

Flexible dry surface-electrodes for ECG long-term monitoring

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Abstract—In this paper a new generation of dry electrodes for ECG-recording purposes is presented. These electrodes are flexible, biocompatible, biostable and perform a dry signal acquisition without the use of any electrolyte gel or adhesive. Thereby no skin preparation is needed. The material properties allow integration into textiles to form intelligent clothes for long-term monitoring duties. The electrodes can be washed together with the carrier textiles and provide a very good wearing comfort resulting in wide acceptance by the patients. The Department Medical Engineering and Neuroprosthetics of the Fraunhofer Institute for Biomedical Engineering developed these electrodes mainly to process the Electrocardiogram, however, in first tests they proved their capability even for other biosignal requirements like surface-EMG. In either case the signal quality of the dry electrodes is comparable to commercial Ag/AgCl gel-electrodes.

I. INTRODUCTION

THE increasing of healthcare-related costs, caused by demographic alteration and the growing expenses of modern high-quality healthcare will dramatically change the social security system. The relocation from hospital centered health system to the homecare domain within the scope of prevention, post-operative treatment, disease management, rehabilitation, and wellness will be one fruitful possibility and chance. Here, Telemedicine and especially Telemonitoring are the essential disciplines. This fast-growing business requires new innovative ideas to successfully position new reliable products in this hotly contested market [7].

Reaching high acceptance by the patients plays a decisive role in this process. The systems must be comfortable for the wearer, without delimitating daily routines, and for aesthetic reasons they should not be visible for the environment. Long-term monitoring devices should provide high patient autonomy. For elderly people, for example, it is not feasible to care about electrode positioning, replacement or even contact quality. Therefore electrodes for a long-term monitoring should provide:

- Unchanged signal quality for a long period,
- An easy-to-use application. Ideally the sensors should be integrated into textiles to determine the right connection and position,
- A high wearing comfort without mechanical or biochemical stress for dermal tissue.

Commercial electrodes for clinical use like Ag/AgCl electrodes need an electrolyte gel or paste between sensor and tissue to establish a reliable skin-to-electrode connection. These substances dry up with the time causing a drastic decrease of the signal quality. In addition these gel substances and the adhesives to fix the electrodes on the body can provoke dermal irritation and even allergies.

As a more adequate recording method different approaches on dry signal acquisition have been pursued [6] to offer a more reliable technique for long-term monitoring aspects. By stitching conductive yarns consisting of metal-coated filaments into garments, highly flexible electrodes can be formed providing a very good wearing comfort [1, 5]. However signal quality and biocompatibility of these sensors are questionable. Rubber electrodes consisting of conductive polymers represent another option of dry electrodes [4]. They are also flexible but more susceptible for motion artifacts inducing lower signal quality. Finally capacitive electrodes provide good signal quality but show an increased baseline drifting, are inflexible and therefore uncomfortable for a long-term monitoring, and need extra voltage supply [3].

II. MATERIALS & METHODS

It is obvious that no type of known electrodes completely satisfies the requirements of a long-term monitoring system. To tackle this problem a new kind of surface electrode were developed at the Fraunhofer Institute for Biomedical Engineering (IBMT) to record the ECG for a long period (Figure 1 a).

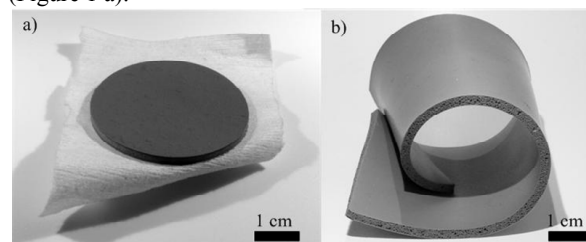


Fig 1. IBMT flexible ECG electrode: (a) textile integration; (b) Demonstration of the electrode's flexibility.

The main aim was to reach high-quality and reliable recording of biosignals, as well as sufficient wearing

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comfort for the patients, long-term stability, biocompatibility, and to provide an easy-to-use application. Figure 1 b demonstrates the material's high flexibility.

A. Long-term characterization

At the beginning of the developing process the adequacy of different materials for a long-term application was evaluated. In part well-known and commercially used materials as well as self-designed innovative materials were investigated. To assess the electrochemical long-term stability, a new measurement device was developed providing a fully automated impedance measurement of up to 128 electrodes simultaneously for at least one week [2]. 16 different materials divided into the 5 following groups were investigated:

- Polarizable metals
- Non-polarizable metals
- Polymer-coated metals
- Conductive polymers
- Nanoparticles in polysiloxane

B. Electrode material and manufacturing

On the basis of the results of the longtime characterization and the mechanical and electrochemical properties, a self-developed material was chosen to build up the IBMT surface electrodes. This 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.

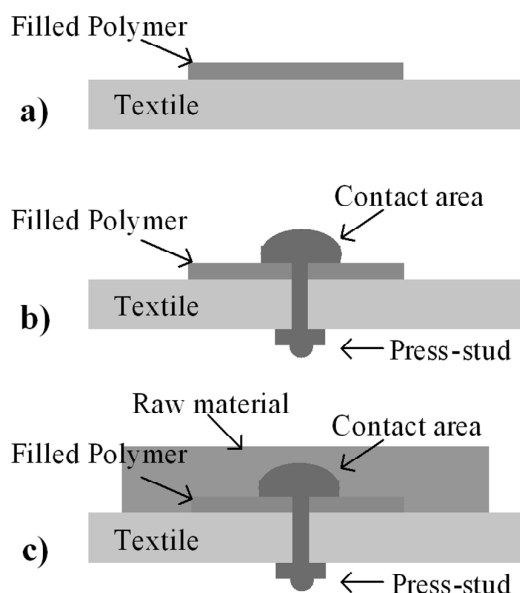


Fig. 2. Schematic view of the IBMT electrode's manufacturing process.

Figure 2 shows the schematic view of the IBMT polysiloxane electrode. Optionally, to improve the connectivity between the electrode material and the connector a conductive filled polymer paste can be used to

increase the contact area (Figure 2 a).

The standard version of the electrode uses an ECG press-stud to have a good compatibility to commercial monitoring systems (Figure 2 b).

Alternative designs provide common wire connection. In the next step (Figure 2 c) the highly viscous raw material is integrated into garments by screen printing process technology. The electrodes are producible in arbitrary geometries and dimension to customize them for different measurement tasks. Finally a complex tempering profile is needed to achieve maximum flexibility and mechanical capacity during the electrode processing.

C. Evaluation

Different test routines were performed to assess the IBMT electrode's capability for long-term monitoring application:

1. *Biocompatibility* (ISO 10993): Bioservice Scientific Laboratories GmbH, Planegg. Methods:
 - Tests for in-vivo irritation
 - Tests for in-vitro cytotoxicity
 - Test for skin Sensitization
2. *Irritation Test*: Additionally to the biocompatibility tests the electrodes were applied on 7 healthy probands (male, age 20-29) for 8 days with an interruption of only 30 minutes daily to investigate potential dermal irritation.
3. *Electrode characterization* by measuring skin-to-electrode impedance compared to disposable Ag/AgCl gel-electrodes (Co-med, Golmed GmbH). The measurement voltage of 50 mV is provided with a frequency range of 0.1 Hz – 100 kHz by a frequency response analyzer (1255, Solartron instruments). The skin-to-electrode impedance of the electrodes was measured in two-electrode configuration with an electrochemical interface (1287, Solartron analytical). Electrode distance: 9cm. Application area: forearm.
4. *Dry Signal Acquisition and Signal quality*: Measurement equipment:
 - Topas, Schwarzer GmbH, Sampling frequency 400Hz, Filter low: 0.1Hz, Filter high: 200Hz, Notch filter
 - BT12, Corscience GmbH, No Filter
 - In part the signal quality was compared to disposable Ag/AgCl gel-electrodes (Co-med, Golmed GmbH)
5. *Textile integration* was evaluated for the following carrier tissues:
 - Flexible Thorax-Belt (Velcro® Strap, Pro-Tech® Services)
 - Functional Sports wear (Falke®, Ergonomic Sport system)

III. RESULTS

A. Biocompatibility

According to the terms of ISO 10993 the biocompatibility of the electrode material was evaluated by an external accredited laboratory within 3 required tests. The investigation of *in-vivo* irritation proved that the electrode material showed no irritant/corrosive effects and thus was classified into the lowest response category. Regarding the determination of cytotoxicity it was stated that no leachable substances were released in cytotoxic concentrations from the test items. The third test showed no reactions identified as sensitization for each concentration tested.

Overall these three examinations yield the biocompatibility of the electrode material for an exposure time of more than 30 days on unharmed skin.

The additional test with 7 probands over 8 days continuously wearing the electrodes also showed absolutely no indication for any dermal irritation.

B. "Dry" signal acquisition

The signal quality of commercial gel electrodes becomes insufficient within hours corresponding to the drying process of the electrolyte gel between skin and sensor. The skin-to-electrode coupling of the polysiloxane electrode works dry, i.e. without skin preparation and the use of any additional substances to improve the connectivity. For that reason the signal quality of the electrodes is stable for a long period. The omitting of electrolyte gel furthermore prevents from dermal irritation often provoked by these substances and used adhesives.

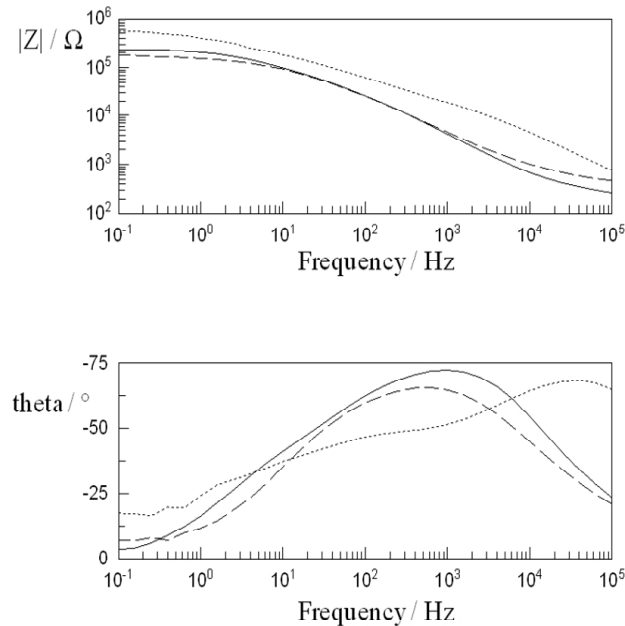


Fig. 3. Skin-to-electrode impedance (top: magnitude, bottom: phase): Dry electrodes, directly after application on skin (···), and after 10 minutes (---), in comparison to Ag/AgCl electrode (—).

Figure 3 shows the skin-to-electrode impedance (Magnitude and phase) directly, and 10 minutes after the application in contrast to disposable Ag/AgCl gel-electrodes for the frequency range from 0.1Hz-100kHz (x-coordinate). In both cases the polysiloxane electrode shows sufficient impedance values for the reliable use with modern ECG devices. After 10 minutes, caused by the appearance of a minimal amount of sweat, the magnitude and the phase curves are nearly equal to those of Ag/AgCl.

C. Signal quality

The IBMT electrodes were successfully tested with different clinical devices. Figure 4 represents an ECG recording (Topas, Einthoven bipolar lead I) under ergometric conditions simultaneously with the dry electrodes (top) and standard Ag/AgCl electrodes (bottom). Here as well as in many other experiments it was shown that the signal quality, the signal-to-noise-ratio and the formation of the QRS-complexes are totally comparable for both electrode types.

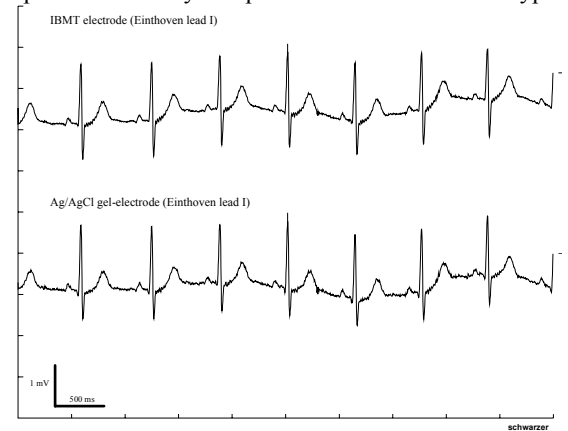


Fig. 4. Simultaneously recorded ECG under ergometric conditions. Top: IBMT dry electrode. Bottom: Commercial Ag/AgCl electrodes (bottom) in Einthoven's lead I configuration.

As another demonstration of the good signal quality Figure 6 shows ECG-signals (deactivated filters) of limb and chest lead recorded with 10 IBMT electrodes with the wireless ECG-monitor BT12 from Corscience.

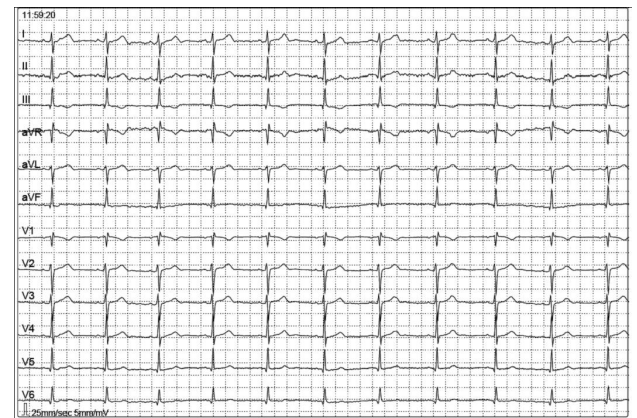


Fig. 5. 12-channel ECG recording using polysiloxane electrodes: Einthoven (I-III), Goldberger (aVR, aVL, aVF), chest lead (V1-V6).

D. Textile integration

For long-term monitoring systems an “easy-to-use” application of the sensors is essential. Even for handicapped or elderly people those systems must provide a good usability so that the patients can apply them autonomously. For that reason IBMT electrodes can be integrated during the manufacturing process in nearly every garment. The patients apply their sensors easily by wearing intelligent clothes. The only limitation is to provide an adequate contact pressure for example by using a stretchy sport shirt. The following figures illustrate different approaches of textile integration: Realization of an ECG belt with standard press-stud connectors (Figure 6), functional sport shirt with four integrated electrodes and connectors to provide a 3-channel ECG (Figure 7).

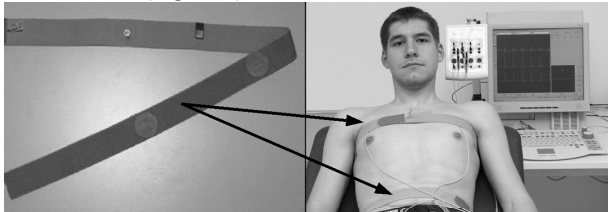


Fig. 6. Flexible ECG belt with 3 integrated electrodes.

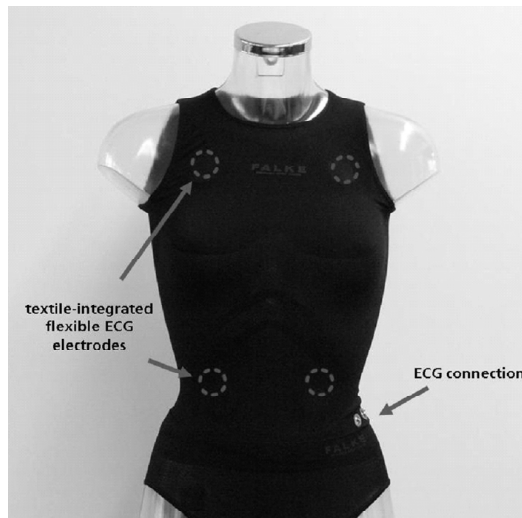


Fig. 7. Functional sport shirt with 4 electrodes and stud connectors.

The electrodes are machine washable which is essential for a permanent application in a long-term monitoring system. The electrodes were tested in two cleaning methods:

- 10 times standard washing programme (60°C)
- 20 times cleaning with Ethanol (70%)

The mechanical and electrochemical properties of the investigated electrodes were absolutely unchanged after the tests.

IV. CONCLUSION & DISCUSSION

The IBMT electrodes have proved their capability for long-term applications within many experiments and trial tests. They can form a very flexible unit with almost every

garment providing a maximum wearing comfort. The electrodes are machine washable (up to 60°C) and they can be disinfected without changing their characteristics. The electrode-skin connection works dry, i.e. without the use of any additional electrolyte gel. The signal quality of the electrodes is comparable with standard disposable Ag/AgCl gel electrodes. A complete evaluation was carried out for the polysiloxane electrodes according to EN 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 every measurement task.

Figure 8 shows the integration in Polyurethane foam, normally used as padding material in limb-prostheses. This combination can be used for the acquisition of surface-EMG signals to control the prosthesis. This is one example of many other possible applications for the IBMT dry electrode besides the Electrocardiography.



Fig. 8. Electrode integration into Polyurethane foam.

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