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Concurrent validation of an index to estimate fall risk in community dwelling seniors through a wireless sensor insole system: A pilot study

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ABSTRACT

Falls are a major health problem for older adults with immediate effects, such as fractures and head injuries, and longer term effects including fear of falling, loss of independence, and disability. The goals of the WIISEL project were to develop an unobtrusive, self-learning and wearable system aimed at assessing gait impairments and fall risk of older adults in the home setting; assessing activity and mobility in daily living conditions; identifying decline in mobility performance and detecting falls in the home setting. The WIISEL system was based on a pair of electronic insoles, able to transfer data to a commercially available smartphone, which was used to wirelessly collect data in real time from the insoles and transfer it to a backend computer server via mobile internet connection and then onwards to a gait analysis tool. Risk of falls was calculated by the system using a novel Fall Risk Index (FRI) based on multiple gait parameters and gait pattern recognition. The system was tested by twenty-nine older users and data collected by the insoles were compared with standardized functional tests with a concurrent validity approach. The results showed that the FRI captures the risk of falls with accuracy that is similar to that of conventional performance-based tests of fall risk. These preliminary findings support the idea that theWIISEL system can be a useful research tool and may have clinical utility for long-term monitoring of fall risk at home and in the community setting.

1. Introduction

Approximately 30% of community-dwelling older adults fall at least once a year [1,2]. This incidence increases sharply with age up to 50% for subjects aged 85 years or older [3]. Falls represent a major health problem for older people, causing both immediate negative consequences (e.g. fractures and head injuries), as well as longer term problems (e.g. disability, fear of falling and loss of independence) [4–8] and societal costs (estimated 0.85–1.50% of total healthcare expenditures around the world [9]).

The majority of falls have a multifactorial etiology due to a complex interaction between intrinsic (i.e. patient-related) and extrinsic (e.g. environmental) factors [10–13]. Most falls occur during walking [14,15]. Thus, an altered gait pattern is associated with fall risk. Changes associated with an increased risk of falls include slower speed, higher stride-to-stride variability in cadence and stride time, and reduced step length [16–22].

In order to identify and subsequently reduce fall risk, several systems that electronically acquire and analyse gait data to classify a user's fall risk have been evaluated. Different sensors can be used to acquire gait data during daily life, such as accelerometers, gyroscopes and pressure sensors. Accelerometers and gyroscopes (i.e., inertial measurement units) are extremely adaptable to various kinds of analyses and have been used to detect falls [23], log daily activity [24] and classify fallers [25–27]. In addition, footswitches have been utilised to measure average stride time and gait variability in order to examine their contribution to fall risk [17].

The increasing number of studies aimed at developing wearable gait

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analysis systems demonstrates the growing interest in finding technological solutions that will enable more precise measurement and better classification of fall risk [28]. In particular, wearable systems offer the opportunity to collect data outside of the laboratory and capture information about human gait during everyday activities [29–32]. In the last decade, instrumented insoles have been shown to have the ability to assess and analyse the variability in gait parameters [33]. From this perspective, the European project WIISEL (Wireless Insole for Independent and Safe Elderly Living, G.A. no: 288878) sought to develop a tool to collect and analyse gait data in real time in real-life settings and to correlate parameters related to the subjects' risk of falls [34,35].

This article aims to present an initial validation of the WIISEL Fall Risk Index (FRI). In particular, its novel characteristics will be described, including the identification of spatial and temporal measures in real-world environments over relatively long periods of time, together with intelligent algorithms that continuously learn from the incoming data in a minimally obtrusive way.

In addition, we compare the results of the index with several widely used measures of fall risk to provide initial information about concurrent validity.

2. Materials and method

2.1. Hardware components

The system is based on a pair of electronic insoles able to wirelessly transfer data to a Smartphone with a customized app [36] in real-time using the Bluetooth Low Energy (BLE), a wireless personal area network technology and transfer it to a backend computer server via mobile internet connection (WiFi or 3G). No additional sensors are placed on the user's body. The main components of the system (described in further detail in [34]) and how they concur in calculating the FRI are:

- The Integrated Insole System containing 14 thin-film resistive pressure sensors encapsulated into polyurethane material (Fig. 1), a combined 6D accelerometer and gyroscope integrated circuit and a serial data interface. Data collected were compared with the GaitRite system and results reported an accuracy of 93.9% in quantifying spatial and temporal gait measures, confirming that WIISEL can be used for gait evaluation.
- A rechargeable single-cell Lithium Polymer battery supplies power for about 20 h to each insole. It is placed in the heel area and is charged using the inductive Qi standard through a coil embedded in the insole.

2.2. Fall risk index (FRI)

At the backend server, a Gait Analysis Tool (GAT) analyses the data to produce the FRI. Before producing parameters, three filtering operations are carried out. For the first filter, non-walking situations are excluded. The remaining data is defined as being in movement, based on executing steps (this also excludes, e.g. driving in a car). In terms of sensors, a step is a sequence of events:

1. Heel contact of one foot (initialization of step recognition);
2. Toe-off-event of the other foot;
3. Heel contact of the other foot;
4. Toe off of the first foot;
5. Heel contact of the first foot (finalization of step recognition).

As a second filter, the remaining data is scanned for "clean walking situations", defined as periods over the day in which the subject continuously walks for at least 60 s over an even surface. This allows for the assessment of (relatively) steady-state walking.

The third filter excludes the data segment under consideration:

- if the altitude measured by the accelerometer of the insoles (i.e. the difference in the Z axis from the ground to the highest level reached by the foot) at the end of a step differs by more than 1 cm from the beginning (indicating, for example, that the subject is climbing stairs);
- if the stride lasts too long (more than 4 s) or is too short (less than half a second);
- if the step length is unrealistic (comparing pressure sensors data with accelerometers measurements);
- if a stride differs from the average strides of the same subjects;
- the highest and the lowest values within a step period, in order to exclude peaks.

The above filters are set in the GAT and can be modified for further analysis approaches.

For the remaining steps, the system measures the time until the walking operation ends or the filter for the altitude is triggered. At the end of the process, the first and the last 5 s are removed, because the gait values during that time would alter the measurement. The calculation is done on a daily basis and the results are typically available the day after measurement. However, if the user decides to force an upload of the data in the smartphone, results could be available 15–30 min after upload.

The system is modifiable. Currently, it supports the calculation of 26 gait parameters. Experimental tests performed during the development

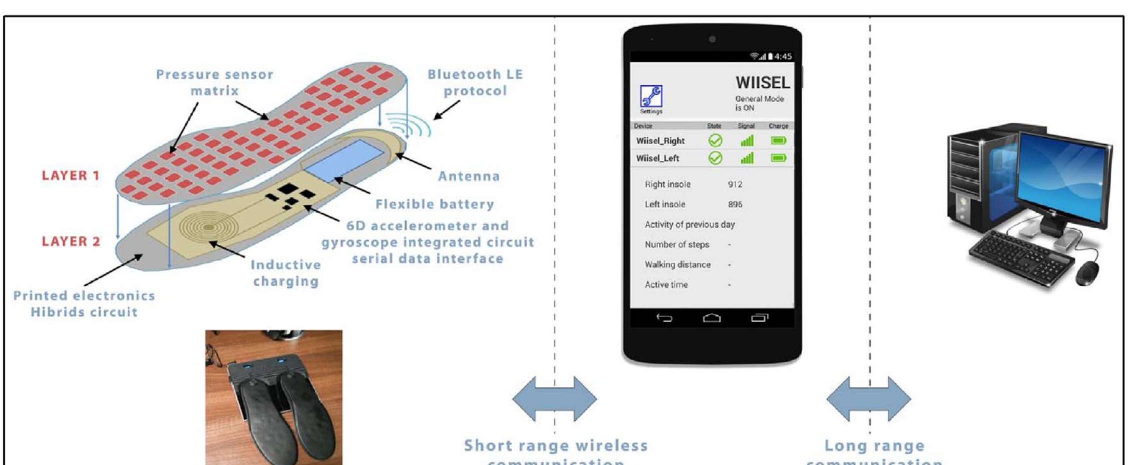

Fig. 1. WIISEL main components.