluated with the timed 25-foot walking test (T25FW) while wearing a commercially available accelerometer. PwMS also rated the impact of the disease on their walking abilities using the 12-item MS walking scale (MSWS-12).

Results: All parameters objectively measured, except stride length, were significantly modified in pwMS with higher EDSS, with respect to HC and lower disability participants. Moderate to high correlations (r =0.57–0.79) were observed between gait parameters and MSWS-12 for pwMS of higher EDSS. The correlation was found moderate for the intermediate EDSS category (r =0.42–0.62).

Conclusion: Wearable accelerometers are a useful tool for assessing gait performance for pwMS in a clinical setting, especially in cases of mild to moderate disability. Compared with other quantitative techniques, these devices allow patient testing under realistic conditions (i.e., fully dressed, with their usual shoes) using a simple procedure with immediate availability of data.

1. Introduction

Gait dysfunctions, which originate from a combination of fatigue, muscular weakness, spasticity, ataxia, and balance deficits (Cameron and Wagner, 2011), represent a distinct feature of multiple sclerosis (MS). In addition to other issues, they may result in reduced speed, decreased step length and cadence, and alteration of the physiological stance/swing phase duration. Their impact is relevant for people with MS (pwMS), given that approximately 40% of them (Larocca, 2011) report walking problems, which negatively affect their quality of life. This explains the search for the most appropriate way to measure walking disability, a process that should be easy to perform while supplying reproducible, reliable, and clinically meaningful results (Kieseir and Pozzilli, 2012). In fact, periodic and accurate gait pattern assessments are crucial for clinical purposes like monitoring disease progression, and in verifying the effectiveness of pharmacologic and rehabilitative treatments.

Specific measures to assess MS gait performance in clinical settings include timed tests for walking speed (timed 25-foot walk, T25FW, 10–30–100 m walking test, 10MTW, 30MTW, and 100MTW) or distance (2- or 6-min walking test, 2mWT, and 6mWT). They are often integrated with subjective measures of impact for walking ability and related pathology, such as the MSWS-12 (Hobart et al., 2003). However, despite their usefulness, timed tests do not provide detailed and precise knowledge of all the spatiotemporal and kinematic variables associated with the gait cycle, such that more refined analyses might require detailed quantitative measures, which can be obtained only using devices specifically designed for human movement analysis.

The gold standard for gait analysis is currently found in optoelectronic stereophotogrammetry (Cameron and Wagner, 2011; Bethoux and Bennett, 2011). However this technique, although successfully applied in characterizing specific features of MS gait, (Cofré Lizama et al., 2016) has limited use in clinical settings. In fact, a dedicated laboratory is needed and since the system is not portable it is

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practically impossible to assess walking in 'real-word' settings like the subject's home and related environments. Moreover, the equipment is expensive, data acquisition processing is time-consuming and can only be performed by specialized personnel (Cameron and Wagner, 2011).

To overcome some of these limitations, in recent years research has focused on the development of lightweight, portable, and wearable sensors for objective gait assessment, allowing for pwMS testing under more realistic conditions (Iosa et al., 2016). The advancements in micro-electro-mechanical systems (MEMS) technology makes miniaturized sensors (including accelerometers and gyroscopes) available at an affordable cost, so that it is possible to collect data for mobility features outside of the laboratory.

Wearable accelerometric sensors (alone or in combination with gyroscopes and in some cases magnetometers thus composing a so-called "inertial measurement unit", IMU) have been used on pwMS for almost twenty years particularly in performing long-term measurements of mobility in everyday life (Ng and Kent-Braun, 1997; Pearson et al., 2004; Sosnoff et al., 2012a, 2012b; Motl et al., 2013; Sandroff et al., 2014; Neven et al., 2016), extracting quantitative features associated with the Timed-Up-and-Go test (Kuusik et al., 2014; Greene et al., 2014) and assessing disability on the basis of lower limb kinematics (Motta et al., 2016). However, less explored is the possibility of employing such devices as tools for supplying data on spatio-temporal parameters that are not deductible from the aforementioned timed tests to integrate the routine clinical assessment.

As such, this study proposes the application of inertial sensors to assess spatiotemporal gait parameters for pwMS in a typical clinical environment. At the same time the T25FW test, which is considered the best objective measure of walking disability for MS, (Kieseir and Pozzilli, 2012) will be administered. The results of both tests will be correlated with the MSWS-12 for agreement between patient-reported and objective measurements of gait features, carried out with other tools dedicated to walking assessment, and widely employed with MS (Pilutti et al., 2013).

2. Methods

2.1. Subjects

A convenience sample of 105 pwMS (74 female, 31 male, mean age 42.2 ± 9.5 years) with an EDSS score in the range 0–6.5 (mean EDSS 2.2 ± 1.6) were voluntarily enrolled in the study at the Multiple Sclerosis Center of Cagliari (Sardinia, Italy) after a neurological evaluation by a neurologist expert in MS (EC, GC, LL, MGM). The main criteria for inclusion were a diagnosis of MS according to the 2005 or 2010 revisions of the McDonald criteria (Polman et al., 2005, 2011), the ability to independently ambulate with or without assisting devices (cane, crutches, or walking frames) for at least 100 m, and the absence of other conditions that affect gait. Participants were stratified in three classes, according to disability level.

- Class 1: mild disability (EDSS 0–1.5, n =54)
- Class 2: mild to moderate disability (EDSS 2.0–4.0, n =31)
- Class 3: moderate disability (EDSS 4.5–6.5, n =20)

A control group (HC, n=47, mean age 39.4 ± 12.7 years) of healthy individuals was recruited among medical staff and pwMS parents and caregivers. Participants' main features are shown in Table 1. The local Ethics Committee approved the study, and all participants signed an informed consent agreeing to participate in the study.

2.2. Quantitative measurement of gait parameters

Spatiotemporal parameters of gait were obtained with a wireless inertial sensing device (G-Sensor®, BTS Bioengineering S.p.A., Italy), previously validated in gait assessment for healthy subjects and those with Parkinson's disease (Bugané et al., 2012; Pau et al., 2015; Kleiner et al., 2016). This small, wearable unit (Fig. 1) includes a tri-axial accelerometer, a gyroscope, and a magnetometer, and allows for gait analysis through processing of trunk accelerations due to the fact that the foot contact with the ground causes distinct, rapid, and easily identifiable oscillations of the accelerometric signal (Kavanagh and Menz, 2008). Details on the procedure of calculation of the gait parameters from the accelerometric signal can be found in Bugané et al. (2012).

Table 1
Anthropometric and clinical features of participants by subgroup. Values are expressed as mean ± SD.

	Healthy Controls	MS Class 1 EDSS 0–1.5	MS Class 2 EDSS 2.0–4.0	MS Class 3 EDSS 4.5–6.5
Participants number (M,F)	47 (26M, 21F)	54 (17M, 37F)	31 (9M, 22F)	20 (5M, 15F)
Age (years)	39.4 ± 12.7	39.6 ± 8.3	43.6 ± 9.3	52.1 ± 10.2
Height (cm)	163.9 ± 8.5	163.4 ± 8.1	164.9 ± 9.2	162.0 ± 8.0
Body Mass (kg)	60.7 ± 12.0	62.2 ± 13.0	59.6 ± 10.4	55.9 ± 10.8
EDSS	NA	1.0 ± 0.2	2.6 ± 0.6	4.6 ± 1.1

MS: Multiple Sclerosis; EDSS: Expanded Disability Status Scale; NA: Not Applicable

Experimental tests were performed in a clinical setting (Multiple Sclerosis Center, Cagliari, Italy) with participants walking along a 15-m hallway at a self-selected speed, and in the most natural manner. The inertial sensor was attached at the lower lumbar level (centered on the L4–L5 intervertebral disc) with a semi-elastic belt. The device acquired acceleration values (along three orthogonal axes: anteroposterior, mediolateral, and superoinferior) which were transmitted in real time via Bluetooth to a PC and processed with dedicated software (BTS Bioengineering G-Studio®) to derive the following gait parameters:

- Stride length: distance between two consecutive heel contacts of the same foot (m);
- Gait speed: mean instantaneous speed within the gait cycle (m s^{-1});
- Cadence: number of steps per minute (steps min^{-1});
- Stance and swing duration: expressed as a percentage of the gait cycle, representing the proportion of a gait cycle involving foot support (from heel strike to toe with the same foot) and swing of the lower limb;
- Double support duration: the duration of phase support on both feet, expressed as a percentage of the gait cycle.

During the walking trial with the inertial sensor, an operator using a stopwatch manually recorded the time necessary to cover a 25-foot distance (T25FW), which was marked on the hallway floor with visible tape. In this way, the acceleration phase was discarded to perform a modified version of the T25FW test, according to Phan-Ba et al. (2012). This was necessary to obtain a reliable comparison of gait speed with the two techniques, as the software that manages the inertial sensor automatically discards the first and last two steps of the trial to calculate all parameters in stationary conditions (i.e., constant speed). The number of valid steps considered by the software for the calculation of the spatio-temporal parameters varied depending on participant's height, and was in the range of 6 - 14 (mean value 8). All participants performed the minimum number of steps requested by the management software to consider the trial valid.

2.3. Patient-reported measures

The MSWS-12 is a patient-based measure of the impact of MS on walking, developed by Hobart et al. (2003), which was recently validated for the Italian population (Solaro et al., 2015). The scale is