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Body-worn sensors capture variability, but not decline, of gait and balance measures in multiple sclerosis over 18 months

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ABSTRACT

Gait and balance deficits are a frequent complaint in MS but poorly captured by stopwatch-timed tests or rating scales. Body-worn accelerometers and gyroscopes are able to detect gait and balance abnormalities in people with MS who have normal walking speeds. Few longitudinal studies exist using this technology to study the evolution of mobility deficits. The purpose of this study was to determine if body-worn sensors detected any decline in gait and balance measures in people with MS over time. Twenty-seven people with MS (13 mildly disabled, self-rated expanded disability status scale 0–3.5; 14 moderately disabled, SR-EDSS 4.0–5.5) who had normal walking speeds and 18 matched control subjects underwent gait and balance testing using body-worn sensors every 6 months for 18 months. While no parameter worsened over time, the moderately disabled MS cohort performed more poorly than the mildly disabled MS cohort who, in turn, was worse than control subjects for both objective and subjective walking and balance measures. Furthermore, the moderately disabled MS cohort demonstrated greater variation in between-visit performance than did the less disabled MS cohort or controls (Bonferroni-corrected $p < 0.05$). Variability may be a key indicator of worsening gait and balance disability in MS.

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1. Introduction

Gait and balance impairment, the hallmark of MS, is a frequent and disabling complaint affecting about a quarter of people with MS at disease onset and nearly half by five years [1]. Yet typical clinical measures capturing gait and balance dysfunction are insensitive to mild disease or subtle worsening. For instance, at least 20% slowing in the walking time is required for the Timed 25 Foot Walk (T25FW) to be considered clinically significant [2]. The expanded disability status scale (EDSS), a physician-administered global rating scale of MS neurological disability, is notoriously slow to detect change and prone to intra- and inter-rater reliability problems [3]. Because MS gait and balance problems occur early and commonly, measures of mobility dysfunction with greater sensitivity than the T25FW and EDSS may detect MS worsening sooner than the typical 2 year clinical trial needed to demonstrate clinical worsening [4]. Improved establishment and monitoring of MS functional status is necessary to individualize MS treatment including optimizing disease-modifying therapy, identifying deficits with rehabilitation potential, and encouraging lifelong treatment adherence.

Until recently, specialized motion-analysis laboratories were required to capture sophisticated gait and balance data. Portable technologies now that collect equivalent data rapidly and with instant analysis are being widely explored for use in MS both in clinic and at home. These include accelerometers, pedometers, and pressure mats for gait analysis [5,6]. Novel, synchronized, body-worn inertial sensors housing both accelerometers and gyroscopes derive data most closely matched to the 3-dimensional information obtained in a motion-analysis laboratory [7]. We previously demonstrated that these body-worn sensors detected objective gait and balance deficits among people with MS who had normal walking speeds compared to matched control subjects when traditional T25FW could not suggesting improved sensitivity of these measures [8].

To our knowledge, no studies have examined the use of body-worn inertial sensors longitudinally in MS as a measure of functional decline. We followed our original cohort of MS subjects with normal walking speeds and matched control subjects every 6 months for 18 months and asked if the abnormal gait and balance parameters captured by body-worn sensors *worsen* over time in this cohort.

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2. Patients

The Oregon Health & Science University Institutional Review Board approved the study in accordance with the Declaration of Helsinki. All subjects gave written informed consent prior to assessments.

Subject recruitment and sample size estimations are described in the baseline analysis paper [8]. Briefly, people with MS of any type were included if their T25FW time was within two standard deviations (<5 s, *e.g.* normal walking speed) of the age- and sex-matched control group, and had no other cause for gait or balance dysfunction. Visits were postponed by at least 60 days after an MS exacerbation.

3. Methods

3.1. Protocol

Two trials of the T25FW were recorded with a stopwatch and averaged according to instructions for the multiple sclerosis functional composite [9].

Instrumented tasks were completed while subjects had portable body-worn sensors attached to their wrists, ankles, sternum and lumbar back according to previously described methods [8]. For the gait task, subjects were instructed to stand up from a chair, walk 25 feet, turn, walk back to the chair and sit down, all "as quickly and safely as possible". The balance task was completed by having subjects stand with arms crossed and feet placed by a template for 30 s in eyes opened (EO) and eyes closed (EC) conditions [10,11]. Three trials of each instrumented task were completed, and the median and standard deviation over the 3 trials was calculated.

Self-reported gait and balance measures included the multiple sclerosis walking scale 12, V1 (MSWS12) and the activities of balance confidence scale (ABC) [12,13]. Subjects rated their MS disability using a self-rated EDSS (SR-EDSS) shown to correlate with the physician-rated version [14,15].

3.2. Equipment

A total of six body-worn sensors (Xsens, Enschede, The Netherlands www.xsens.com) each including a 3-dimentional gyroscope and tri-axial accelerometer sampling at 50 Hz were used, as previously described [8]. The sensors were wired serially and connected to a portable data-receiver on a waist belt. The data-receiver then wirelessly streamed data to a laptop.

3.3. Data analysis

Gait and balance objective measures were automatically derived from acceleration and angular velocity signals using the APDM Mobility Lab software (APDM, Inc., Portland, OR, USA) and a user interface. Pre-processing of signals to extract gait and balance measures has been previously described [10,11]. Briefly, the algorithm segments automatically the different parts of the gait task and provides separate analysis and measures for each part. Specifically, to analyze steady-state gait, after detecting sit-to-stand and stand-to-sit transitions and turns, steps within turns and transitions were removed. Only the remaining steps, which were taken only during straight walking, were used for further analysis [11].

Here, we present those gait and balance measures that were significantly different between MS and control groups in our previously published paper [8]. These included trunk yaw range of motion (*Trunk ROM yaw*) during gait, turning duration, sway acceleration amplitude (reported in this paper as the correlated measure of sway range in the mediolateral direction EC; *Sway Range ML EC*), and sway jerkiness EC ML (*nJerk ML EC*, Jerk is calculated from the first derivative of the acceleration) during quiet stance. In addition, we included other commonly reported mobility measures such as: gait velocity, sway area in the EO and EC conditions, and the percentage difference in area of sway between EO to EC condition (*Sway Area Ratio*, computed as the ratio between the median sway area in the EO and EC conditions normalized to EO).

3.4. Statistical analysis

Subjects from the baseline study (MS = 31, controls = 28) were included for analysis if they completed at least 2 of the 4 testing visits (MS = 27, controls = 18). The MS group was divided in two subgroups based on their initial SR-EDSS: MSmild (n = 13, SR-EDSS = 0–3.5), and MSmoderate (MSmod, n = 14, SR-EDSS = 4.0–5.5), similar to other studies [16].

Normality of the data was verified with the Shapiro–Wilk test before parametric analyses were performed. To assess the longitudinal changes in the self-rated and objective measures and the differences between the three groups (Controls, MSmild, MSmod), we performed a linear mixed model analysis considering group and time (sessions) as fixed factors. Significant main effects were subjected to *post hoc* Student's t-tests and Bonferroni corrected for multiple comparisons (specifically, group effect is corrected for 3 comparisons) [17].

As a secondary exploratory analysis, variability was assessed by the standard deviations within the three repetitions of the motor tasks (within-session) and between the different longitudinal visits (between-sessions). A 2 × 3 ANOVA, variability type (within-session, between-session) × group (Controls, MSmild, and MSmod) was used to investigate group differences among the within-session and between-session variability of the objective measures. Only the cases of significant group effect were subjected to *post hoc* Student's t-tests and Bonferroni corrected for multiple comparisons (group effect for 3 comparisons) to investigate if the between-session variability differed by group. All statistical analyses were made using NCSS Software, Kaysville, UT.

4. Results

The demographics of the 27 MS and 18 matched control subjects included in analysis are found in Table 1. MS subjects and controls were matched for age, sex, race and BMI. Mean MS disease duration was 10 years (median 5, range 0–46 years). All of the MS subjects had relapsing remitting disease, and about half (59%) were taking disease-modifying therapies. One MS subject took 4-aminopyridine, a symptomatic therapy that could affect walking speed, for one visit only but had no appreciable change in walking speed. The average SR-EDSS at baseline was 3.3 (0–5.5) with 13 in the mild disability group (MSmild, 2.2 average SR-EDSS) and 14 in the moderate disability group (MSmod, 4.3 average SR-EDSS). At the end of 18 months, the average change in SR-EDSS was −0.24 (−2.5 to 2.0) for all MS, −0.21 (−2.0 to 1.5) for MSmild, and −0.27 (−2.5 to 2.0) for MSmod. Eighty-nine percent of the MS subjects completed at least 3 of 4 study visits while only 44% of the controls did likewise. Month 12 (third of four visits) had the least compliance with 36% of all subjects (30% MS and 44% Controls) missing this visit.

Objective gait and balance measures did not worsen over the 18 months testing period (Fig. 1A–F; see no significant *Time* or *Interaction* effect, Table 2) in any group. Similarly, the T25FW, disability (SR-EDSS), and self-rated gait (MSWS12) and balance (ABC) did not worsen over time in MS or controls (Table 2).