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Validation of the wearable sensor system - MoveSole® smart insoles

Antti Alamäki[1], Elina Nevala[1], Juha Jalovaara[1], John Barton[2], Salvatore Tedesco[2], Joan Condell[3], Karla Muñoz Esquivel[3], Daniel Kelly[3], David Heaney[3], James Gillespie[3], Shvan Karim[3], Richard Davies[4], Anna Nordström[5,6], Markus Åkerlund Larsson[5]

[1] Research, Development and Innovation activities (RDI) & Physiotherapy Education, Karelia University of Applied Sciences, Finland; [2] Tyndall National Institute, University College Cork, Ireland; [3] Intelligent Systems Research Centre, Ulster University, Magee Campus, Derry/Londonderry, Northern Ireland, UK; [4] Jordanstown Campus, Ulster University, UK; [5] Department of Public Health and Clinical Medicine, Umeå University, Sweden and School of Sport Sciences; [6] The Arctic University of Norway, Tromsø, Norway

M.Sc, pt, Antti Alamäki, Karelia University of Applied Sciences, Tikkarinne 9, FI-80200 Joensuu, FINLAND. Email: antti.alamaki@karelia.fi

Abstract

Biomechanical analysis of gait is commonly used in physiotherapy. Ground reaction forces during phases of gait is one element of kinetic analysis. In this article, we analyze if the MoveSole® smart insole is valid and accurate equipment for measuring ground reaction forces in clinical physiotherapy. MoveSole® StepLab is a mobile measurement system for instant underfoot force measurements during gait. Unique electromagnetic film (EMFI) based sensor technology and printed electronics production technology is integrated in the MoveSole® StepLab measurement system. The MoveSole® StepLab measures plantar ground reaction force distribution over the sensors and provides an estimation of the maximum total ground reaction force.

We developed a two phase validation process to extract relevant parameters and compared the results to a Kistler force plate using the BioWare® analyzing program as a reference method. Our results show that MoveSole® smart insoles reach the strong level of accuracy needed in clinical work concerning highest ground reaction forces during step (Pearson correlation .822 - .875). The correlation of the time when the maximum ground reaction force occurred was moderate, e.g. during heel strike or toe-off (Pearson correlation natural gait speed .351 - .462, maximum gait speed .430). Our conclusion is that MoveSole® smart insoles are a potential tool for analyzing and monitoring gait ground reaction forces during physiotherapy processes.

Keywords: gait analysis, smart insoles, validation, physiotherapy, rehabilitation, health technology

Introduction

Ground reaction forces of steps during walking is one of the typical kinetic analyses that are used to measure and monitor gait demands that the body meets and produces. In every case of functional capacity activities (ICF) [1] problems and imbalances (walking, running, standing, balance), ground reaction forces can be measured. With ground reaction forces it is possible to measure and describe the distribution of the body weight to the lower limbs. High pressure load on certain areas of the foot can be connected with ulcers due to diabetes or other blood vessel problems [2]. The typical results which are wanted for both research and clinical work include movements of the center of mass during steps, distribution of ground reaction forces or pressure to different areas of the foot during steps (x, y, z, propulsion directions), and recognition of properties in different step phases (e.g. heel strike, toe-off, mid stance, the effect of pronation and supination of the foot, time of step). Sensor insoles usually measure gait ground reaction forces or pressure using the piezoelectric phenomenon. The sensors produce microvolts and microcurrent (µV, µC) measurements which are then processed by various algorithms to convert these readings to pressure and/or force values.

Step ground reaction forces can be measured with force plates (Kistler, AMTI) [3,4] electric walking mats (GAITRite®) [5] or with different smart insoles. While the first two methods are accurate, the number of steps is limited, and the equipment is expensive (e.g. GAITRite® 42 000€) and fails to describe the wider range of normal walking during the day. Insoles, on the other hand, are not limited in the same way and are therefore more applicable to use for a wider perspective.

Our goal was to analyze if the MoveSole® [6] is valid equipment for clinical use in rehabilitation processes. We designed and conducted a two phase validation process (concurrent criterion validity) to analyze its properties and compared the results to a Kistler force plate using the BioWare® analyzing program and other measuring equipment described later. In the first phase, we measured how the ground reaction forces are manifested with two walking speeds (Kistler and MoveSole® Health technology comparison, walking speed measured). In the second phase, we analyzed if the different foot properties (Navicular height and drop test, Jack test) [7,8] and results without any kind of shoe are affecting Kistler and MoveSole® results. The original MoveSole® algorithm was developed on the basis of measures where the insole was placed inside a wrestling shoe. The hypothesis was that the wrestling shoe has an impact on the results of the distribution of ground reaction forces acting as a leverage in the Windlass phenomenon [8] and absorbing the ground reaction force at some level.

This validation study was conducted as part of the NPA (Northern Periphery and Arctic Programme 2014-2020) [9] funded SENDoc (Smart sENnsor Devices fOr rehabilitation and Connected health) [10] project. One of the aims of NPA projects, is to support the development of SME companies. This is one example of product development and co-operation in that area.

The research permission was granted according to Karelia UAS 2017 instructions. According to the interpretation of Finnish National Board on Research Integrity [12] instructions for this research ex ante evaluation was not necessary (evaluation of equipment/device).

Material and methods

Voluntary participants were recruited from Karelia University of Applied Sciences students and staff with written and verbal announcements. The implementation of the research protocol, use of the data and results, and data protection was explained to the participants. A consent form was signed by participants. Four researchers conducted the protocol with previously agreed tasks. The protocol was pre-tested by researchers several times. Used equipment were calibrated and operations were tested. Data was collected after each sample to a Microsoft Excel file and then transferred to IBM SPSS Statistics program [11].

In phase one of the protocol, first the body weight and shoe and insole size were measured. After that the participants trained a few times to walk through the 10 m distance, so that they could ensure that their left foot would land on the first Kistler plate (5th step) and the right foot on the second Kistler plate (6th step). The two Kistler force plates were placed at approximately the middle of the total distance so that the walking speed could feasibly accelerate to a selected level. Participants walked two times with their natural walking speed and two times with their maximum speed. The walking speed was measured from the middle four meters after the acceleration of wanted gait speed.

First in the phase two, the body weight and insole size were measured and selected. Second, an experienced physiotherapist made an evaluation of the participants' foot properties (Navicular height & drop and Jack test). Each participant walked seven meters four times with their natural walking speed and the third (left foot) step ground reaction force was measured.

Statistical analysis was carried out for both phase one and two experiments using the SPSS program [11]. For Kistler and MoveSole® correlation, paired-samples T-test (Pearson correlation, significant level .001), and Bland-Altman test were carried out. Linear regression analysis was applied to analyze the significance of different variables (body weight, walking speed) to ground reaction forces [13].

The following types of equipment were used to measure particular parameters during each phase of the tests.

Body weight: Inbody® Body Composition Analyzer (Inbody Co. Ltd) [14]. Bioimpedance based measurement of body weight and composition.

Walking speed: Photoelectric cell measuring equipment Racetime 2 Light Radio Kit® (Microgate Ltd) [15]. Photoelectric based device for measuring used time in walking. Starts and stops automatically when person crosses the line between the photoelectric sensors.

Ground reaction force: MoveSole® Smart Insoles (seven sensors) with MoveSole® StepLab app on Samsung mobile phone. A sampling rate of 100 Hz. [6]. Measures ground reaction forces with seven sensors installed insoles. Six different sizes (36-46) available.

Two Kistler force platforms 9260AA6 (Kistler Group). Uses piezoelectric technique for measuring ground reaction forces. A sampling rate of 100 Hz, Measuring rate from -2.5 to 2.5 kN, crosstalk between Fx, Fy, and Fz ≤ ± 2,5%, hysteresis ≤0,5 %HSO. with BioWare® software for Data Acquisition of Force Plates [3].

Results

Phase one results

The purpose of the first phase was to compare the highest ground reaction force results to the vertical (Y) direction of Kistler force plate and MoveSole® smart insoles. Additionally, the time of highest ground reaction force appearance was compared (heel strike or toe-off) and the impact of walking speed to highest values were measured.

In total, 132 samples of gait were collected and analyzed. 33 healthy young persons participated in the phase one validation study. Nineteen of them were females (57.6%) and 14 males (42.4%). The mean age was 23.2 years (19 – 34 years SD 2.91), and the mean weight of participants was 70.8 kg, (50.3 – 110.0 kg SD 12.81). The average size of the insole was 251.5 mm (225 – 292 mm). Weight distribution measured with MoveSole® was higher on the left side in twenty-one cases (46,8 % - 54%, mean 50,5%) and in twelve cases (46% - 53,2 %, mean 49,5 %) on the right side. The mean gait speed with natural walking speed was 1.55 m/s (SD .14) and maximum walking speed was 2.3 m/s (SD .32). These measurements are normal for healthy adults according to the literature [16].

Fifth (left) and sixth (right) steps were measured. The mean ground reaction force of steps of Kistler results given all velocities was 988.98 N (left) and 958.45 N (right). For natural speed, the mean values were 858.95 N (left) and 868.36 N (right). With maximum speed, the mean forces were 1119.02 N (left) and 1051.34 N (right). Measured with MoveSole®, the mean ground reaction force of steps with all velocities was 920.33 N (left) and 881.63 N (right). With natural walking speed, the mean forces were 849.81 N (left) and 806.98 N (right). When walking with maximum speed, the mean forces were 992,66 N (Left) and 963,73 N (right). When analyzing both individual samples and comparing the means of the highest ground reaction force values, the increased walking speed caused higher ground reaction forces (Table 1.) When comparing means of vertical ground reaction forces, the MoveSole® system reported values 8.9-10.8% smaller than those recorded by the Kistler force plate.

Table 1. Mean vertical forces (Newtons) measured with Kistler and MoveSole®.

	N	Minimum	Maximum	Mean	Std. Deviation
Kistler left (natural)	66	534,26	1422,40	858,95	171,58
MoveSole® left (natural)	66	478,00	1330,00	849,82	187,38
Kistler right (natural)	66	604,82	1395,60	868,36	168,04
MoveSole® right (natural)	66	421,00	1470,00	806,98	188,85
Kistler left (max)	66	724,32	2102,60	1119,02	290,81
MoveSole® left (max)	64	660,00	1710,00	992,66	211,12
Kistler right (max)	64	695,97	1822,20	1051,34	205,67
MoveSole® right (max)	60	520,00	1630,00	963,73	201,96

Correlations of the highest ground reaction forces between Kistler and MoveSole® were strong. When all measurements were compared, the correlation was: left foot (all) .809, right foot (all) .835 (Pearson .001). When correlations of the highest ground reaction forces of different walking speeds were compared, they remained about the same level: natural speed left .823, right .822, maximum speed left .785, right .794. The mean difference between Kistler and MoveSole® values were 9,1 N / 61,4 N (left / right) while walking with natural speed, and 130,8 N / 82,3 N (left / right) while walking maximum speed. When comparing only the mean values in every case, Kistler values were higher than MoveSole® values.

The Bland-Altman test shows growing disagreement of ground reaction force results while the walking speed increases. Values walking with natural speed are inside an acceptable confidence interval (t=0.689, df=63, p. 0.493 One sample t-test, N=66, mean difference = 9N, three values outside 95% confidence interval = 4,6%) (Figure 1), but with maximum speed Bland-Altman test show too much percentage of values outside it (Figure 2).

Examining the force values of the left foot at maximum walking speed (t=5.713 df = 63, p.<0.001 One sample t-test), the difference between values diverge statistically very significantly from the value 0, which means that there is consistent bias [13]. (N=64, mean difference = 131N, three values outside 95% confidence interval = 4,7% of values which is almost in the critical value 5%).

Table 2. Mean difference of Kistler and MoveSole® ground reaction forces (Newtons).

	N	Minimum	Maximum	Mean	Std. Deviation
Difference of natural speed steps (left)	66	231,73	265,15	**9,13**	107,72
Difference of natural speed steps (right)	66	89,75	418,53	**61,38**	108,34
Difference of maximum speed steps (left)	64	220,40	872,60	**130,80**	183,16
Difference of maximum speed steps (right)	60	201,01	353,30	**82,30**	130,68

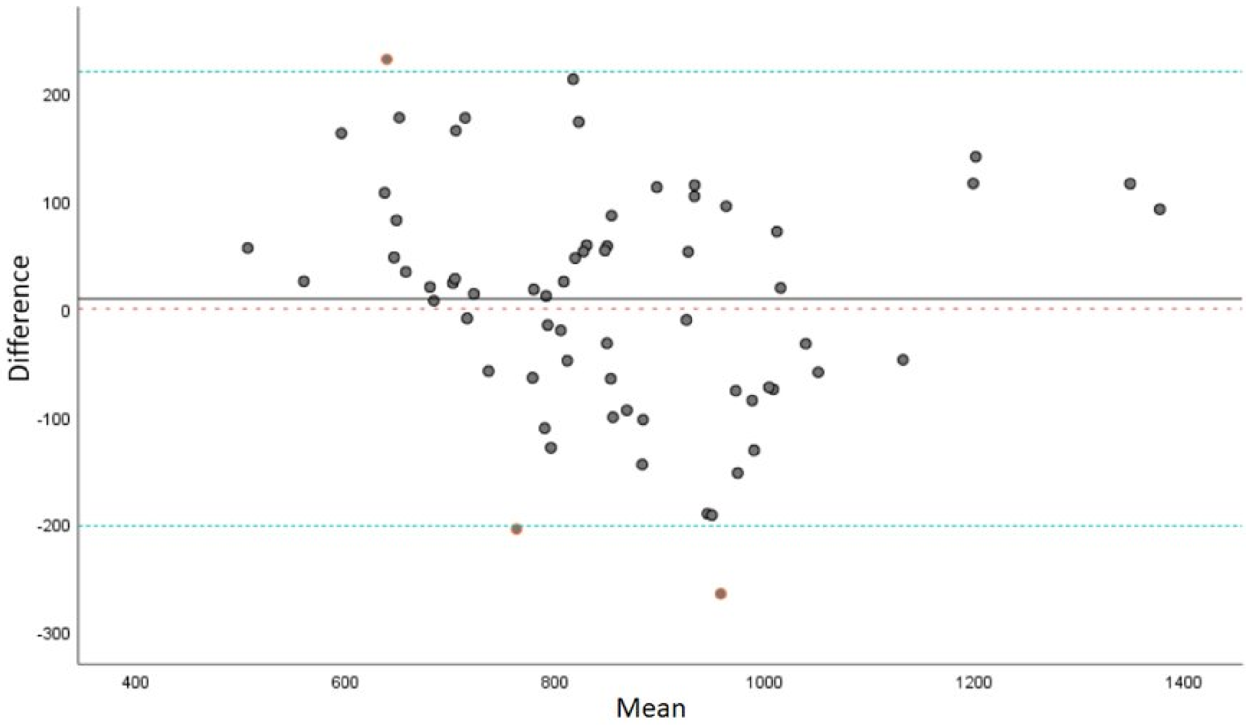

Figure 1. Bland-Altman for left foot force values with natural walking speed.

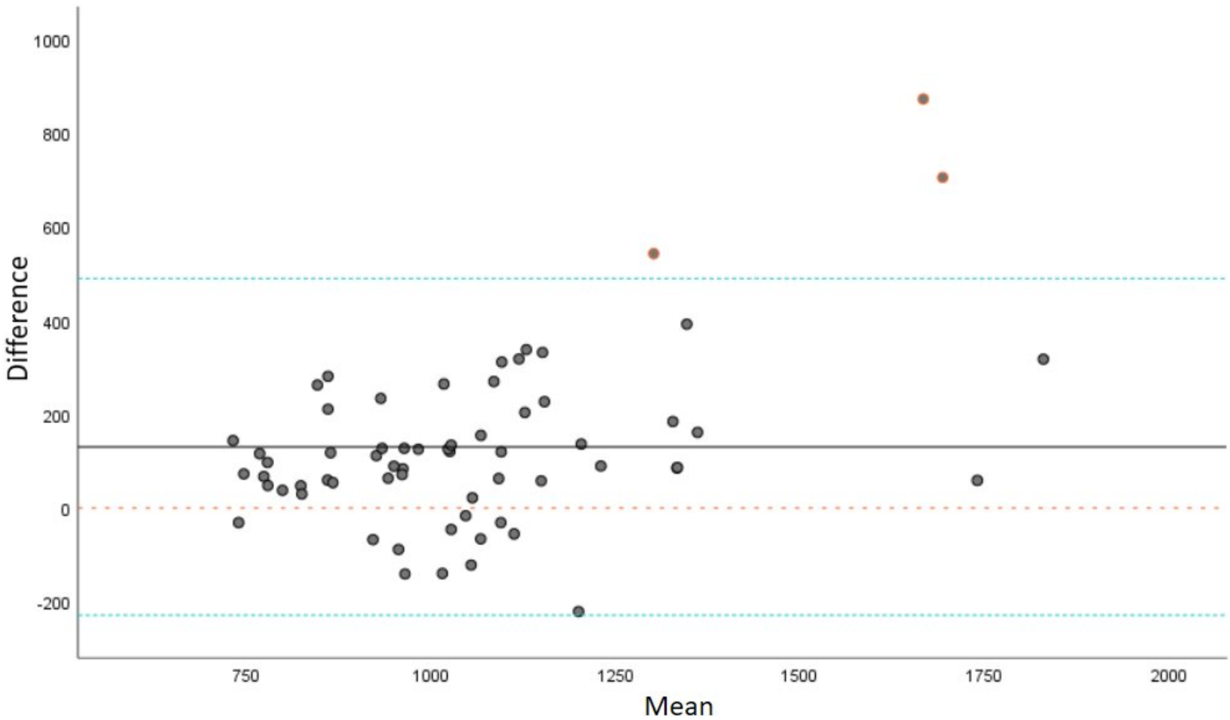

Figure 2. Bland-Altman for left foot force values with maximum walking speed.

Differences of the highest vertical force appearance was obvious in step graphs (Newtons and msec) of Kistler and MoveSole®. Because of this finding, we measured the correlations from the time parameter (msec) of the highest ground reaction force. Correlations were moderate (natural speed .351, maximum speed .430).

When analyzing the impact of different variables to vertical forces in regression analysis, different walking speeds, together with weight, had the highest explanation percentage of the vertical ground reaction forces both in Kistler force plate (79.3% - 94.7%, R Square) and MoveSole® (64.0% - 78.9%, R Square). Correlations of vertical ground reaction forces to participant's body weight values are strong (Kistler .811 - .947 in left and .845 - 897 right) and about the same level with MoveSole® (.852 - .884 in left and .791 - .844 right).

Phase two results

The set-up was developed to find out how accurate the algorithm is when ground reaction force was measured in a scenario as close as possible to barefoot. The original algorithm of MoveSole® StepLab was developed through wrestling shoe measurements. We wanted to analyze if the foot elasticity properties, analyzed with clinical tests, could be detected in MoveSole® values. In the second phase, we compared Kistler and MoveSole® ground reaction force results of step when the insoles were inside a thin but tight sport sock and on top of those, an anti-slip Instant Grip Sock® (CareCare ltd) [17].

In total, 40 samples of gait were collected and analyzed. Ten healthy young volunteers, both male and female (21 - 34 years, mean age 24.7 years, mean weight 73.2 kg), participated in the experiment. All participants had normal values of the Navicular height & drop test and the Jack test (Windlass) [7, 8], so the effect of the variation in elasticity of the medial arch of the foot could not be compared.

The correlation between Kistler and MoveSole®´s highest ground reaction forces was strong (.875). The correlation between body weight and vertical forces was also strong (.877 MoveSole® and .940 Kistler). While analyzing measurements, it was noted that MoveSole values were higher in 29 trials and Kistler values were higher in 11 trials. The mean difference between Kistler and MoveSole® values was 44,7 N. The correlation of the time when Kistler and MoveSole® highest ground reaction forces appeared (heel strike or toe-off) was moderate (.462).

Discussion

The accuracy of MoveSole® reached clinically strong levels (Pearson correlation 0.822 - .875). According to the Bland-Altman analysis the reliability in different gait speed should be detected more. The reference methods often used in this kind of research are either Kistler [3] or AMTI [4] force plates.

In a normal step, the highest vertical ground reaction force values are measured either during heel strike or toe-off phases of stance. This can be detected from a force-time graph and measured time. This depends on the personal walking style and properties of the foot, step, and the gait speed [16]. There were differences in MoveSole® smart insoles results compared to Kistler results when detecting the time of the highest ground reaction forces during step (Pearson correlation natural gait speed .351 - .462, maximum gait speed .430). This can cause some limitations for clinical use. The fact that the algorithm was built based on insole measurements inside wrestling shoes may be one reason for those differences.

The single measurement differences between MoveSole and Kistler varied between 1 - 418 N. The majority of the differences were between 100 – 200 N, which means about 10 – 20 kg in practice. Given this, a risk could be caused if these insole measures are used in medicine and therapies. For example, if you have allowance for limited weight on your lower limb (for example 15 kg after surgery), a 5 - 10 kg variation in the measurements could be a loading risk. Factors that might have an impact on the results could be how well the insole fits the shoe, and how well the shape of the insole and position of sensors corresponds the individual shape and the size of the foot (width and length). With some participants, movement of the foot inside the shoe might increase, especially with higher walking speed.

In both phases the mean walking speeds of the participants, and the force reactions due to them, were analogous to the ones suggested by literature. It was about 1,2 x bodyweight with natural gait speed. The maximum vertical (Y-direction) ground reaction force increased (20-40%) when walking speed increased as literature has previously shown [16].

By monitoring foot ground reaction forces with several sensors in longer periods of patient´s everyday life, healthcare personnel can receive more accurate and objective information about the possible risks of health and functional capacity problems, e.g. gait and force production imbalances. The early detection of exceptional loadings in the foot might prevent diabetic and neuropathic foot ulcers and that way improve a patient´s quality of life and save healthcare costs.

Conflict of interest

The authors declare no conflict of interest.

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