2017-11-22

Sensor Interface for Cardiac Rehabilitation Monitoring: Pilot Clinical Study

Lara, JS

Sensor Interface for Cardiac Rehabilitation Monitoring: Pilot Clinical Study

Juan S. Lara[a], Jonathan Casas[a], Marcela Munera[a], Emmanuel Senft[b], Bahar Irfan[b], Luisa F. Gutierrez[c], Lorena Pinzón[c], Tony Belpaeme[b], Monica Rincon[c] and Carlos Cifuentes[a]
[a]Department of Biomedical Engineering at the Colombian School of Engineering Julio Garavito, 111166, Bogotá Colombia; [b]Centre for Robotics and Neural Systems at Plymouth University, PL48AA, Plymouth UK; [c]Fundación Cardioinfantil Instituto de Cardiología, 110131, Bogotá Colombia.

Abstract
In this paper, is presented a pilot clinical study of a monitoring system designed for cardiac rehabilitation (CR). The system allows measuring three main metrics: cardiovascular, spatiotemporal gait and difficulty in physical activity parameters. In this study, the sensor interface was used with two volunteer patients from the phase II of CR. During the experiment, the monitoring system was used to report the parameters and store the information from the patients without interrupting the session. It was found that there is no difference between the data from the interface and the measurements that are normally taken by physiatrists. Additionally, the system allows the continuous measurement and visualization of the status of the patient, which might prove useful for physiatrists. This work presents an exploratory experiment for an on-line assessment method for CR sessions, which in turn, opens the possibility of implementing different biofeedback methods to improve the rehabilitation effects of CR.
Keywords: Biofeedback, Cardiac Rehabilitation, Monitoring System, Sensor Interface.

1. Introduction

Cardiovascular disease (CVD) refers to the conditions that involve narrowed or blocked blood vessels that might lead to a heart attack (Mayo Foundation for Medical Education and Research, 2017). Furthermore, according to the World Health Organization, around 17.5 million people die each year from CVDs, number that represents approximately 31% of all deaths worldwide and the leading cause of death in the world (World Health Organization, 2017). The treatment of CVDs is known as cardiac rehabilitation (CR), which can be considered as a tool to enhance the quality of life of patients who have suffered a CVD and as a prevention tool.

CR covers different areas like: nutrition and weight management, assessment and management of depression, physical exercise in relation to comorbidities, health education and medical therapy (Kraus & Keteyian, 2007). Likewise, CR is based on the health benefits that can be obtained from physical activities and exercises, among the benefits can be found: coagulability decrement, fibrinolysis increment, improvement in the endothelial function and endothelium-depend vasodilation, overall improvement of myocardial flow, reduction in exercise intolerance and improvement in cardiovascular parameters such as peak cardiac output, heart rate, heart variability, stroke volume, among others (Myers, 2003).

Considering that CR is indispensable for patients who have suffered a CVD and due to the prevalence of these health incidents, a consequence is the high demand for CR services, e.g., a study in the United States (Pack et al., 2014) shows that even with substantial expansion of all existing CR programs, there is insufficient capacity to cover the national service needs. Furthermore, not all the patients who had a CVD are actively enrolled onto CR, e.g., a study in England (Bethell, Turner, Evans, & Rose, 2001) showed that only between 14% and 23% of infarct patients actively continue with the program.

The CR program differs depending on the country of application, however, it is usually divided into three or four phases (Graham et al., 2011). For instance, in Colombia, the *Fundación Cardioinfantil Instituto de Cardiología* (FCIIC) implements a protocol that consists of three phases: **Phase I** or inpatient phase, takes place within 24 to 48 hours after a cardiovascular event, and begins when the patient is hemodynamically stable. During this phase, the patient must perform low intensity exercise and education to maintain muscular tone and to reduce risks or any complication; **Phase II** is an outpatient phase, which begins immediately after the patient leaves the hospital, and lasts around 3 months consisting of weekly sessions approximately three times per week. This phase consists of moderate intensity exercises, and an education program that covers risk factors,

healthy habits, adhesion to the treatment, motivation and monitoring of physical activities; **Phase III** is also an outpatient phase, with an average duration of nine months with one or two sessions per week. The main objective during this phase is to reinforce the habits gained during the previous phases, whereas, the main challenge is to assure the patient's adherence to the program.

CR relies on the necessity to evaluate and control the current state of the patient. This can be achieved by the assessment of three main metrics that were defined by a medical specialist in a previous work: cardiovascular, spatiotemporal gait and physical difficulty parameters (Lara et al., 2017). In the context of CR at the FCIIC, these parameters are usually measured by means of several sensors and the data management is manually registered by the clinical staff.

The level of training effects in a CR session generally depend on the use of appropriate feedback about the performance (Lunenburger et al., 2007). In addition, there is evidence that biofeedback systems in parallel with functional task training can increase patient motivation, and lead the patient towards a specific goal by incorporating challenges (Chen, He, & Xiao, 2007). Further, the appropriate feedback could benefit the physiatrists, due to the continuous monitoring and corresponding post-treatment analyses.

Considering the aforementioned, this paper presents a clinical pilot study that was performed at the FCIIC with two patients who are currently enrolled in phase II of cardiac rehabilitation. This study is based on a human-robot sensor interface that was developed in a previous work (Lara et al., 2017), thus, some necessary considerations for the use and implementation of the system in a clinical scenario are explained.

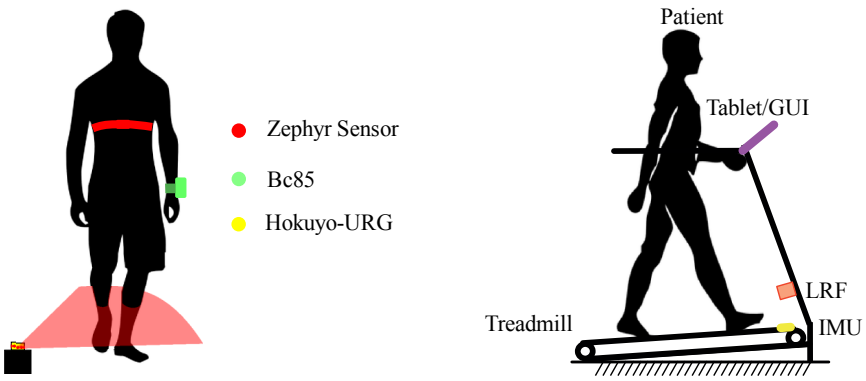
2. Methodology

Currently, the CR program at the FCIIC is based on exercising on a treadmill, while, the physiatrists periodically measure the state of the patients by means of the aforementioned parameters. The interface that was developed in a previous work (Lara et al., 2017) allows the on-line measurement of these parameters. This paper shows the clinical methodology about this system, thus, in the two following subsections, the clinical setting and the conditions of the two patients who participated in the study are explained in detail.

2.1. Clinical setting

As mentioned above, the system allows to measure three types of parameters selected by a medical specialist from the FCIIC. These parameters were selected for taking on-line measurements to assess the status of the patient during a CR session. Each measurement is recorded with the following sensors:

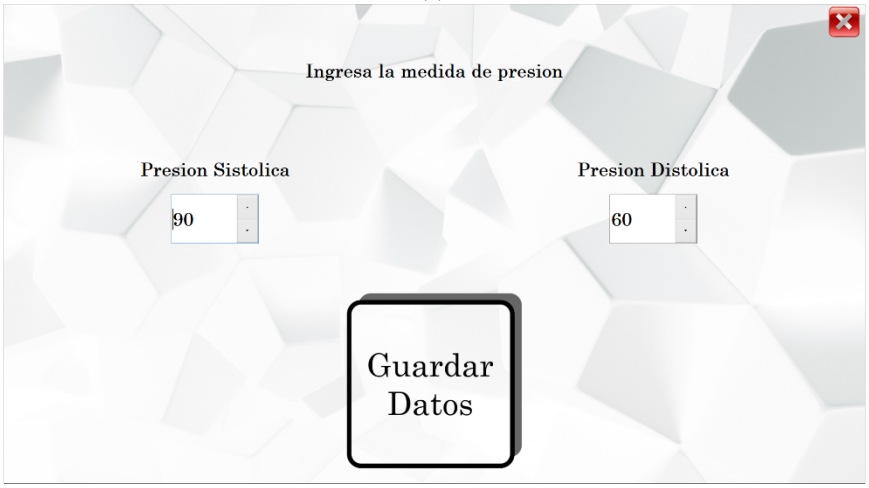
- **Spatiotemporal gait parameters**: considering that the CR program is based on exercising on treadmill, it is necessary to evaluate variables that can identify the human gait, therefore, a Hokuyo URG-04KX-UG01 (Hokuyo, Japan) Laser-Range Finder sensor is used to estimate the cadence, step length and speed of the patient on the treadmill. This sensor is placed on the treadmill in front of the patient as shown in Figure 1. Due to the constraints of the sensor, it is placed 30 centimeters above the ground.
- **Cardiovascular parameters**: two main physiological parameters are measured: on the one hand, a Zephyr (Medtronic, Ireland) heart rate monitor is placed on the chest of the patient as shown in Figure 1.a, which allows a continuous measurement of the heart rate using Bluetooth communication; on the other hand, a BC85 (Beurer, Germany) digital tensiometer is used to measure blood pressure, which is placed on the patient's forearm as shown in Figure 1.a and is only used at the beginning and at the end of the session.
- **Physical activity difficulty parameters**: two main metrics are considered to measure the physical activity difficulty: on the one hand, a MPU9150 Inertial Measurement Unit (InvenSense, United States) is placed on the treadmill such that one of its rotation angles corresponds to the main rotation axis of the treadmill as shown in Figure 1.b; on the other hand, a tactile computer monitor (i.e. a tablet) with a graphical user interface (GUI) is used to measure the patient's perceived fatigue through the Borg rating of perceived exertion scale (Centers for Disease Control and Prevention, 2017), which is placed on the treadmill as shown in Figure 1.b. The perceived exertion scale is a standardized value for cardiac rehabilitation, where there is an associated heart rate for each value in the Borg scale (Borg, 1982).



(a) (b)

Figure 1. Sensor placement in the interface: (a) the tools for measurements of the patient include a Zephyr Sensor, a BC85 tensometer and a Hokuyo - URG laser-range finder sensor that must be 30 centimeters above the ground; (b) the treadmill instrumentation includes the MPU9150 IMU, the placement of the laser-range finder and a tactile computer monitor with a graphical user interface.

(a)



(b)

Figure 2. Windows used in the graphical user interface in the two following cases: (a) when it is chosen to use the digital tensiometer, a window is shown with the instructions for use and (b) when the blood pressure is added manually, two input spaces are shown to manually register systolic and diastolic blood pressure.

One of the main changes in the interface in contrast with the previous work (Lara et al., 2017) is the addition of the measurement of the systolic and diastolic blood pressure at the beginning and at the end of the CR session. For this purpose, a digital tensiometer was implemented, this sensor allows the patient to easily perform the measurements and transfer the data through a serial interface, thus, the instructions on how to use the system were added to the GUI of the system (Figure 2.a). Nevertheless, despite the ease of use of this sensor, the physiatrists in the clinic mostly prefer to manually measure the blood pressure instead, due to reliability issues. Therefore, an option was added to the interface to manually enter the blood pressure values (Figure 2.b).

Age is one of the most important risk factors in developing CVDs. A study that used statistics from the World Health Organization and the United Nations. shows that the risk of suffering a CVD is tripled for each decade (Finegold, Asaria, & Francis, 2013), for this reason, a great percentage of patients in CR are older adults. Furthermore, a qualitative study of older adults' use of information and communications technology shows that the key issue of many elders ambivalence toward this kind of technology is the limited relevance of new technologies to their daily life (Selwyn, 2004).

Considering the aforementioned, the designed GUI must be user-friendly and understandable by the elderly people. One of the main advantages of the CR program at the FCIIC is the strong health education provided to the patients, which can be evidenced in the informational and explanatory poster concerning the Borg scale that is in the middle of the CR room as shown in Figure 3.a. Due to this reason, and due to the rigorous explanations given by the physiatrists to the patients, they are familiar with the meaning and the interpretation of the Borg rating of perceived exertion scale. Taking advantage of this fact, as shown in Figure 3.b, the GUI was designed based on the informational poster with the purpose of making the interface more intuitive and natural.

The sensor interface allows the continuous and on-line assessment of the status of the patient, which can be used to provide biofeedback to the patient during the session. For instance, as shown in Figure 3.b, the GUI contains a layout designated to display parameters like heart rate, slope of the treadmill, speed, cadence, step length and the last registered Borg scale value. This information is useful for the patient, who can assess his own state while exercising. Similarly, physiatrists would be able to monitor the status of the patient at any time during the session. Indeed, this basic biofeedback system can be very useful in CR, however, the training effects can be improved through a biofeedback method, for instance , through the use of a social robot to provide motivation and immediate feedback (Lara et al., 2017).

2.2. Pilot clinical study protocol

The pilot clinical study consists on the evaluation of the measured parameters from two patients who are in the phase II of the cardiac rehabilitation program at the FCIIC and voluntarily accepted to participate in the experiment. The first patient (female, 1.67m, 55 Kg, 73 years old) presented acute myocardial infarction and has been 36 months in the program, the second patient (male, 1.72m, 85Kg, 56 years old) with syncope diagnosis and has been 12 months in the program.

The test consists of the continuous measurement of the heart rate, the spatiotemporal gait parameters and the inclination of the treadmill. Furthermore, a medical specialist decided that the Borg scale should be asked at 3^{rd}, 10^{th} and 17^{th} minutes of the endurance conditioning phase (the maximum total duration of this phase is 20 minutes). In addition to that, the systolic and diastolic blood pressures are measured at the beginning and at the end of the session by the head nurse or therapists and is manually registered into the system. At the end of the session, the system requests from the patient through the GUI the satisfaction and motivation level through a Likert scale where 1 is to lowest level and 10 is the highest level.

(a)

(b)

Figure 3. Development of the natural graphical user interface: (a) informational poster concerning the Borg scale in the CR room at the FCIIC, (b) designed GUI that is shown to the patient during a CR session.

3. Results and discussion

On the grounds that the maximum duration of the endurance conditioning phase is 20 minutes, in the pilot study, the interface was online for 15 minutes during the session of the first patient and 13 minutes in case of the second patient. The parameters that were continuously measured are shown in Figure 4, and the discrete parameters and some statistical values are shown in Table 1-3.

Regarding the cardiovascular parameters, in Figure 4.a and Figure 4.f show the measured heart rate of each patient respectively, and Table 1 shows the summary that is provided by the sensor interface at the end of the session: the initial blood pressure at the beginning of the session and the final value at the end of the session, the range and the average value of the heart rate during the endurance conditioning phase and the standard deviation of heart rate (S_{HR}) as a metric representing the heart rate variability.

One of the main advantages of the system is that the physiatrists have the possibility to access the heart rate value at any time during the session, which represents a significant improvement in comparison with the current state of the FCIIC where the clinical staff only have the initial and final heart rate value. An initial study showed that there is no difference between the HR monitor data and the manual physiatrists' measurements. The system also provides the S_{HR} value, which can be used by the physiatrists in the post-treatment to assess patients who suffered acute myocardial infarction and recognize risk factors (Malik, 1996).

Table 1. Cardiovascular parameters, the abbreviations represent: average heart rate (M_{HR}), maximum heart rate (max_{HR}), minimum heart rate (min_{HR}), standard deviation of HR intervals (S_{HR}), initial-systolic blood pressure (I_{SBP}), initial diastolic blood pressure (I_{DBP}), final systolic blood pressure (F_{SBP}) and final diastolic blood pressure (F_{DBP}).

Patient	M_{HR} (bpm)	max_{HR} (bpm)	min_{HR} (bpm)	S_{HR} (bpm)	I_{SBP} (mmHg)	I_{DBP} (mmHg)	F_{SBP} (mmHg)	F_{DBP} (mmHg)
1	90.82	96.00	83.00	2.46	110	60	110	60
2	103.63	110.00	88.00	5.08	120	70	90	60

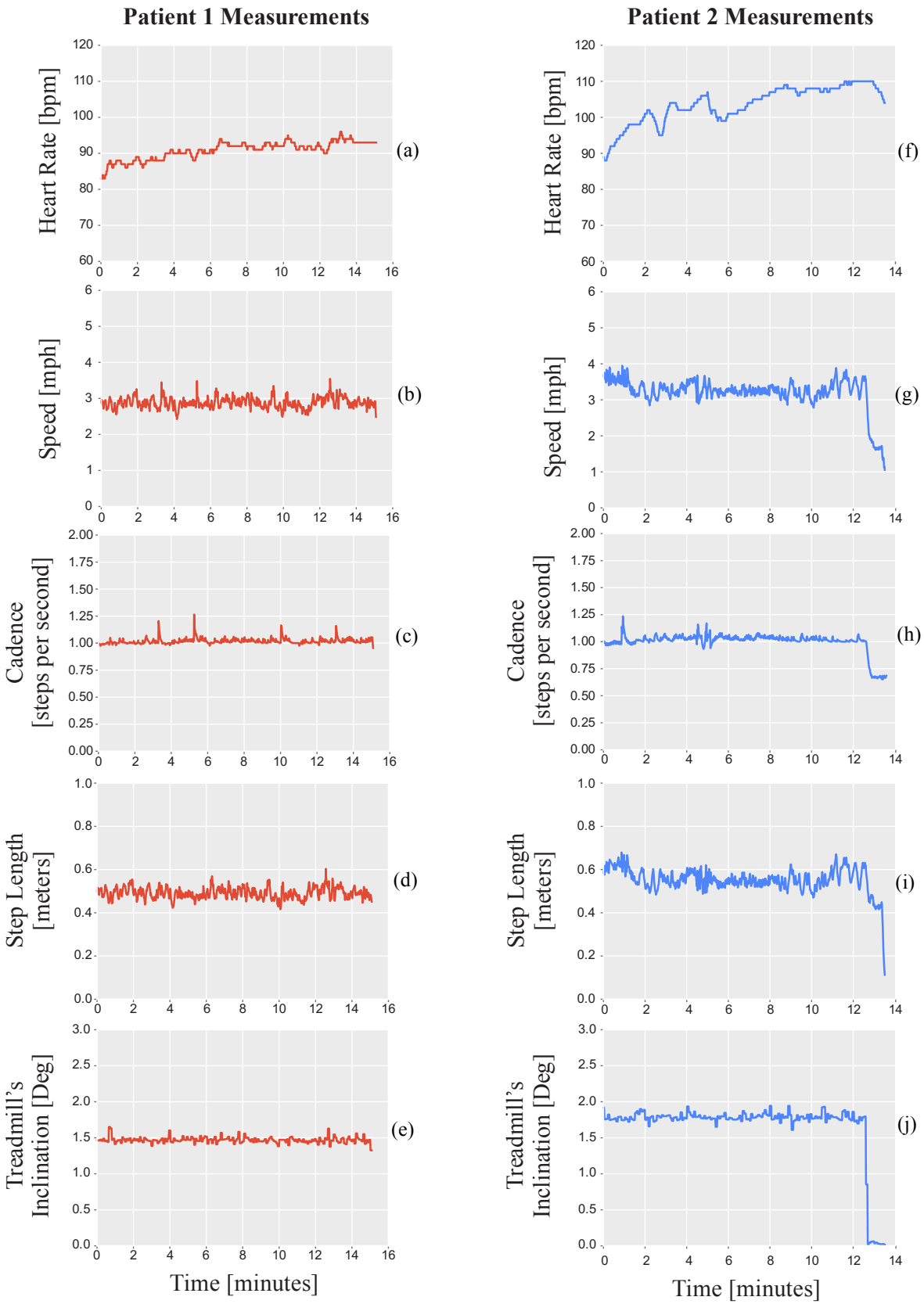


Figure 4. Continuous measured parameters using the interface: the signals from the patient 1 are shown in the first column and have a red color and the signals from the patient 2 are shown in the second column and have a blue color.

The spatiotemporal gait parameters are used to assess the biomechanical performance of the patient, similarly, information such as the speed and the inclination of treadmill can be used to evaluate the difficulty of the exercise. Therefore, Figure 4.b – 4.e and Figure 4.g – 4.j show the measured parameters, similarly, Table 2 shows the provided summary of these parameters, which could be used by physiatrists as a qualifier of the performance and the level of difficulty of the endurance conditioning phase.

During the experiment, the speed of the treadmill was set to 2.8 mph for the patient 1 and 3.2 mph for the patient 2. As can be seen in Table 2, the measured speed is close to the configured speed. However, a pilot study that was made with 6 volunteer participants shows that the speed has an estimation error less than 10% and a variation coefficient less than 10% during constant speed phases, which, according to the physiatrists from the FCIIC are acceptable values for this kind of application.

Table 2. Spatiotemporal gait parameters and treadmill's inclination: the abbreviations represent: average speed (A_{SPD}), average cadence (A_{CAD}), average step length (A_{SL}) and average inclination of the treadmill (A_{SLP}).

Patient	A_{SPD} (mph)	A_{CAD} (steps per second)	A_{SL} (meters)	A_{SLP} (Deg)
1	2.877±0.14	1.01±0.02	0.49±0.02	1.46±0.042
2	3.20±0.51	1.00±0.09	0.55±0.09	1.67±0.043

As mentioned in Section 2.2, the physiatrists recommended to request the Borg scale at 3rd, 10th and 17th minutes of the endurance conditioning phase, nevertheless, considering that the sessions of both patients didn't last more than 15 minutes, this parameter was only asked at 3 and 7 minutes. Likewise, the perceived exertion scale is a standardized value for cardiac rehabilitation, i.e., there is an associated heart rate for each value in the Borg scale (Borg, 1982). For this reason, the physiatrists from the CR program of the FCIIC, look for this parameter to be around a value of 12, this comportment can be seen in the clear convergence of the measurements from both patients that are shown in Table 3. Finally, the system registers the motivation of the patient to come back and his satisfaction with the session, this information can be approached by physiatrists who can use these values as a feedback to their work.

Table 3. Physical activity difficulty parameters: the abbreviations represent: requested Borg scale value after 3 minutes (BORG-3) and 7 minutes (BORG-7) after the beginning of the session, motivation of the patient to come back to CR (MOT) and the satisfaction of the patient with the session (SAT).

Patient	BORG-3	BORG-7	MOT	SAT
1	9	11	9	9
2	8	11	8	8

4. Conclusions and future work

This work presented a first clinical study of a sensor interface that was designed specifically for cardiac rehabilitation. The system combines measurements from different sensors such as a heart rate monitor, a digital tensiometer, a laser-range finder, a IMU with a graphical user interface that allows to automatically register the Borg rating of perceived exertion scale. Furthermore, the sensor interface continuously reports the measured parameters, providing in this way, a useful tool for the physiatrists and the patients.

One of the key concepts that arise from this work is the necessity of a user-friendly and intuitive system for a cardiac rehabilitation scenario, where a great percentage of patients consists of elderly people that are not familiar with technology. Furthermore, it is possible to design user interfaces based on the health education programs that are offered in cardiac rehabilitation. Similarly, these interfaces can process and analyze different physiological and significant parameters with the purpose of determining possible risk factors. For instance, in this work is shown a natural user interface based on a graphical user interface specially designed for this application and a sensor interface based in the most significant parameters in CR according to a specialist medical staff, nevertheless, in a future work the system will be proven with more patients and the benefits of the human-computer interaction through the developed system will be evaluated.

The training effects of cardiac rehabilitation can be improved with appropriate biofeedback, for this reason, the current research work is focused in a biofeedback method based on socially assistive robotics, which is a field of robotics, where the main goal is to provide assistance to patients through social interaction. It is based on the hypothesis that human-robot interaction could improve the engagement of the patient with the session while

motivating him. However, this kind of system opens the possibility of implementing different types of biofeedback methods that can take advantage of the information collected in the interface such that it can improve the training effects in cardiac rehabilitation.

5. References

Bethell, J., Turner, S., Evans, J., & Rose, L. (2001). Cardiac rehabilitation in the United Kingdom. How complete is the provision?

Borg, G. (1982). Psychophysical bases of perceived exertion. *Medicine and Science in Sports and Exercise*.

Centers for Disease Control and Prevention. (2017). Perceived Exertion (Borg Rating of Perceived Exertion Scale). Retrieved from https://www.cdc.gov/physicalactivity/basics/measuring/exertion.htm

Chen, X., He, J., & Xiao, Z. (2007). Networking Telemedicine in Portable Rehabilitation Robot Monitor System. *Applied Information Technology*.

Finegold, J. A., Asaria, P., & Francis, D. P. (2013). Mortality from ischaemic heart disease by country, region, and age: Statistics from World Health Organisation and United Nations. *International Journal of Cardiology*, *168*(2), 934–945. https://doi.org/10.1016/j.ijcard.2012.10.046

Graham, I. M., Fallon, N., Ingram, S., Leong, T., Gormley, J., O'Doherty, V., … Benson, S. E. (2011). Rehabilitation of the Patient with Coronary Heart Disease. *Hurst's The Heart, 13e*, 1–33. Retrieved from http://mhmedical.com/content.aspx?aid=7823315

Kraus, W., & Keteyian, S. (2007). *Cardiac Rehabilitation*. Totowa, N. J: Humana Press.

Lara, J. S., Casas, J., Aguirre, A., Munera, M., Rincon-Roncancio, M., Irfan, B., … Cifuentes, C. A. (2017). Human-robot sensor interface for cardiac rehabilitation. In *2017 International Conference on Rehabilitation Robotics (ICORR)* (pp. 1013–1018). https://doi.org/10.1109/ICORR.2017.8009382

Lunenburger, L., Colombo, G., Riener, R., Lünenburger, L., Colombo, G., & Riener, R. (2007). Biofeedback for robotic gait rehabilitation. *Journal of NeuroEngineering and Rehabilitation*, *4*(1), 1. https://doi.org/10.1186/1743-0003-4-1

Malik, M. (1996). Guidelines Heart rate variability. *European Heart Journal*, 354–381.

Mayo Foundation for Medical Education and Research. (2017). Heart Disease. Retrieved from http://www.mayoclinic.org/diseases-conditions/heart-disease/home/ovc-20341555

Myers, J. (2003). Exercise and cardiovascular health. *Circulation*, *107*(1), e2–e5. https://doi.org/10.1161/01.CIR.0000048890.59383.8D

Pack, Q. R., Squires, R. W., Lopez-Jimenez, F., Lichtman, S. W., Rodriguez-Escudero, J. P., Zysek, V. N., & Thomas, R. J. (2014). The current and potential capacity for cardiac rehabilitation utilization in the United States. *Journal of Cardiopulmonary Rehabilitation and Prevention*, *34*(5), 318–26. https://doi.org/10.1097/HCR.0000000000000076

Selwyn, N. (2004). The information aged: A qualitative study of older adults' use of information and communications technology. *Journal of Aging Studies*, *18*(4), 369–384. https://doi.org/10.1016/j.jaging.2004.06.008

World Health Organization. (2017). Cardiovascular Diseases. Retrieved from http://www.who.int/mediacentre/factsheets/fs317/en/