Instrumented Shoe Insoles to Detect Changes in Gait Variability Across Disability Status in People with MS During a 500m Walk

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INTRODUCTION

- During prolonged walking, gait variability increases in people with multiple sclerosis (PwMS) [1].
    - Clinical assessments cannot objectively capture these digital gait biomarkers.
- Instrumented shoe insoles are an unobtrusive technology that can be integrated into commonly used clinical assessments to objectively assess gait quality.
    - Devices stream raw pressure, accelerometer, and gyroscope data to a mobile device via Bluetooth.
- By providing clinicians with objective tools, they can better understand the needs of their patients and advise earlier interventions to improve/maintain quality of life.

OBJECTIVE

- Analyze changes to gait variability in PwMS across disability status using extended disability status scale (EDSS) scores throughout a prolonged 500-metre walking session.

METHODS

PARTICIPANTS:
- 38 PwMS: 9 Male, 29 Female
    - 51.79 years (±13.39), EDSS 3.25 (±1.63; range: 0-6)

PROCEDURE:
- Participants walked up to 500 metres between two pylons placed 25 metres apart (i.e., 20 laps of 25 metres).
    - Participants were asked to perform both left- and right-hand turns to make a figure-8 pattern (Figure 1).
- Raw instrumented insole data were streamed to a mobile app (Celestra Health, Canada).

Figure 1. Illustration of experimental protocol.

ANALYSIS:
- Raw data were collected from the insoles using a smartphone app (Celestra Health, Canada) and exported for further use.
    - Pressure, Accelerometer, Gyroscope
- Custom Python scripts detected gait events (i.e., heel strike, foot-on-floor, heel rise, and toe off), following the methodology of [2] (Figure 2).

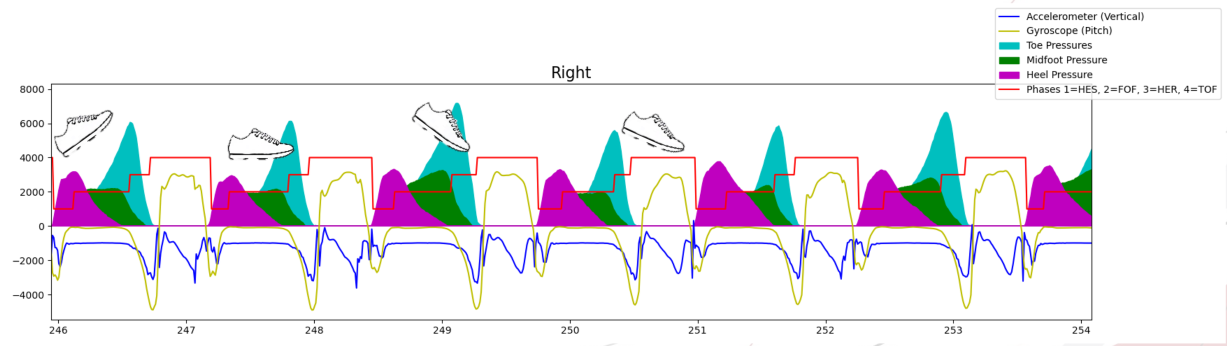

Figure 2. Gait detection from pressure, accelerometer, and gyroscope data.

- A trained deep neural network [3] identified walking, turning, and standing activities, which were used to parse the trial by laps (Figure 3).

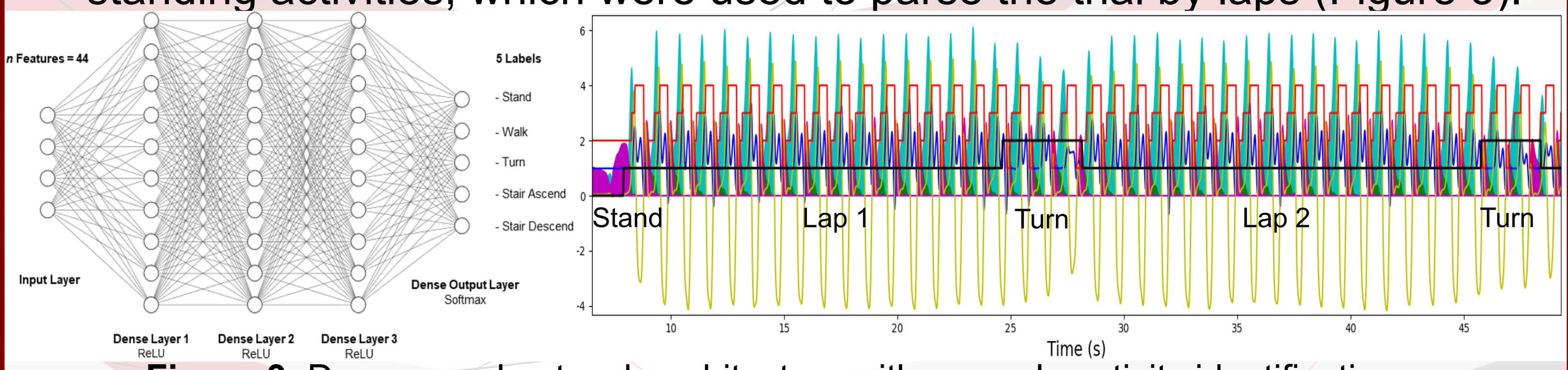

Figure 3. Deep neural network architecture with example activity identifications.

- 7 spatiotemporal variables were calculated using custom Python scripts:
    - Stride time, Stance time, Swing time, Single support time, Double support time, Stride length, and Stride velocity.
    - The standard deviation between strides was taken as a measure of gait variability for each spatiotemporal variable.
- Each measure of gait variability was calculated per quarter of the trial:
    - Q1: laps 1-5; Q2: laps 6-10; Q3: laps 11-15; Q4: laps 16-20
- Participants were separated into groups based on disability status:
    - Low (EDSS 0.0-2.0; n = 11)
    - Mid (EDSS 2.5-4.0; n = 15)
    - High (EDSS 4.5-6.0; n = 12)

STATISTICS:
- Two-way mixed design ANOVA (SPSS v28.0, IBM, USA)
    - Between subjects: EDSS group
    - Within-subjects: lap quarter
- Partial eta square (η^2) represents effect size [4]:
    - Small: 0 - 0.06; Medium: 0.06 - 0.14 ; Large: > 0.14

RESULTS

- Over the 500 m walk, stance time, swing time, and double support time variability significantly increases ($p < 0.05$) between quarters (Table 1).
    - A medium effect size ($0.06 < \eta^2 < 0.14$) is found for these variables.
- A significant interaction ($p < 0.05$) between quarter of the 500 m walk and disability group is found for stride time, stance time, swing time, single support time, and double support time variability (Table 1).
    - A large effect size ($\eta^2 > 0.14$) is found for these variables.

Table 1. Mean standard deviation values per quarter with significance testing between quarters and for quarter by disability status interactions

Spatiotemporal parameter	Quarter						Quarter * Group	
	Q1	Q2	Q3	Q4	*p*-value	η^2	*p*-value	η^2
Stride time (s)	0.027	0.028	0.029	0.029	0.112	0.062	0.001*	0.268
Stance time (s)	0.021	0.021	0.024	0.023	0.035*	0.097	0.001*	0.284
Swing time (s)	0.016	0.016	0.016	0.017	0.044*	0.076	0.001*	0.226
Single support time (s)	0.016	0.016	0.016	0.017	0.110	0.060	0.011*	0.160
Double support time (s)	0.015	0.015	0.018	0.018	0.010*	0.120	0.004*	0.190
Stride length (m)	0.047	0.050	0.048	0.051	0.102	0.062	0.418	0.056
Stride velocity (m/s)	0.050	0.050	0.048	0.050	0.555	0.019	0.680	0.035

Note: * = statistically significant ($p < 0.05$); η^2 = partial eta square; m = metre; s = second

- Post hoc analysis revealed that the significant differences found between quarters were mainly driven by changes in gait variability for the high disability group (Figure 4).

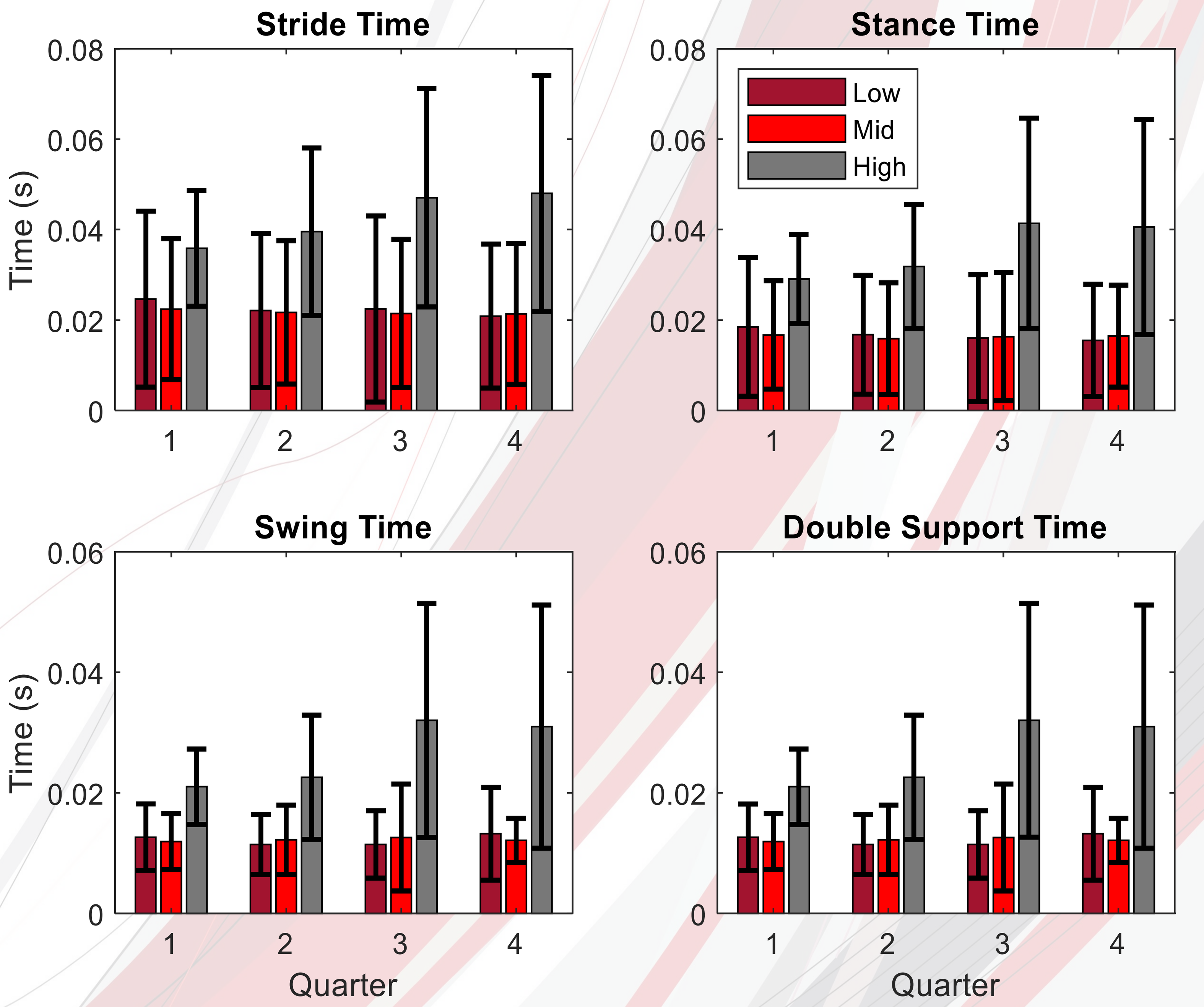

Figure 4. Example differences in gait variability for stride time, stance time, swing time, and double support time for each quarter of the 500 m walk by disability group.

DISCUSSION

- The presented gait analysis method using instrumented insole data can detect changes in gait variability across a prolonged 500 m walking bout.
    - For most spatiotemporal variables, gait variability is found to increase over a 500 m walk for the high disability group.
        - Increases in gait variability are possibly induced by physical fatigue as fatigue leads to poorer gait performance in PwMS [5].
- The increased variability observed in temporal parameters between quarters indicates that fatigue leads to increased fluctuations in the duration of the phases of the gait cycle.
- Clinicians/researchers can employ this method to calculate digital gait biomarkers and identify changes in gait variability that occur with fatigue.
- The objective gait information calculated using this method can provide further insights into the health status of PwMS, and can be used to:
    - Identify when PwMS are becoming fatigued.
    - Create personalized treatment plans.
    - Identify a need for an intervention.
    - Evaluate the effectiveness of an intervention.
    - Promote patient advocacy in their treatment plan.
- **FUTURE DIRECTIONS**:
    - Measure within- and between-day changes in gait variability in PwMS using instrumented insoles.
    - Assess the effect of changes in gait variability on gait stability.

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