A Contribution to Motorized Rehabilitation Devices

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Abstract: One of the most critical situations in life of seniors is a fall. Paper describes an experience of authors from the development of a special rehabilitation tool for training of seniors who are in higher risk of falls. Rehabilitation shoe SMILING is output of the international project supported by the European Commission. Authors shortly describe the mechanical design of the motorised rehabilitation device controlled by a chaotic signal. Paper is focusing on some results from the experimental work during clinical testing of the prototype in Slovakia.

1 INTRODUCTION

Technological innovation, widely present in the field of computer techniques, sensor networks, mobile devices, contributes to the rehabilitation of persons with mobility impairments. Every improvement in the mobility is related to higher independence, safety, in outside and home environment during daily activities. 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 aim to increase the quality of life and social inclusion of elderly as well as people with disabilities.

There were several projects oriented on falling and its prevention. The reason is that it is very significant factor causing serious complications in life of seniors, often ending by their death (Aizen 2007, Donald 2010, CDC 2011). We mention here some of them showing variety of approaches applied to the seniors fall prevention. Project Domeo was focusing on communication with healthcare centre through an assistive robotic system, and on physical assistance for mobility functions using the RubuWalker – intended for helping with walk, sitting and rising, monitoring vital functions and data processing (Canou, 2010).

Project VitaliShoe (shoe with embedded sensors) developed a device that monitors 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 elderly.

Project BioSensing developed a sensor system that quantifies simultaneously body acceleration, knee angle, foot pressure, 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, a combined angular velocity and acceleration sensor, a foot sensor, a data acquisition system, and a wireless communication system. 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), (Vlaskamp, 2011).

Another type of rehabilitation device was developed in frame of the SMILING project. The main goal was to develop a complex training system for improvements of seniors' stability using a new mechatronic sophisticated rehabilitation shoes. Shoe is a wearable rehabilitation device adjustable for different feet sizes and different types of users from the point of view of their abilities and mobility functionalities. Such concept offers a flexible use of the shoe for the wide variety of users.

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2 SMILING MOTORISED REHABILITATION SHOES

The project SMILING main tasks were to develop adjustable perturbation algorithms to fit individual user's specific needs and to implement a training system to be used in rehabilitation, health care, and fitness centres for a reorganization of the rehabilitation process in ageing population.

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 design (Figure 1) (Carus 2010) and TUKE design (Figure 2), (Simsik, 2010).

Figure 1: STRATH design of the rehabilitation shoes.

Figure 2: TUKE design of the rehabilitation shoes.

Each rehabilitation shoe consists of a mechanical unit with 4 drives, motor control unit MCU, swing phase detector with wireless communication unit S-module based on gyro and accelerometer and user control unit UCU (Simsik, 2010).

The MCU must get and store, before each training session, a suitable set of perturbations patterns used for driving motors. It has to be modified for every person reflecting his/her functionalities and level of training. Driving of motors by MCU must be synchronized with a human walking activity that is detected by an external accelerometer and gyroscope S-Sense processing unit (Bulgheroni, 2009, Tacconi, 2010).

2.1 Chaotic Signal for Perturbations of the Shoe Position

The motors change their position 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 accelerometers (Penders 2010).

The 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 (Figure 3). Perturbations vary independently of the size of a shoe to ± 10° in the sagital and frontal plane, and the change in the sole height of up to 15 mm.

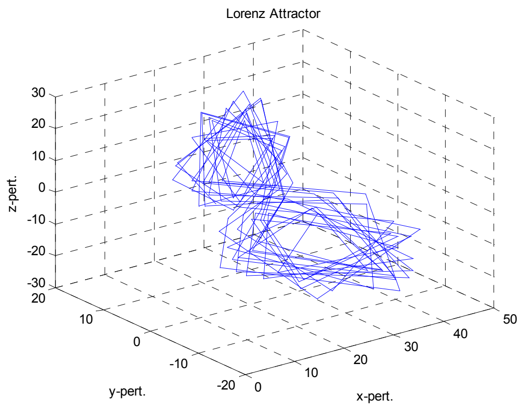

Figure 3: Generation of chaotic signal – speeded up.

2.2 Experiments with Shoes

A complex clinical testing of SMILING shoes was provided in 4 countries with STRATH design.

The verification of SMILING rehabilitation training influence on senior´s stability during walking were published in several pilot studies in terms of kinetic gait analysis, which confirmed the positive impact of rehabilitation on the system stability and dynamics of walking. (Marianni 2010, Galajdova 2011). We describe below results from standardised functional test provided during training in Slovakia.

2.2.1 Evaluation the Effectiveness of the System Operation

Physical and cognitive functional tests were provided during trainings with SMILING shoes in 4 countries (Israel, Italy, Switzerland, and Slovakia). For inclusion criteria were used:

- Tinneti Performance Oriented Mobility Assessment Tool (POMA), for risk of falls group score below 26 (strictly) and for healthy control group above 25 (strictly).
- Mini Mental State Examination (MMSE), with score ≥ 24
- Any positive answer to the "Two-Questions case-finding instrument for depression", for healthy controls group.

2.2.2 Standardized Functional Tests

Standardized functional tests were provided following the recruitment stage and the performance of the baseline tests (T0), a randomized controlled cross-over trial was performed to assess the efficacy of the SMILING system and training programme (Figure 4).

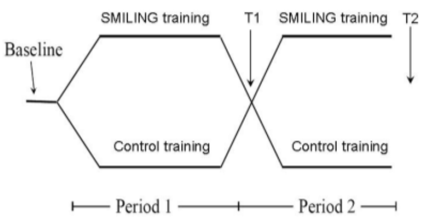

Figure 4: Smiling training programme.

During the recruitment phase, 40 elderly were screened, at the end of this phase, twenty elderly individuals were included in the study. The subjects who passed the enrolment process were 2 male and 18 female, with a mean age of 69,95±4,2 years, and a mean weight of 70,38 ± 8,3kg.

The Tinetti assessment tool (POMA) is an easily administered task-oriented test that measures an older adult's gait and balance abilities. The participant is scored on 16 tasks (9 balance tasks and 7 gait tasks) graded on a scale where the maximum score is 28. High score indicates higher levels of balance function, while 19 or less indicates high risk of fall. Across all Slovak participants at T0 the mean score was 27,25 (STD = 0,8) and 100% of them were included in the range of "low fall risk" (25-28). This test shows no significant differences between two groups after 4 weeks of training with Smiling shoe – first group of 10 people and with Dummy shoe (control group), second group of 10 people at T1 and the same results we obtained also after changing between these two groups of seniors at T2.

The 6-Minutes Walk test is a measure of functional status (executed with S-Sense to obtain gait analysis parameters) and was performed indoors, along a flat, straight, 30m corridor, with a hard surface. As regards the distance covered by the subjects, all the participants finished the task in six minutes without any stops, and the mean distance covered at T0 is 426,53 m (STD = 61,0), from a minimum of 272,5 m to a maximum of 521,6 m.

The Short Physical Performance Battery (SPPB) assesses global physical performance and in particular lower extremity function through balance and gait tasks. The scoring system goes from a value of 12 for the "best performance" to a value of 0 for the "worst performance" and across all participants the mean value is 11,00 (STD = 0,77) at baseline T0.

The Modified Narrow base walking test is an easily administered task-oriented test that measures an older adult's gait stability and balance abilities during both single and dual task conditions. Across all 20 participants at baseline T0 the mean length of stride was 0,61 m (STD = 0,06) in the single task condition and 0,58 m (STD = 0,06) in the dual task condition; the mean stride velocity was 0,867 m/s (STD = 0,12) in the single task and 0,752 m/s (STD = 0,16) in the dual task; regarding the mean step error rate we can report that it was 0,023 (STD = 0,04) in the single task, 0,017 (STD = 0,02) in the dual task. We noticed that during dual task the stride velocity decreased.

The primary outcome of the study is distance, measured during a self-paced 6 minutes walk and length and velocity of stride during narrow base walking test. The reason for this choice was the fact that age-related decline in both gait speed and gait stability are associated with increased fall risk in older adults.

In Table 1 we can see parameters before first training where participants are divided in two groups, so we can compare parameters and see consistency between these two groups.

Table 1: Results for baseline T0 in Slovakia, Baseline functional data (Mean ± STD; range) – Slovakia.

	Mean ± STD; range	
	Smiling group	Control group
Distance covered in 6MWT (m)	426,36 ± 55,7	426,69 ± 71,8
SPPB	10,9 (STD = 0,88)	11,1 (STD = 0,74)
Narrow base walking test (length of stride)	0,59 m (STD = 0,06	0,57 m (STD = 0,07
Narrow base walking test (stride velocity)	0,78 m/s (STD = 0,19)	0,72 m/s (STD = 0,14)

Table 2: Results for T1 in Slovakia, TI Functional data (Mean ± STD; range) – Slovakia.

	Mean ± STD; range	
	Smiling group	Control group
Distance covered in 6MWT (m)	426,90 ± 34,3	465,95 ± 93,09
SPPB	11,1 (STD = 0,74)	10,9 (STD = 0,74)
Narrow base walking test (length of stride)	0,59 m (STD = 0,07	0,60 m (STD = 0,07
Narrow base walking test (stride velocity)	0,799 m/s (STD = 0,18)	0,80 m/s (STD = 0,15)

Table 3: Results for T2 in Slovakia, T2 Functional data (Mean ± STD; range) – Slovakia.

	Mean ± STD; range	
	Smiling group	Control group
Distance covered in 6MWT (m)	451,9 ± 62,12	478,6 ± 45,63
SPPB	11,1 (STD = 0,74	11,2 (STD = 0,63)
Narrow base walking test (length of stride)	0,62 m (STD = 0,07	0,63 m (STD = 0,04
Narrow base walking test (stride velocity)	0,93 m/s (STD = 0,22)	0,88 m/s (STD = 0,13)

If we compare results for T0 mainly distance covered during 6mwt and results from narrow based walking test for stride velocity and for stride lenght both groups were homogenous. At T1 after four weeks of training with Smiling shoe (Smiling group) and four weeks training of control group we can see the differences: Control group achieved better result in distance covered during 6mwt, and Smiling group did not achieved better results. Also in narrow base walking tests the results achieved by control group were better. After T1 groups changed training between Smiling and control group (Smiling group performed training without Smiling shoes and control group started use Smiling shoes, we achieved results stated in Table 3. In T2 booth group achieved better result in walking distance and also in narrow base walking test (length of stride and stride velocity).

As in Slovakia were tests performed only on group of 20 seniors, the results did not show statistically significant change. If we will take into account all group from four countries (80 participants) we can see tendency still statistically non-significant in stride length (Figure 5) and double support (Figure 6) – two secondary outcome parameters and important gait characteristics for gait and balance quality.

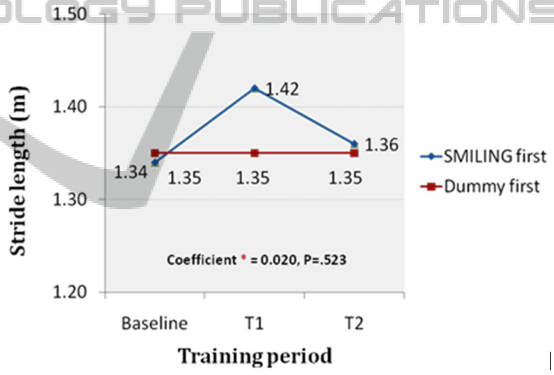

Figure 5: Stride length.

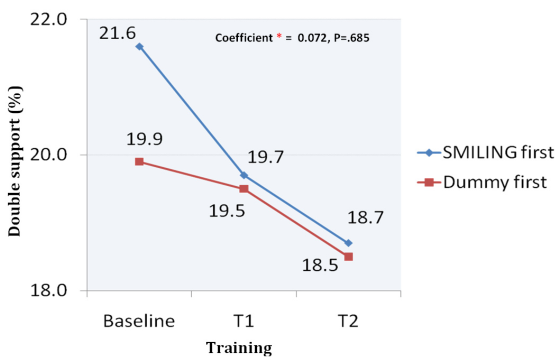

Figure 6: Double support.

Figure 7 shows the stride velocity changes throughout the trial. Clinically significant improvement in the SMILING group over the first training period diminished, when analysed by the mixed-model tests over the whole cross-over protocol, revealing the absence of statistical significance between the groups.

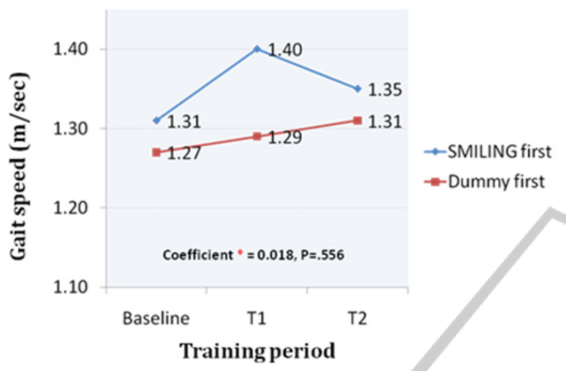

Figure 7: Stride velocity.

The assessment of functional status of subjects was performed by standardized functional tests, such as POMA, 6MWT, SPPB and Narrow Base Walking Test.

The Tinneti Performance Oriented Mobility Assessment Tool (POMA) aimed to assess the mobility problems of the subjects. Higher scores of the POMA test indicate better gait and balance. Overall, mean POMA scores changed in both training groups, but no difference achieved statistical significance. Overall POMA balance score did not increased significantly from 15,3 (at Smiling Baseline) to 15,4 (at T2) and from 15,4 (at control Baseline) to 15,6 (at T2). Overall POMA total score changed from 27,1 (at Smiling Baseline) to 27,4 (at T2) and from 27,4 (at control Baseline) to 27,6 (at T2).

The Short Physical Performance Battery (SPPB), based on standing balance, chair stand, and gait speed, is a predictor of progressive disability, hospitalization, nursing home admission and death in the elderly population.

No significant changes were seen after SMILING, nor in dummy trained subjects during the whole experiment. The initial mean SPPB score was quite high (the scale ranges from 0 to 12) and this may be a reason for the absence of response of this parameter to any training.

3 CONCLUSIONS

The rehabilitation shoes SMILING have an original design based on sophisticated wearable individually adjustable mechatronic unit controlled by a microcontroller using the chaotic signal generated by the Lorenz attractor. A complex of measurements was provided during clinical testing in 4 countries. Presented Slovak experience indicates that training with SMILING shoes gives a positive impact on improvement of users' stability in walk.

Results of experiments showed some positive effects on improving walking abilities of trained persons. However, to prove the efficiency of the new rehabilitation method will need more experiments, and their evaluation including non-linear analysis.

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REFERENCES

Aizen E., Shugaev I., Lenger R., "Risk factors and characteristics of falls during inpatient rehabilitation of elderly patients." *Archives of gerontology and geriatrics 2007*;44(1):1-12.

Bulgheroni M, D'Amico E, Bar-Heim S, Carus D, Harrison CS, Marcellini F. "The SMILING project: Prevention of falls by a mechatronic training device." *Proceedings of Telehealth and Assistive Technology 2009*, Cambridge.

Canou, J.:, "Domestic robot for elderly assistance", http://ocg.at/AAL-F09/files/s1-zagler.pdf , 2010.

Carus, D., Hamilton, R., Harrison, C.,S.: Motorised Shoe Mechanisms to Apply Chaotic Perturbations for Gait Training. 2010. *In ICABB-2010*, Venice, (Italy).

CDC – Center for Disease Control and Prevention, "Falls Among Older Adults", An Overview 2011, (online), 2011, http://www.cdc.gov/homeandrecreationalsafety/falls/adultfalls.html

Donald,I.P., Christopher J. Bulpitt, "The prognosis of falls in elderly people living at home", http://findarticles.com/p/articles/mi_m2459/is_2_28/ai_n27549408/pg_4/

Galajdova A, Dolna Z, Simsik D. "A study of the influence of mechatronic shoe design on gait parameters during stance phase." *Trendy v biomedicínskom inžinierstve; 2011*; pp 163-166.

Mariani, B., Paraschiv-Ionescu, A., Aminian, K.: An Instrumented 6 Minutes Walk Test: Assessment of 3D gait variability for outcome evaluation in elderly population. 2010. In Proceedings of the 1st *International Conference on Applied Bionics and Biomechanics,* Venice, Italy.

Mariani, B., Hoskovec, C., Rochat, C., Bula,C., and Penders,J.: 3D gait assessment in young and elderly subjects using foot-worn inertial sensors. 2010. In *Journal of Biomechanics, vol. 43, num. 15*, p. 2999 - 3006.

Penders,J., van de Molengraft, J., Fabien Masse, Benoit Mariani and Kamiar Aminian: S-sense: a wireless 6D inertial measurement platform for ambulatory gait monitoring. 2010. *In: ICABB-2010*, Venice, (Italy).

Šimšík D., Drutarovský M., Galajdová A., Galajda P., 2010. Embedded Microcontroller Unit For Gait Rehabilitation Shoes. *In: ICABB-2010*, Venice, (Italy), 2010, pp.1-8.

Tacconi C., Paci G., Rocchi L., Farella E., Benini, L., Chiari L., "User Control Unit For The Smiling System: Design And Functionalities*", In Icabb-2010*, Venice, (Italy), 2010, P. 2.

Vlaskamp, F., Cremers,G., Rianne Pas, Chris Arts, Bert Bonroy, Ruud Gransier, Sytze Kalisvaart, Vincent Kerkhofs, Peter Koomen, Rob van Lummel, Kenneth Meijer, Hans Sauren, Mariëlle Swinkels, Bart Vanrumste, Gerard Verschuren, Luc de Witte: "BioSensing: using motion sensors in real life care situations", *In: Assistive Technology Research Series – vol. 29*, AAATE-2011: p.48-56.