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Validity and reliability of textile system Sensoria for posturographic measurements

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***ABSTRACT.** Smart fabrics and interactive textiles are a relatively new area of research, with many potential applications in the field of biomedical engineering. The ability of smart textiles to interact with the body provides a novel means to sense the wearer's physiology and respond to the needs of the wearer. Physiological signals, such as heart rate, breathing rates, and activity levels, are useful indicators of health status. These signals can be measured by means of textile-based sensors integrated into smart clothing which has the ability to keep a digital record of the patient's physiological responses since his or her last clinical visit, allowing doctors to make a more accurate diagnosis. Similarly, in rehabilitation, it is difficult for therapists to ensure that patients are complying with prescribed exercises. Smart garments sensing body movements have the potential to guide wearers through their exercises, while also recording their individual movements and adherence to their prescribed programme.*

In this paper, we present the new wireless textile system Sensoria, with pressure sensing capability for static posturography. The gold standard for static posturography is currently the use of a pressure or force plate but, due to their very complexity and expensiveness, the applicability outside laboratories is extremely limited. This paper focuses on the agreement between the static computed posturography assessed by means of a traditional stabilometric platform and the Sensoria system, in twenty subjects with Parkinson's Disease (PD). Preliminary results showed a significant agreement between the two methods, suggesting a clinical use of Sensoria for low cost home care based balance impairment assessments.

***Key words:** e-textile; posture, centre of pressure (CoP), rehabilitation, Sensoria, Zebris.*

RIASSUNTO. I tessuti intelligenti ed interattivi rappresentano un nuovo paradigma di ricerca, con molte potenziali applicazioni nel campo dell'ingegneria biomedica.

Gli e-textiles, noti anche come smart garments, smart clothing o smart textiles, sono tessuti che consentono di incorporare al loro interno componenti digitali ed elettronici in grado di rilevare, acquisire e trasmettere segnali fisiologici.

Si adattano perfettamente al corpo umano, ed il loro sviluppo si pone come obiettivo il miglioramento della qualità della vita del paziente e l'aumento della sua autonomia.

In questo articolo, vi presentiamo il nuovo sistema basato su tecnologia e-textile Sensoria, con capacità di rilevamento della pressione plantare per la posturografia statica. Il gold standard per posturografia statica è attualmente l'uso di pedane di pressione o forza, ma, a causa della loro complessità e del loro elevato costo, il loro utilizzo al di fuori dei laboratory clinici di misura è estremamente limitato.

Introduction

Recently, there has been a move towards improving individual patient healthcare by providing monitoring systems that are safe, effective, patient-centred, timely, efficient, and equitable (1). These aims call for systems that are portable and economic, i.e., affordable systems that are located on the patient or user. The requirement for such systems is that they are designed for long-term health monitoring. Additionally, these systems must send critical feedback data to remote healthcare personnel while remaining unobtrusive to the patient as they perform their daily activities. These features will best be realized by a wearable monitoring system that is integrated into everyday clothing. The current technologies used for developing these wearable health monitoring systems have been named "electronic textiles." A wearable electronic textile-based monitoring system must be able to monitor a person during daily activity. This long-term type of monitoring outside of the hospital or clinic will enable early diagnosis, prevention, and/or detection of illnesses that go undetected in clinical environments. This is especially true when monitoring patients that are considered high health risks, like post-heart attack or stroke patients, and monitoring of patients in rural hard to access areas (2, 3, 4). In addition, a wearable electronic textile-based monitoring system will decrease the length of time patients stay in the hospital thereby reducing healthcare costs. With reduced healthcare costs, lower income populations, those generally without health insurance, will also gain access to healthcare (5). Therefore, numerous benefits will arise from the development of health monitoring systems that are suitably integrated into clothing. Smart textiles for healthcare include textile sensors, actuators and wearable electronics systems embedded into textiles that enable registration and transmission of physiological data, and wireless communication between the wearer and the 'operator', for example, patient and medical personal. Such systems ensure patients' mobility, thereby providing a higher level of psycho-physiological comfort, especially when a long-term bio-monitoring is required. In this paper, we present a smart fabric system with pressure sensing capability for static posturography. Posturography provides information about the mechanisms underlying

L'obiettivo di questo documento è di condurre una analisi comparative tra una misura di posturografia statica ottenuta mediante una tradizionale pedana stabilometrica, ed una misura ottenuta mediante il nuovo Sistema Sensoria. A tal fine sono stati reclutati venti soggetti con malattia di Parkinson (PD) e sottoposti ad un test posturografico registrato mediante i due suddetti metodi di misura. I risultati preliminari hanno mostrato un importante accordo tra i due metodi, suggerendo un possibile uso clinico di Sensoria per le valutazioni dei disordini posturali.

Parole chiave: textile, postura, centro di pressure (CoP), riabilitazione, Sensoria, Zebris.

the balance control during quiet standing (7). Particularly, the maintenance of upright posture implies two fundamental requirements: the first is to maintain the centre of gravity within the support base, the second is to create a reference system to the body moving parts (8). This capacity at rest during voluntary head, arm, and body movements, during transfers and wheelchair use (both indoors and outdoors) needs the coordination of several sensorial and motor mechanisms. Posturography provides information tended to address specific rehabilitation programs (9-11). The gold standard for static posturography is currently the use of a pressure or force plate, (12-14), which allow the assessment of the variations of the centre of pressure (CoP), namely the centroid of all the external forces acting on the plantar surface of the foot. The spatial and temporal variations (sway measures) of the CoP are commonly used as a measure of the balance control.

Despite the effectiveness of the pressure or force plates in evaluating the balance control, they are commonly used in a clinical environment, due to their very complexity and expensiveness. So, their applicability outside laboratories is extremely limited. Also, the process of operation is time consuming and requires a trained technician for its use and interpretation of results. These factors limit its availability and use by clinicians and therapists (15). These considerations lead to the need to explore novel portable, inexpensive balance assessment systems which allow more easy and extensive home availability especially for older and chronic disable people (16-18). The development of small, lightweight, low-cost and energy efficient textile-oriented systems offer the promise of home health care devices that integrate flawlessly into the wearer's everyday lifestyle with different functions and applications, particularly both in sport and rehabilitation fields. New wireless textile system Sensoria (19), originally designed as fitness and sport monitoring device, have recently been commercially available. Worn just like normal athletic socks, the Sensoria Fitness Socks appear as one of the first example of a truly wearable devices potentially part of each consumer's daily workflow.

Aim of the paper has been a preliminary evaluation of static computed posturography in subjects with Parkinson's Disease (PD) by means of pressure signals derived by a pair of Sensoria socks, comparing their agreement's degree with results at the same time performed by a gold standard clinical stabilometric Zebris force platform.

Materials and methods

A. E-textile Sensoria socks

Sensoria fitness socks (19) are a product by Sensoria Inc. Redmond WA United States originally designed for fitness and sport application and aimed to help subjects become better runners and prevent common injuries allowing to identify and assess harmful running styles. Sensoria pressure sensor fabric is a knitted nylon & elastan coated with a proprietary conductive formulation (piezoresistive fabric). The material is washable and generates a raw signal that is predictable and repeatable over time (19). Pressure is detected by a variable resistor fabric. The change in resistance is proportional to the amount of pressure exerted over the sensor. As the pressure increases the resistance decreases, and vice versa. The socks detect real-time heel or toe foot striking. Each smart sock is infused with three proprietary textile sensors under the plantar area (Figure 1) located in the following positions under the foot: I) fifth metatarsal bone (MTB5), close to the little toe, II) first metatarsal bone (MTB1), close to the big toe and III) Heel, to detect main foot pressure sites.

When the Sensoria Fitness Socks, designed as textile circuit board, are connected with two companion anklets, which also include 3-axis accelerometer, they are able to collect the pressure. The anklet wirelessly transmits continuously through Bluetooth Smart all 3 textile

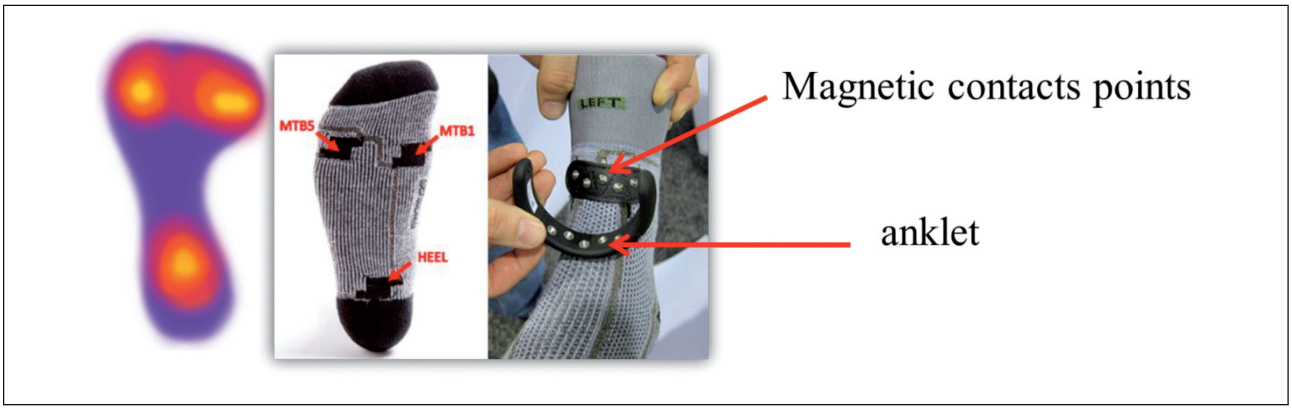

Figure 1. *On the left the 3 textile pressure sensors located in key positions under the foot. On the right the socks' magnetic contacts for the attachment of the anklet*

pressure sensors and 3-axis accelerometer signals at 32 Hz sampling rate.

B. Posturographic clinical gold standard device

The stabilometric platform of the latest generation ZEBRIS PDM-Sx (Figure 2) has been considered as the gold standard device for the assessment of the balance control. It is equipped with 1920 capacitive sensors of new generation arranged in a matrix of 34 x 41 cm (55 x 40 cm) with a sampling frequency of 120 Hz. This organization permits analysis of changes in the distribution of vertical force in the forefoot and hind-foot of both feet; in addition, centre of pressure data (COP) were analysed in anterior-posterior (AP), medio-lateral (ML) directions. The COP trajectory reflects the body sway during standing and the ability of the nervous and musculoskeletal systems to integrate information from multiple sensory systems, including the visual, the somatosensory, and the vestibular system to maintain balance. Impairments of the postural control system induces changes of COP characteristics; thus, the investigation of such impairments is crucial to define effective rehabilitation protocols (20-22).

C. Study population

Thirty people (20 males and 10 females; mean age 63±9 yrs) with Parkinson's disease were recruited as participants in this study. They had a clinical diagnosis of idiopathic PD and were on a stable medication regime. The Unified Parkinson's Disease Rating Scale (UPDRS) and the Hoehn and Yahr Scale were administered to quantify disease severity. Participants from both groups were required to be free of signs of dementia according to the Addenbrooke's Cognitive Examination (Total score <82 out of 100) and be free from serious co-morbidities or acute illnesses that would interfere with static standing motion. This study has been carried out in accordance with Good Clinical Practice, the Declaration of Helsinki, and the moral, ethical and scientific principles that justify medical research, and all participants provided informed consent.

Figure 2. ***ZEBRIS PDM-Sx posturographic system***

D. Test Protocol

We asked participants to remove their shoes, to wear both the Sensoria socks and stand upright on the Zebris force plate. Before each trial, feet position was kept consistent by a wooden template with a divergent angle of 30 degrees and with a 20-cm distance between the heels. Subjects have been asked to remain as still as possible in a relaxed posture (Figure 3) putting arms to their sides in a comfortable position and distributing their body weight evenly on both feet while breathing normally.

Subjects underwent to two trials, each consisting of 60 seconds, with at least 120 s of rest between trials. A 60-second assessment was chosen to mimic constituent periods of standing during typical activities of daily living (e.g., waiting for a bus or elevator). To avoid inconsistencies in the data at transitions, we in-formed the participants of the data collection start time 5 seconds before the actual start time. Data have been simultaneously collected (hand synchronization) using the Sensoria system and the Zebris measurement system and automatically stopped on both system after 60 s. At the test end Zebris system automatically calculate the main posturographic indexes. The two raw pressure data array of each Sensoria socks were wirelessly transmitted by a Bluetooth connection on a pc laptop workstation instrumented with the Sensoria Developer Kit for Windows. Both arrays were off-line post processed by a customized Matlab®.

E. Centre of Pressure Estimation

The quantitative evaluation of balance is associated with the evaluation of the displacement of the centre of gravity (COG), which is the projection of a person's centre of mass onto the base of support and represents a meaningful outcome parameter (23). Due to permanent balance correction movements of the human body, the direct measurement of the COG is not possible, thus the centre of pressure (COP) is usually alternatively used for COG estimation, since it fluctuates around the COG position with a higher magnitude and frequency as the COG. At each instant, the COP coordinates in the media-lateral (COPML) and anterior-posterior (COPAP) direction has been calculated processing

Figure 3. ***Test subject standing on the zebris ® pressure plate while wearing Sensoria Socks***

raw pressure Sensoria data. Measurement of centre of pressure (COP) excursions in the anterior-posterior and mediolateral direction were collected considering the following configuration:

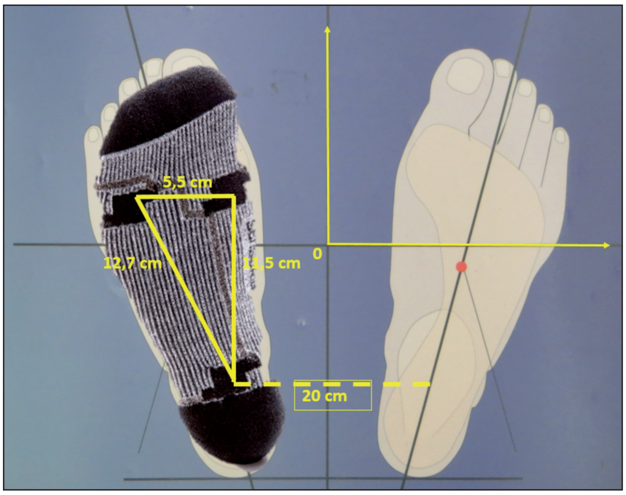

Figure 4. ***Geometric representation of the distribution of pressure sensors under the feet. The yellow***

The COP in the media-lateral (ML) and anterior-posterior (AP) direction can be calculated as the weighted sum of all 14 pressure sensors from both sensor soles with respect to the geometrical placement of the sensors (Figure 4) and the distance between the feet:

$$COP_{ML} = \frac{1}{P}\sum_{i=1}^{14} P_i(ML)_i$$

$$COP_{AP} = \frac{1}{P}\sum_{i=1}^{14} P_i(AP)_i$$

P_i is the pressure of sensor *i* and P is the summarized pressure of all sensors. $(ML)_{i \text{ and}}$ $(AP)_i$ are the spatial positions of sensor $_i$. The resulting COP over time in the transverse plane is therefore (COP_{ML}, COP_{AP}). Based on the COP several parameters can be calculated. Then, a Butterworth low pass filter (3rd order, cut-off frequency of 5 Hz) was applied on the COP data to reduce noise and high frequency characteristics. In this work two parameters are considered more closely: (i) the *Sway Path (SP)*, calculated as the total length of the COP path:

$$SP = \sum_{n=1}^{N-1}((AP[n+1] - AP[n])^2 + (ML[n+1] - ML[n])^2)^{1/2}$$

Then the (ii) *Mean Velocity (MV)* is calculated, which is the aver-age speed that the COP moved, calculated by total distance covered and diving by total time of test. The same sway path index, as automatically calculated by the Zebris system (ZSP), has been used as the gold standard value.

F. Statistical Analysis

Descriptive statistics of continuous variables are reported as mean ± standard deviation (sd). In order to quantify the degree to which the posturographic variables are related, the results have been analyzed by means of the Pearson correlation and Passing Bablok Regression. Passing and Bablok regression analysis is a statistical procedure that allows valuable estimation of analytical methods agreement and possible systematic bias between them (24). It is robust, non-parametric, non-sensitive to distribution of errors and data outliers. Statistically significant differences with $p<0.05$ were considered significant (*$p<0.05$; **$p<0.01$; ***$p<0.001$; ****$p<0.0001$).

Results

The experimental results presented here were obtained by using the aforementioned plantar pressure measurement and analysis system based on textile Sensoria socks. The raw Pressure sensors data collected by means of the socks are shown in Figure 5. The statokinesigram, the time series of the projections traced on the antero-posterior (CoPAP) and medio-lateral direction (CoPML), is shown in Figure 6.

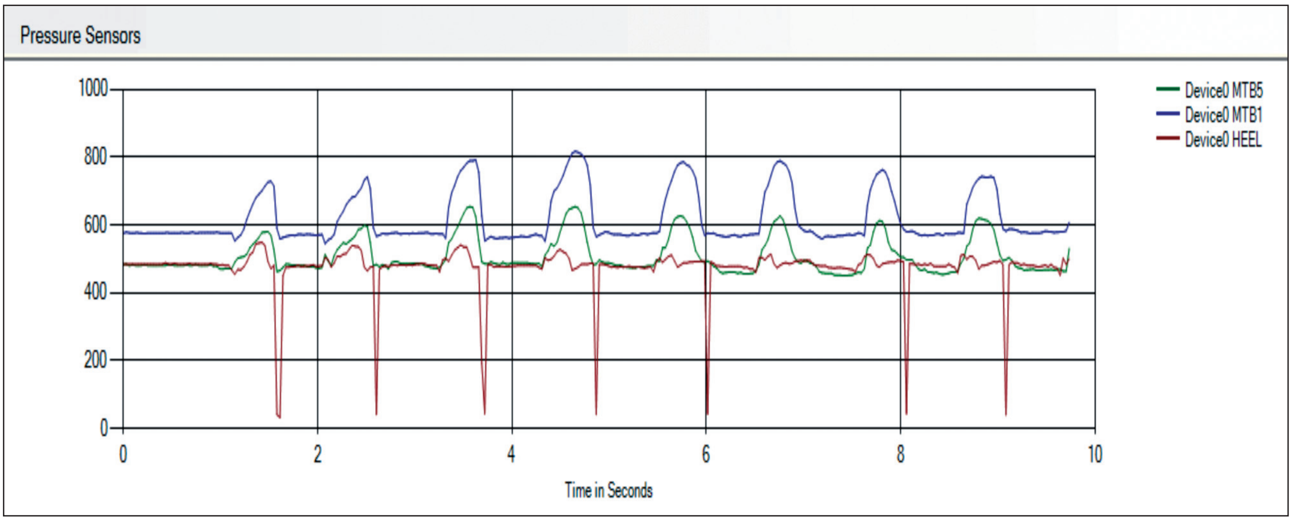

Figure 5. ***The three raw pressure data collected with the Sensoria socks. On the x-axis is reported the time (seconds), on the y-axis the raw pressure data, after the quantization in the 10-bit A/D converter, are reported***

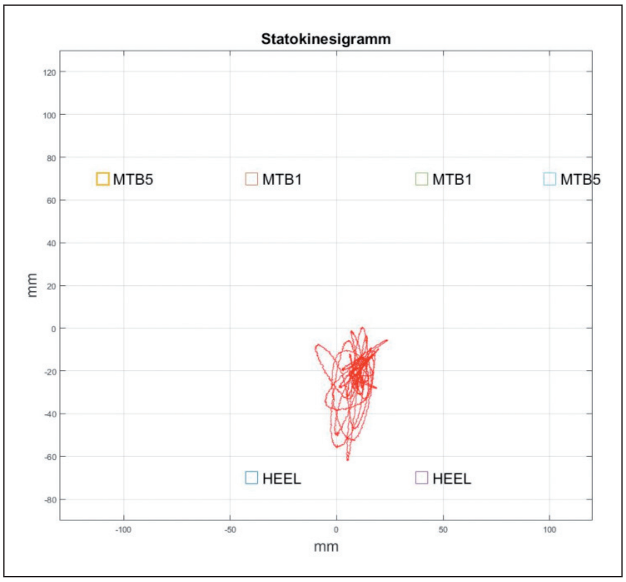

Figure 6. *Example of a PD subject's statokinesigram (red trace). The squares represent the position of the sensors under the feet (MTB1= first metatarsal bone; MTB1= fifth metatarsal bone)*

The Passing Bablok regression analysis for the Sway path index is summarized in Table I.

Relatively to the sway path index, the regression equation (y = -26,2 + 1,02x) revealed systematic (regression line's intercept a= -26,2) and proportional (regression line's slope b=1,02) differences with their confidence intervals of 95% (95% CI). Figure 7 shows the scatter plot Passing and Bablok regression, while Figure 8 shows the residuals from fitted regression line in order to reveal outliers and identify possible non-linearity.

Table I. *Passing Bablok Regression for Sway Path index*

Sway Path	
Variable X	Sensoria (851 ± 69)
Variable Y	Zebris (868 ± 81)
Regression Equation	y = −26,22 + 1,02x
Systematic differences	
Intercept A	−26,22
95% CI	−147,53 to 114,04
Proportional differences	
Slope B	14,98
95% CI	0,8706 to 1,1769
Random differences	
Residual Standard Deviation (RSD)	14,98
± 1.96 RSD Interval	−29,36 to 29,36
Linear model validity	
Cusum test for linearity	No significant deviation from linearity (P=0,48)
Spearman rank correlation coefficient	
Correlation coefficient	0,93
Significance level	p<0,0001
95% CI	0,86 to 0,97

The Passing Bablok regression analysis for the mean velocity index is summarized in Table II.

Relatively to the mean velocity index, the regression equation (y=-1,64 + 1,18 x) revealed systematic (regression line's intercept a=- 1,6426) and proportional (regression line's slope b=1,1876) differences with their confidence intervals of 95% (95% CI). Figure 9 shows the scatter plot Passing and Bablok regression, while Figure 10 shows the residuals from fitted regression line in order to reveal outliers and identify possible non-linearity.

The 95% CI for intercept and slope includes respectively the 0 value and 1 value, indicating a good agreement between the two methods, for both sway path and mean velocity indexes. Cumsum test for linearity indicates no significant deviation from linearity (P > 0.10).

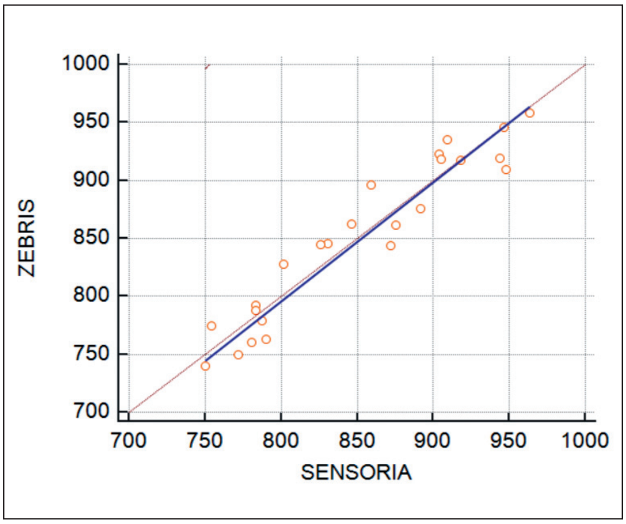

Figure 7. *Passing and Bablok regression analyses of two methods (Sensoria and Zebris) for sway path index; scatter diagram with regression line. Identity red line is dashed*

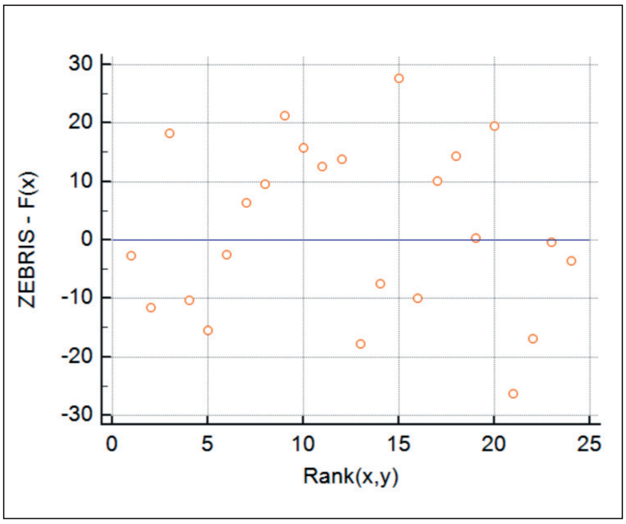

Figure 8. *Passing and Bablok regression analyses of two methods (Sensoria and Zebris) for sway path index; residual plot presents distribution of difference around fitted regression line*

Table II. ***Passing Bablok Regression for Mean Velocity index***

Mean Velocity	
Variable X	Sensoria (9.19 ± 0,85)
Variable Y	Zebris (9.13 ± 0.66)
Regression Equation	y = −1,64 + 1,18 x
Systematic differences	
Intercept A	−1,6426
95% CI	−3,4574 to 0,2708
Proportional differences	
Slope B	1,1876
95% CI	1,00 to 1,3836
Random differences	
Residual Standard Deviation (RSD)	0,17
± 1.96 RSD Interval	−0,34 to 0,34
Linear model validity	
Cusum test for linearity	No significant deviation from linearity (P=0,48)
Spearman rank correlation coefficient	
Correlation coefficient	0,97
Significance level	P<0,0001
95% CI	0,96 to 0,99

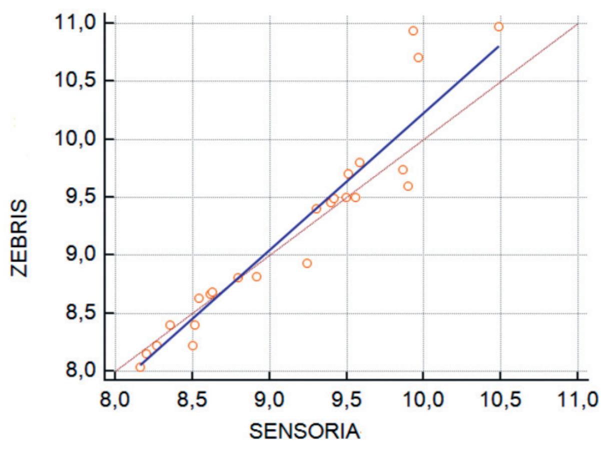

Figure 9. ***Passing and Bablok regression analyses of two methods (Sensoria and Zebris) for mean velocity index; scatter diagram with regression line. Identity red line is dashed***

Discussion

Textiles represent an attractive class of substrates for realizing wearable bio-sensors. Electronic textiles, or smart textiles, describe the convergence of electronics and textiles into fabrics which are able to sense, compute, communicate and actuate. As many different electronic systems, can be connected to any clothing, a wearable system becomes more versatile, and the user can change its look depending on environmental changes and individual preference. The vision of wearable computing describes future electronic systems as an integral part of our everyday clothing serving as intelligent personal assistants. Therefore, such wearable sensors must maintain their sensing capabilities under the demands of normal wear, which can impose severe mechanical deformation of the underlying garment/substrate.

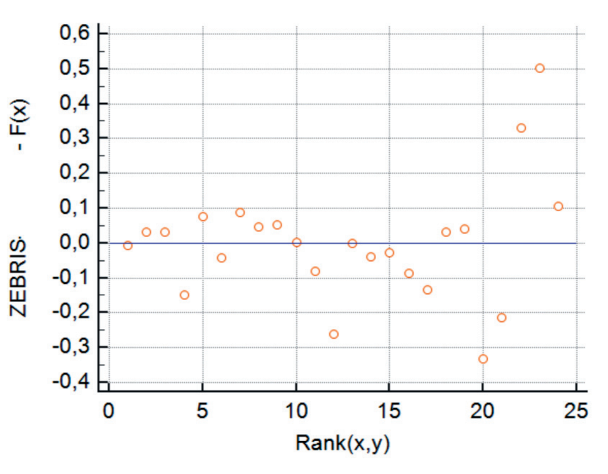

Figure 10. ***Passing and Bablok regression analyses of two methods (Sensoria and Zebris) for mean velocity index; residual plot presents distribution of difference around fitted regression line***

Balance is generally tested quantitatively in laboratory experiments (25). The most commonly used device is a force platform. When using this device, data about body sway, a factor related to balance, are obtained by recording the vertical force applied by the body on the force platform (26). Tests using a force platform are generally performed in a static state. Values tested using a force platform can explain body sway, through various variables (27). However, force platform is time-consuming in terms of performance of tests and careful installation of related software (28). Moreover, it is placed beneath the floor, which is not easily or conveniently transported, and it increases costs considerably (29). Although a force platform is suitable for use in laboratory experiments, it is unsuitable for assessment of patients in clinical setting (29). In the last years, there is a growing need for the development of systems both user-friendly and inexpensive for facilitating simple and efficient balance assessment and monitoring. Recently the development of small, easy to use E-textile fabrics with the electronics and interconnections woven into them, is gaining a high interest for the home health monitoring applications. In this preliminary study, we aimed to evaluate if the use of the e-textile system Sensoria could be considered a valid method for assessing static COP path length, comparing results with a gold standard clinical stabilometric Zebris force platform. Preliminary results about a use of Sensoria system as a clinical tool to evaluate balance impairments seems to be encouraging, showing a good accordance between the posturographic indexes measured with Sensoria socks and Zebris platform, in open eyes conditions on 20 pathological subjects. Future studies will be focused on calculating other typical posturografic indexes, for example using frequency domain analysis (30-37), derivable from Sensoria socks pressure signals, studying their reproducibility and extending this preliminary results also in different eye closed condition.

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