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Concurrent validity and reliability of wireless instrumented insoles measuring postural balance and temporal gait parameters

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ABSTRACT

Background: The OpenGo seems promising to take gait analysis out of laboratory settings due to its capability of long-term measurements and mobility. However, the OpenGo's concurrent validity and reliability need to be assessed to determine if the instrument is suitable for validation in patient samples.
Methods: Twenty healthy volunteers participated. Center of pressure data were collected under eyes open and closed conditions with participants performing unilateral stance trials on the gold standard (AMTI OR6-7 force plate) while wearing the OpenGo. Temporal gait data (stance time, gait cycle time, and cadence) were collected at a self-selected comfortable walking speed with participants performing test-retest trials on an instrumented treadmill while wearing the OpenGo. Validity was assessed using Bland-Altman plots. Reliability was assessed with Intraclass Correlation Coefficient (2,1) and smallest detectable changes were calculated.
Findings: Negative means of differences were found in all measured parameters, illustrating lower scores for the OpenGo on average. The OpenGo showed negative upper limits of agreement in center of pressure parameters on the mediolateral axis. Temporal reliability ICCs ranged from 0.90–0.93. Smallest detectable changes for both stance times were 0.04 (left) and 0.05 (right) seconds, for gait cycle time 0.08 s, and for cadence 4.5 steps per minute.
Interpretation: The OpenGo is valid and reliable for the measurement of temporal gait parameters during walking. Measurements of center of pressure parameters during unilateral stance are not considered valid. The OpenGo seems a promising instrument for clinically screening and monitoring temporal gait parameters in patients, however validation in patient populations is needed.

1. Introduction

The idea that in-shoe measurements can help screening and monitoring patients exists for more than two decades [1] and current instrumented insoles could potentially transfer gait analyses out of laboratory settings. Clinical screening and monitoring by means of instrumented insoles could be useful in various chronic conditions affecting gait such as diabetic neuropathies [2], rheumatoid arthritis [3], or knee and hip osteoarthritis [4,5]. For example, hip osteoarthritis is associated with lower physical performance (including balance) [6] and persons with hip osteoarthritis show altered stance times and cadence [4]. Since balance and gait difficulties are risk factors for falling [7], it seems important to clinically screen and monitor such alterations in persons with hip osteoarthritis to support clinical decision-making (e.g. if therapy is indicated or to evaluate a chosen therapy).

Currently available insole technology enables the measurement of balance and temporal gait parameters. The popular and the more recently developed instrumented insoles have wired external modules attached to the wearers' shoes [8,9], legs [10], or waist

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[11], which serve as data recorders or transmitters. Technology advancements enabled the development of instrumented insoles for long-term gait analysis without wires or external modules. The Moticon OpenGo is wireless and free from modules and consists of two thin and lightweight insoles that are instrumented by pressure sensors, temperature sensors, and accelerometers. Therefore, due to its mobility, the OpenGo seems to be a potentially useful instrument for gait analyses in clinical environments.

For clinical use it is important to have instrumented insoles of high clinimetric quality. Unfortunately, full-fledged clinimetric studies on instrumented insoles on balance and temporal gait parameters seem scarce. Some of the OpenGo's clinimetric properties concerning center of pressure and temporal parameters were reported in two studies [12,13]. However, there are parameters (e.g. cadance) and clinimetric properties (e.g. measurement error) that were not examined. Furthermore, some methodological choices might limit the clinical applicability (e.g. fixed walking speeds or standardized footwear). Consequently, more information on clinimetric properties in a healthy population is needed to determine if the OpenGo is suitable for future validation in patient populations.

For assessing the OpenGo's clinimetric properties in a healthy sample the following research aims were used: (1) to determine the OpenGo's concurrent validity with an AMTI force plate measuring center of pressure; (2) to determine the OpenGo's concurrent validity with a ForceLink instrumented treadmill measuring stance time, gait cycle, and cadence time; and, (3) to determine the OpenGo's reliability measuring stance time, gait cycle time, and cadence.

2. Methods

2.1. Participants

Participants were recruited by convenience sampling at the KU Leuven facilities. Participants were included when aged 18–65. Participants were excluded if there was a known presence of disease or had a lower extremity injury, disorder, deformity or amputation. In addition, participants were excluded if they had acute low back pain, a total knee or hip replacement in the past year, or were dependent on (custom) orthopedic shoes or insoles. Lastly, participants were excluded when the OpenGo did not fit their shoes. The study was approved by the KU Leuven Research Ethics Committee and all participants gave written informed consent. Twenty healthy volunteers were tested at the Movements & Posture Analysis Laboratory Leuven in Belgium. Sample characteristics are presented in Table 1. Three participants did not complete all unilateral stance trials under eyes closed conditions, resulting in the exclusion of these trials from analyses (i.e. 10% missing data under eyes closed condition).

2.2. Instruments

The Moticon OpenGo (Moticon GmbH, München, Germany) has 13 capacitive pressure sensors, a temperature sensor, a tri-axial accelerometer, and a data storage chip per insole. Pressure sensors cover 52% of the insole area (Fig. 1). Four pairs of insoles were used ranging from European size 38–45.

The AMTI OR6-7 force plate (Advanced Mechanical Technology Inc., Watertown, USA) with strain gage bridge sensing elements weighs 28.18 kg while its dimensions are 464 × 508 × 82.55 millimeters. Force plates are generally considered a gold standard for center of pressure parameters and are used to test concurrent validity in other research [14,15].

The ForceLink instrumented treadmill (ForceLink, Culemborg, the Netherlands) is a split-belt treadmill with two embedded force plates. Instrumented treadmills are generally considered a gold standard for temporal gait parameters and are used to test concurrent validity in other research [16]. Other instrumented treadmills showed good reliability and acceptable standard errors of measurement for various temporal gait parameters [17,18].

Table 1
Sample characteristics and characteristics by gender.

	n	Mean (SD)	Range
Age (Years)			
Male	10	28.60 (4.22)	22–34
Female	10	25.90 (3.73)	22–32
Total	20	27.25 (4.12)	22–34
Weight (kg)			
Male	10	77.49 (8.82)	67.17–92.70
Female	10	62.06 (7.78)	52.63–75.16
Total	20	69.78 (11.32)	52.63–92.70
Height (cm)			
Male	10	182.0 (7.0)	173–196
Female	10	169.1 (7.3)	153–177
Total	20	175.6 (9.6)	153–196
Body Mass Index			
Male	10	23.46 (3.00)	19.53–28.61
Female	10	21.67 (1.90)	18.66–24.27
Total	20	22.57 (2.61)	18.66–28.61
Walking speed[a] (m/s)			
Male	10	1.53 (0.19)	1.22–1.75
Female	10	1.43 (0.15)	1.31–1.72
Total	20	1.48 (0.17)	1.22–−1.75

[a] Calculated from the corrected Timed 25 Foot Walking test, cm: Centimeters, kg: Kilograms, m: Meters, n: Sample size, s: Second, SD: Standard deviation.

2.3. Procedures

A two-minute insole acclimatization period was given before participants stood on the AMTI OR6-7 force plate to complete one unilateral stance trial for each leg under eyes open and closed conditions lasting 30 and 15 s, respectively. Body posture during testing was standardized by crossing the arms over the chest while lifting the heterolateral foot to about ankle height [19]. Time started as soon as the participant was stable after raising the heterolateral foot. The OpenGo was worn without shoes but between the participants' own socks and an extra pair of thin cotton socks provided by the researchers. Foot position was standardized by a template fixed on the force plate showing insole outlines corresponding to all insole sizes to match the insoles' axes with the force plate's axes. Trials still succeeded if participants deviated momentarily from the standardized body posture (e.g. opening the arms that were crossed over the chest), because participants were not judged on balance performance. Trials failed when deviating from the standardized foot position (e.g. shifting the weight bearing foot) or when balance could not be maintained for the required time (e.g. the heterolateral foot touched the ground). Participants took 30 s rest between trials and insoles were zeroed to remove residual weights possibly biasing subsequent measurements.

Self-selected comfortable walking speed was calculated using the corrected Timed 25 Foot Walking test [20]. Participants were instructed to walk safely and comfortably along a 10.62-m walkway once. Time needed to cover the final 7.62-m (i.e. 25 ft.) was captured with a stopwatch and used to calculate the walking speed. The walking speed was used to set the ForceLink instrumented treadmill belt speed in a two-minute familiarization and insole acclimatization trial. Belt speed was not adjusted during the subsequent trials. Participants rested one minute before

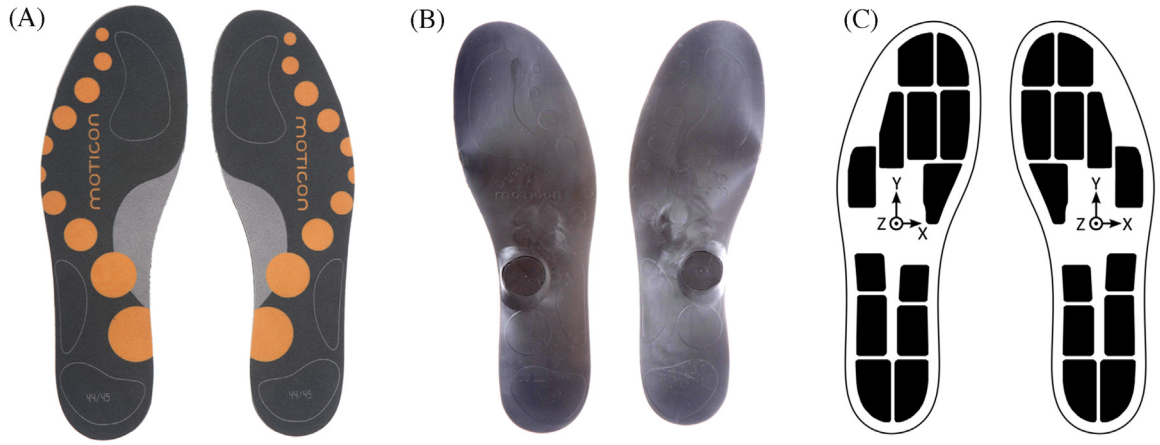

Fig. 1. OpenGo instrumented insoles and their sensor lay out (USB antenna not shown).
Images showing the OpenGo instrumented insole front (A), the back with battery compartment (B) and the sensor lay out (C).

continuing. Participants walked on the instrumented treadmill for 90 s at their calculated walking speed while wearing the OpenGo in their own comfortable walking shoes. After the first trial the insoles were zeroed and to avoid fatigue [21] the participants rested 30 s. Thereafter, the participants performed another 90-s walking trial. Trials succeeded if participants could complete the 90 s. Trials failed when participants could not complete a trial safely or when a foot touched the contralateral force plate incorporated in the treadmill.

2.4. Data collection

The OpenGo sampled at 50 Hz and was wirelessly connected by USB antenna to a computer running Moticon's Beaker 5 software (Moticon GmbH, München, Germany) to initiate and stop data recordings. Trial data was saved to the storage chip embedded in the insoles and downloaded afterwards to Beaker 5 via USB cable. AMTI force plate and ForceLink treadmill data were captured at 1000 Hz using Vicon Nexus software (Vicon, Oxford, UK). Force plate and treadmill data were processed in MATLAB (The MathWorks Inc., Natick, USA) while OpenGo data were processed in Beaker.

Table 2
Center of pressure concurrent validity of the OpenGo versus the AMTI OR6-7 force plate.

		Instrument scores		Concurrent validity	
				Instrument agreement	
	n	OpenGo's mean (SD)	Gold standard's mean (SD)	Mean of differences (SD)	95% LoA LL-UL
Eyes open condition					
Left foot					
Standard deviation AP (mm)	20	6.78 (2.56)	7.38 (1.48)	−0.61 (2.05)	−4.62–3.41
Standard deviation ML (mm)	20	2.40 (0.80)	7.13 (1.92)	−4.73 (1.68)	−8.02 to −1.45
Range AP (mm)	20	36.72 (12.34)	46.24 (13.59)	−9.52 (9.18)	−27.50–8.47
Range ML (mm)	20	12.21 (3.40)	38.09 (13.00)	−25.88 (13.02)	−51.40 to −0.37
Velocity (mm/s)	20	35.45 (10.49)	46.29 (17.42)	−10.84 (10.66)	−31.75–10.06
Right foot					
Standard deviation AP (mm)	20	6.36 (3.31)	7.82 (2.12)	−1.46 (2.23)	−5.84–2.92
Standard deviation ML (mm)	20	2.39 (1.03)	7.41 (1.97)	−5.02 (1.62)	−8.19 to −1.84
Range AP (mm)	20	36.40 (18.50)	47.41 (15.50)	−11.01 (12.50)	−35.51–13.48
Range ML (mm)	20	12.71 (3.66)	37.58 (8.96)	−24.88 (8.15)	−40.85 to −8.90
Velocity (mm/s)	20	35.24 (11.69)	48.49 (21.49)	−13.25 (13.79)	−40.29–13.79
Eyes closed condition					
Left foot					
Standard deviation AP (mm)	18	12.86 (4.98)	14.83 (3.70)	−1.97 (3.40)	−8.63–4.69
Standard deviation ML (mm)	18	5.05 (1.47)	13.67 (3.75)	−8.62 (3.28)	−15.06 to −2.19
Range AP (mm)	18	65.79 (24.15)	83.21 (18.02)	−17.42 (18.42)	−53.53–18.69
Range ML (mm)	18	20.98 (4.08)	55.94 (12.73)	−34.96 (11.59)	−57.68 to −12.25
Velocity (mm/s)	18	65.11 (23.74)	108.04 (31.23)	−42.92 (20.12)	−82.36 to −3.49
Right foot					
Standard deviation AP (mm)	18	11.65 (5.43)	15.16 (1.73)	−3.51 (4.61)	−12.54–5.52
Standard deviation ML (mm)	18	4.14 (1.94)	13.61 (3.81)	−9.47 (3.61)	−16.55 to −2.38
Range AP (mm)	18	60.83 (24.16)	83.99 (18.19)	−23.15 (25.04)	−72.22–25.92
Range ML (mm)	18	18.51 (6.37)	56.87 (13.20)	−38.36 (14.16)	−66.12 to−10.60
Velocity (mm/s)	18	63.59 (33.19)	105.89 (37.48)	−42.30 (24.25)	−89.83–5.22

AP: Anteroposterior axis, LL: Lower limit, LoA: Limits of agreement, ML: Mediolateral axis, mm: Millimeters, n: Sample size, SD: Standard deviation, s: Second, UL: Upper limit.

Center of pressure data were synchronized by trial end-points. The end-point for the OpenGo data was defined as the time-point where the total plantar pressure under the balancing foot drops to half of the applied pressure during the trial, indicating a pressure distribution in bipedal stance when stepped of the force plate. The force plate signal end-point was defined as the moment when the vertical ground reaction forces dropped below half of the body weight, resembling loss of balance or bipedal stance. From both end-points, the preceding 30 or 15 s of data were used for analyses. While Beaker used unfiltered data for center of pressure analyses, the force plate center of pressure data were smoothed using a 6th order Butterworth filter with a cut-off frequency of 10 Hz determined by Winter's residual analysis technique [22]. The standard deviation parameter was defined as the standard deviation of the displacement amplitude in millimeters for both the anteroposterior and mediolateral axes. The range was defined as the absolute difference in millimeters between any two points on the center of pressure path for both the anteroposterior and mediolateral axes. The mean total velocity was defined as $\overline{v} = \frac{1}{T}\sum_{1}^{T}\sqrt{(x_{t+1} - x_t)^2 + (y_{t+1} - y_t)^2}$ in millimeters per second, with (x) and (y) being successive anteroposterior and mediolateral displacements respectively for each time point (t), and finally computing mean total velocity over the total duration (T) of the measurement.

For OpenGo data, the 'balance report' function was used to obtain the center of pressure parameter outcomes. Equal or similar center of pressure parameters are utilized for assessing postural balance on force plates in patient samples [23,24].

The first 25 and final 5 s of the treadmill trials were excluded, leaving 60 s of data for processing. Every first trial of the test-retest trials on the instrumented treadmill was used for the OpenGo's concurrent validity. Treadmill and OpenGo trials were synchronized by using the first complete step in each trial. Stance time was defined as the time in seconds from heel-strike to toe-off using a 20N threshold on the force plates. Gait cycle time was defined as the time in seconds from heel-strike till the first subsequent homolateral heel-strike. Cadence was defined as the number of steps per minute. For OpenGo data, the 'gait report' function in Beaker was used to obtain temporal parameter outcomes.

2.5. Data analyses

For validity, Bland-Altman plots were constructed to assess the inter-instrument agreement between the gold standard and OpenGo [25]. Absolute agreement intraclass correlation coefficient (ICC) model (2,1) was used to assess reliability [26,27]. The standard error of measurement (SEM) and smallest detectable change (SDC) were calculated as part of reliability by using $SEM_{agreement} = \sqrt{\sigma^2_{rater} + \sigma^2_{residual}}$ and $SDC = 1.96 * \sqrt{2} * SEM_{agreement}$ [26]. The SDC was expressed as a percentage (%SDC) in individual scores. The sample's mean%SDCs with accompanying 95% confidence intervals were reported. Cases with missing data were excluded from analyses on those variables where data was absent. Statistical analyses were performed in SPSS Statistics 20 for Macintosh (IBM Corp., Armonk, USA). ICCs were interpreted as followed: ICC < 0.75 was poor to moderate, ICC 0.75–0.89 was good, and ICC ≥ 0.90 was excellent [28].

3. Results

3.1. Concurrent validity

Tables 2 and 3 show the mean instruments' scores, means of differences and 95% limits of agreement for center of pressure and temporal gait parameters, respectively. The limits of agreement widen under eyes closed conditions, except for the range parameter on the mediolateral axis for the left foot. Negative upper limits of agreement for center of pressure parameters on the mediolateral axis were found. In all measured parameters negative means of differences were found, illustrating lower scores for the OpenGo on average. Figs. 2 and 3 show Bland-Altman plots for, respectively, center of pressure parameters under eyes open conditions and temporal gait parameters.

3.2. Reliability

Table 4 shows reliability ICCs and measurement errors for temporal parameters. The ICCs ranged from 0.90 to 0.93. The 95% confidence intervals for both the left and right stance time were narrower than for gait cycle time and cadence. All 95% confidence interval upper bounds of the mean%SDC were below 10%.

4. Discussion

The aims of this study were to determine the OpenGo's concurrent validity and reliability measuring balance and temporal gait parameters in a healthy sample. When interpreting the Bland-Altman plots, the OpenGo was found not to be interchangeable with a force plate for center of pressure parameters. The question is whether or not it is clinically acceptable that 95% of the differences between measurements lie within the limits of agreement [25]. The OpenGo generally tends to underestimate center of pressure parameters and the limits of agreement are considered too wide when expecting force plate grade measurements from the OpenGo. For the temporal gait parameters the limits of agreement are considered acceptable. For example the right stance time lower limit of agreement equals 5.5% of the force plate's mean score, which is deemed acceptable. For cadence this is even lower, at 2.3% of the force plate's mean score. Excellent reliability was found for the measurement of temporal gait parameters. The SDCs were considered acceptable for a healthy sample, because none of the mean%SDC confidence interval upper limits exceeded 10%.

Only one study assessed the center of pressure validity during a balance task using the OpenGo [13]. An identical pattern emerged

Table 3
Temporal gait parameter concurrent validity of the OpenGo versus the Force Link instrumented treadmill.

		Instrument scores		Concurrent validity	
				Instrument agreement	
	n	OpenGo's mean (SD)	Gold standard's mean (SD)	Mean of differences (SD)	95% LoA LL-UL
Left stance time (s)	20	0.61 (0.03)	0.62 (0.03)	−0.007 (0.013)	−0.033–0.018
Right stance time (s)	20	0.62 (0.03)	0.63 (0.03)	−0.009 (0.013)	−0.035–0.017
Gait cycle time (s)	20	1.01 (0.05)	1.01 (0.04)	−0.000 (0.013)	−0.026–0.025
Cadence (steps/min)	20	59.44 (2.79)	59.44 (2.71)	−0.002 (0.709)	−1.391–1.387

LL: Lower limit, LoA: Limits of agreement, min: Minute, n: Sample size, s: Seconds, SD: Standard deviation, UL: Upper limit.

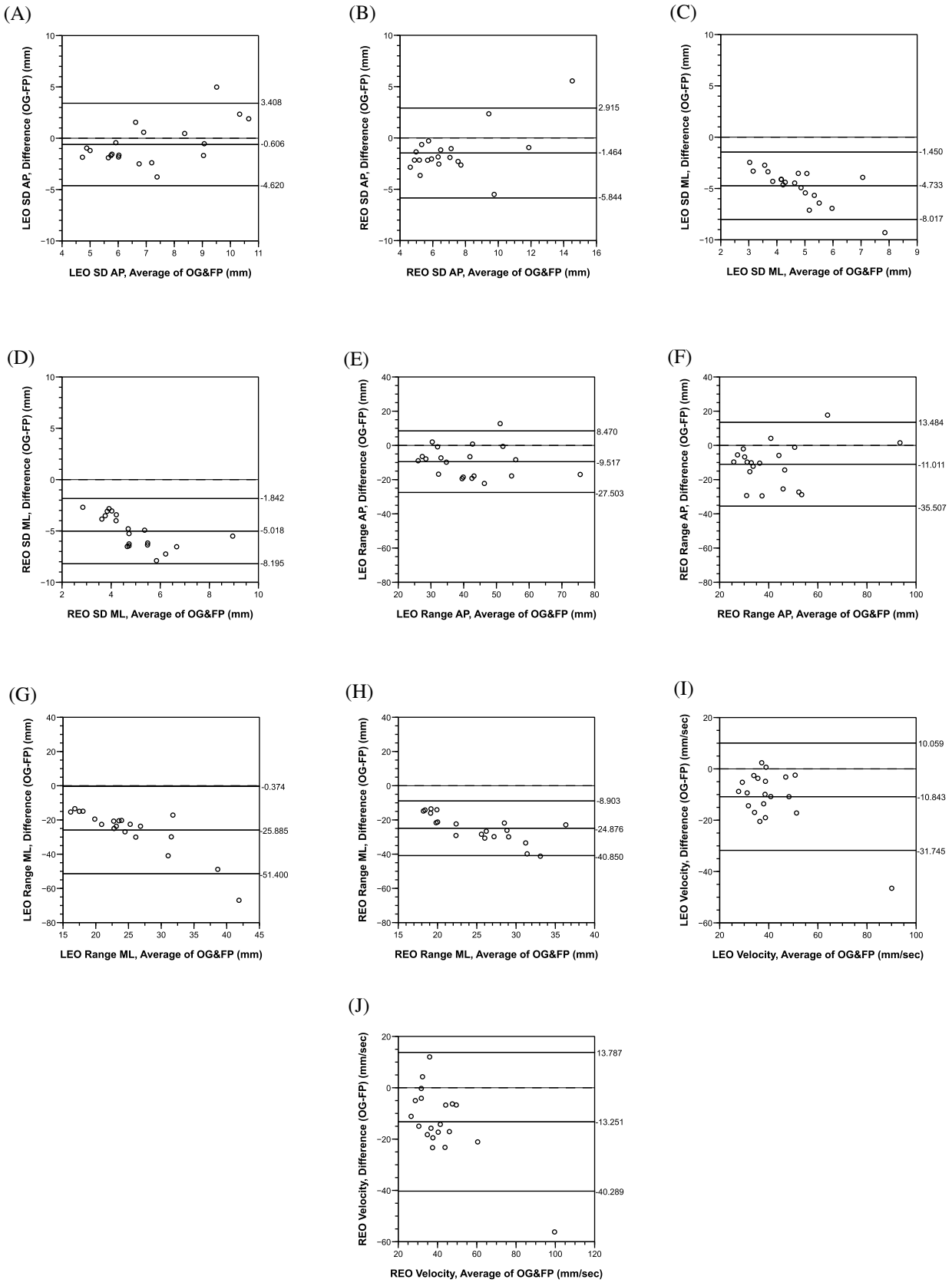

Fig. 2. Instrument agreement on center of pressure parameters under eyes open condition.
AP: Anteroposterior axis, FP: Force plate, LEO: Left foot with eyes open, ML: Mediolateral axis, mm: Millimeter, OG: OpenGo, REO: Right foot with eyes open, sec: Second, SD: Standard deviation. Bland-Altman plots showing instrument agreement for the standard deviation parameter on the anteroposterior axis for the left (A) and right (B) foot, and on the mediolateral axis for the left (C) and right (D) foot. Furthermore, instrument agreement is shown for the range parameter on the anteroposterior axis for the left (E) and right (F) foot, and on the mediolateral axis for the left (G) and right (H) foot. The velocity parameter instrument agreement is shown for the left (I) and right (J) foot.

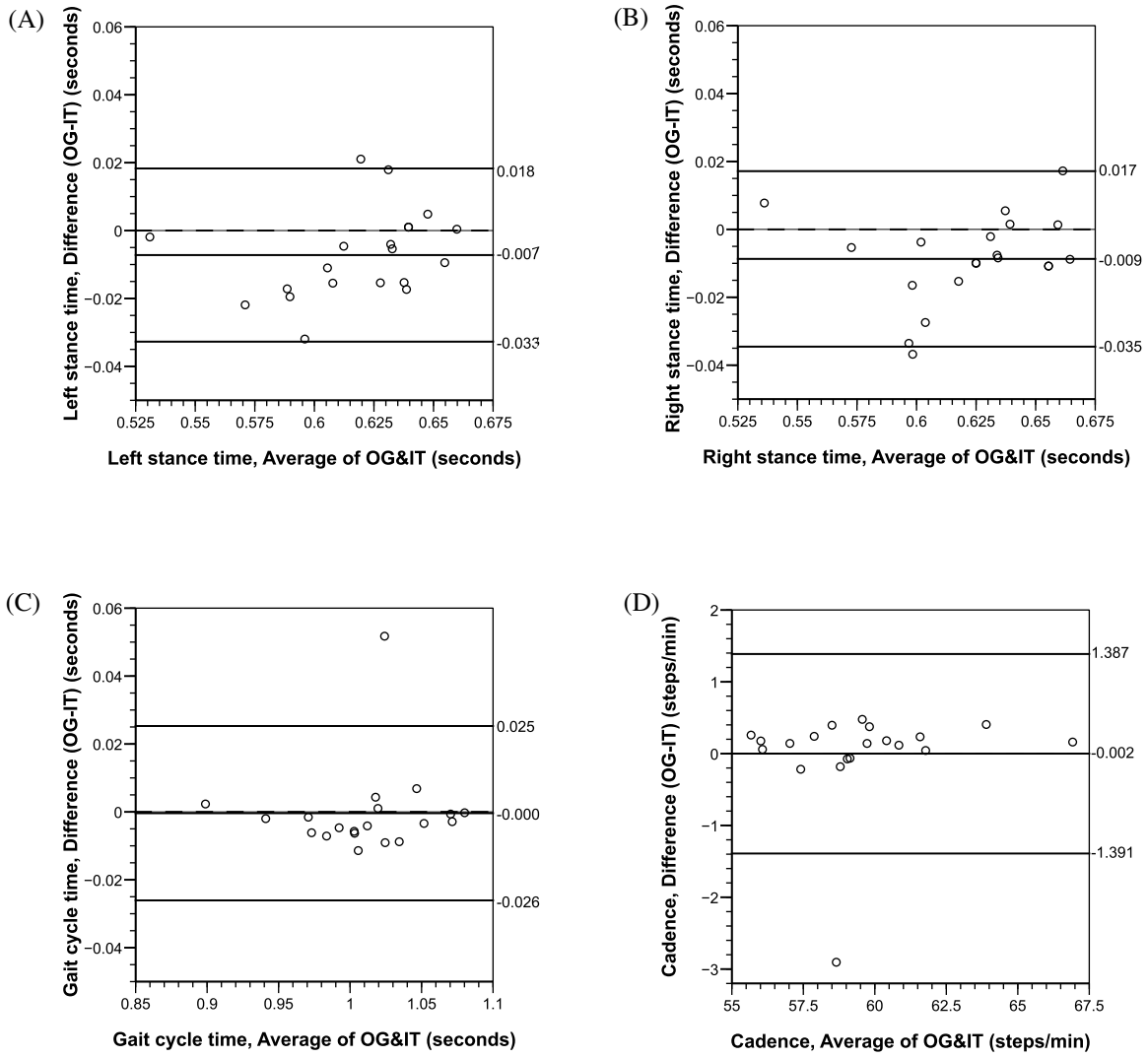

Fig. 3. Instrument agreement on temporal gait parameters.
IT: Instrumented treadmill, min: minute, OG: OpenGo. Bland-Altman plots showing the instrument agreement on left stance time (A), right stance time (B), gait cycle time (C), and cadence (D).

Table 4
Reliability of the OpenGo measuring temporal parameters.

		OpenGo scores		Reliability				
				Reliability	Measurement error			
							Mean of%SDC[a] (95% CI)	
	n	Mean test score (SD)	Mean retest score (SD)	ICC (95% CI)	SEM	SDC	Test	Retest
Left stance time (s)	20	0.61 (0.03)	0.62 (0.03)	0.93 (0.82–0.97)	0.014	0.040	6.53 (6.35–6.70)	6.49 (6.31–6.66)
Right stance time (s)	20	0.62 (0.03)	0.62 (0.03)	0.93 (0.82–0.97)	0.018	0.050	8.12 (7.90–8.34)	8.06 (7.85–8.26)
Gait cycle time (s)	20	1.01 (0.05)	1.02 (0.05)	0.90 (0.75–0.96)	0.029	0.080	7.98 (7.80–8.15)	7.91 (7.74–8.09)
Cadence (steps/min)	20	59.44 (2.79)	59.00 (2.86)	0.91 (0.78–0.96)	1.618	4.485	7.56 (7.40–7.72)	7.62 (7.45–7.79)

[a] Mean of the SDC expressed as a percentage from individual scores, CI: Confidence interval, ICC: Intraclass correlation coefficient model(2,1), min: Minute, n: Sample size, s: Seconds, SD: Standard deviation, SDC: Smallest detectable change, SEM: Standard error of measurement (agreement).

where the OpenGo generally underestimated center of pressure parameters with increased underestimations on the mediolateral axis when compared to the anteroposterior axis. Differences between the mediolateral and anterioposterior axes are also reported for other instrumented insoles during walking, where parameters on the mediolateral axis show lower correlation [15,29]. It was suggested that a low sampling frequency could limit the instrument agreement and that an insufficient spatial sensor resolution could limit the measurement of small variations [30]. The lack of agreement in the current study might have been caused by the sensor layout. An n = 1 follow-up test on a pressure plate suggested that the center of pressure trajectory probably runs partially over a non-instrumented area of the OpenGo when visually comparing results from both instruments. The follow-up test also revealed that the OpenGo still underestimated trajectory ranges when balancing only on the instrumented anterior part of

the insole. This might indicate that the sensors' sampling frequency is too limited to detect small and quick changes in the center of pressure trajectory. Furthermore center of pressure computations are obscured in Beaker, which complicates explaining the instrument disagreement in terms of calculations.

Two clinimetric studies assessed the OpenGo's stance time validity [12,13]. However, one of the clinimetric studies only reported ICCs [12], which makes direct comparison difficult. The second study found similar results [13], supporting the finding reported in the current study. When comparing the OpenGo to other instrumented insoles, the Runalyser showed narrower limits of agreement for stance time while using a running protocol [9]. The narrower limits of agreement might be explained by the difference in sampling rate, where the Runalyser sampled at 247 Hz. For the outlier (Fig. 3), the automatic gait event detection in Beaker might have failed to determine heel strike or toe-off events. The insoles might have difficulties following weight increases in fast motions and when persons have well-defined foot arches showing low weight in the mid-foot area, which could cause misdetections. When looking at the outlier's ground reaction forces captured by the instrumented treadmill, the graphs did not reveal larger drops in ground reaction force during mid-stance compared to other participants (Fig. 4). This might indicate that during gait the outlier applied force on the non-instrumented part of the insole, so the applied force was captured by the instrumented treadmill and not by the OpenGo.

When discussing ICCs it should be noted that ICC values are dependent on the heterogeneity of the sample [26], which suggests that variations in applied ICC models and measurement protocols are not the only determinants influencing ICC values. For stance time reliability high ICCs (ICC = 0.96–0.99) were reported for the OpenGo [12], supporting the reliability results in the present study. The small discrepancy could be explained by a possible difference in sample heterogeneity [26] or by the variation in applied ICC model [27]. The Runalyser insoles showed a higher reliability (ICC = 0.97) while running [9] and the Pedar-X insoles showed a lower reliability (ICC = 0.81–0.87) in an over-ground walking protocol [31]. Variations in sampling rate, measurement protocol and sample heterogeneity could explain such differences.

No clinimetric study using the OpenGo reported its measurement error. For clinical interpretability, the SDC was calculated directly from the SEM. The SDC reflects the smallest 'real' within-person change beyond the SEM that can be measured by the instrument [32,33]. The Runalyser's SDC was smaller (SDC = 0.016 s) for stance time while running [9]. This could be explained by the Runalyser's higher sampling frequency, probably allowing a more precise temporal registration in foot-floor contact. Although tested in a linear trajectory over-ground walking protocol, the Pedar-X SDCs (SDC = 0.04–0.05 s) were comparable for stance time [31]. This similarity between the Pedar-X and OpenGo SDCs is interesting since the Pedar-X has 99 sensors per insole versus 13 in the OpenGo. However, both sampled at 50 Hz and therefore the sampling frequency might be influencing the measurement error in temporal parameters. When considering the reported SDCs in a patient context, a mean difference in cadence of 7.4 steps was observed when comparing persons before and after arthroplasty [34]. The OpenGo can measure such magnitude of change within individuals since its SDC for cadence was about 4.5 steps per minute. In persons with diabetic polyneuropathy, a mean difference of 0.09 s for gait cycle time was observed when walking on different surfaces [35] which could be measured by the OpenGo since its SDC was 0.08 s. This indicates that the OpenGo's SDCs are theoretically small enough for measuring changes within individual patients. For research purposes, the OpenGo could theoretically measure even smaller changes on group level since the measurement error is reduced when measuring in groups [32].

When choosing valid and reliable instrumented insoles, it seems important to consider if measurements will be conducted under walking or running conditions, while practical concerns might also be a deciding factor (e.g. what system is at hand? Or, might wires and external modules affect the intended measurement?). The current study showed that the OpenGo could be chosen when temporal parameters are measured during walking or when wires and external modules are suspected to influence measurement outcomes.

The strength of the present study is the generalizability of results due to three aspects. The first aspect is the use of ICC(2,1) for reliability, which is the preferred model [33] and allows for generalization between raters [27]. The second aspect is the lack of standardization of footwear, allowing the OpenGo to be used in the wearer's comfortable shoes. The final aspect is the self-selected walking speed varying between persons, which allows for the use

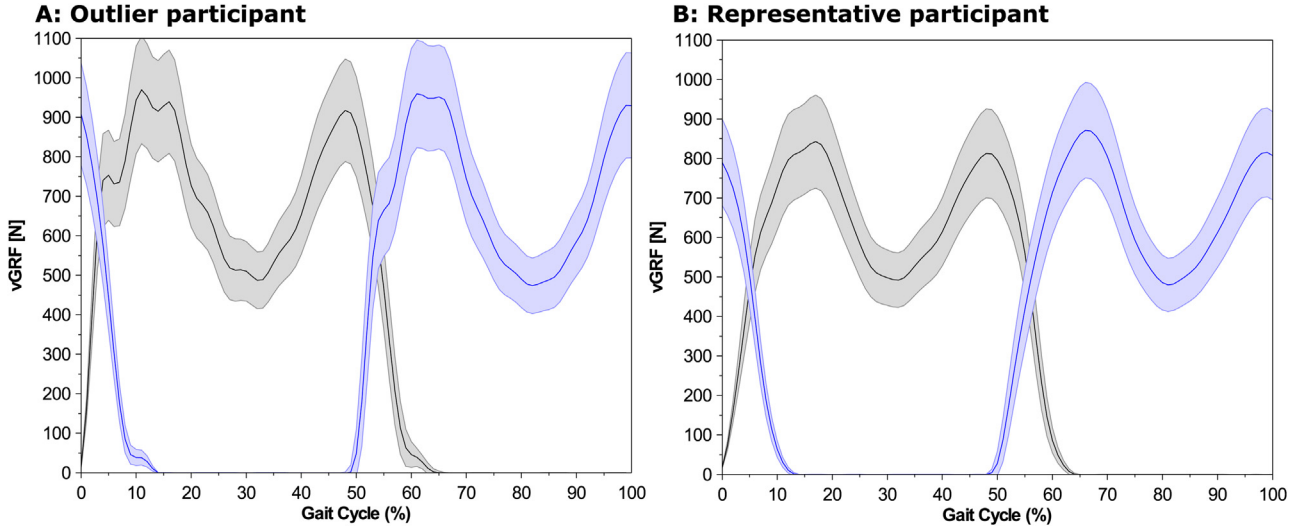

Fig. 4. Normal vertical ground reaction force in the outlier and a representative participant.
N: Newton, vGRF: Vertical ground reaction force.
Average vGRF curve (with shaded standard deviation) for the outlier (A) and for a representative participant (B) during the first treadmill walking trial. The black line represents the left foot and the blue line represents the right foot throughout the gait cycle.

of self-selected walking speeds on treadmills. However, the walking speed calculated from the corrected 25 Foot Walking test can be considered fast for a comfortable speed and could have had its cause in the way the walking speed was measured. The 10.62-m walkway might be too short for healthy persons to determine a walking speed for the purpose of maintaining that speed 90 s on a treadmill, suggesting the (sub)maximal speed of their comfortable walking speed was captured instead. Besides this, only one trial was used to calculate the walking speed instead of a two-trial average.

Future research could focus on assessing the OpenGo's center of pressure validity with a higher sampling rate. Furthermore, reliability and validity of temporal gait parameters could be assessed in patient samples or in more challenging and real-life environments. It could also be interesting to confirm laboratory results from healthy persons in clinical settings.

In conclusion, the OpenGo is valid and reliable for measuring temporal gait parameters while walking on a treadmill without standardizing walking speed and footwear. Clinical unilateral center of pressure measurements at 50 Hz with the limited amount of sensors cannot be recommended during unilateral stance. The OpenGo seems promising for clinically screening and monitoring temporal gait parameters in patients, although validation in patient populations is needed.

Conflict of interest

The authors declare that there is no conflict of interest.

Declaration of interest

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us.

We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual property.

We further confirm that any aspect of the work covered in this manuscript has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript.

We understand that the corresponding author (Benedicte Vanwanseele) is the sole contact for the editorial process. She is responsible for communicating with the other authors about progress, submissions of the revisions and the final approval of proofs. We confirm we have provided a current and correct email address, which is accessible by the corresponding author.

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