Expert Systems With Applications 95 (2018) 57–71

Contents lists available at ScienceDirect

Expert Systems With Applications

journal homepage: www.elsevier.com/locate/eswa

Design and evaluation of a smart insole: Application for continuous monitoring of frail people at home

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ARTICLE INFO

Article history:
Received 10 February 2017
Revised 19 October 2017
Accepted 10 November 2017
Available online 11 November 2017

Keywords:
Connected object
Smart insole
Monitoring system
Gait parameters
Frail people
Support active aging

ABSTRACT

The objectives of this work are to develop a technological solution designed to support active aging of frail older individuals and to conduct a first evaluation of the devices. We wish to bring a reflection in the field of connected health by setting up a remote medical follow-up. In this context, the connected object presented in this article aims at implementation a longitudinal follow-up of the walk by a health professional. Continuous remote data analysis applies behavior learning methods by modeling walking habits and allows the detection of deviations by application of thresholds defined by the expert. We propose an instrumented shoe insole to provide such monitoring (number of steps, distance covered and gait speed). In this perspective, we designed a low power microelectronic device integrated into the thickness of an insole in order to demonstrate the technical feasibility of such a device in laboratory and in living conditions. The project called "FOOT-TEST" is funded by the DIRECCTE of the Midi-Pyrenees Region in France. This project brought together a manufacturer who specializes in the design of foot-care systems, geriatricians and our laboratory specialized in electronics to propose a technical solution adapted to frail individuals. Two smart insole prototypes have been produced and a first evaluation of the smart insole in real use conditions has been performed. According to user feedback, the smart insole seems to be much easier to use than commercial connected pedometers. Moreover, in terms of performance, the smart insole provides better results. In this paper, we present specifications of the device, technological choices and the design of two versions of the smart insole, methods used to measure desired settings, a first evaluation of the system and, finally, preliminary conclusions and work in progress.

1. Introduction

The recent development in the area of Internet of Things and the launch in many countries of economical and political programs about "silver economy" enable first of all general practitioners or geriatricians to reconsider the way they monitor their patients and then patients to be actors of their health. We wish to bring a reflection in the field of connected health by setting up a remote medical follow-up that supplies further information to the health professional in order to make the decision easier. In this context, the connected object presented in this article aims at implementing a distant follow-up of the walk by a health professional and supporting active aging of frail older individuals as walking speed is more and more considered as the 6th vital sign.

An aging population has emerged as a major societal issue. Generally, activity measurement is used as an indicator of elderly health. Recent studies on the causes of disability point to frailty as a specific precursor (Van Kan et al., 2008). In France, follow-up of frail people is performed periodically during hospital visits and by phone every three months. Fried et al. criteria (Fried, Ferrucci, Darer, Williamson, & Anderson, 2004) are most commonly used by the medical community to identify frail subjects: slow gait speed, less muscle strength, exhaustion, sedentariness, and involuntary weight loss. Several studies show that walking speed is the most predictive criterion of disability (Cesari et al., 2005; Montero-Odasso et al., 2005). Frailty is potentially reversible (Pahor et al., 2006), and a number of healthy lifestyle interventions now can be proposed, such as a gait program (Daniels, Rossum, Witte, Kempen, & Heuvel, 2008; Nelson et al., 2004; Pahor et al., 2006).

The use of technology could be relevant to support active aging and evaluate frailty (Fontecha, Hervás, Bravo, & Navarro, 2013), as well as for promoting and monitoring exercise at home (Makai et al., 2014). Remote exercise interventions managed via a telecommunications system at home seem to be efficient (Van Het Reve, Silveira, Daniel, Casati, & de Bruin, 2014), and remote feedback in home-based physical activity interventions seems to be as effective as supervised exercise interventions (Sparrow, Gottlieb, Demolles, & Fielding, 2011). Monitoring could

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https://doi.org/10.1016/j.eswa.2017.11.024

potentially improve adherence and performances (Yamada, Mori, & Nishiguchi, 2012). Commercial connected objects are already proposed to young robust people to encourage them to practice sport. By contrast, in current clinical practice, no connected devices are used to measure activity and gait speed and give feedback to the patient. In fact, remote follow-up of frail elderly patients is almost nonexistent. However, to reach our goal we need to make more accurate measurements, especially concerning gait speed, and to make it less obtrusive for the end users. Given the importance of the relationship between gait speed at usual pace and risk of adverse events, and because of the amount of change for a 0.1 m/s variation (Abellan van Kan et al., 2009), we are seeking 0.1 m/s accuracy (accuracy greater than 95% for 1 m/s), which is not provided by commercial devices and mobile phones. In addition, to ensure long-term acceptability it is important to develop a discreet, transparent, and self-reliable device. Practically, this means that there should be no need for direct human intervention in data transmission and battery charging. That is far from being the case with commercial devices and mobile phones delivered today.

We believe that there is a specific need for the development of a patient-centered device that provides accurate and unobtrusive assessment of physical activity and gait speed, as well as intervention adherence through feedback and self-motivation. Our overall objective is to develop and validate a smart technological tool to support healthy aging for frail older individuals. Indeed, a connected object would complement classic follow up by:

- continuous monitoring over the medium and long term;
- involving the patient;
- displaying data to the physician for more dynamic monitoring.

The tool we propose is a connected insole. There are several reasons for this choice:

- an insole could be worn without disturbing the person;
- several studies show that inertial sensors worn on the feet allow accurate measurement of walking speed (Mariani et al., 2010; Martin Schepers, Asseldonk, Baten, & Veltink, 2010; Tien, Glaser, Bajcsy, Goodin, & Aminoff, 2010);
- walking could be exploited to charge the smart insole with a piezoelectric generator (Glynne-Jones, Tudor, Beeby, & White, 2004; Meninger, Mur-Miranda, Amirtharajah, Chandrakasan, & Lang, 2001; Roundy & Wright, 2004);
- pressure sensors under feet plants could be used to monitor weight changes automatically (Fried and al. criterion).

Some previous papers related to this work have been published by the authors of this paper (Campo, Charlon, & Brulin, 2015; Charlon & Bourenanne, 2013; Charlon, Campo, Drulin, & Piau, 2015; Piau, Charlon, Campo, Vellas, & Nourhashemi, 2015). This one presents the latest enhancements of hardware and software, overall results and feed-back from researchers and users.

The paper is organized as follows: Section 2 describes FOOT-TEST project features, Section 3 focuses on the design of the first prototype of the smart insole, Section 4 concerns the design of the second version of the insole including an energy harvesting system, Section 5 deals with the first evaluation of the global system, and Section 6 presents the conclusions and work in progress.

2. FOOT-TEST project features

2.1. Medical specifications

Typically, the gait speed of frail patients is measured at the hospital by a standard test conducted on four meters in a straight line. The smart insole must provide a daily indicator to the physician who can estimate changes in gait speed compared to that recorded with the standard test. In order to set up a daily monitoring, patients that will follow the clinical protocol will be invited to put the insoles in their usual pairs of shoes. This involves moving the smart insoles from one pair of shoes to another that could be consider as a weakness because we suppose that the person will not forget to move insoles. However, it is the same problem for all pedometers regardless of which part of the body wears it.

According to needs reported by the medical field, the insole should be able to measure, during three months of monitoring, according to time (day, week, and month):

- distance covered and the number of strides;
- periods of activity;
- average gait speed during activity periods.

In order to ensure that the gait speed measurement is relevant, accuracy must be greater than 95% during natural gait. To increase accuracy, we propose to set up a learning phase to calibrate the smart insole to the real gait of each individual.

We also plan to measure a second Fried criterion, weight change, with a pressure sensor integrated into the thickness of the insole. This optional measure aims to complete the absolute weight measurement performed with a connected weighing scale. In order for this measurement to be relevant, the system must be able to measure a variation of 1 kg in a patient's weight, to detect significant variations (several kilograms), and to warn the physician automatically. The FOOT-TEST system must inform:

- the subject of his/her activity to motivate him/her to walk;
- the physician who sets the objectives for this patient and follows his/her evolution.

The main constraints related to use of the tool use are:

- the device should be unobtrusive and need no maintenance;
- the system must be autonomous concerning measurements, communication and energy.

The time of use of the tool must be three months (usual interval between two medical consultations).

2.2. Technological barriers

The technological barriers concern:

- integration of electronics in the thickness of an insole;
- accuracy of the measurements in ambulatory;
- energy autonomy of the system over the three months of follow-up.

Two prototypes were produced:

- a first version of smart insole supplied by a lithium battery;
- a second version of smart insole supplied by a hybrid system composed of a battery and an energy harvesting system.

2.3. General architecture of the FOOT-TEST system

The general architecture of the system consists of (Fig. 1):

- a computer and a radio beacon to collect the data from the insole;
- a secure remote database;
- a web application accessible by the patient and the physician.

3. Design of the first prototype of a smart insole

3.1. State of the art and technological choice for gait monitoring

The main objective is to provide activity data to the physician and patient (distance and number of steps) and a reliable speed