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

Michiel S. Oerbekke[a,b], Mirelle J. Stukstette[a,b], Kurt Schütte[c,d], Rob A. de Bie[e], Martijn F. Pisters[a,b,f], Benedicte Vanwanseele[c,f,*]

[a] Physical Therapy Research, Department of Rehabilitation, Nursing Science and Sport, Brain Center Rudolf Magnus, University Medical Center Utrecht, Utrecht, The Netherlands
[b] Center for Physical Therapy Research and Innovation in Primary Care, Julius Health Care Centers, The Netherlands
[c] Department of Kinesiology, Faculty of Kinesiology and Rehabilitation Sciences, KU Leuven, Leuven, Belgium
[d] Department of Sport Science, Stellenbosch University, Stellenbosch, South Africa
[e] Department of Epidemiology, CAPHRI School for Public Health and Primary Care, Maastricht University, Maastricht, The Netherlands
[f] Department of Health Innovation and Technology, Fontys University of Applied Sciences, Eindhoven, The Netherlands

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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

* Corresponding author at: KU Leuven, Department of Kinesiology, Tervuursevest 101, bus 1501, 3001 Leuven, Belgium.
E-mail address: benedicte.vanwanseele@faber.kuleuven.be (B. Vanwanseele).

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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