Identifying Gait Differences in MS Disability Status Using Instrumented Shoe Insoles

Alexandre Mir-Orefice[1], Matthew P. Mavor[1], Ryan B. Graham[1,2]

INTRODUCTION

- Instrumented shoe insoles are unobtrusive wearable devices that can be placed in a user's normal footwear [1].
  - Devices can stream raw pressure, accelerometer, and gyroscope data to a mobile device via Bluetooth.
  - Logical and machine learning algorithms can then be used to detect gait events and calculate spatiotemporal metrics to be used as digital biomarkers.
- Digital biomarkers from instrumented insoles may be useful for:
  - Detecting disability status.
  - Detecting gait phenotypes.
  - Unobtrusively monitoring disease progression in people with multiple sclerosis (PwMS).

Objective

- Analyze differences in gait spatiotemporal parameters across disability levels (i.e., extended disability status scale (EDSS) score) for PwMS using instrumented insoles.

METHODS

PARTICIPANTS:

- 38 participants: 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).

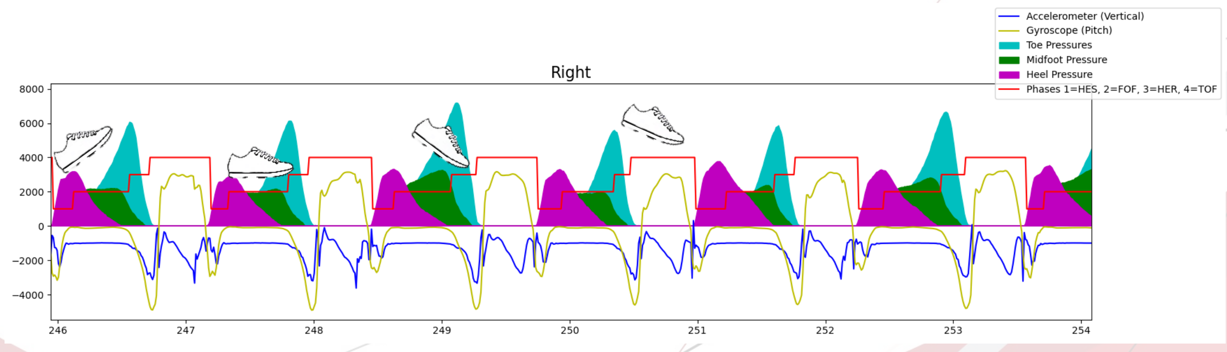

Figure 2. Gait detection from pressure, accelerometer, and gyroscope data.

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

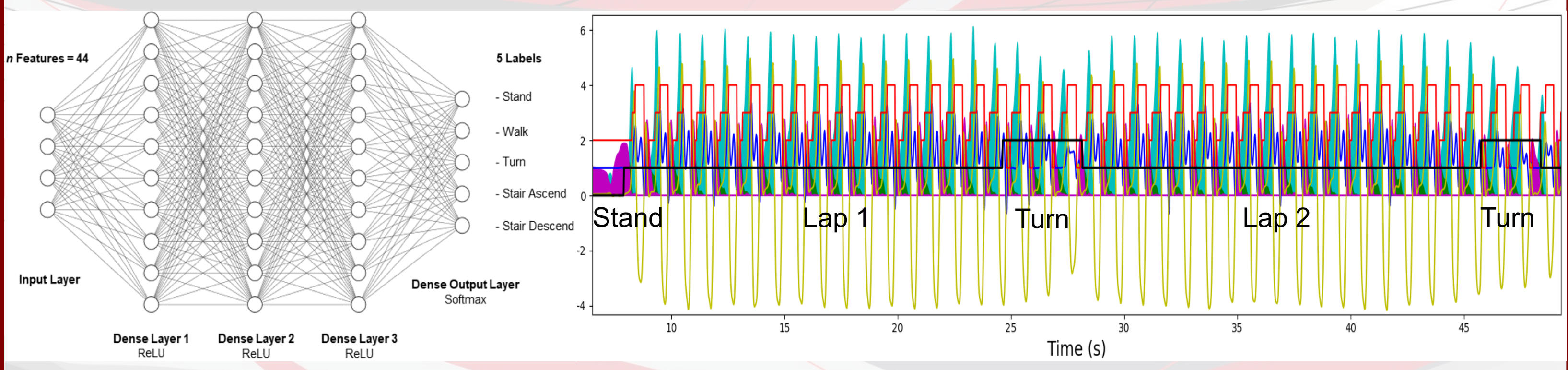

Figure 3. Deep neural network architecture with example activity identifications.

- 7 spatiotemporal variables were calculated using custom Python codes:
  - Stride time, Stance time, Swing time, Single support time, Double support time, Stride length, and Stride velocity.
  - The mean value across all strides was taken for each spatiotemporal variable.
- 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:

- A one-way analysis of variance (ANOVA) was used to evaluate spatiotemporal metrics SPSS v28.0 (IBM, USA).
  - Between-subject factor: disability status
- Partial eta square (η^2) represents effect size [3]:
  - Small: 0 - 0.01; Medium: 0.01 - 0.06 ; Large: 006 - 0.14

RESULTS

- Spatiotemporal values differed significantly ($p < 0.05$) between groups with large effect sizes ($\eta^2 > 0.14$), except single support time (Table 1).

Table 1. Significance testing and effect sizes between disability groups.

Variable	*p*-value	Partial eta squared (η^2)
Stride time (s)	0.003*	0.288**
Stance time (s)	0.003*	0.277**
Swing time (s)	0.040*	0.168**
Single support time (s)	0.192	0.090
Double support time (s)	0.006*	0.254**
Stride length (m)	< 0.001*	0.393**
Stride velocity (m/s)	< 0.001*	0.437**

Note: * = statistical significance ($p < 0.05$); ** = large effect size; m = metre; s = second

- Post hoc analyses revealed differences between the mid and/or low disability group, and the high disability group (Figure 4).

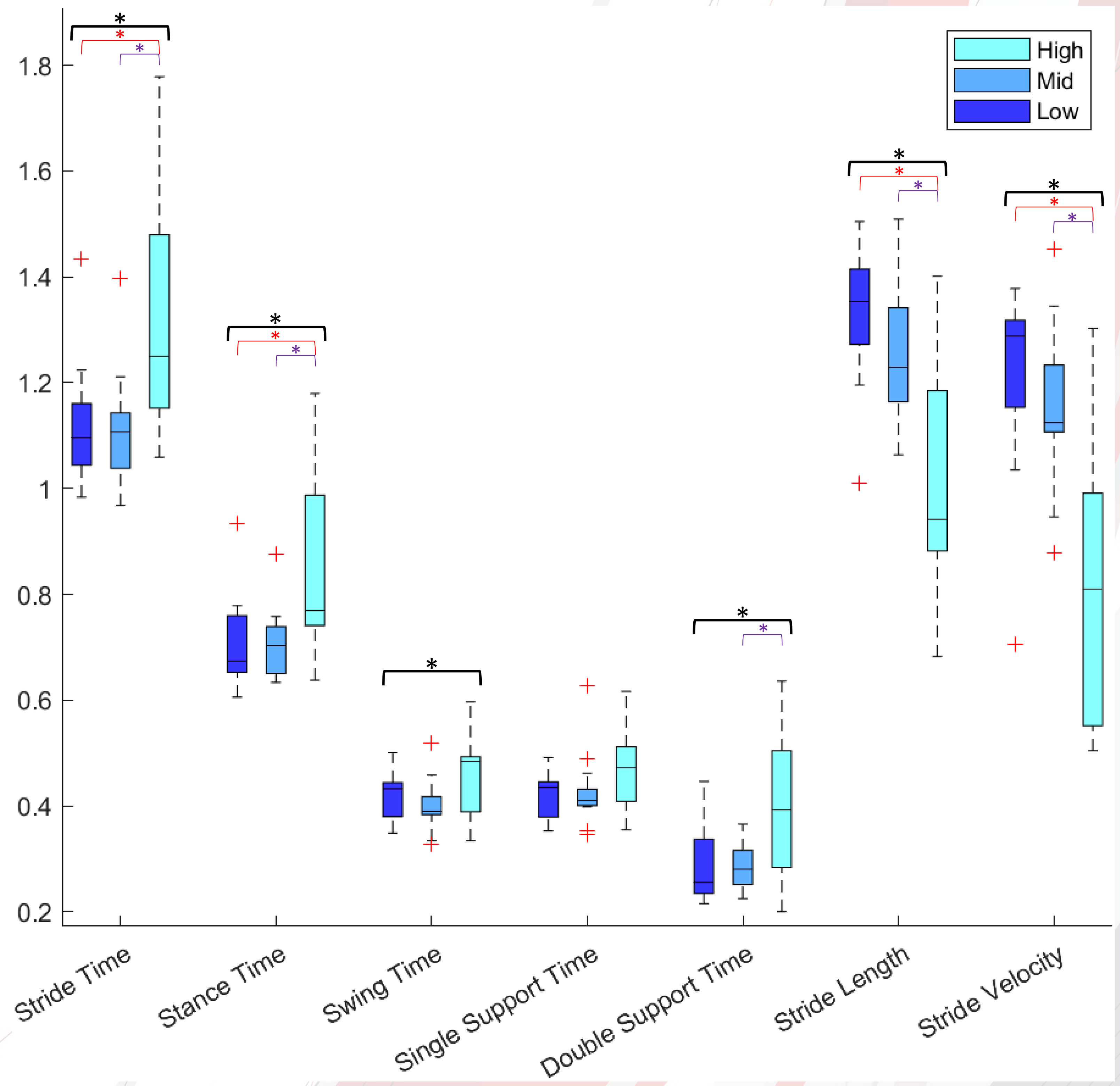

Figure 4. Box and whiskers plot representing mean spatiotemporal values per disability group. *Note:* + = outlier; * = main effect; * = low disability ≠ high disability; * = mid disability ≠ high disability.

DISCUSSION

- From instrumented insole data, digital gait biomarkers can be calculated and be used to identify spatiotemporal gait differences as a function of disability status in PwMS.
- Similar relationships between EDSS score and spatiotemporal variables have been found in previous literature [4]:
  - ↑ EDSS → ↑ Step time variability, stride time, stance time, and double support time.
  - ↑ EDSS → ↓ stride velocity, stride length, and cadence.
- Instrumented shoe insoles and mobile applications, such as Celestra Health, enable the unobtrusive curating of digital gait biomarkers.
- Instrumented insoles can also be potentially used to longitudinally track an individual's digital gait biomarkers and be used by:
  - Patients to:
    - Monitor their health.
    - Advocate for their healthcare.
  - Clinicians/researchers to:
    - Identify improvements/worsening in gait quality.
    - Identify relapses in relapse-remitting MS patients.
    - Understand the impact of an intervention (e.g., exercise, assistive device, surgical, pharmacological) on gait quality.
    - Explain changes in gait quality to patients.

- **FUTURE DIRECTIONS**:
  - Using instrumented insoles to measure gait stability in PwMS.
  - Assessing the reliability of our method in real-world environments.
  - Developing a gait quality score for PwMS.

REFERENCES

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[1]School of Human Kinetics, Faculty of Health Sciences, University of Ottawa, Ottawa, ON, Canada.
[2]Ottawa-Carleton Institute for Biomedical Engineering (OCIBME), Ottawa, ON, Canada.

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