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Electrode structures for acquisition and neural stimulation controlling the cardiovascular system

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Abstract — **In this study we present an innovative electrode system, for many different applications in the field of cardiovascular diseases. It is a combination of intelligent communicating dry-surface electrodes, which are able to interact with different sensors especially with an invasive, ultra flexible electrode-system.**

Dry and smart surface electrodes, which can be integrated in textiles and therefore such electrode are almost "invisible" for patients, are used for ECG acquisition and can be integrated in a communication network. In combination with a pulse oximeter or impedance spectroscopy the pulse transit time (PTT) can be calculated. Additionally, with invasive electrodes the nervous vagus can be stimulated and therefore cardiovascular functions can be controlled. The association of an implanted stimulator with an interacting and smart monitoring system results into a cardiovascular controlling.

In this work we will focus on the feasibility, suitability, fabrication and characterization of invasive and dry-surface electrode systems as a basic element and foundation for cardiovascular regulation in a closed loop.

I. Introduction

Electrodes play a pivotal role in many different neurologically and cardiovascular applications. Electrodes are used as an interface between technical devices and the biological tissue. Electrodes translate the ionic current of a biological response of the peripheral or central neural system as well as muscles into a current of electrons. So they are used for the acquisition of bioelectric signals like ECG, EMG, ENG, and EEG.

Basically one can divide electrodes into two groups: surface- and invasive electrodes. Surface electrodes are mainly used for clinical applications. The interfaces of the biological systems with the electrodes are in size of some centimeters and closely attached to the skin. Besides detecting neural signals such electrodes are sometimes used to stimulate nervous tissues or muscles. On the one hand one of the advantages of such an electrode is the easy handling due to the non invasive application. On the other hand electrodes, commonly used in the field of cardiovascular diseases, have also some disadvantages, such as the contact gel, the attachment to the skin, which causes skin irritation in many cases. Furthermore, the number of large electronic acquisition and stimulation devices reduces the mobility of the patients drastically. Such electrodes should be flexible and directly attached to the skin, in order to eliminate such disadvantages [1]. Such electrodes could also be easily textile integrated due to the fabrication process, which would also be an advantage in the daily use [2].

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Additionally, surface electrodes are not suitable for a selective detection or for spatial pattern analysis of neural signals. To increase the selectivity invasive electrodes should be used. With implantable electrodes, which are directly attached in or to the nerve, more precise addressability is achieved due to the integration in the body. Such implants achieve a very high selectivity and are almost able to address a single neuron [17], [18]. Unfortunately such a surgical intervention has a high risk to damage the neural tissue. In general, a higher selectivity of the signal increases the damage to the neural tissue [3]. In order to decrease such risk factors invasive electrodes are always specifically tailored for each application [4]–[7].

Therefore we will show in this work the suitability of how these two electrode systems, when combined, can control the cardiovascular systems by non-invasive means and wireless acquisition, and invasive neural stimulation with a high neural selection.

II. Establishing of Dry-Suface and Invasive Electrode System

A. Characterization of smart, textile integrated and intelligent dry-surface electrodes

Providing a high temporal resolution in recording cardiovascular parameters is a great enhancement in classifying the health state of a patient. For this purpose we developed a wearable, non invasive sensor system, enabling a continuous long-term measurement of important cardiovascular parameters (e.g. ECG, HRV, PTT). The technical monitoring system provides an easy-to-use application, invisibility for the surrounding, and a good wearing comfort that is essential to achieve a good patient

Figure 1: Dry electrode in the style of an commercial Ag/AgCl electrode with, left: one single electrode; sensor side, right: connector side with a standard ECG press stud.

acceptance and thus a good compliance.

The system is equipped with flexible silicone electrodes providing a dry signal acquisition (see Fig.1). No skin preparation and no use of any additional substances to improve the connectivity are needed. The signal quality of the electrodes is stable for a long period and comparable to Ag/AgCl disposable electrodes (see Fig.2).

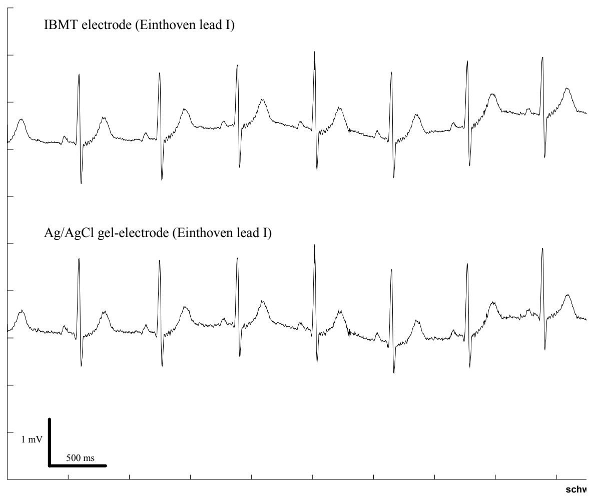

Figure 2: Dry electrodes (shown in figure 1, top) versus commercial Ag/AgCl electrodes (bottom) in Einthoven's lead I [12]. The data was taken from volunteers during exercise.

The electrode material is based on a medically approved polysiloxane framework (Pt catalyzed) loaded with conductive nano-particles to realize the electron conductive component. To improve the electrode-to-skin impedance, a general-purpose electrolyte part was added to provide the ion-conductivity. A complete evaluation was carried out for the electrodes according to ISO 10993 showing the biocompatibility of the electrodes for the use on skin. The electrodes can be produced in arbitrary geometries and sizes and therefore be adapted to any recording application.

B. Communication network of smart, textile integrated and intelligent dry-surface electrodes

Such dry-surface electrode can be integrated in a communication network on the basis of the Seed-Demonstrator [8], [9], which is based on the microcontroller MSP430F2013 from Texas Instrument and the radio chip MG2455 from RadioPulse. The system is conceived in a modular way: The available preamplifier units for different vital parameters are contactable through a micro-plug. Recorded analogous signals are processed in the microcontroller after the analogue-digital converting and afterwards it will be transferred by the radio chip.

The sampling rate of the ECG was set to250 Hz with an oversampling of 64. The controller dsicretized the recorded signal through an analogue/digital converter with a resolution of 16 bits and summarizes 25 values to a package. This package will completely transmit to the radio chip which sends all packages time-synchronised to the base station. The radio transmission was realized by the ZigBee standard in the 2.4GHz-band. The prototype of the electrode was realized as multilayer (4 layers) printed circuit board which consists of flexible laminate (Polyimid) (see figure 3).

The triangular design of the Seed-demonstrator is based on the electrode arrangement including the earth electrode which can be unequipped according to the used preamplifier. The preamplifier records the single channel ECG based on an instrument amplifier AD627 from Analog Devices and contains a drive-right-leg circuit for the common mode rejection and also a band rejection filter for the 50 Hz noise voltage.

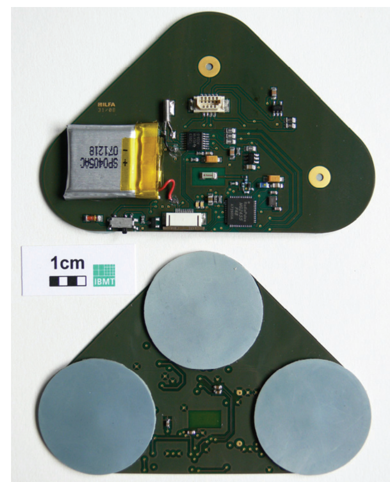

Figure 3: Prototype of the Seed-Demonstrator; smart communicating ECG electrode system. The setup allows implementing signal pre-processing, such as filters and amplifiers or other.

For the energy supply a Li-ion battery (180 mAh) from Varta is used, which guarantees an operation time of more than 3 hours. Through an integrated FFC plug connector (Flexible Flat Cable) an additional device which allows the battery charging and the programming of the IC's can be connected. Within the electrode interconnection the recorded signals of the single electrodes will transfer to a central data logger (PDA). By sending synchronizations signals a time synchronous measurement on the electrodes will be allowed. The communication between the electrodes enables the localization and the identification of each electrode within the interconnection. Thereby it is possible that single electrodes can independently combine with the electrode interconnection [10].

C. Pulse transit time recording

This wearable textile-integrated monitoring device optimizes the treatment of cardiovascular diseases by long term recording of important parameters like ECG, Heart Rate Variability (HRV), and in combination with an IR-Plethysmography sensor the Pulse Transition Time (PTT). PTT is the time interval for a pulse pressure wave to travel from the aortic valve to the periphery. It is a simple and non-invasive measurement for pulse wave propagation in arteries. (Normally it is measured as the time interval from the R-wave of electrocardiogram (ECG) to the maximum slope of the photoplethysmographic (PPG) signal in the same heart cycle). PTT is influenced by multi-factors, such as cardiac output, the arterial compliance, venous return and other cardiovascular variables and therefore represents the

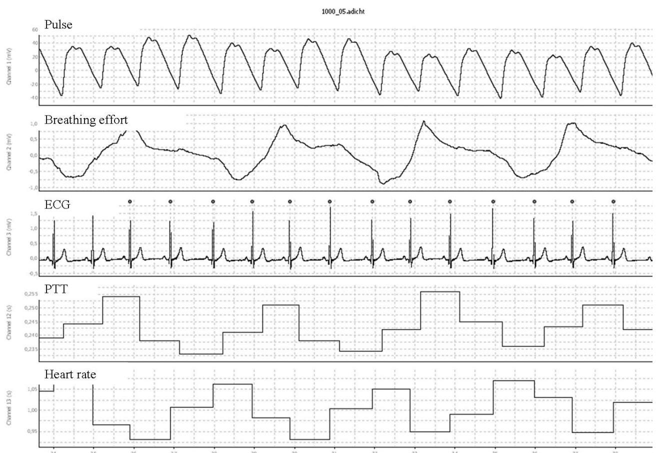

Figure 4: Relationship between Pulse (finger), PPT (online beat-to-beat mode), breathing afford, ECG and heart rate measured be the presented dry-surface electrodes plotted versus the time in seconds.

dynamic regulation of the autonomic cardio-vascular system.

Figure 4 shows the strong relationship between the PTT, the Heart Rate and Respiration. Additionally blood pressure variation can be derived from PTT. This opens the possibility to monitor continuously the blood pressure without the disadvantage of commercial available devices.

D. Assembly of invasive electrodes system for neural stimulation and recording application

The electrical stimulation using electrodes can evoke responses in neural tissue [3]. This is done by exciting the neurons reaching a specific current threshold and therefore

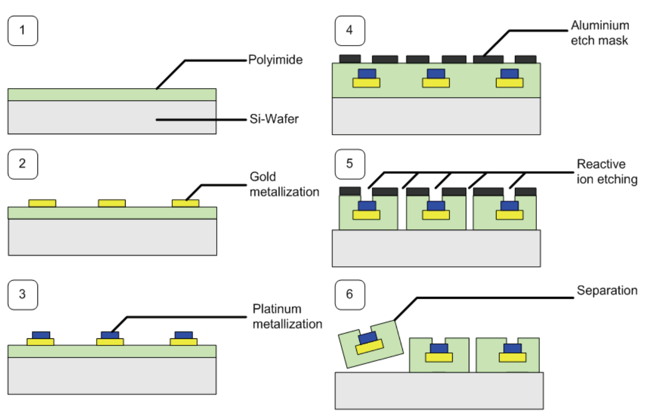

Figure 4: Schematic view of the fabrication process of invasive electrode system on the basis of polyimide.

reaching the activation potential [11]. Evoking such potential also depends on other parameters, such as the alignment of the electrodes and the characteristic of the applied signal. Usually a biphasic current is used, where the cathodic part is exciting and the anodic part of the signal is preventing the damage of the neural tissue [12]. All such stimulation method requires especially tailored electrodes, as the electrodes are implanted at different places in the body. But not only in this case is a unique design pivotal, also in case of acquisition, the electrodes have to be adjusted to the application [2]. The fabrication process is shown as a scheme in figure 4 and details can be found in [7].

E. Characterization of invasive neural stimulation electrodes.

Electrical characteristics: Ultra flexible microelectrodes, which can be used for stimulation purposes have to be electrochemically characterized. The state of the art is the characterization by means of impedance spectroscopy. In figure 5 such a spectrum is presented for a three polar cuff electrode. On the upper graph the impedance is plotted, while in the lower graph the phase is plotted versus the frequency. Each electrode contact on the invasive electrode system is characterized. Figure 5 clearly show the filter characteristics, which can be expected by such electrode contacts. Such a spectrum can be fitted by means of

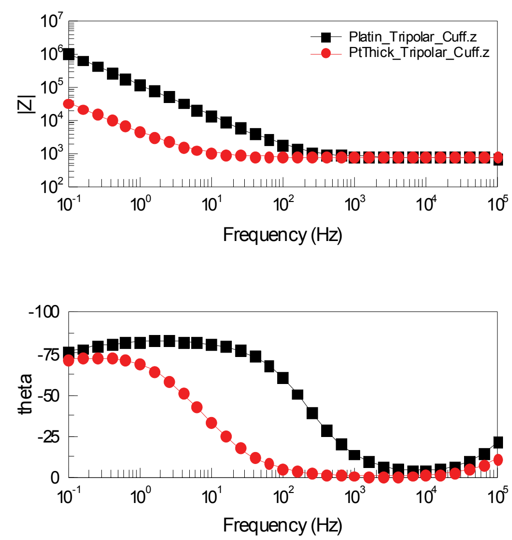

Figure 5: Impedance spectroscopy of a cuff-tripolar electrode. The squared markers correspond to a tripolar cuff electrode, which is sputtered with platinum, while the rounded are taken from an electrode with platinum black surface. Both electrodes have the same size.

equivalent circuit; a Helmholz layer, acting as a capacitor and a Faraday-resistor in parallel with the electrolyte resistor in order to characterize such electrodes (see for details [14]). Furthermore each electrode contact has a similar trend, which proves the high reproducible rate of the process. The lower the impedance of an electrode, the better functionality is received. This results into a better signal to noise ration and in better energy efficiency of the systems and fits well with the in literature given values [11], [14], [19].

Biocompatibility: Such implantable electrodes have a direct contact to the nervous system inside a living body. So these systems are exposed to different body fluids and tissues. These fluids and tissues react as kind of aggressive media against the materials in contact. Therefore it is important to use materials with the ability to resist this harsh environment over its intended application time. These materials should not degrade or transform inside the body in any possible toxic way nor should the body fluids and tissue harm the electrode. This is called biocompatibility, which is crucial for the use of materials and systems for medical applications in the human body.

The evaluation of the biocompatibility of a material and its needed investigations is regulated in the EN ISO 10993-1 for both: surface and implantable electrodes. This standard and its continuative standards describe the biological tests which should be done to characterize the biological toxicity of a material related to its application time and field. Polyimide was proofed in vitro by means of OLN 93 cells according ISO 10993-5 and ISO 10993-12.

Outcome of those entire tests and characterization proved the suitability for the invasive stimulation at the peripheral nerve systems of implantable electrode system based on polyimide.

III. Conclusion and Outlook

We have presented two electrode systems, which on their own are innovative in their field and could serve as a basic setup for future cardiovascular treatment methods.

The dry electrode systems resolve the problem of skin irritation and long term application. They also provide a smart setup, which can be wireless or connected to bodily PDA station. Furthermore, the dry-surface electrodes allow measuring other cardiovascular or pulmonary parameters by the impedance spectroscopy (for example respiration, movement pattern, blood flow or heart rate). Including other information such as weight or blood pressure, taken by additional in this system integrated sensors, would make the setup up of non- and invasive electrode systems unique.

The implantable electrodes are well established in applications concerning the peripheral nerve system and can be easily transferred to the central nerve system by changing the design [13]-[15]. The diversity in design makes such electrode based on polyimide suitable for any nervous stimulation as well as the neural acquisition [16].

Future projects will have to take advantage of both systems and combine them. Within this it will be possible to arrange monitor systems with neural stimulation systems in a way that cardiovascular parameters can be easily recorded for a long time period without any disadvantages for the person and in case of cardiovascular diseases a neural stimulation can interact active and intelligent with the central nerve systems (in example: *nervus vagus*) with respect to the monitored information. For example blood pressure and other cardiovascular parameters could be monitored and treated at the same time. Such a monitor system of textile integrated electrodes in combination with a vagal stimulation could be the state of the art in a few years, when treating cardiovascular diseases.

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