

# Revolutionizing Gait Quality Monitoring in Multiple Sclerosis: An Instrumented Shoe Insole Solution

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## INTRODUCTION

- Clinical walking assessments often involve measuring the distance walked over a set time limit, the time taken to complete a given task, and the time to walk a set distance [1].
- However, far more information can be gathered about the human gait pattern by measuring spatiotemporal (ST) gait metrics.
  - ST metrics significantly differ between healthy persons (HP) and persons with multiple sclerosis (PwMS) even at lower disability levels [2].
- If spatiotemporal metrics were calculated at regular intervals, they could become powerful biomarkers to monitor disease progression and the effectiveness of interventions.

## CHALLENGES:

- Traditional motion capture is infeasible: cost, expertise, small capture volume, and patient travel.
- Incorporating gait metrics into new data-driven models of care.

## SOLUTIONS:

- Use wearable sensors, such as instrumented shoe insoles, to regularly assess gait quality during daily life and at clinical visits.
- 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.

## OBJECTIVE:

- Demonstrate an instrumented Insole Framework (IF) that automatically identifies ambulatory activities, gait detection, and calculates spatiotemporal gait metrics to produce a GCI.

## RESULTS

- The artificial neural network was 94.6% accurate at identifying ambulatory activities.
- The average ICC<sub>2,1</sub> comparing MoCap to the logical algorithms was 0.862. The temporal and spatial bias was 0.01 seconds and 1.7% (Table 1).

Table 1. ICC and Bland-Altman Results

Metric	ICC <sub>2,1</sub>	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

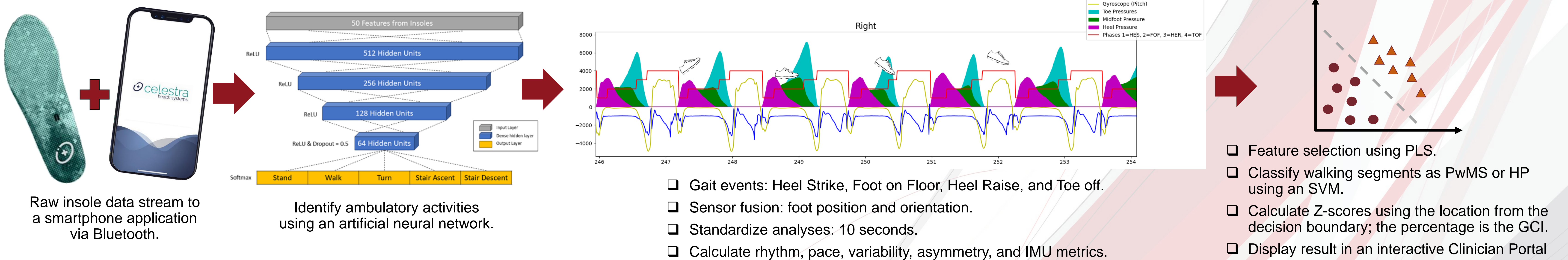
- The SVM had a classification accuracy and F1 score of 90.3% and 92.8%.
- Using 6 months of HP treadmill walking data, 23 ST metrics were reliable and used to train the GCI.
  - ICC<sub>3,1</sub> ≥ 0.70 or relative change ≤ 10% and within-subject variability ≤ 20%.
- Nine PwMS increased and 10 decreased 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)



## METHODS

### PARTICIPANTS:

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

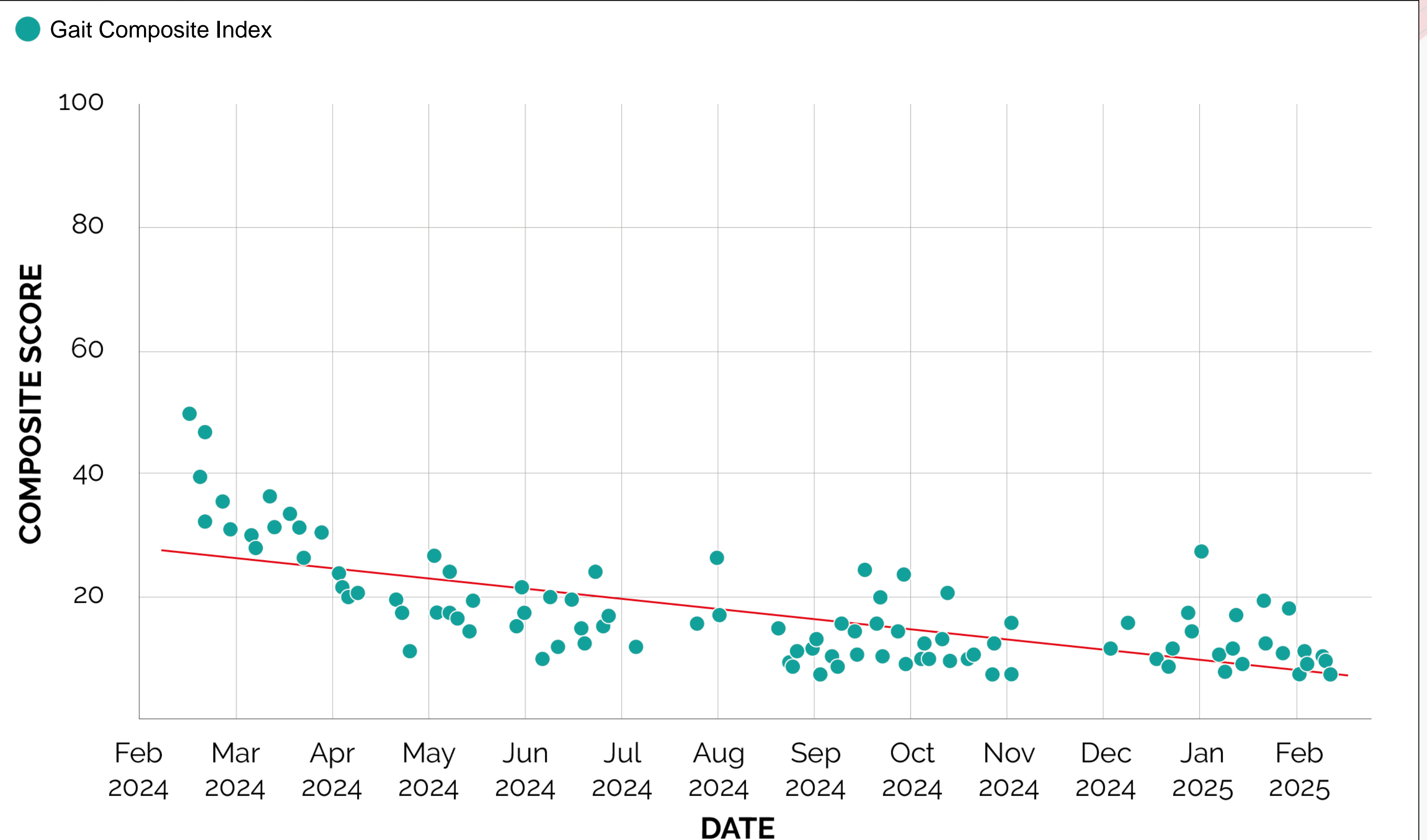
### PROCEDURE:

- Participants wore instrumented shoe insoles (50 Hz; ReGo, Moticon, Germany) that streamed raw data to a smartphone application (iOS or Android; Celestra Health, Canada).
  - Pressure, accelerometer, gyroscope.
- 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-minute 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.
  - At each clinical visit, 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<sub>2,1</sub> 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<sub>3,1</sub> 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



### DISCUSSION:

- 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<sub>2,1</sub> 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 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] Graham JE, et al. (2008). J. Eval. Clin. Pract., 14(4), 552-562. [2] Martin CL, et al. (2006). MS J. Sep 2;12(5):620-8.