Can digital footprints capture clinically relevant gait endpoints in non-clinically setting? A Proof of Concept

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Background

This proof of concept has two components; mining the literature to identify the gait parameters that correlate with cognitive decline and determining if those endpoints could be captured using smart-insoles. There is growing interest in gait change as a marker for cognitive decline, with reports of gait disturbances found to precede dementia by more than 5 years. The use of wrist worn physical activity monitors (PAM) to collect steps and gait cadence is well established. While gait speed has been identified as signal, other spatiotemporal characteristics also appear have potential as key indicators of cognitive decline. Assessing spatiotemporal gait is not a simple process with the use of electronic walkways and specialist clinics common. This can impact the number of locations available for gait assessments particularly in clinical trials. New technology such as smart-insoles is emerging. This has the potential to capture more nuanced assessment of gait change including balance, inter-gait variability even stance. If alternative viable technologies were available gait could be assessed outside of specialist clinics, including residential care setting or the patient's own home.

Methods

A literature review identified Gait speed, Stride Time Variability (STV) and Balance as the gait parameters most commonly correlating with cognitive decline (1,2)
The following assessments were carried out by 2 healthy volunteers (A and B) using smart insoles (Moticon GmbH, Munich, Germany) placed into their shoes.
Gait: Subject B walked at different speeds using a metronome to set the following paces; 60 beats per minute (bpm), 90 bpm, 120 bpm, 150 bpm and a "free walk" without the metronome where the pace changed from slow to fast, fast to medium, medium to fast and fast to slow.

Stride Time variability: Swing duration; that is the amount of time that passes during the swing phase of one extremity in a gait cycle was used to assess (STV). The standard deviation of swing duration reflects the variation from one stride to another.

Balance: The standing elements of the Berg Balance assessment was conducted with eyes open and eyes closed (to induce balance instability). Each assessment lasted 60 seconds and repeated 5 times. Static stance on two feet, shoulder width apart eyes open and eyes closed, Single foot stance (right and then left) eyes open and eyes closed. Subject A repeated the static stance with the insoles fitted into 3 different shoe types; Comfortable flat shoes, tight flat shoes, high heels shoes.

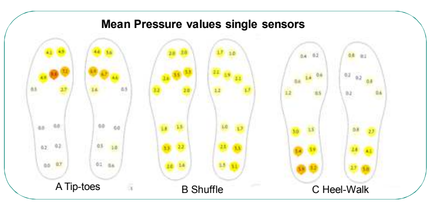

Figure 1: The smart insoles generate data from 13 embedded tri-axial accelerometers each capable of generating 100hertz data. The static report shows pressure distribution, single pressure values and total forces for the single sensors embedded in the insoles.

Results

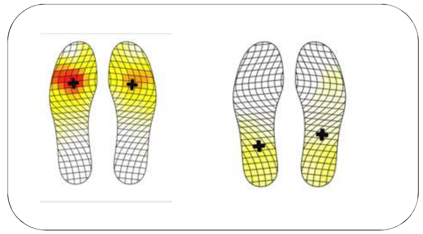

Figure 2: Heat map showing pressure from static stance of the same subject wearing high heels and flat shoes

Standard Deviation	Standing on Two Feet		Standing on Right foot		Standing on Left Foot	
Centre of Pressure (COP) (mm)	Eyes Open	Eyes Closed	Eyes Open	Eyes Closed	Eyes Open	Eyes Closed
X axis (left)	0.7	0.8			1.9	3.7
Y axis (left)	6	8.3			5.5	9.4
X axis (right)	1.1	1.6	1.9	4.5		
Y Axis (right)	7.9	11.7	6	11.2		

Table 3: Average Standard Deviation of Centre of Pressure of static stance assessment

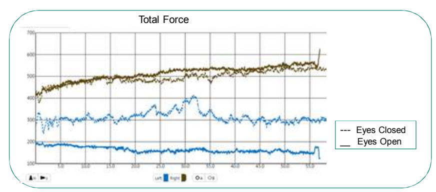

Figure 3: Symmetry Report analyses the data with respect to the symmetry between the left and right leg. It can be used to compare symmetry over time here it was used to compare static stances eyes open and eyes closed.

Results Continued

Gait Using a Metronome to set the pace we are able measure the cadence (steps per second) for each walking speed. At 150 bpm subject B was unable to sustain the walking pace which impacted the gait cadence.

	60 bpm	90bpm	120bpm	150 bpm
Mean gait cadence (strides per minute)	33.5	45.1	59	60.6

Stride Time Variability: Using the standard deviation of swing duration as a way of assessing stride time variability we were able to show the increasing stride variation as walking speed increase to the 150bpm. It was difficult for subject B to maintain the 150 bpm gait speed and this assessment exhibited the highest standard deviation of swing duration (Table 2)

	90bpm		120bpm		150bpm		Free walk	
	Left	Right	Left	Right	Left	Right	Left	Right
Swing Duration (sec) (SD)	0.02	0.02	0.16	0.14	0.31	0.40	0.20	0.18

Table 1: Swing duration is the amount of time that passes during the swing phase of one extremity in a gait cycle. Its standard deviation measures its variation from one stride to another.

Balance: There are a number of endpoints generated by the Moticon software, Centre of Pressure (CoP); the point of application of the ground reaction force, was used to assess balance in the static tests. The average standard deviation was compared for each test and the results from Subject B tabulated below. Similar results were recorded for subject A. There was a slightly higher variability from one leg stance, however it should be noted both subjects were healthy subject who lead very active lifestyles and had very good balance.

Conclusions

Using smart insoles we were able to quantify gait speed and stride variability. The potential value of smart-insoles is the portability of the technology that would enable their use outside of specialist gait clinics and potentially to monitor gait change in the individual's home or residential care setting. These devices generate vast quantities of data leading to the possibility of using machine learning and data analytics platforms to identify new clinical sensitive signals within the data set. It was outside the scope of this pilot to determine the minimal clinically important differences (MCID) for cognitive decline; this would require a significant body of research. In addition is should be noted that factors such as footwear and data transfer could impact the operationalization of these devices in clinical trial and needs careful consideration before implementation in a clinical trial.

References

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2. Beauchet O, Allali G, Launay C, et al. Gait variability at fast-pace walking speed: a biomarker of mild cognitive impairment? Neurol Sci. 2013 Aug;34(8):1275-82.