Real-World Gait Monitoring in MS: A Smart Insole Framework for Data-Driven Gait Quality Assessments

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INTRODUCTION

- Spatiotemporal (ST) metrics can serve as valuable digital biomarkers to monitor the progression (i.e., improvement, maintenance, worsening) of multiple sclerosis (MS).
  - ST metrics significantly differ between healthy persons (HP) and persons with multiple sclerosis (PwMS) even at lower disability levels [1] and amongst PwMS across disability levels [2].
- However, the practical use of ST metrics as a digital biomarker is constrained by:
  - The intervals between collections, use of traditional motion capture technology (i.e., sparsity, cost, capture area), ecological validity (i.e., active tests versus passive monitoring), and the necessity for expert interpretation.

SOLUTIONS:

- Use wearable sensors, such as instrumented shoe insoles (Insoles), to passively assess gait quality in free-living environments as well as actively during clinical walking tests.
- Automatically analyze and disseminate gait quality.
  - A single Gait Composite Index score (gCI; 0 to 100%) and ST metrics.
- Provide tools to longitudinally and acutely monitor disease progression.
  - Improvements, maintenance, and worsening.
  - Fatigue-related changes within a walk.

OBJECTIVE:

- To demonstrate an instrumented shoe Insole Framework (IF) that identifies ambulatory activities, detects gait events, and calculates ST metrics to produce a gait composite index (gCI; 0-100%) for a comprehensive evaluation of gait quality.

RESULTS

- The artificial neural network was 94.6% accurate at identifying ambulatory activities.
- The average $ICC_{2,1}$ comparing MoCap to the logical algorithms was 0.862. The temporal and spatial biases were 0.01 seconds and 1.7%, respectively (Table 1).

Table 1. ICC and Bland-Altman Results

Metric	$ICC_{2,1}$	CI95%	Bias [Upper, Lower]
Stride Time	0.999	[1.00, 1.00]	-0.014 [0.044, -0.073]
Stance Time	0.981	[0.97, 0.99]	-0.002 [0.079, -0.082]
Swing Time	0.835	[0.75, 0.90]	-0.012 [0.079, -0.103]
Single Support Time	0.833	[0.75, 0.90]	0.003 [0.085, -0.080]
Double Support Time	0.906	[0.86, 0.94]	-0.004 [0.134, -0.141]
Stride Length	0.983	[0.97, 0.99]	0.011 [0.227, -0.206]
Step Time	0.967	[0.95, 0.98]	0.001 [0.098, -0.096]
Cadence	0.976	[0.96, 0.99]	-0.213 [19.40, -18.98]

Note: metrics calculated bilaterally were averaged for visualization. Bias calculated as IF - MoCap. CI95% = 95% confidence interval

- The SVM had a classification accuracy and F1 score of 90.3% and 92.8%.
- Using 6 months of HP treadmill walking data, 23 ST metrics were reliable and used to train the gCI.
  - $ICC_{3,1}$ $\geq$0.70 or relative change $\leq$10% and within-subject variability $\leq$20%.
- Nine PwMS increased and 10 decreased their gCI over 500 m.
  - gCI group * distance interaction $p < 0.001$; the average response was a gCI decrease.
- Spearman correlation coefficients comparing the gCI to disability metrics are presented in Table 2.

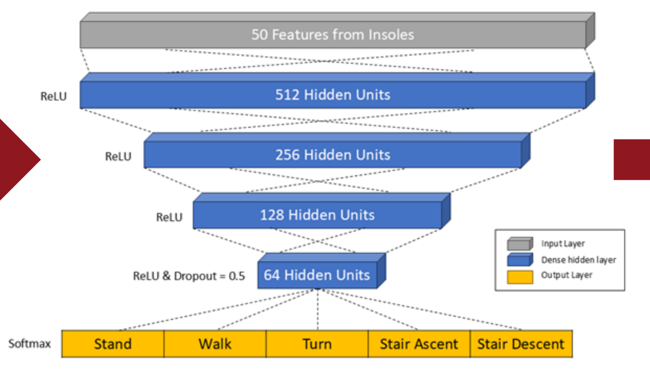
Table 2. Spearman Rho Correlations

Metric	EDSS	MSWS-12	T25FW	SDMT	9HPT
gCI	-0.840	-0.817	-0.792	0.752	-0.666
EDSS	1.000	0.835	0.797	-0.566	0.600

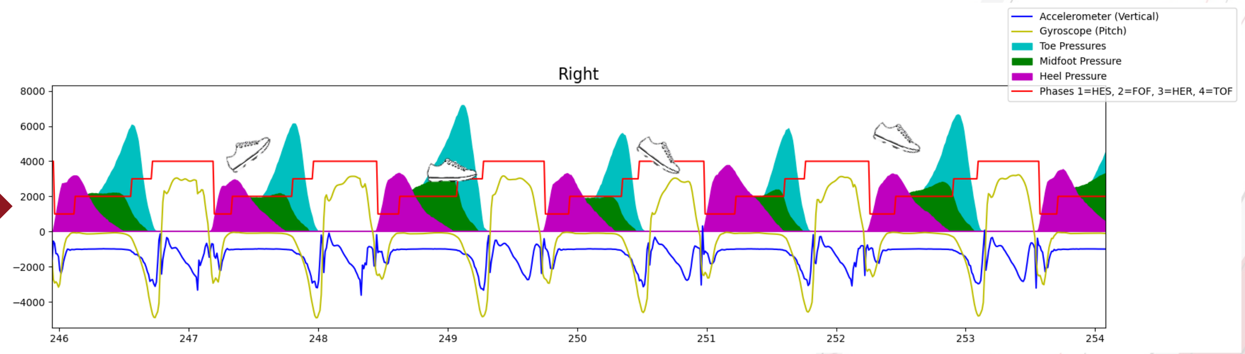
Note: gCI = Gait Composite Index; EDSS = Expanded Disability Status Scale; MSWS-12 = 12-item MS Walking Score; T25FW = Timed 25-foot Walk; SDMT = Symbol Digit Modalities Test; 9HPT = 9 Hole Peg Test

INSOLE FRAMEWORK (IF)

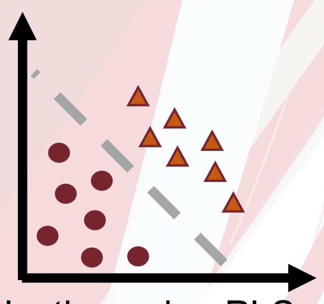
Raw insole data stream to a smartphone application via Bluetooth.



Identify ambulatory activities using an artificial neural network.



- Gait events: Heel Strike, Foot on Floor, Heel Raise, and Toe off.
- Sensor fusion: foot position and orientation.
- Standardize analyses: 10 seconds.
- Calculate rhythm, pace, variability, asymmetry, and IMU metrics.



- Feature selection using PLS.
- Classify walking segments as PwMS or HP using an SVM.
- Calculate Z-scores using the location from the decision boundary; the percentage is the gCI.
- Display result in an interactive Clinician Portal.

METHODS

PARTICIPANTS:

- People with Multiple Sclerosis (PwMS):
  - 45 participants: 11 Male, 34 Female. 49.1 years (±14.2).
    - EDSS: 3.57 (±1.80; range: 0.5-6.0), MSWS-12: 52.7% (±24.3%).
- Healthy Participants (HP):
  - 27 participants: 14 Male, 13 Female. 27.7 years (±6.20), no current musculoskeletal injury.

PROCEDURE:

- Participants wore Insoles (50 Hz; pressure, accelerometer, gyroscope; ReGo, Moticon, Germany) that streamed raw data to a smartphone application (iOS or Android; Celestra Health, Canada).
- 19 HP and 19 PwMS: 6 m walks (in lab), 500 m walk (25 m hallway), and 125 m walk with stairs.
  - Used for initial algorithm development and validated against a markerless motion capture system (MoCap; Theia 3D, Canada).
- 6 HP: 6-min walks 1x/week for 6 months on an instrumented treadmill.
  - Data used to assess gCI stability in HP.
- 26 PwMS: 15-min walks, 3x/week for 6 months in free-living conditions. Clinical evaluations were performed at baseline, 3 months, and 6 months.
  - EDSS, MSWS-12, T25FW, SDMT, and 9HPT scores were obtained.
  - Data used to assess IF generalizability.

DATA ANALYSIS:

- Raw Insole data were processed through the IF to produce 68 gait metrics.
  - 19 metrics were validated against the MoCap system using intraclass correlations ($ICC_{2,1}$ consistency) and Bland-Altman limits of agreement.
  - E.g., stride time, double support percentage, swing time asymmetry, stride length, cadence, etc.
- All spatiotemporal metrics were assessed for reliability using the HP treadmill protocol.
  - Linear mixed effects, $ICC_{3,1}$ absolute agreement.
- Reliable metrics were used to identify partial least squares (PLS) latent variables to train a support vector machine (SVM) to classify walking segments as a PwMS or HP.
- gCI scores from 5 free-living walks closest to a clinical visit were averaged and correlated to all disability metrics using Spearman Correlations.
- gCI degradation over 500 m was assessed using a linear mixed model.

DISCUSSION

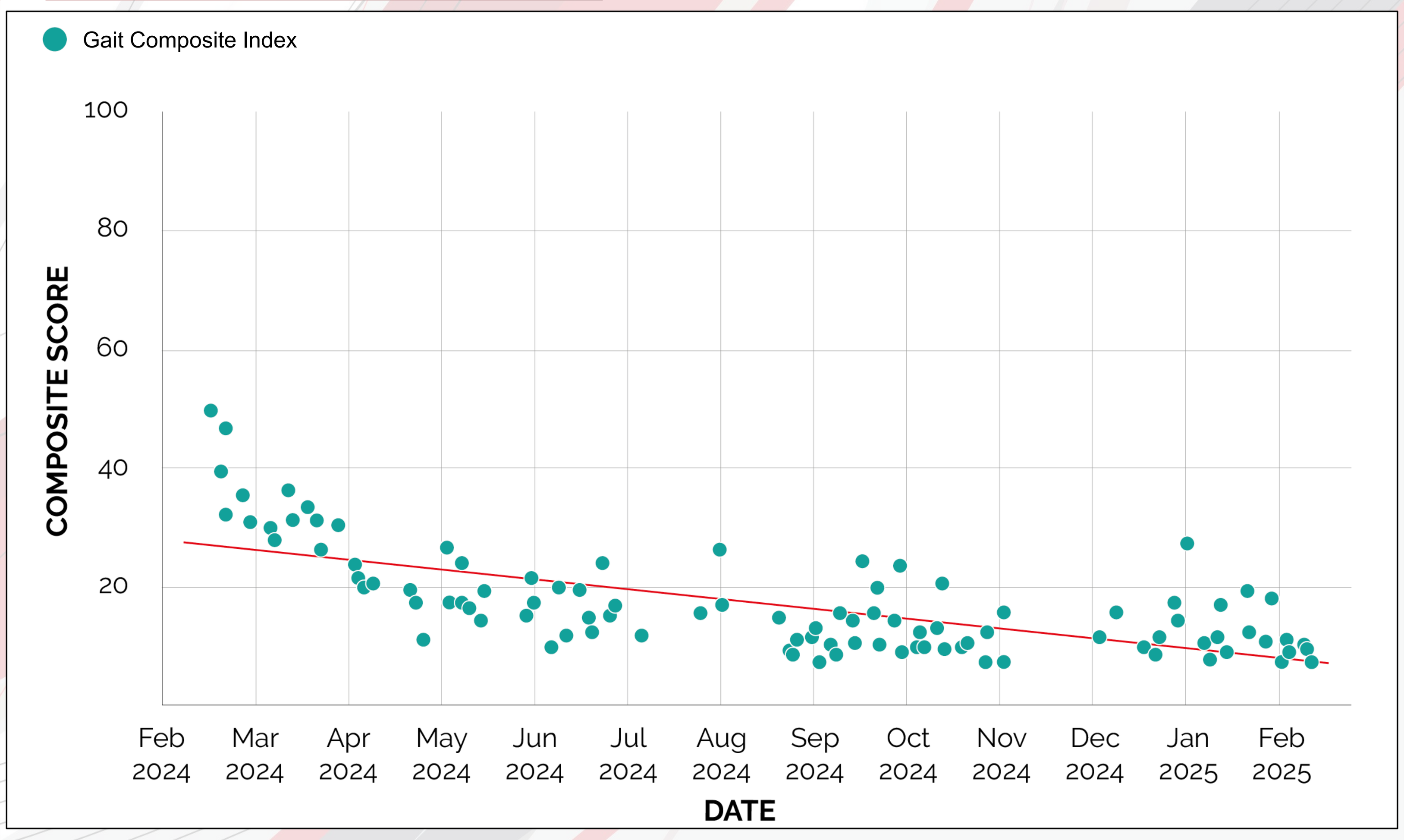


Figure 1. gCI results for a PwMS over one year, as depicted in the Clinician Portal. Users can select walking samples to investigate the spatiotemporal metrics driving the change in gCI score.

- The IF can identify ambulatory activities, gait events, and calculate spatiotemporal metrics comparable to a gold-standard MoCap system.
  - Many metrics have near-perfect $ICC_{2,1}$ values and small bias and limits of agreement.
- The gCI is strongly correlated to many disability metrics used in the current standard of care.
  - Often exceeding the relationships with EDSS.
- Calculating the gCI every 10 seconds allows for investigations into fatigue-related changes to gait quality.
- Using the IF, the gCI can serve as a digital biomarker to proactively monitor disease progression in free-living conditions, assess the effectiveness of interventions (pharmacological, exercise, assistive devices), and reduce healthcare barriers for individuals in rural communities.

FUTURE DIRECTIONS:

- Automatically identify gait phenotypes. E.g., spastic, ataxic, hemiplegic.
- Automatically identify assistive device usage. E.g., cane, walker, ankle-foot orthosis.
- Enhance longitudinal analyses and expand the functionality of the clinician portal (Figure 1).

References

[1] Martin CL, et al. (2006). MS J. Sep 2;12(5):620–8.

[2] Socie, MJ et al. (2013) Gait and Posture, 38(1), 51–55.

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