Wearable Insoles for the Real-Time Capture of Gait Measures: Preliminary Feasibility and Validity Data in Older Adults With and Without Subjective Cognitive Decline

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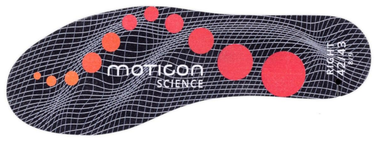
INTRODUCTION

- Integration of wearable devices into regulated clinical trials for the assessment of cognition and functioning continues to be a topic of growing interest. If appropriately implemented, measurements from validated wearable technologies have the potential to revolutionize the conduct of clinical trials by facilitating development of site-less clinical trial designs.
- In order to be truly informative, however, endpoints collected by these devices must undergo the same clinical and technological validation process required by other currently accepted tools.
- We present preliminary data from an ongoing study examining the reliability of industry-grade pressure sensing insoles for the real-time capture of gait measures in older adults, and the relationship between gait measures and standard measures of cognition and functioning.

METHODS

Device

- Moticon Science Insoles are research grade devices designed to passively collect gait and movement data through 3-axis accelerometer and angular rate sensors as well as 16 unique pressure sensors.



Participants

- Our sample currently includes 28 older adults (age 55 or greater), including 19 healthy controls (HC) and 9 individuals with subjective cognitive decline (SCD). Individuals with SCD were categorized as such based on total scores of ≥ 4 on the Cognitive Functional Instrument (CFI). An additional 2 participants were deemed ineligible to wear the insoles based on a foot exam by a study clinician, 1 participant had shoes too large for the largest size insoles and 1 participant withdrew after visit 1. In 5 participants, a malfunction of the insoles prevented their data from being included in these analyses. Participant characteristics are displayed in Table 1.
- The study design includes: 1) a baseline laboratory assessment, which involves data collection from the Moticon insoles during four standardized walking tasks and completion of a cognitive test battery; 2) a one-week period of data collection from the insoles during participants' daily lives; 3) a one-week follow-up laboratory assessment, which involves data collection from the insoles during the same four standardized walking tasks.
- The standardized walking tests include:
  - Timed 25 Foot Walk (T25FW): participants are instructed to walk 25 feet quickly, but safely;
  - Dual task version of the T25FW: participants repeat this test while counting out loud backward from 100 by 3's;
  - Timed Up and Go (TUG) test: participants start from a seated position, stand and walk a distance of 3 meters, then turn and walk back to the chair and sit down;
  - 500 foot walk: participants walk at a comfortable pace.

Table 1. Participant Characteristics

	Mean	SD
Age	68.29	6.49
Education (Years)	15.18	3.36
Height (cm)	166.46	9.28
Weight (kg)	79.36	14.95
Gender		
Male	11 (39.3%)	
Female	17 (60.7%)	
Race		
White	17 (60.7%)	
African American	10 (35.7%)	
Other	1 (3.6%)	
Subgroup		
Healthy Controls	19 (67.8%)	
Individuals with subjective cognitive decline	9 (32.1%)	

Gait Measures

The Moticon insoles produce measures that characterize a subject's gait across a gait cycle, as well as within specific phases of the gait cycle (Figure 1)

- Gait Line: At the beginning of the gait cycle, marked by the initial heel strike, the center of pressure (COP) of the subject's weight on the insoles starts near the heel. The COP sweeps forward throughout the gait cycle until the toe off for that foot. Each of these sweeps creates a gait line (Figure 2). The mean gait line length and width are reported.
- Ground Reaction Force: The force exerted by the ground on the subject's foot. The mean GRF and maximum GRF during the stance phase are ratio normalized by the subject's weight.
- Temporal parameters:
  - Cycle Time: The mean time to complete a single gait cycle (a stride)
  - Cadence: The mean number of strides per minutes
  - Double support time: Time during which both feet are in contact with the ground. We report here side-specific mean double support time, with the left mean double support time considering the time starting from the right foot's initial contact, until the left foot's toe off.
  - Stance duration: Time that a given foot (left or right) is in contact with the ground. We report here both the mean and standard deviation of stance duration.
  - Swing duration: Time that a given foot is not in contact with the ground (toe off until next heel contact for that foot)
- Spatial parameters:
  - Mean stride length: The displacement of the same foot in walking direction.
  - Mean walking speed: The mean stride length divided by the mean gait cycle time.

Functional Capacity Measure

The Virtual Reality Functional Capacity Assessment Tool (VRFCAT©) is a computer based virtual-reality measure of functional capacity. The VRFCAT uses a realistic simulated environment to recreate routine activities of daily living (i.e., Meal planning and preparation, using transportation for getting places, shopping for groceries, and handling money).

Figure 1. Phases of the Gait Cycle

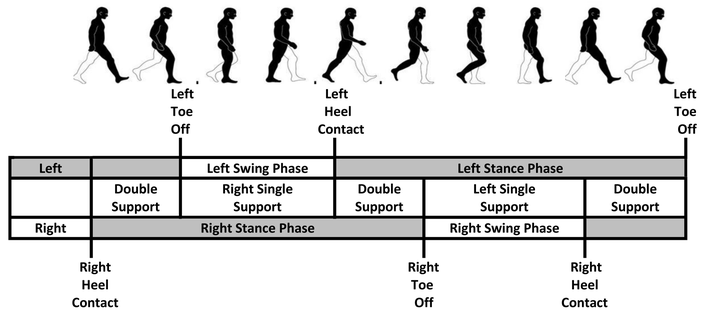
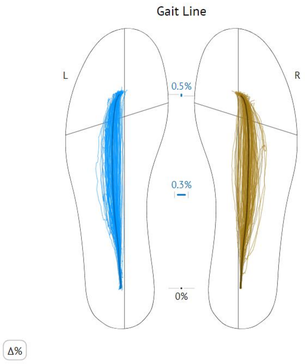


Figure 2. Gait Lines and Mean Gait Lines from a Subject Completing the 500 Foot Walk



Cognitive Measures

The Brief Assessment of Cognition (BAC) is an electronic cognitive assessment battery. We report here on individual subtest scores. Subtests include:

BAC-Expanded Verbal Memory-Total Learning: This subtest includes five trials of 15-word list learning, and one trial each of list word recognition, delayed free recall, and cued recall.
Visuo-Spatial Working Memory: Participants encode object-location pairs by tapping items as they appear in sequence on a grid, then tap the location on a blank grid where the object first appeared. Sequence length and grid size increase throughout the task.
Digit Sequencing Task: Subtest that presents clusters of numbers of increasing length. Participants are asked to respond with the numbers in order, from lowest to highest.
Token Motor Task: This subtest presents a screen with a virtual container and automatically replenishing set of tokens. Participants are asked to touch tokens simultaneously and slide them two at a time into the container as quickly as possible. A 60-s time limit is imposed.
Verbal Fluency: Category Instances: Animals; Controlled Oral Word Association: F, S.
Symbol Coding: As quickly as possible, participants enter numerals 1 –9 as matches to symbols into a virtual response sheet for 90 s.
Tower of London: Participants are shown two pictures simultaneously on the tablet screen, where each picture shows three balls of different colors arranged on three pegs (unique arrangement in each picture). Participants are asked to give the total number of times the balls in one picture need to be moved in order to make the arrangement of balls identical to that of the other, opposing picture. There are 20 trials.

Analysis

- Intraclass correlation coefficients (ICC) were computed to assess one-week test-retest reliability of the gait variables during the 4 walking assessments.
- Partial Pearson correlation coefficients were calculated to test the association of gait measures collected during the 500 foot walk with cognitive and functional capacity measures while controlling for subject height.

RESULTS

Gait Measure Test-Retest Reliability

- ICCs varied between gait measures and walking assessments. The 500 foot walk generally produced more reliable gait measures than the other walking assessments (Table 2).

Table 2. Test-Retest Reliability of Gait Measures

Gait Category	Endpoint	500 Foot Walk	25 Foot Walk	25 Ft Walk w/Serial 3's	Timed Up and Go
Gait Line	Mean length of gait line (left) (mm)	0.45	0.49	0.22	0.55
	Mean length of gait line (right) (mm)	0.68	0.43	0.29	0.43
	Mean width of gait line (left) (mm)	0.61	0.51	0.52	0.38
	Mean width of gait line (right) (mm)	0.58	0.70	0.59	0.45
Ground Reaction Force	Mean force stance phase (left) (N/kg)	0.56	0.38	0.40	0.50
	Mean force stance phase (right) (N/kg)	0.67	0.57	0.65	0.65
	Max force stance phase (left) (N/kg)	0.45	0.27	0.39	0.43
	Max force stance phase (right) (N/kg)	0.62	0.52	0.65	0.62
Temporal Parameters	Cycle Time	0.63	0.13	0.18	0.17
	Cadence	0.58	0.10	0.34	0.32
	Mean double support time (left) (s)	0.65	0.24	0.19	0.35
	Mean double support time (right) (s)	0.69	0.41	0.00	0.49
	Mean stance duration (left) (s)	0.63	0.51	0.39	0.81
	Mean stance duration (right) (s)	0.68	0.53	0.48	0.54
	SD stance duration (left) (s)	0.06	0.10	0.21	0.76
	SD stance duration (right) (s)	0.27	0.15	0.45	0.47
	Mean swing duration (left) (s)	0.47	0.12	0.36	0.36
	Mean swing duration (right) (s)	0.62	0.40	0.32	0.11
	SD swing duration (left) (s)	0.62	0.17	0.56	0.34
	SD swing duration (right) (s)	0.70	0.44	0.51	0.47
Spatial Parameters	Mean stride length	0.58	0.21	0.01	0.19
	Mean walking speed (m/s)	0.64	0.07	0.21	0.21
	Mean	0.57	0.34	0.36	0.44
	SD	0.15	0.19	0.19	0.18
Highlighted cells indicate the walking test that produced the highest ICC for each gait variable					

Association of Gait Measures with Cognitive and Functional Capacity

- Several gait measures significantly correlated with functional capacity and cognitive measures (Table 3).
- Double support time and right/left single leg stance duration measures (see Figure 1) demonstrated significant correlations with the performance based measure of functional capacity (VRFCAT) (r=.45 to .54), as well as with the BAC subtests letter fluency (r=-.48 to -.53) and delayed cued recall (r=-.43 to -.52).

Table 3. Partial Correlations (Controlling for Height) of Gait Measures with Functional Capacity and Cognition

Gait measures that did not produce significant correlations are omitted for brevity

	VRFCAT-Adjusted Total Time	BAC-Digit Sequencing	BAC-Token Motor	BAC-Semantic Fluency	BAC-Letter Fluency	BAC-Symbol Coding	BAC-Tower of London	BAC-Verbal Memory-Total Learning	BAC-Verbal Memory-Delayed Free Recall	BAC-Verbal Memory-Delayed Cued Recall	BAC-Visuospatial Working Memory
Mean length of gait line (right) (mm)	0.21	-0.10	-0.25	-0.13	-0.36	-0.02	-0.24	-0.16	-0.49	-0.31	-0.16
Max Force Stance (left) (N/kg)	-0.23	0.21	0.07	0.15	-0.03	0.01	0.22	0.45	0.05	0.10	0.25
Max Force Stance (right) (N/kg)	-0.26	0.27	0.24	0.04	0.19	0.18	0.44	0.32	0.09	0.29	0.24
Mean double support time (left) (s)	0.45	-0.40	0.00	-0.39	-0.48	-0.31	-0.50	-0.33	-0.12	-0.43	-0.16
Mean double support time (right) (s)	0.29	-0.20	-0.13	-0.33	-0.50	-0.34	-0.28	-0.18	-0.08	-0.25	-0.10
Mean stance duration (left) (s)	0.47	-0.36	-0.24	-0.33	-0.52	-0.39	-0.37	-0.34	-0.32	-0.48	-0.14
Mean stance duration (right) (s)	0.47	-0.47	-0.29	-0.45	-0.53	-0.31	-0.40	-0.46	-0.28	-0.52	-0.24
SD of stance duration (left) (s)	0.54	-0.26	-0.18	-0.32	-0.24	-0.06	-0.31	-0.53	-0.38	-0.30	-0.36
SD of stance duration (right) (s)	0.03	0.12	-0.21	-0.19	-0.29	-0.22	-0.19	-0.03	0.00	-0.05	-0.15
Highlighted cells: p<.05											

DISCUSSION

Reliability of Gait Measures

- One-week test-retest reliabilities of the gait measures generally fell in the good range (> .60; Cicchetti, 1994) for the 500-foot walk assessment. For the shorter walking tasks, reliabilities were considerably more variable and generally fell in the fair to poor range.
- This pattern of findings is in line with evidence that the reliability of the gait measures increases with longer walking assessments (Godi et al., 2014).
- These interim reliability analyses suggest that gait measurements during the 500 foot walk show the strongest evidence of stability across assessments, which is a key property for use in clinical trials.

Relationship to Function and Cognition

- Several gait measures during the 500 foot walk also showed promising relations with functional capacity, as well as aspects of cognition including verbal fluency, executive functioning, verbal working memory, and verbal learning and delayed recall.
- These relationships between gait measures and performance-based measures of function and cognition are in line with previous findings (Choi et al., 2019; LaRoche et al., 2014).
- Further, we previously reported that older adults with SCD, who are at heightened risk for developing Alzheimer's disease, show impaired performance on both functional capacity assessed by the VRFCAT and on objective cognition tasks in the BAC (Atkins et al., 2018).
- In conjunction with other recent findings (Ayers & Verghese, 2019; Sekhon et al., 2019; Verghese et al., 2019) the current results suggest gait variables may provide sensitive tools for identifying older adults at-risk for developing Alzheimer's disease and for evaluating responsiveness to treatment.

Future Directions

- We continue to enroll subjects into this study. As the sample size expands, we will evaluate the robustness of these initial findings and assess whether these gait measures differentiate those with versus without SCD.

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