Fully-Wireless Sensor Insole as Non-invasive Tool for Collecting Gait Data and Analyzing Fall Risk

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Abstract. This paper presents the final results and future projection of the European project WIISEL (Wireless Insole for Independent and Safe Elderly Living), that reached to build the first full-wireless insole (that include both wireless communication and wireless charging). These insoles provide a new set of non-invasive tools that can be used either at the clinical installations or at home. That solution improves the usability and user experience compared with traditional tools (smart carpets, wired insoles, etc.) that are oriented to clinical installations. And hence, provide a powerful tool for Ambient Intelligent for Health, especially for elderly people, increasing their autonomy and providing means for long term monitoring.

Health parameters analysed are fall risk and gait analysis. Both are assessed on the establishment of clinical parameters such as fall risk index, and gait pattern and fall detection and algorithms. All those can be obtained thanks to our fully-wireless flexible insole that contains the sensors, embedded processing and wireless communications and charging. Pressure and inertial sensors are embedded into the insoles and a smartphone collects data utilizing Bluetooth Low Energy that is later sent to a main server analysis for its management, analysis and storage. This provides the selected information to the corresponding platform users being either end-users/patients, their relatives or caregivers and the related clinicians.

Keywords: Fall risk · Gait analysis · Wireless insole · Sensors · Bluetooth low energy · Qi wireless charging · Software tools for gait analysis · Fall risk index (FRI)

1 Introduction

Falls are a major health problem for elderly causing both immediate effects as well as long term loss of independence [1]. Non-invasive continuous monitoring allows early detection of risk of falling for individuals under analysis. This is important for the

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health providers and for the global health systems since therapy avoids accidents and therefore improves person's quality of life.

The main goal of WIISEL [2] was to develop a flexible research tool to collect and analyze gait data from real users, being either elderly or patients recovering from previous fractures or diseases that affect its mobility. The developed tool consists of a combination of a wearable insole device collecting data related with gait together with flexible software platform. Risk of falls is assessed based on multiple gait parameters and gait pattern recognition. WIISEL allows quantifying activity, assessing the quality of gait under real life conditions and enable researchers to evaluate and monitor fall risk in elderly patients, in the home and community environment, mostly reflecting everyday life behaviour.

The potential utility and impact of using the WIISEL system on the research and clinical community is the following: (i) allowing for remote and quantitative assessment of a user's fall risk, (2) measuring activity and mobility in daily living conditions, (3) as a clinical assessment tool, allowing its use as part of any research and assessment of gait parameters, (4) enabling the early identification of functional mobility decline in performance (i.e. assessment of motor fluctuations and disease progression), (5) enabling fall detection in the home setting.

2 Solutions for Motion Detection and Gait Analysis

During the last few years, an increasing number of research works aimed at developing wearable gait analysis systems have been developed and published, demonstrating the large interest to find technological solutions for ubiquitous gait analysis. Our classification of those systems (that include both indoor and outdoor systems) is related to their inner usage model that leads to different products such as: (1) HomeSafe and GoSafe from Philips (pendant) [3], (2) MoveTest and The MoveMonitor from McRoberts (belt) [4], (3) Fall Detector (Wrist Worn) From Chubb [5]. Many other products are following these 3 different strategies [6–8] to wear the fall detectors and gait analysis tools. We considered that integrating higher number of sensors, for both feet offer much more information that those alternatives.

Therefore, we started looking at plantar sensory systems, and specifically to smart insoles, according to their properties such as: embedded sensors for gait measurements, software for monitoring gait, communications technology, power consumption and related autonomy and also cost. The result obtained from the surveillance on the above fields has been structured as follows: Table 1 shows the current list of commercial systems available and its comparison with our current system. This table is indicative and is extracted from the corresponding publically accessible product web pages.

We have to mention that one has to take into account that those prices should be reviewed in detail according to each specific cost models for the insoles and the complete data management system.

Table 1. Current smart insole systems

Device name and company	Application	Sensors	P [kPa] Range	RA[1] [KPa]	IE[2]	Acq[3] [Hz]	D[4]	BA[5] [h]	Price
WIISEL	Continuous gait monitoring, analysis and fall risk assessment	piezoresistive (14) Inertial	350	0.34	Yes	33.3	BLE	16	Pending
Pedar By Novel	Footwear design and injury prevention	pressure (99)	600	2.5	No	100	BT	1	15,450€
F-Scan (insole) By Tekscan	gait analysis & biomechanics, diabetic offloading , sports medicine	pressure (960)	862		No	165	USB Wifi	0.2	16,000$
BioFoot By IBV	Sports Gait analysis Footwear design	pressure (64)	1200	0.1	No	500	Wire WiFi	1	12,995 €
paroLogg/paro Tecc by paromed	Foot pressure analysis	Pressure (32) Inertial	625		No	300	Wifi	1.5	
Foot Pressure MS By Medilogic	Gait, Sports, Health Prevention, Prosthesis and Orthotics, Diabetics	SSR sensors (240)	640		No	300	Wireless		
SmartStep™	rehabilitation process				No		Card		6,000$
SmartInsoles™ By 24eight, LLC	medical, sports and gaming	Pressure (4) Inertial	241		Yes		wireless	~100	
OpenGo science By Moticon	Medical and sports science Rehabilitation and training analysis	Pressure (13) Inertial, Temp	400	2.5	Yes	100	Wire-less		2,000 €
Footswitches Insole from B&L Engineering	Gait analysis	4 pressure sensors			No		Wire-less		299$ + 9,000$ SW

[1] Resolution & Accuracy;[2] Integrated Electronics;[3]Max Data acquisition rate, [4] Data Transfer Type, [5]Battery Autonomy

3 System Description

Our platform is composed of the following elements (depicted in Fig. 1):

- A **wearable and unobtrusive sensing insole** that continuously captures spatial–temporal data related to human gait and balance: stride time, single support time, swing time, double support time, cadence, nº steps per day, stride length, gait speed, heel acceleration slope, maximum pressure values on heel and toe.
- **Large data-base** with real-life and long-term human gait data useful for the scientific community.
- A **fall detection algorithm** to feed gait pattern recognition.
- **Intelligent algorithms**, which utilizes data analysis including pattern recognition to quantify fall risk and provide useful information on fall risk assessment. A self-learning analysis framework has been implemented as a basis for further research in optimizing fall risk prediction and identifying fall risk factors.
- A **Fall Risk Index** based on multiple gait parameter pattern to assess and quantify the risk of fall of elderly population. It is based on single support, double support, acceleration amplitude ML, heel strike force slope.
- From a components and related architecture point of view, the system consists of:
- A **pair of** electronic electrically isolated **insoles**. Electrical isolation is reached through wireless charging using the Qi standard and a Bluetooth low energy transmission to a Bluetooth 4.0 (or above) device.
- A **smartphone** that stores data locally and sends it to the main server for its management according the desired policy.
- A **server** that contains the Gait Analysis Tool and the corresponding administrative web application.
- The **user access devices**.

Fig. 1. Gate analysis system architecture

The data from the sensors are sent wirelessly to a Smartphone using Bluetooth Low Energy protocol where the data is stored over the day, before it is sent to a server, which distributes it to instances of the Gait Analysis Tool for further analysis. Researchers and clinicians will be able to analyse data via the Gait Analysis Tool with the help of embedded algorithms, which calculate compute gait behaviour and calculate the current risk of fall. An administration tool on the server allows configuring users, access rights, relationships between insole users and researchers/clinicians. The complete WIISEL system is shown in Gate Analysis System Architecture.

4 Wireless Insoles

The insoles were designed for all day, every day use. At the same time, the insoles are complex multi-layered structures that contain the different electrical and mechanical elements.

The electronics of the WIISEL system is basically composed of three main blocks: (1) the signal acquisition and conditioning system, charged of getting the data from the sensors, (2) the global control of the system including local storage and communication (with antenna), (3) the energy management related with the battery and the wireless Qi protocol.

The pressure sensor layer is made by 14 commercial sensors from Tekscan. These sensors are integrated in a Kapton printed circuit. This layer is interconnected to the electronics layers. An encapsulation material is integrating these layers into comfortable but robust materials (Fig. 2).

Fig. 2. Pressure sensor layer of the insoles

The electronic layer is built using industrial rigi-flex technology what allows the required degree of flexibility of the insole (Fig. 3). The components selected for the electronics layer are:

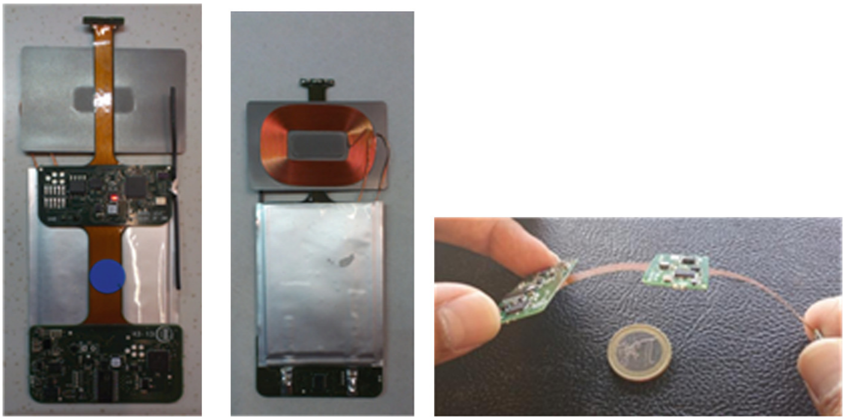

Fig. 3. Electronic layer of the wireless insoles

- Inertial sensors (Gyroscope and Accelerometer) for measuring spatial and temporal parameters (e.g. step length, step frequency).
- A MCU to control the acquisition and ADC for the pressure sensors.
- The main SoC (System-on-Chip) that includes a microprocessor and the Bluetooth Low Energy (BLE) core that relays sensors data to the smartphone.
- Semi-flexible Polymer Lithium-ion battery (1 mm thin, 3.7 V and 200 mAh).
- Embedded coil to power the battery through inductive coupling from a Qi charger.
- The Qi standard commercial Energizer external charger.
- 30 mm wire antenna 2.4 GHz Bluetooth for short range communication.
- Memory for local data storage (for the case of off-line functioning of insole when no wireless connection is available to the smartphone).

A structure with 7 different layers is required to build the complete insole including different materials used in the integration step. The finished insole is completely closed without cables or connectors. In this way, the Qi base charger (Fig. 4) uses a magnet to disconnect the insole from the smartphone system in its stand-by mode.

The smartphone serves two primary functions. First, the smartphone acts as a communications hub, whereby data from the insole sensors are sent wirelessly via Bluetooth Low Energy (BLE) to the Smartphone, which will be worn by the user. The Smartphone then uploads this data to a server via a Wi-Fi or 3G/4G connections.

Second, the Smartphone acts as a system interface for the user wearing the insole. A WIISEL application on the phone provides a number of features such as: battery power status and signal strength status, error messages if problems occur with the

Fig. 4. Example of a final insole in the charging station

insole or communications system, summary of the user's gait and activity, such as steps per day counts, distance measurements and the current fall risk (customisable), and a fall detection system interface.

The Smartphone is used to collect data wirelessly from the insoles using the Bluetooth Low Energy standard. Most of the current smartphones are compatible with Bluetooth 4.0 or above and therefore have built-in Bluetooth low-energy communication. Incoming data is processed locally at reception in order to detect falls. Alarm messages via SMS and email can be configured individually, via the administration tool on the server. In the current implementation, the Smartphone is not used to compute gait parameters. Instead, all data collected from the insoles will be stored locally on the Smartphone memory and transferred via wireless internet to a backend server once per day. Current smartphone app is shown in Fig. 5.

The maximum data transfer rate per insole is 2 kbps. Collecting data at this rate from two insoles for 24 h would require in total 330 Mbytes to be stored. This represents the extreme (unrealistic) condition. Since common smartphone have around 8 Gbytes of flash memories, we do not expect that internal memory space will limit the amount of collected data.

5 Gait Analysis Tools

WIISEL gait analysis tool consists in all-in-one software which covers the whole process of gait analysis. It offers the following functionalities: (1) raw data input in different data formats; (2) raw data filtering with flexible filter settings; (3) gait parameter definition via an editor (oriented to clinicians); (4) automatic pattern extraction; (5) customizable evaluation matrix for the computation of the Fall risk index which helps classify an individual's fall risk and (6) individual subject fact sheets.

A core building block of the system is an intelligent pattern recognition algorithm. The algorithm compares a data population of known fallers with one of known

Fig. 5. Screenshot of the current user app at the Smartphone

non-fallers. Relevant classifiers are then extracted, using self-learning algorithms, which are based on a modified Pearson Correlation method. The modification adds a non-linear component that weights elements of the recent past in a stronger way. A Fall Risk Index which aggregates multiple gait parameters (e.g., stride time, gait speed, step length, double support time, variability, non-linear metrics) and gait pattern recognition has been defined. The fall risk index provides quantitative information on possible gait trends and risk of fall.

Figure 6 shows the raw data filtering section in which the subject's data can be previewed. This section facilitates an up to milliseconds study of data values, data filtering and gait parameter extraction shows the fall-risk index definition section, in which weighted clusters of selected patterns (classifiers) can be built and be applied to the data. The result is a classification of each data set in a Fall-risk-index that ranges from zero (meaning no fall risk) to 100 (meaning high risk of falls) (Fig. 7).

Figure 8 shows an example of individual Fact Sheet. Furthermore, the system also provides an import function which allows researchers to insert and analyse their own data or third party data.

6 Validation and Results

Our system has been tested during the validation studies with elderly volunteers at three different clinician sites: TASMC in Israel, INRCA in Italy and NUI-Galway in Ireland. The objective of the validation studies was mainly to assess the feasibility, usability and functionality of the system and the ability of the potential target user to use the system and receive valuable information from it to help them address their risk of falls. Important improvements in usability and user acceptance were achieved after the system was adjusted according to the feedback from experts and users.

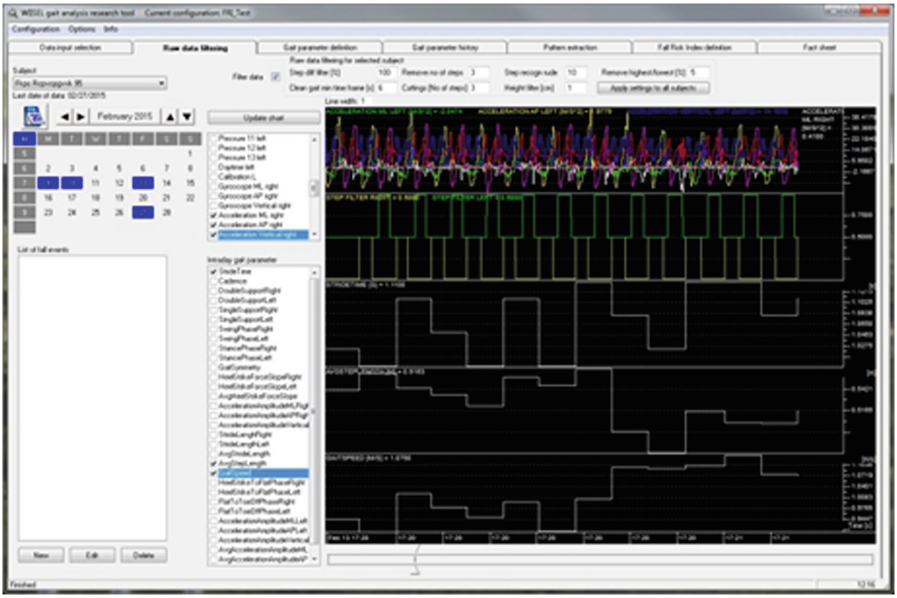

Fig. 6. Screenshot for data filtering of the gait analysis and monitoring tool.

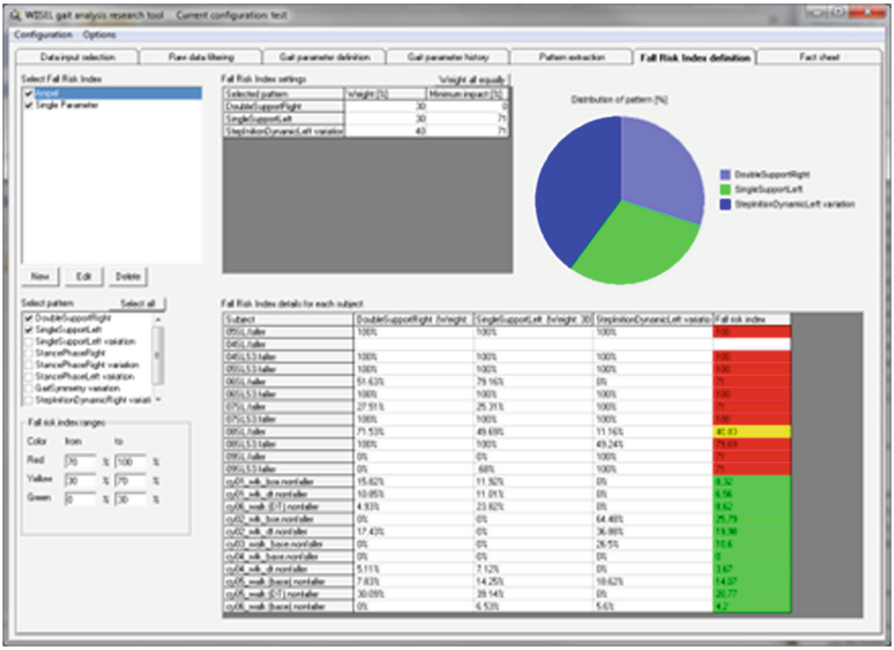

Fig. 7. Screenshot of the fall-risk index definition tool (set and selection).

Fig. 8. Screenshot of individual Fact Sheet.

More specifically the validation studies addressed the following aims to: (1) assess the comfort and durability of the insole, (2) evaluate the functionality in collecting gait data, (3) measure the ability to recognize walking patterns, activity and sedentary periods and to identify risky behaviors, (4) assess the users' feasibility to operate independently at home (donning, doffing, charging, …) and (5) evaluate the usability according to the ability of users to understand the information provided. The clinical validation studies were divided into pilot (assisted) and validation (weaker support) phases.

The pilot phase consisted of 3 days of assessment: 1 day in a laboratory followed by 2 days in the participant's home. Subjects recruited were volunteers with a history of falls and healthy age-matched older adults. A wide range of gait patterns was collected. These allowed the improvement and validation through a comparison between 'high risk patterns' and normal patterns (with minimal fall risk). Later, for about two weeks, insoles were used in patient's daily living environment. At the end, participants provided their feedback on usability and acceptance of the WIISEL system. Data was collected for gait, postural control, functional status of the subjects, fall risk assessment, device acceptance, perceived degree of safety, and social and psychological aspects. Results clearly show the success of the wireless insole system achieved after several iterations that improved both performance and usability.

Results show that the FRI predicts quite well the clinical fall risk identified by the cluster in a statistically significant way. These initial findings suggest that the fall risk level assignment based on the new FRI is valid, as it performs similarly to conventional fall risk tests.

7 Conclusion

The present results support the idea that the WIISEL system can, potentially, be useful as a tool for studying fall risk and as a clinical tool for long-term monitoring of fall risk in the home and community setting, advancing research in this area and leading to relevant savings in terms of time and money.

The wireless insoles are much easier to use than conventional wired insoles that can be almost exclusively used in the laboratory. User's acceptance of this new technology is encouraging. Many aspects of the insole and the smartphone interface were already deemed to be acceptable by most users. The implemented SW platform is flexible and can be adjusted and tailored to the group of users. The new Fall Risk Index proposed apparently captures fall risk to a degree that is achieved using conventional, widely used performance-based tests of fall risk like the Tinetti gait and balance test and the Dynamic Gait Index.

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