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DEVELOPMENT OF UNDERWEAR WITH INTEGRATED 12 CHANNEL ECG FOR MEN AND WOMEN

Stephanie Trummer[1], Andrea Ehrmann[2], Alexander Büsgen[1]

[1]Niederrhein University of Applied Sciences, Faculty of Textile and Clothing Technology, Mönchengladbach, Germany
[2]Bielefeld University of Applied Sciences, Faculty of Engineering and Mathematics, Bielefeld, Germany
Corresponding author: andrea.ehrmann@fh-bielefeld.de

Abstract:

Cardiovascular diseases are the most frequent cause of death worldwide. Cases of cardiac arrest can often be attributed to undetected cardiac arrhythmia. Detecting rare episodes of arrhythmia necessitates long-term ECG measurements along days or weeks. However, due to the relatively small number of electrodes used for these ECGs, abnormal episodes can still go unrecognized. This article thus describes the development of underwear with ten inbuilt textile ECG electrodes, allowing for the measurement of long-term 12-lead ECG. As against the constructs of other research groups, the position of electrodes offers the same detection directions as the common 12-lead ECG equipment in hospitals or medical practices. Long-term tests have shown the suitability of the sensory underwear variants for men and women to detect reliable ECG signals without disturbing the patients' comfort.

Keywords:

Sensory shirt, 12-lead ECG, textile electrodes, pattern construction, conductive paths

1. Introduction

In Germany, more than 40 % of cases of death result from cardiac diseases [1], often following long times of undetected arrhythmia [2]. Event recorders or long-term ECG measurements can be used for the examination of possible rare arrhythmia episodes; however, it is well known that due to the high amount of both false-positive and false-negative findings, long-term ECG can only provide additional information and not replace the more informative 12-lead ECG [3-6]. Since the 12-lead ECG measures the heart currents in different directions, using the so-called 6 precordial leads V1, V2, V3, V4, V5 and V6, according to Wilson, together with the 3 limb leads I, II, III (according to Einthoven) and the 3 augmented limb leads aVR, aVL, aVF (according to Goldberger), it allows a comprehensive observation of all electrical processes in the heart [7].

On the other hand, 12-lead ECGs used in sleep laboratories affect the patients' sleep due to the large amount of leads and possible skin irritations by the glued ECG electrodes. The common 12-channel ECG equipment necessitates fixing the electrodes on the skin and increasing the skin contact, which is usually done by gluing the electrodes and using silver-silver chloride electrodes. Both materials, the glue as well as the electrode gel, can cause skin irritations or even severe allergic reactions.

A 12-lead ECG, which can be used for days or even weeks, would thus be supportive for patients and doctors. In order to avoid skin irritations and restrictions due to the leads, underwear containing textile ECG electrodes and textile connections from the electrodes to the data evaluation system is an obvious approach. Nevertheless, there are several challenges to be dealt with, which are described here.

Conductive yarns can be integrated into non-elastic textiles by, for example, weaving or embroidering [8, 9]. Since conductive yarns are normally not or only slightly elastic [10, 11], their integration in elastic textiles, such as underwear, necessitates other techniques. In a former project, we have tested different undulating sewing patterns [12] which could also be used for the recent development. For the data lines, a stainless steel filament yarn was used that was not damaged by 50 washing cycles or by mechanical impact during wearing of the developed 12-lead ECG underwear.

The textile electrodes, consisting of a conductive knitted fabric coated with a conductive liquid silicone rubber, have also proven to be reliable in a former project [13].

The main challenge thus is guaranteeing a sufficient pressure of the ECG electrodes on the skin to ensure an adequate electric contact between skin and electrode surface. Former projects conducted by us and other groups have shown that unintentional displacements of the electrodes with respect to the position on the skin lead to significant signal disturbances but are hard to avoid [12, 14]. Even when a breast belt is used, only the positions on the sides of the body offer a reliable skin contact – a problem which does not occur in projects that use non-textile glued electrodes [15-20].

A 12-lead ECG, however, necessitates 10 ECG electrodes, 6 of which are positioned on defined locations on the chest on both sides of the sternum (breastbone), while the other 4 are located symmetrically on both arms and legs [21]. Thus, a new approach for fixing the textile electrodes on the skin – without using glue to avoid skin irritations – is necessary for the development of a textile-based 12-lead ECG system.

A few projects of other research groups dealt with a similar approach. A 12-lead ECG fabric electrode belt system was

invented by Montplaisir [22] which is based on belts, the leads in them connected with USB connectors. Simple belts, however, are far less comfortable than complete textile underwear and do not allow situating the ECG electrodes at the correct positions. The USB connectors especially may cause skin irritations. Additionally, the leg leads are positioned differently than in the usual definition, making comparisons with common 12-lead ECG results difficult. A long-term test of reliability and wearing comfort is not reported.

The EKGear shirt by NanoSonic Inc. is also reported to be able to measure a complete 12-lead ECG, although it does not include trousers where the leg electrodes could be fixed [23]. Additionally, the electrodes used here are not textile but consist of conductive rubber [24] making them less comfortable to wear than textile electrodes.

In other projects, such as TexVital by ITV Denkendorf [25], ECG systems with less than 10 electrodes are included, allowing for only a limited number of ECG leads to be measured. In our project, the first completely textile 12-lead ECG system was developed.

2. Experimental

The following requirements had to be taken into account during pattern making of the underwear included with 12-lead ECG: A compromise between good skin contact of the textile electrodes and wearing comfort must be found. To avoid made-to-measure clothing, the electrode positions should be individually modifiable. Textile materials must be breathable to avoid sweating. Despite the necessity to have a connected underwear system including arms and legs, daily situations like work, sleep, sports or also a visit to the toilet should not be uncomfortable or connected with unnecessary effort to open and close connections between shirt and trousers. It should be possible to wear the ECG underwear under normal garments without attracting attention; thus, the female version needs either integration of a bra or the possibility to wear one's own bra under the ECG underwear. Finally, the complete ECG underwear must be washable at 60 °C.

These requirements lead to the following choices: To enable inconspicuous appearance, exterior layers in light colors have been chosen, consisting of 95 % cotton and 5 % elastane or 92 % cotton and 8 % elastane, both knitted fabrics with high breathability. These materials were chosen for different regions of the underwear, depending on the necessary elongation properties at respective positions. Additionally, a pure cotton woven fabric was chosen for areas with low stretchability.

A common elastic strap with width 4 cm was used to support the pressure of the electrodes on the skin. In order to allow for fitting the electrode positions to the wearer's body, hook-and-loop fasteners of width 4 cm were integrated. In the first prototypes described here, the data lines were connected to the ECG measurement equipment using pressure buttons; in future project stages, this mechanical connection can be exchanged by wireless data transfer.

Since the first tests with shirts using tunnels to integrate elastic straps led to the problem of unintentional shape distortions, we decided to start with a base consisting of elastic straps, which can afterwards be expanded to a shirt. Fig. 1 shows a first approach of creating such a base of elastic straps and inelastic bands, with the press buttons depicting the positions V1 (upper left), V2 (upper right), V3-V5 (lower left to lower right) and V6 not visible here. The first three positions are slightly shifted in comparison with the original positions according to Wilson, as usual for female patients.

While the measurements between electrodes V4, V5 and V6 already showed satisfying results, the electrodes V1, V2 and V3 do not have enough skin contact in this construction. Additionally, the vertical middle part is too short and drawn up, which should be avoided. Thus, in the next approach as shown in Fig. 2, the vertical middle part is more flexible and less broad. In this version, electrodes V1, V2 and V3 also have reliable skin contact and allow the measuring of stable ECGs. To ensure a sufficient pressure of the electrodes V1 and V2 on the skin, these points were additionally padded in the final prototype.

While the arm electrodes can be integrated in the wristbands of short arms of the final shirt, adding the leg electrodes is a heavier challenge. If complete trousers were added to the ECG underwear, they had to be unconnected and connected for each undressing and dressing, respectively. This would lead to undesired effort of the patient. Thus, another solution had to be found that allows for adding leg electrodes to the ECG underwear. Here, we decided not to use complete trousers with legs but only straps which are connected to the shirt. These straps are closed by hook-and-loop fasteners, allowing for setting the desired elongation and to be opened easily during a visit to the toilet.

Figure 1. First approach of elastic strap base for 12-lead ECG – female version with electrodes V1, V2 and V3 slightly shifted according to breast form

Figure 2. Second approach of elastic strap base for 12-lead ECG – female version, with elastic and slimmer vertical middle part, compared to Fig. 1

Figs. 3 and 4 show the resultant prototypes for men and women. The textile ECG electrodes are included at the above described positions and connected with snap buttons along the right body side, using stainless steel filament yarns (Fig 5). It should be mentioned that these yarns must not get in contact with neighboring yarns to avoid measurement errors.

In long-term wearing comfort tests, the prototypes were found to be comfortable to wear, without any limitations which would necessitate changes of the pattern making.

3. Results and discussion

To test the reliability of 12-lead ECG measurements using these prototypes, ECG measurements were performed on female and male probands, using common ECG equipment as well as the newly developed prototypes. Fig. 6 shows, as an example, the results of ECG measurements for a female proband, using a MAC1600 Elektrokardiograph by GE (left panel), connected to the common glued electrodes, and a VariaCardio TF5 system, connected to the prototype underwear (right panel). Apart from the lower resolution of the latter, both results are comparable.

The latter uses a slightly changed scale that makes the signal amplitudes look smaller. Tests with a data acquisition card using a LabView program showed that signals taken with textile electrodes and textile connection lines are maximally 5-10 % smaller than those measured with the medical system MAC1600 Elektrokardiograph, although the textile conductive materials can be expected to have a significantly higher resistance than the commercial equipment. This underlines that with textile electrodes and signal transfer lines, the measured signals can reach the same quality as the common ECG systems.

The results of the other six leads as well as measurements with the prototype for men verify that the new 12-lead ECG underwear allows for measuring reliable ECG signals.

Figure 3. Prototype of the 12-lead ECG underwear for men; front (left) and back (right)

Figure 4. Prototype of the 12-lead ECG underwear for women; front (left) and back (right)

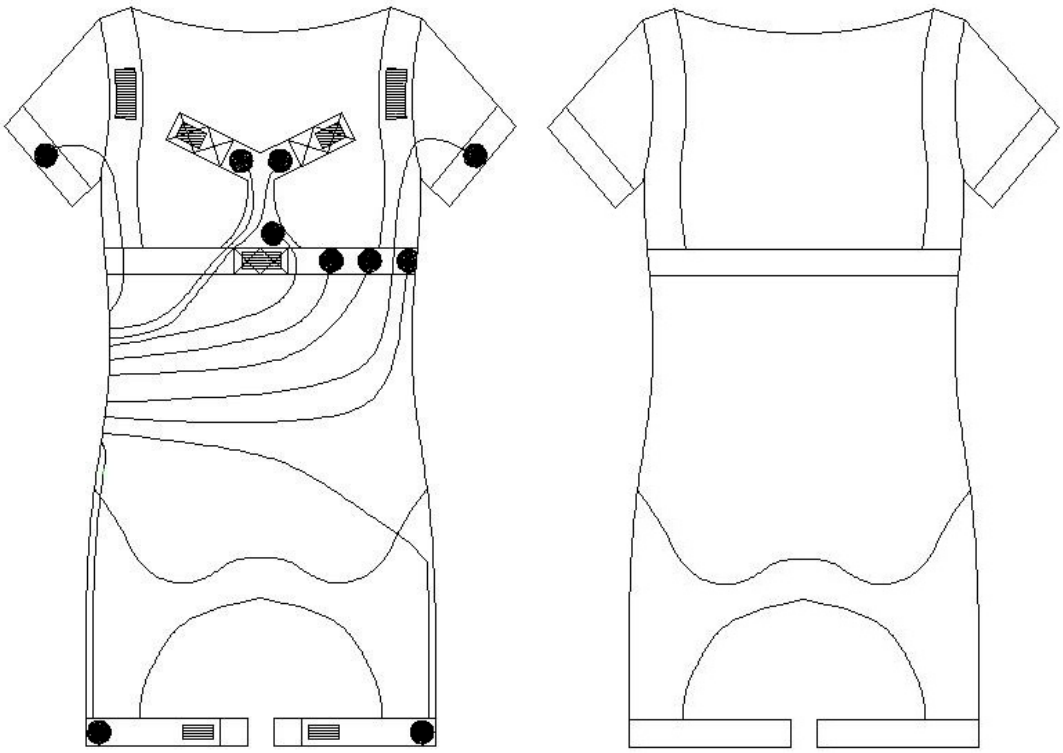

Figure 5. Engineering drawing of the 12-lead ECG underwear for women, showing textile ECG electrodes (black circles), conductive connection lines (black lines) and hook-and-loop fasteners enabling fitting the underwear to the patient's body shape (striped rectangles)

Figure 6. Results of 12-lead ECGs, measured with glued electrodes (left panel) and textile electrodes in the prototype underwear for women (right panel)

To examine the possible limitations of the electrodes due to skin irritations or disturbance of the wearing comfort, 20 probands wore breast belts with the electrodes being pressed onto their skins so that reliable ECG measurements could be taken. Two of the probands showed severe problems with common silver-silver chloride ECG electrodes, that is, strong skin irritations after a short test of 10 minutes and for one proband, even oozing wounds after 24 hours. All probands tested the electrodes for at least one week, without showing any sign of skin irritation. Two male probands felt slightly irritated by the pressure of the belt around their breast initially, which changed after the first testing day. Afterwards, none of the probands felt any discomfort while wearing the belt.

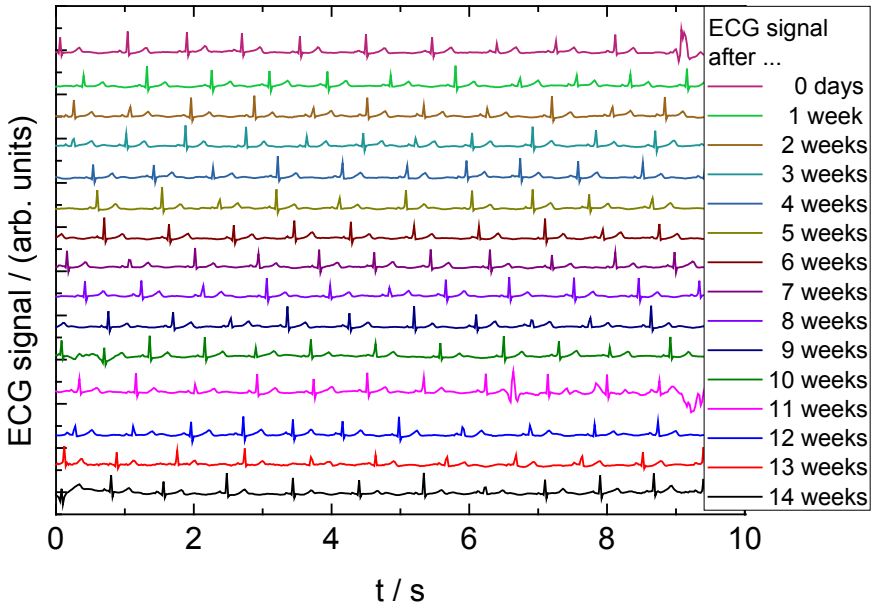

Figure 7. Long-term ECG measurements with textile electrodes, exemplarily shown for Einthoven I (cf. the first line in Fig. 6)

ECG signals were measured regularly on a female proband for more than three months with washing the underwear weekly. Fig. 7 depicts exemplarily the results of these long-term measurements for the Einthoven I lead. As can be seen here, the signal quality stays relatively constant during this time. Deviations from the ideal signal shape can be attributed to movement artifacts, while wearing and washing does not significantly influence the signal quality for more than 10 washing cycles.

4. Conclusions

In a recent project, we have developed the first 12-lead ECG underwear that allows for measuring a complete 12-lead ECG with high reliability and signal quality, equivalent to commercial gel electrodes due to realization of constant skin contact. Due to using solely textile materials for the ECG electrodes and integrating the data lines in the underwear, patients are not disturbed in their daily life, but can wear the ECG underwear for days or weeks. In the future, it will be possible to detect rare episodes of cardiac arrhythmia.

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