

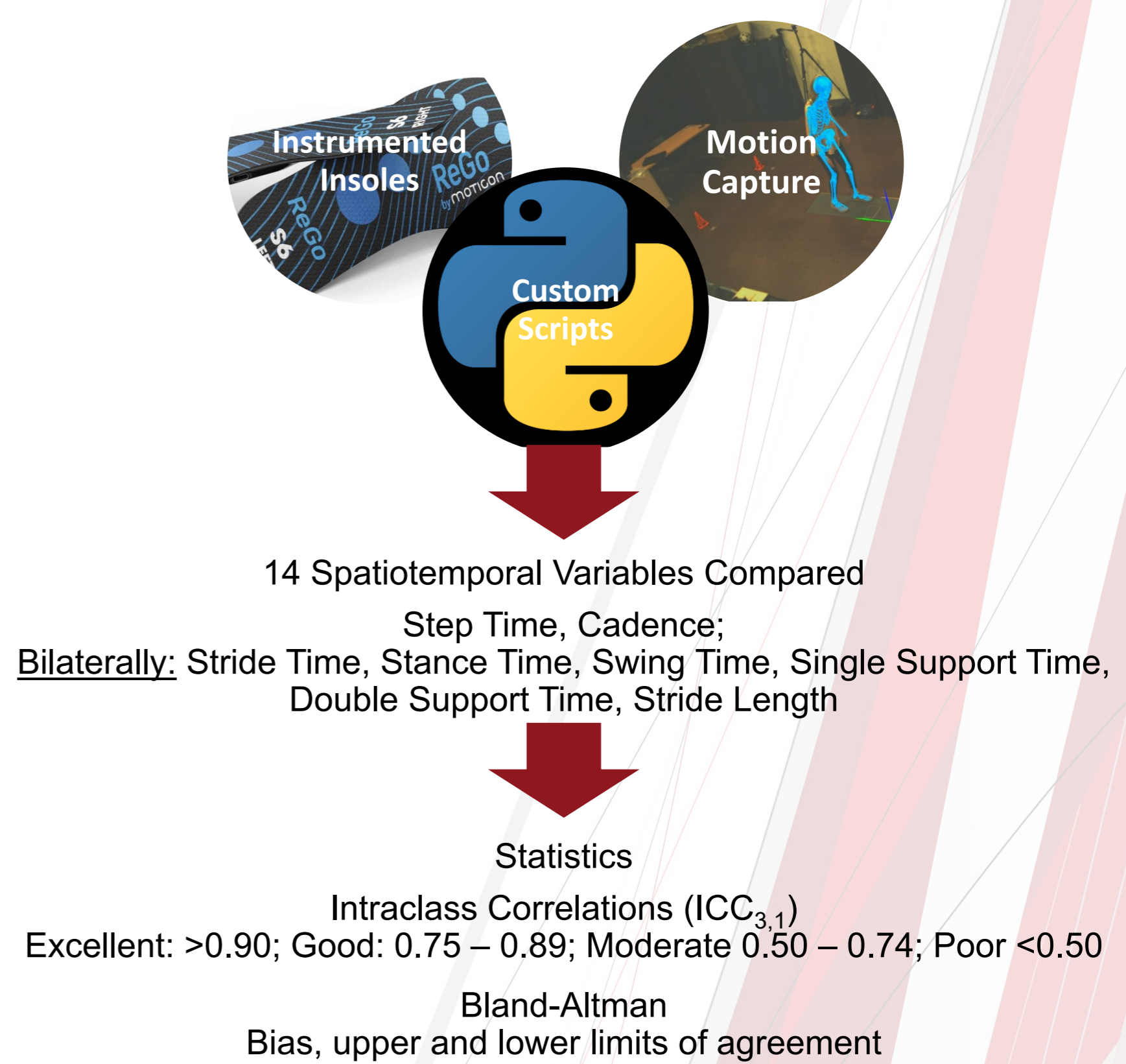
Validation of an Instrumented Shoe Insole to Unobtrusively Monitor Gait Patterns

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INTRODUCTION

- Clinical gait analyses are often used to provide objective information for prescribing and assessing treatment plans [1].
 - For people with multiple sclerosis (PwMS) these assessments are done infrequently and are performed semi-subjectively through visual observations and patient reported outcomes [2].
- Wearable devices, such as instrumented shoe insoles, provide an opportunity to regularly and unobtrusively assess gait quality.
 - Devices are placed in the user's regular footwear and contain pressure, accelerometer, and gyroscope sensors.
 - Users can be prescribed to perform targeted gait tests (e.g., 500-metre walk) and perform ad-hoc walking bouts during daily life.
- By applying machine learning and logical algorithms to raw data, insoles can provide digital biomarkers for monitoring disease progression such as
 - Trends of mobility improvement/worsening.
 - Objectively assess walking fatigue [3], detect gait phenotypes, etc.
 - Delivering personalized interventions and objectively measuring their outcomes.
 - Exercise, surgery, assistive device, pharmacological.
 - Patient advocacy
 - PwMS can monitor their mobility trends and be more active with their treatment.

Framework



Objective

- Validate spatiotemporal algorithms that use raw data from instrumented shoe insoles against a laboratory-grade optical motion capture system.

METHODS

PARTICIPANTS:

- PwMS:
 - 40 participants: 10 Male, 30 Female
 - 52.25 years (± 13.25), EDSS 3.19 (± 1.64 ; range: 0.5-6.0)
- Control:
 - 56 participants: 30 Male, 26 Female
 - 28.46 years (± 7.49), no current musculoskeletal injury

PROCEDURE:

- Participants walked ~6 metres over 2 in-ground force plates. Assistive devices were used as required.
- Simultaneously, data were collected from
 - 8 video cameras (Vue, Vicon, United Kingdom, 60 Hz)
 - Instrumented shoe insoles
 - ReGo, Moticon, Germany; 50 Hz
 - Neurogait 3.0, Salted, Korea; 100 Hz

DATA ANALYSIS:

Insoles:

- 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 were used to
 - Detect gait events: heel strike, foot-on-floor, heel rise, and toe off Figure 1.
 - Calculate spatiotemporal variables.

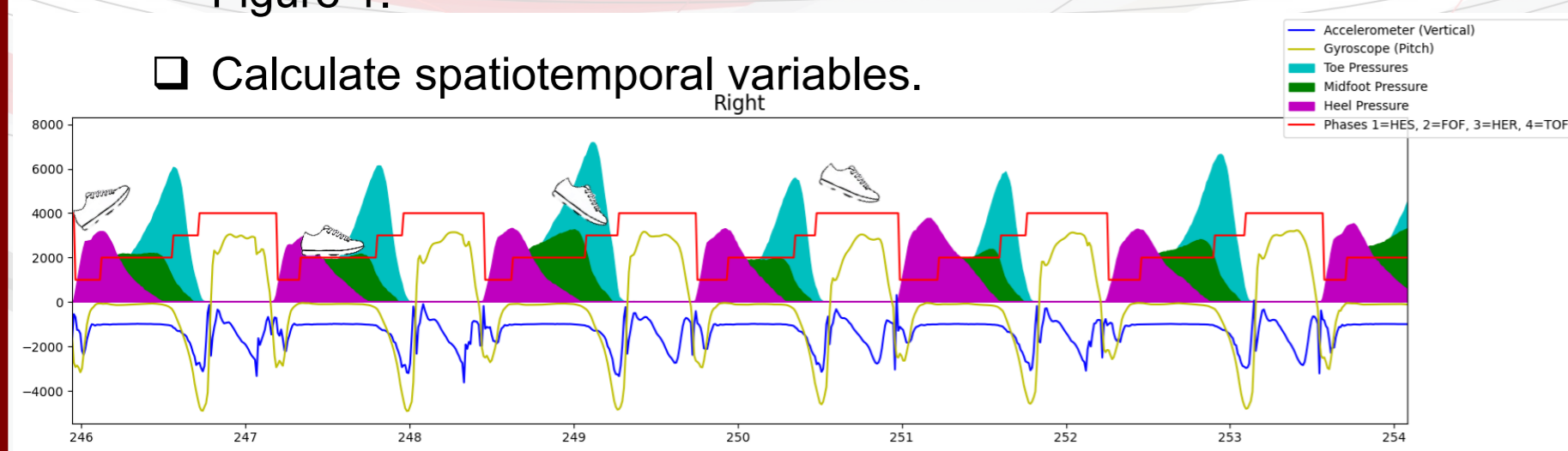
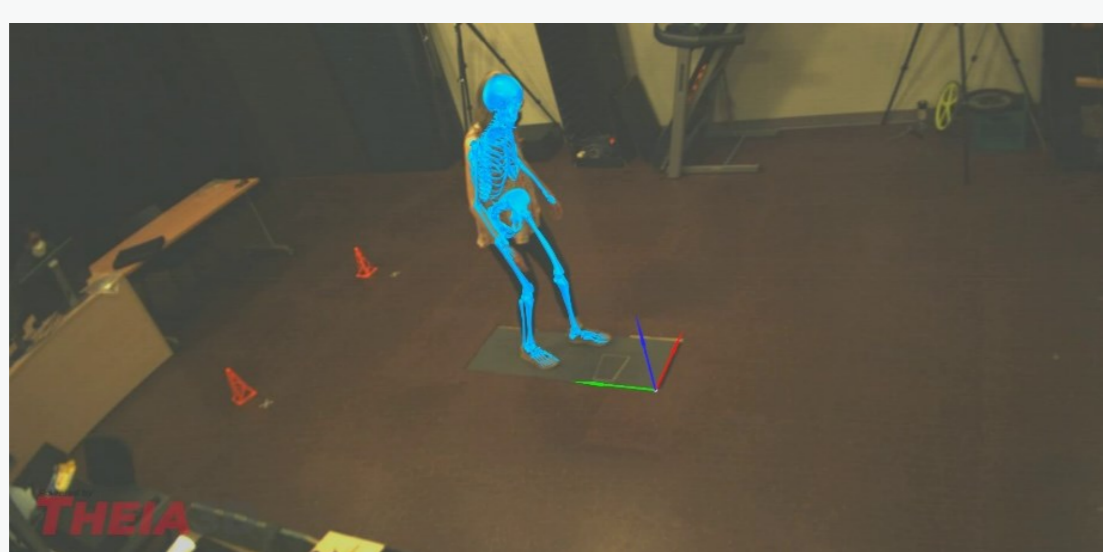


Figure 1. Depiction of gait detection algorithm.

Optical Motion Capture:

- 3D whole-body kinematics were calculated using Theia 3D (Canada; 50 Hz) Figure 2.
- Initial gait detection was performed in Visual 3D (C-motion, USA).
 - Manual detections were performed as necessary.
- Spatiotemporal variables were calculated in Matlab.



RESULTS

- Overall, calculating spatiotemporal gait metrics using raw data from instrumented insoles had good to excellent reliability when compared to data obtained from a laboratory-grade motion capture system (Table 1).
 - 10/14 metrics had excellent reliability (i.e., >0.89).
 - 4/14 metrics had good reliability (left and right swing and single support time; 0.75 – 0.89).

Table 1. ICC and Bland-Altman Results

Metric	ICC _{3,1}	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 Insole - Mocap system.

DISCUSSION

DISCUSSION:

- The developed algorithms using raw data from instrumented insoles can reliably calculate spatiotemporal metrics of controls and PwMS.
 - Many of metrics have near-perfect ICC_{3,1} values and small bias and limits of agreement.
 - Highlights the feasibility of using instrumented insoles to collect important biomarkers for PwMS.
- Algorithms using raw data from different insole vendors had similar levels of agreement to the laboratory-grade data collection system.
 - Demonstrates the robustness of algorithms to vendor change.
- By calculating accurate biomarkers, mobile applications, such as Celestra Health, can provide objective information about an individual's gait quality.
 - Patients can advocate for their healthcare.
 - Clinicians/researchers can objectively.
 - Understand how gait quality is improving/worsening.
 - Evaluate the impact of an intervention (e.g., exercise, assistive device, surgical, pharmacological).
 - Explain changes to gait quality to patients.

FUTURE DIRECTIONS:

- Assess the frequency of gait assessments needed to understand a user's initial gait quality and identify longitudinal trends.
- Evaluate the effects of environmental factors such as terrain and footwear.

References

- [1] Simon 2004. J. Biomech. 37(12).
- [2] Muro-de-la-Herran et al., 2014. Sensors 14(2).
- [3] Mir-Orefice et al., 2023. MSMilan 2023, Poster.
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