

The mechatronic shoe: A new rehabilitation tool for improving mobility

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Purpose Our aim is to apply a rehabilitation device in household. The development of a rehabilitation device is based on the principle of the exoskeleton. **Method** We describe the mechatronic shoe developed as result of research in 7FP-project SMILING with application in geriatric rehabilitation medicine. The overall objective is to develop and construct an advanced prototype of a wearable non-invasive computerized miniature rehabilitation device for mechanical chaotic perturbations of gait pattern in order to counteract and prevent tendencies to fall. The main tasks were to develop perturbation algorithms fitted to suit individual user's specific needs and to implement a training system to be used in rehabilitation, health care, and fitness centers for a reorganization of the rehabilitation process in ageing. The SMILING shoe is a complex mechatronical system that requires interaction of various sensors data, mechanical components, and human activity. Two different designs were developed: STRATH and TUKE. Both left and right shoes are equipped with 4 mechanical units driven by DC-motors. Two are in the front and two are in the back side. In generally, mechanisms change the height after each or several steps, and in such way they change inclinations of the shoes sole in two planes – frontal and sagittal. The SMILING shoe is worn on a standard shoe used by user. The user has to react to changes of the shoe inclinations to stay balanced when walking while completing specific tasks. Beside the SMILING shoe, we are working on the development of a rehabilitation robot for upper limbs using pneumatic air muscles. The robot is designed on the principle of exoskeleton and is intended for the rehabilitation of the shoulder and elbow; the device has 4 degrees of freedom and uses an antagonistic pneumatic air muscles arrangement. **Results & Discussion** In the testing phase, 4 pairs of the SMILING shoes produced by the University of Strathclyde were tested in clinical trials with senior users. The objective of the trials was to determine whether a training program with SMILING shoes enhances gait performance. Seniors from Israel, Italy, Slovakia, and Switzerland participated in this cross-over randomized-controlled trial. In Slovakia we cooperated with the Highly Specialized Geriatric Institute of St. Lukas Košice.

Keywords: *rehabilitation shoe, mechatronic, automatization, robot*

INTRODUCTION

The ageing of population, numerous but also relative incensement of higher age groups of population is primarily result of progress in economic, social and medical field and it presents global problem of society with extensive impact on economic growth of the country. The EU countries within the context of ageing population over 65 (according to the EU countries the number of elderly will grow in 2025 to 21.7%¹) are struggling with decrease rhythm of economics, which impact the use of public finances, funding of the healthcare mostly.

The changes connected to the natural ageing impact basic movement structure of human, i.e. walk and other motoric tasks, which are part of the everyday tasks. One of the critical situations in the life of elderly is fall. The main cause of falls in old age is reduced ability of quick postural adaptation to the changing and hindered conditions². Every year 1/3 of seniors suffers of fall and almost 2/3 of these people suffer of fall frequently. Falls can bring light injuries without the need of long-term hospitalization (25%), but in most cases the serious injuries are ensued,

such as fracture of femur cervix (90% of these fractures are caused by fall among over 65), traumatic head injuries which can lead to the increase of the early death or permanent disability (10-15%)³. The risk of death caused due to the health complications by fall is increasing pro rate with age and the number of 16.4% in Europe is very high³. European commission have coordinated the research in connection with the ageing of population within the project „More Years, Better Lives - The Potential and Challenges of Demographic Change“ on several summits. The main idea of the project is that the member states participate to the initiative of the programming of the research in the areas such as research of the possibilities of helping the elderly to stay active as long as possible, in good health with better life quality and also to ensure to keep the healthcare systems in the future⁴. One option how to provide the better quality of life of elderly is creating of conditions and resources for prevention and social inclusion. Today's direction of the fulfilling the aims of the programmes in member states are highly influenced by the technical progress and development of the tech-

nologies. Several European researches are oriented to this area of development of ICTs in connection with providing of the social care.

At our department, we deal with development of the new complex diagnostic and rehabilitation system focusing on the people with risk of fall, with the possibility of rehabilitation in household.

PROGRAMMES ORIENTED TO THE DEVELOPMENT OF ICT FOR PEOPLE WITH RISK OF FALL

Technological innovation, omnipresent in the field of computer techniques, sensor networks, mobile devices, contribute to the incensement of independence, safety, in home environment in several daily activities though increasing the presumption of maintaining the social contact with psychical support and physical stimulation. European research in the field of ICTs deals with the projects oriented to the technologies creating intelligent environment and embedded systems using wire and wireless networks, different sensors of environment parameters or user status in terms of health but also identification of non-standard situations in daily activities its aim to increase the quality of life and social inclusion of elderly as well as people with disabilities.

Project Domeo

The focus of the project communication with healthcare centre through the digital network is support and development of assistive robotic systems, which enable learning by physical simulation to users. The support is directed to two platforms:

1. RubuMate – for verbal and nonverbal interaction with user (Fig. 1 top)
2. RubuWalker – oriented more on the physical side of the help for help with walk, sitting and rising, monitoring vital functions and data processing (Fig. 1 bottom)¹².



Fig.1. Robotic assistance systems based on platforms and RubuMate and RubuWalker¹²

Project VitaliSHOE

Project VitaliShoe (shoe with embedded sensors) (Fig. 2) is developed to monitor movement during the walk with focus on the prevention for falls and injuries. Several types of sensors are installed in the sole of the shoe to detect the obstacles and prevent the fall among elderly¹³.

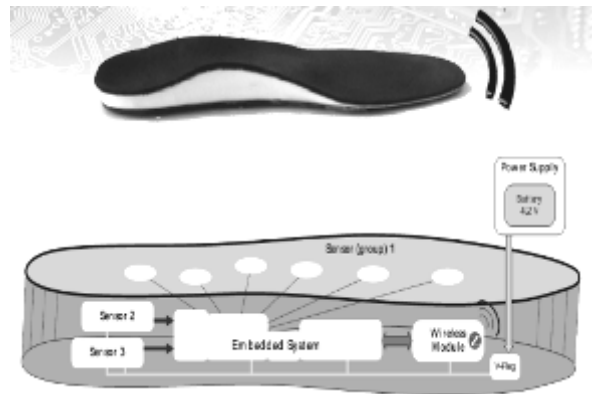


Fig.2. VitaliSHOE – location of sensors in shoe soles¹³

Project BioSensing

A sensor system was developed that quantifies simultaneously body acceleration, knee angle (Fig. 3), foot pressure (Fig. 4) and repetitive loading patterns of the knee joint during activities of daily living. Patients get feedback if they move too much, too little, or move in the wrong way. The sensor system consists of a smart knee brace that measures the knee angle (developed by TNO), a combined angular velocity and acceleration sensor (McRoberts), a foot sensor (Zephyr/TNO), a data acquisition system (IDEE), and a wireless communication system (IDEE/Neways). Data is uploaded to a webserver and presented via a web application. Demonstrators were created for the medical specialist (diagnostics), for the physiotherapist (training), and patients at home (training, monitoring)¹⁴.



Fig.3. Knee brace (left), Demonstration of the hybrid sensor: measuring knee loads (right) – BioSensing¹⁴



Fig.4. Foot sensor – BioSensing¹⁴

MATERIALS AND METHODS IN THE SMILING PROJECT

We describe the mechatronic shoe developed as result of research in 7FP-project SMILING with application in geriatric rehabilitation medicine [1-6]. The overall objective is to develop and construct an advanced prototype of a wearable non-invasive computerized miniature rehabilitation device for mechanical chaotic perturbations of gait pattern in order to counteract and prevent tendencies to fall.

The main tasks were to develop perturbation algorithms fitted to suit individual user's specific needs and to implement a training system to be used in rehabilitation, health care, and fitness centers for a reorganization of the rehabilitation process in ageing. The SMILING shoe is a complex mechatronic system that requires interaction of various sensors data, mechanical components, and human activity.

The SMILING shoe is worn on a standard shoe used by user. The user has to react to changes of the shoe inclinations to keep balance when walking while completing specific tasks. Both left and right shoes are equipped with 4 mechanical units driven by DC-motors. Two are in the front and two are in the back side. In generally, mechanisms change the height after each or several steps, and in such way they change inclinations of the shoes sole in two planes – frontal and sagittal.

Two different mechanical designs of SMILING shoes were developed: STRATH (Fig. 5) and TUKE (Fig. 6).

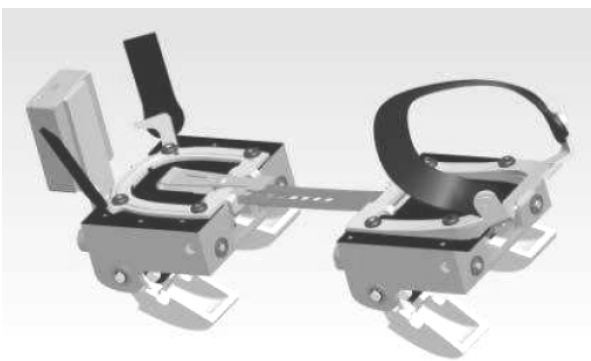


Fig.5. SMILING shoe – STRATH design



Fig.6. SMILING shoe – TUKE design

DIAGNOSTICS AND REHABILITATION SYSTEM

Development of complex system for diagnostics and rehabilitation is divided into two functional modules. Development of the diagnostic part lies in the design, testing and verification of objective qualitative and quantitative methods and means for detecting abnormalities in human walking stereotype that predicted the risk of falls. Qualitative evaluation includes clinical testing of mental and physical condition of the patient, through clinical standard - physical and cognitive functions tests. Walking stereotype was evaluated by qualitative methods. The experimental part of gait analysis was conducted at our Laboratory of Movement Analysis, which is equipped with systems allowing linear (via opto-SMART-kinematic analysis, two piezoelectric force plates Kistler - kinetic analysis) as well as nonlinear (via Gyro) analysis of the motion activities.

The rehabilitation part of our system is using motorized rehabilitation shoes developed in the SMILING project - Self Mobility Improvement in the elderly by counteracting falls Nb.215493 (2008-2010)^{5,9,10,11}. However, our current approach to rehabilitation training is modified. The essence of the training program is not focused on a series of exercises to increase muscle strength and nature of joint mobility, as most of the traditional rehabilitation programs, but the dynamic behavior of the human motor system during walking while providing regular daily life physical activities (carrying out normal activities at home).

SMILING shoe architecture

In our current experiments we use TUKE version of rehabilitation shoes. As we said shoes are a complex mechatronic system that requires interaction of sensors, data, mechanical parts and human activity. Mechatronic concept of the rehabilitation shoe is on (Fig. 9). The main components of mechatronic concept consist of mechanical unit, motor control unit MCU (Fig. 7), Swing detector with wireless communication unit named S-modules based on gyro and accelerometer (Fig. 7) and user control unit UCU (Fig. 8)⁵.

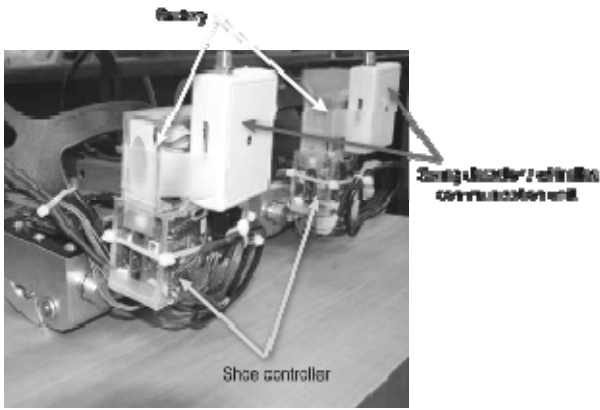


Fig.7. Motor control unit (MCU)

The MCU must store suitable set of perturbation patterns and drive motors according to these perturbations. Driving of motors by MCU must be synchronized with a human walking activity that is detected by an external accelerometer and gyroscope processing (S-Sense) unit^{9,11}.

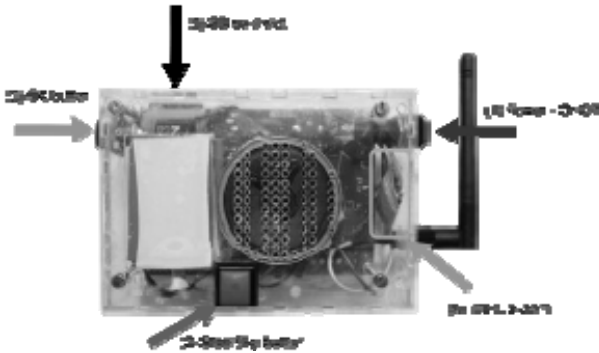


Fig.8. User control unit (UCU)

The architecture of MCU is optimized for acquisition and fast processing of relevant sensors data and control of mechanical actuators used in the SMILING shoe. Control algorithms embedded in the MCU firmware were tailored to the parameters and limitations of mechanical actuators used in the SMILING shoe. Optimization of MCU firmware for tuning of mechanical parts after assembling and durability testing of complete SMILING shoe was also done in order to support MCU by delivering signals for perturbations to shoes which are induced by motors.

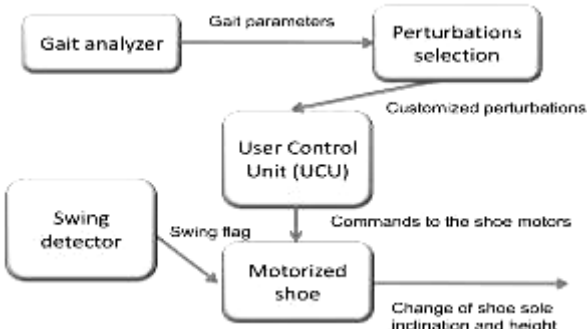


Fig.9. Mechatronic concept of the rehabilitation shoe⁹

Each shoe is equipped with four independent mechanical actuators powered by DC motors, two in front and two in the rear (Fig. 10).

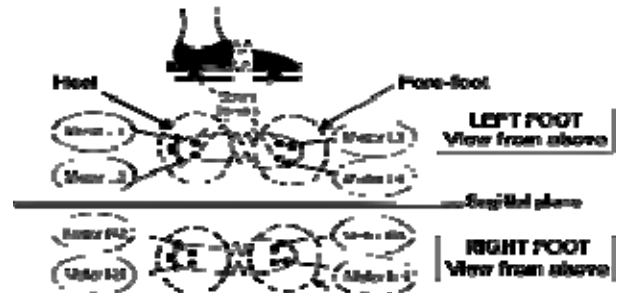


Fig.10. Position of motors in the right and left shoes

The motors are in motion only during the swing phase of gait cycle. Swing phase detection is performed in real-time algorithm running in electronics of the shoes, which processes signals from internal sensors. These sensors, electronics and wireless modules are embedded in IMEC modules for wireless data transmission and S-module to record 6-D gait parameters using gyroscopes and accelerometers¹⁰. The vertical distances of perturbations are changing by motors, to eject shoes that limb swing phase just completed and smoothly passed to a support phase. It also changes the slope of the base shoe, which is the backbone limb exposed to unpredictable environmental change. Predictions of changes of perturbations are based on a previous character of actions. Perturbations are induced by the chaotic signal generating algorithms and theory of dynamical systems. Perturbations tend to vary independently of the base shoe to $\pm 10^\circ$ in the sagittal and frontal plane and the change in height of up to 15 mm.

Training program

Training program with motorized mechatronic shoes (Fig. 11) aims to improve the function of stability while walking. Change the height and tilt base shoe simulates changes in the external environment in which a person is forced to balance the body's centre of gravity to maintain stability and to involve the sensory, effectors, and the neural system. Constant stimulation of the neural system shall disturb incorrect habits and improve elasticity and nerve responsiveness¹⁰.

It was expected that user will learn a new stereotype walk in carrying out rehabilitation activities dealing with unexpected stimulus from the external environment and to overcome the uncertainty and fear when walking.

An important task of the research was to manage control of mechatronic components of TUKE shoes.



Fig. 11. Mechatronic shoes while walking in training

Clinical validation procedure

Four pairs of SMILING shoes were built, to be used for the trials. Each system was fully checked and tested before the release to the clinical centres, to avoid as much as possible technical problem during the trials. The validation and tuning plan completed the research activities of the project. The system was used by about 100 elderly persons in Israel, Italy, Slovakia and Switzerland, to evaluate its efficacy and to define the best training programs to improve mobility and walking. A randomised controlled cross-over study was performed, including 4 weeks of training using the SMILING shoes including perturbation and 4 weeks of training with placebo dummy shoes that does not include perturbations during walking.

The task for SMILING project validation was:

- Validate the effect of training with chaotic perturbation on linear and non-linear gait parameters and on functional tests relating to walking and balance.
- Validate the safety and acceptance of the SMILING system by the target population defined with the main limitations, age ≥ 65 years, able to walk at least 20 meters independently, i.e. without personal assistance and without an assistive device, except for a single point cane, one or more falls in the previous year (falls during sport activities excluded).
- Standardized physical and cognitive functional tests Tinetti's POMA score between 22-26.

Preliminary results showed some improvement in gait performance with the SMILING training. For instance, gait speed and stride length increased, and double support tended to decrease during SMILING training. To approve statistically the efficacy of SMILING training, we need to provide more clinical tests and do cross-over analysis in the entire recruited samples.

CONCLUSION

SMILING rehabilitation shoe and program was designed in frame of the international project SMILING⁹ with cooperation of clinical departments. The verification of SMILING rehabilitation training influence on

senior's stability during walking were published in several pilot studies in terms of kinetic gait analysis¹¹, which confirmed the positive impact of rehabilitation on the system stability and dynamics of walking.

ACKNOWLEDGEMENT

The research leading to these results has received funding from the European Community's Seventh Framework Programme (FP7/2007- 2013) under grant agreement n°215493. The SMILING project was coordinated by Dr. Fiorella Marcellini, INRCA (Italian National Institute on Aging), Italy.

This work has been supported also by the Slovak Grant Agency VEGA contract Nb. 1/1162/11 Theoretical principles, methods and tools in diagnostics and rehabilitation of seniors mobility.

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