Textile-integrated electronics for ambulatory pregnancy monitoring

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Abstract

Constant pregnancy monitoring is a promising alternative to reduce the number of stillbirths and preterm delivery due to false alarms. Tele-monitoring systems can provide regular, accurate and timely monitoring to reduce risks, costs and the time the mothers-to-be spend at hospitals. In this chapter, the ideal characteristics for such wearable monitoring system are described. These were investigated considering technical aspects and user research. Furthermore, a smart garment integrated with sensors and a flexible printed circuit board for ambulatory pregnancy monitoring is proposed. A study was conducted to gather user requirements to ensure comfort during long registrations of Foetal Heart Rate (FHR) and Electrohysterogram (EHG). Based on those requirements, several garment alternatives for the monitoring system are proposed and evaluated.

Keywords: Pregnancy monitoring, user research, body area networks, wearables, textile-integrated electronics.

1. Introduction

Although pregnancy is a natural process and it is not considered a sickness in most of the countries, complications might develop and become life-threatening for both the child and the mother. It has been estimated that around three million annual third-trimester stillbirths occur around the world (Haws et al. 2009; Frøen et al. 2011; Lawn et al. 2011). From these, one of three babies was alive just before the labour began (Frøen et al. 2011; Haws et al. 2009). Previously it has been discussed the fact that these counts are underestimated values, as stillbirths are often not counted nor included in the Global Burden of Disease (Haws et al. 2009; Frøen et al. 2011). Despite the lack of attention towards stillbirths, they cause a profound scar in the life of the parents. The grief for a stillborn baby is comparable to that felt by the death of any other child. Furthermore, stillbirths are often accompanied with stigmatization of the mother and a sense of failure and helplessness (Scott 2011).

Most of these stillbirths occur in low-income countries where interventions in the maternity care are not enough. On the other hand, in high-income countries the rates of stillbirths have been reduced since 1940, but improvements have slowed down in recent years (Flenady et al. 2011). Therefore, assessing foetal well-being during pregnancy and labour is a priority to timely detect any complications and to reduce the number of stillbirths. Screening tools can provide information about the foetal well-being to effectively identify foetal distress and to ensure timely interventions. These tools include foetal movement, heart rate, foetal growth, among others (Haws et al. 2009).

Furthermore, the actions taken after monitoring outcomes are as important as the monitoring itself. A signal of distress often leads to early delivery induction (Haws et al. 2009). Moreover, it is important that the conclusions drawn from the monitoring outcomes are accurate enough to prevent unnecessary early deliveries.

Continuous monitoring might lead not only to timely detection of distress signals, but it would also enable data driven research on accurate foetal distress detection (Brown et al. 2014). If pregnancy is to be monitored continuously, other factors than accuracy in the monitoring come into the picture. These include wireless, low-power, noise-robust devices, that also are comfortable enough to wear for extended periods of time. Thus, smart textiles are a promising solution to develop comfortable garments that constantly monitor pregnancy. These systems would help to better manage risks during pregnancy, and ultimately prevent stillbirths and miscarriages. This possibility will be discussed in the following sections. Section 2 gives an overview of trends in innovative pregnancy monitoring techniques. Section 3 describes the design space of such technologies, its relation to textile technologies, and the importance of considering them for the design of monitoring systems. Section 4 and 5 outline the user's needs to improve monitoring techniques with empirical support on textile features and wearable design. Section 6 describes a case study of how the user requirements can be implemented in a smart textile garment. Finally, section 7 provides a futuristic view of pregnancy monitoring using textiles and further sources of information on the topic.

2. Trends and innovation in pregnancy monitoring

Pregnancy screening usually starts with an assessment of the risk level. Currently, pre-existing or pregnancy-related medical conditions are predictors of high-risk pregnancies (Haws et al. 2009). Maternal diabetes mellitus, obesity, smoking, high maternal age, placental dysfunction disorders and foetal growth complications are often among these (Cnattingius & Stephansson 2011).

Screening strategies for risk detection vary from one country to another. Most pregnant women are scheduled for regular screenings, regardless of their status of high- or low-risk pregnancy. The frequency of such monitoring depends on the resources available in the country (Lawn et al. 2011). Furthermore, high-risk pregnancies are often offered intensive surveillance. In case of high chances of severe complications, women are recommended to take hospital bed based rest and monitoring. This hinders the social life of the woman and conveys additional costs for the healthcare system (Haws et al. 2009; Buysse et al. 2008).

The most common monitoring techniques are foetal movement monitoring and Ultrasound Scans (US). Changes in foetal movement are an indirect measure of decreased oxygenation and therefore a signal of distress (Haws et al. 2009). Foetal movement counting is usually done by the mother. These counts are subjective measures of the health of the baby and are often supported with kick charts to be filled by the mother (Tveit et al. 2009; Brown et al. 2014). On the other hand, ultrasound scans can provide a more objective measure of estimated foetal weight; document placental location; identify foetal abnormalities; and foetal growth restriction or abnormal amniotic fluid volume. Moreover, their interpretation also depends on the subjective decisions of the operators (Haws et al. 2009; Brown et al. 2014). As consequence, there is still some area of opportunity to improve the interpretation of ultrasound outcomes.

Another monitoring technique used before and during delivery is Cardiotocography (CTG). This is a method to electronically record Foetal Heart Rate (FHR) and the presence of contractions using Electrohysterogram (EHG) with a pressure transducer. Abnormal FHR patterns are linked to poor pregnancy outcomes. These patterns include analysis of the baseline rate and variations from that baseline, including accelerations or decelerations. As happens with other monitoring techniques, the major drawback of CTG is the subjective factor in its interpretation. The patterns are often interpreted manually and can potentially lead to inappropriate intervention or false reassurance without intervention (Haws et al. 2009; Brown et al. 2014). After an anomaly is detected with CTG it is common to opt for an early induced delivery or a Caesarean section delivery, depending on the gestational age of the foetus (Haws et al. 2009).

Given the subjective nature of monitoring interpretations, other tools like the biophysical profile (BPP) have aimed to make a compound measure of foetal wellbeing by combining five indicators: heart rate, breathing movements, foetal movements, muscle tone and amniotic fluid volume. Although the rate of false negatives is low, it has been suggested that this scale generates more false positives than CTG alone, which leads to more induced births than necessary (Haws et al. 2009; Brown et al. 2014).

In principle, it is preferable to keep the number of false negatives low to prevent distress signals go unnoticed. Nevertheless, false positives can also be harmful. Whether letting a baby be born prematurely is a good decision or not, depends on the availability of neonatal intensive care units and the gestational age of the foetus. At 22 weeks of gestational age or before, the survival of a premature born baby is almost impossible. Between 22 and 24 weeks the probabilities of survival are around 25%, and only after 24 weeks, the chances of survival start to significantly increase (Field et al. 2008). Therefore, a reduction in false positives is required to avoid premature births whenever it is possible. For this purpose, better, objective, and reliable interpretations of the monitoring outcomes are desirable.

Unfortunately, the signs of foetal distress are not always clearly noticeable, and they only become evident near the stillbirth or miscarriage. Following this reasoning, it would be natural to increase the length and frequency of the monitoring, to prevent distress signals go unnoticed. This strategy is already followed by the management of high- versus low-risk pregnancies. The frequency of monitoring depends on several factors such as resources available, and the risk levels of each pregnancy. For example, in the Netherlands, obstetric care is different for low- and high-risk mothers. Low-risk pregnancies are handled by the primary care system whilst high-risk mothers-to-be are referred to the secondary care for additional check-ups. Interestingly, women at low-risk have a greater risk of prenatal dead than those at high-risk. Furthermore, mortality increases with transfers between primary and secondary care. One of the potential explanations is that foetal distress is not detected on time (Haws et al. 2009; Brown et al. 2014; Evers & Brouwers 2010). Therefore, constant monitoring might prove useful to detect distressful events as they appear.

For some extremely risky cases, it is suggested to have hospital bed rest for regular monitoring at the hospital. However, there is not sufficient evidence of the efficacy of this procedure. In addition, hospital bed-based monitoring also conveys high costs and inconvenience for the mothers-to-be (Haws et al. 2009). Hence, tele-monitoring might prove to be a good solution to provide a timely alert of foetal distress by letting high-risk patients monitor the progress of their babies at home, without increased risk or discomfort.

Previous work has proven the feasibility of such tele-monitoring systems. First, tele-monitoring of pregnancies at risk would imply a considerable cost-reduction per year (Buysse et al. 2008). Second, patient-directed FHR monitoring and transmission has been successfully tested with high level of satisfaction from the patients (Kerner et al. 2004).

Besides the aforementioned advantages of continuous pregnancy tele-monitoring, such devices would also enable data collection for future research of accurate distress signal patterns. In the long term, these would provide timely detection of foetal distress; and also the accuracy of detection to avoid excessive false positive rates. Furthermore, they could improve the pregnancy experience of the mother by avoiding unnecessary hospitalizations and extra reassurance that the unborn baby is healthy.

2.1. Current wireless monitoring systems

Some wireless pregnancy monitors are already available in the market. Most of them focus on FHR and Electrocardiography (ECG) monitoring.

First, the Avalon CTS Cordless Foetal Transducer System by Philips (Philips n.d.) is comprised of a couple of wireless CTG traditional transducers, which can be connected to their whole series of CTG apparatus (Avalon FM 50, FM40, FM30 and FM20). These transducers are cylinders of around 10 centimetres diameter and a couple of centimetres depth that are hold close to the belly using two elastic bands and a button-like coupling system.

Second, the Monica AN24 monitor by Monica Healthcare (MonicaHealthcare n.d.), is a small handheld device connected to several ECG sticky electrodes via wire, and wirelessly to an enabled PC, notebook, or tablet. It monitors FHR, foetal ECG, maternal ECG and uterine Electromyography (EMG). The handheld device includes a processor and algorithms to extract the aforementioned features in real time. This product is intended for hospital use, allowing more comfort by removing the tight bands of traditional CTGs, and more freedom of movement, being it wireless. However, it has been suggested that its performance would not be sufficient for monitoring at home. Its battery only lasts 24 hours; the sampling rate does not allow for all the calculations; the quality of the recordings is diminished between 24 and 36 weeks of gestational age; and the electrodes cause skin irritation (Brown et al. 2014).

A third system is the Remote Foetal Monitor by CIDESI (CIDESI n.d.). It is another handheld monitor wired to several sticky electrodes to be attached to the pregnant belly. Although it is significantly bigger than the Monica AN24, it includes a screen where a plot of the FHR and the foetal movements can be visualized. However, its size alone might make it difficult to carry around.

Fourth, the Telefetalcare monitor (Fanelli et al. 2011) is a textile belt with eight ECG leads embedded in the fabric. The recorded data is sent via Bluetooth and visualized in real time on a PC. Whilst it is a more user-friendly monitoring system, the battery life is still limited, the recordings are prone to movement artefacts (Brown et al. 2014).

Other devices are the Ambulatory Accelerometer-based foetal activity monitor (AFAM) (Mesbah et al. 2011) and the Foetal Movement Acceleration Measurement (FMAM) (Qi 2013) recorder. They use accelerometers to detect foetal movement. Although their sensitivity is limited and they are prone to artefacts, they present a promising approach for objective foetal movement monitoring (Brown et al. 2014).

The aforementioned systems are good attempts to increase mobility of the mother during the measurements. However, there is still room for improvement. Battery life, quality of the measurements and size are still to be improved. Furthermore, most of them consist of a big and relatively cumbersome-to-carry handheld device to which the sensing electrodes are attached using wires. The Telefetalcare is the device providing the most comfort, as it substitutes sticky electrodes and big squared elements with a garment. Despite this fact, it is prone to motion artefacts because the skin-textile electrode contact is not stable. Moreover, the activities the mother can perform while wearing it are limited to passive ones, such as reading a book. Finally, there is no specific evidence of the level of comfort experienced by the mothers-to-be while using such systems for long periods of time (Brown et al. 2014).

2.2. Wireless Smart Energy Body Area Networks

As described in the previous section, the challenges of size reduction, comfort, battery life and motion artefacts remain unsolved in current portable pregnancy monitors. In general, these issues have been addressed by the Wireless Sensor Network (WSN) community. More specifically, they are researched under the name of Wireless Body Area Network (WBAN) (Gonzalez-Valenzuela et al. 2013; Yang 2006; Latré et al. 2010; Chen et al. 2010).

WSN are integrated microsensors with on-board processing and wireless data transfer capability. They are aimed to monitor environments, objects and the interaction between these objects in the environment (Yang 2006). WBANs are a subcategory of WSN that aim to address the challenges of monitoring the human body using small, intelligent devices attached or implanted in the body, which communicate wirelessly to other devices in the network (Latré et al. 2010). WBANs should move around with the user, and thus, be robust against motion artefacts. Moreover, WBANs require lower wireless power, to increase battery life and allow them to interface with other wireless technologies. However, with less power availability, the signal detection becomes more challenging as well (Yang 2006; Gonzalez-Valenzuela et al. 2013).

WBANs are a topic widely researched in several domains, one of them being healthcare. Given their characteristics, WBANs have the potential of improving health monitoring as its nature allows them to provide measurements for long periods of time. They would also enable patients to be monitored while moving around, making hospitalization optional. Furthermore they use the processing power of other devices in the network to provide near real-time feedback. Additionally, by storing the data in a network device, caregivers can access it to provide further assessment.

The main elements in the architecture of a WBAN are three. (1) Sensors to measure the required data; (2) actuators to act according to the data received; and (3) a personal device which gathers all the data acquired, shows it as feedback or forwards it to other devices in the network. The energy consumption of the network depends on the number of elements, the data processing and the wireless communication. The latter is usually the most power consuming aspect. The sampling rate of these devices depends on the nature of the data to be captured. For example, ECG with six leads uses 71 kbps and a motion sensor 35 kbps. Furthermore, the number of sensors in the network also increases the required data rate, which can add up to several Mbps. Additionally, the battery size is directly related to its capacity, and the battery is most likely the biggest element of the system. This indicates that energy management is crucial to reduce the size, and therefore increase the comfort of the monitoring device (Latré et al. 2010; Gonzalez-Valenzuela et al. 2013; Chen et al. 2010).

2.3. Pregnancy monitoring at home

Ideally, the monitoring device is not only to provide accurate monitoring and timely identification of possible complications. It should also ensure the comfort of the mother while doing so. Thus, it is important to develop wireless, comfortable monitoring systems to be used during extended periods of time without interrupting the daily activities of the future mother.

In the previous sections, the limitations of current portable monitoring technologies were outlined as well as the advantages of the so-called Wireless Body Area Networks. Recurrent issues are the size of the devices and the battery life. These have an impact on the quality of the signal obtained and the amount of information that can be processed.

Big boxes indeed pose a drawback for ambulatory monitoring as they are difficult to carry around. Furthermore, current portable monitors still have long cables between the sensors and the personal device gathering the information. These long cables would increase the magnitude of movement artefacts, and therefore diminish the quality of the data. These issues could be solved with the design of a wearable to fit the sensors to the belly. The wearable could be similar to the Telefetalcare, with further improvements in reducing artefacts.

Beside the aforementioned technical challenges, it is also important to ensure the usability of the monitoring system. Although the concept of maternal self-administered FHR monitoring has been successfully tested with high patient satisfaction (Kerner et al. 2004), there is also some evidence of cases where inappropriate interpretation led to dangerous situations (Chakladar & Adams 2009). Since the users do not have a technical background, it is of utmost importance to enable them to correctly use the system and interpret its output (Latré et al. 2010). A failure to do so might lead to incorrect diagnostics from the caregivers or unnecessary worries for the parents (Mamagkaki 2012).

Finally, the monitoring tool can be both a clinical tool and a tool to increase the bond between the parents and the child. It could enable them to feel their unborn babies in a different manner. E.g., through hearing their heart rate and giving them reassurance of the status of their kid. It remains on the design of such tool to convey the correct interpretations and experiences from the monitoring system.

2.4. Integration of textiles and electronics for pregnancy monitoring

Textiles are flexible to conform to the body, nice to touch, soft, light, and easy to use. They have been used by people for long enough to consider clothes as a second skin. In this sense, they are a more natural option to wear than a set of sensors attached to several cables. Therefore, the integration of health monitoring functionalities into textiles provides the monitoring device with the rich set of advantages that regular clothing has.

The so-called smart materials are those which combine traditional textile technology with novel electronic technologies. With this, they enable themselves to interact with the environment, both by sensing it and by acting on it. Medical devices can benefit from them by providing more comfortable and acceptable products with versatile design, materials and structures (Black 2007).

Several options are available to integrate the best features of textiles and hard electronics into wearable technology. Namely, the level of integration ranges from sewing electronic interconnected modules in the textile garment till the more idealistic fully textile electronic device. However, the state-of-the-art in electronic textile integration is mainly limited to sensing devices.

Materials with different physical properties (i.e., piezoelectric materials, shape memory alloys, polymers, etc.) have been used to create several textile electronics. An example is the creation of textile electrodes for neonatal monitoring (Chen et al. 2011), which are made of silver and gold textile electrodes and a blanket. These electrodes aim to replace traditional AgCl electrodes, and are more comfortable to wear and less irritating to the skin. Despite these benefits, movements between the electrode and the skin surface are the main cause of motion artefacts in the recorded signal (Lamparth et al. 2009). To solve this issue, most of the garments using textile electrodes are tightly fitted to the body.

It is particularly challenging for pregnancy monitoring to implement the tight fitting garment solution to skin-electrode contact artefacts. First of all, the shape of the belly is different for every pregnancy. Second, its size and shape are constantly changing. Finally, there is constant movement on the pregnant belly surface: both the mother and the unborn baby are moving. Therefore, even if a good fit is achieved, chances are that the foetus' movements will cause some kind of artefacts by creating belly deformations.

Besides the sensors, other electronic elements are necessary for pregnancy monitoring. These include low-power amplifiers, processing units, and radios to transmit the data to a personal device. Nowadays, these are still hard elements soldered to Printed Circuit Boards (PCBs), which can be sewed into the garment. An example is the Lilypad Arduino (Arduino n.d.), which is a microcontroller board designed especially for its use with wearables. The board connection pins are holes that can be sewed into the fabric using conductive thread. Another approach to integrate PCBs into smart garments is to store them in small pockets.

By using hard elements, some of the benefits of using textile wearables are lost. Mainly, the flexibility of the material is constrained, making it more uncomfortable to wear and to fit it to the body. A first approach to solve this issue is the use of flexible substrates for the PCBs. However, these give flexibility to the circuit in only one direction, and they lack stretch properties. To regain the conformant abilities of textiles, the use of Stretchable Moulded

Interconnections (SMI) has been proposed (Vervust et al. 2012). It consists of standard Surface Mounted Devices, including hard electronic elements arranged in functional islands and interconnected with spring-shaped copper wires. In this manner, the standard PCB circuits are kept small, and the connections between them remain flexible and stretchable. Finally, the whole circuit, including the wired connections between islands are encapsulated in a polymer attached to the textile. This encapsulation isolates the circuitry, and allows it to be washable.

In particular, for pregnancy monitoring, the stretch-ability of the material and its ability to conform to the pregnant belly is of utmost importance to ensure comfort and good electrode-skin contact. Therefore, the techniques that preserve these textile characteristics while avoiding artefacts are preferred.

3. Design space

The design of a portable pregnancy monitoring device is a multidisciplinary challenge. Figure 1 shows the different angles of the design.

First of all, the architecture of the WBAN has to be defined. It includes decisions over the number and type of sensors to be included; where the raw sensor data is to be processed; what information is to be transmitted to where; what technologies and protocols are to be used to transfer the information; the technologies used to store the data; and the topology of the WBAN.

The second design aspect is the hardware of the system. It entails the design of the hardware elements, namely, the signal acquisition board and its interface with the sensors. It also covers the design of the wearable where the acquisition board is to be integrated; decisions over the location of the sensors with respect to the belly; the physical radio to be used to transmit the data; and the hardware of the physical device to receive the data.

The third aspect of the system is the software. The signal acquisition algorithms are an important step to obtain clean data. They include pre-processing to select the appropriate sensor channel, and algorithms to extract relevant features to be used for later diagnostic. The interpretation of that data can be done either manually, by an expert, or automatically by using an algorithm trained in identifying a distress signal.

The fourth aspect is about the interface design. Some of the decisions to be made include the following: What type of visualization is necessary? What level of abstraction is necessary? How to ensure correct interpretation of the measurements? What modality should be used to give feedback? Should it be visual, auditory, kinaesthetic or multimodal?

The type of interface is largely determined by who is going to use it and for what purpose. Therefore, the fifth design dimension is the decision of who the system is for. In the case of pregnancy monitoring, the system is used for both caregivers and parents, especially the mother-to-be. Moreover, the interface between the user and the system also includes the wearable itself, as it is in direct contact with the skin of the future mother.

Finally, the timing within the pregnancy, duration, and frequency of the usage of the monitor also have some impact in the design of the system. It affects the required battery life, the type of algorithms to be used, the type of visualization required to show the data gathered, and the level of comfort required by the garment.

4. Towards the ideal pregnancy monitoring system

Evidence on stillbirth rates, premature births, and pregnancy monitoring efficacy, points out to the need of a continuous tele-monitoring system. According to Brown et al. (2014), pregnancy tele-monitoring devices should fulfil several criteria to provide a reliable long-term diagnostic of the foetal status. They should (1) be safe; (2) be portable and capable of sustained use in the home environment; (3) analyse data in real time; (4) provide objective assessments of foetal health and timely alarms; and (5) not preclude advanced monitoring techniques such as foetal pulse oximetry and foetal scalp blood sampling.

Previous research has already provided insights into these aspects. The WBAN community has already made several recommendations about network architectures (Yang 2006; Gonzalez-Valenzuela et al. 2013; Latré et al. 2010; Chen et al. 2010). Also, research has been done regarding energy-efficient hardware for foetal monitoring applications (Song et al. 2013; Song et al. 2014); the influence of electrode placement on the quality of the measurement signal (Rooijakkers et al. 2014); and about low complexity algorithms to detect foetal ECG and consequently FHR

(Rooijakkers et al. 2011). On the other hand, automated diagnostic algorithms are still to be developed. To the best of our knowledge, research regarding the automated detection of foetal distress using long-term foetal monitoring has not been done yet. This is possibly due to the aforementioned limitations in the current monitoring systems.

Furthermore, statistics on the survival of premature born babies suggest that constant monitoring is recommended after 22-24 weeks of gestation. After this gestational age, there is some probability that the baby will survive outside the womb. Therefore, the continuous tele-monitoring system would be advised to use after these gestational ages.

The least explored dimension is the type of interfaces that the system should have, the differences in the preferred interface for different types of users; and especially, about the comfort of the monitoring device in 24h home monitoring settings (Brown et al. 2014). Mamagkaki (2012) did an exploratory research on the possible use scenarios, ideal cases of use and the desired recommendations from mothers about the monitoring system. The main findings suggest to have the monitoring system used after some complain has been detected or during labour. Mothers-to-be preferred to use such system only in high-risk situations and to help themselves to count the contractions. Furthermore, they would use it for a limited amount of time (30-60 minutes a day), and if the garment is not bulky or too tight.

On the other hand, medical research suggests that the monitoring would be more beneficial if it is done continuously, meaning 24 hours a day. However, mothers-to-be are somehow reluctant to wear such system unless there is a good reason for it. Paradoxically, they cannot know if there is a strong reason to use the monitoring system if they have not been monitored before or until there is already a physical symptom of foetal distress. Therefore, it is of critical importance for a good smart garment design to conform to the user's preferences and needs.

5. User Research

Pregnancy monitoring systems have two types of users. The first consists of the pregnant women who should wear the device, and the second of the caregivers who will read and interpret the measurements. In an ideal case, the interpretation of the measures will be done objectively and with help of an automated process. However, a trained physician should also confirm the outcome and therefore be able to use the system and understand the logic behind the proposed diagnostic. In this manner, the caregiver can ensure that proper follow up monitoring or treatment is provided.

5.1. Caregivers

Trained health professionals deal with several health monitoring techniques on a daily basis. They take the maximum possible advantage from the technologies available, and learn to work around its limitations. Analysing the usage of current technology in more detail can shed light on the best characteristics of traditional pregnancy monitoring technology and on possible areas of opportunity. Furthermore, these positive and negative aspects can be considered for the design of a tele-monitoring system. From these aspects, conclusions can be drawn on the feedback that the system should provide while the garment is worn, and how the data obtained should be interpreted. Therefore, an interview with a caregiver and a task analysis (Beyer & Holtzblatt 1993; Veer van der et al. 1996) of the monitoring process were conducted in this study.

5.1.1. Methods

The regular CTG monitoring for a pregnant woman was observed in a master-apprentice setup, and was followed by an interview to the caregiver responsible of interpreting the outcome of the monitoring at the Obstetric High Care Department of the Máxima Medisch Centrum in Veldhoven.

5.1.2. Analysis and Results

The data obtained during the monitoring session was decomposed in a series of action steps, including the purpose, the actor, the tools, methods used and descriptions of the possible options (Kuniavsky 2003), if available. The answers of the interview were analysed by creating an affinity diagram (Beyer & Holtzblatt 1993).

The most common daily screening tool at a monitoring unit for pregnant women with risk of premature delivery is a 30-minutes-long (measured in terms of well recorded data) CTG measurement. Due to the bad quality of the registrations, it is common for the mother-to-be to stay hooked up to the machine for a longer period of time. These inconsistencies in the recordings are caused by bad contact of the transducers with the skin, and more importantly, by the movement of the baby inside the womb. Current transducers do not cover the whole belly, and they need to be near the foetus in order to detect his HR. Thus, the signal of the FHR is often lost.

Signal loss is indeed the most common source of bad CTG registrations. Caregivers have to cope with the signal loss in various manners. These include using conductive gel and moving the transducer around the belly until they find the FHR of the foetus. The caregivers further use their knowledge of typical FHR to distinguish it from the mother's, from noise, or to distinguish the FHR of two foetuses in case of twins. Furthermore, their knowledge about the position of the foetus in the womb might help to find the FHR.

The above-mentioned FHR is found within three minutes by a trained professional. Once it is found, the transducers are secured with tight elastic bands and the recordings start registering the FHR. If the signal is lost at any moment, the registration has to start again. Whenever the FHR is not found within the allotted time, an ultrasound is performed to locate the foetus. After the registration, an expert examines the data.

From the monitoring process, it becomes evident that a major issue with current monitoring systems is the sensitivity of the transducers. It is quite common to lose track of a moving foetus. The CTG system does provide an on-screen alarm to indicate when the registration is lost, but it is often unnoticed by the caregivers. The reason is that the caregivers usually are in movement checking patients and they are seldom sitting in front of the screens waiting for such alarms. It is usually the mother who detects it. On the other hand, positive points are the feedback provided from current CTG machines, including visual and auditory modalities.

Usually the CTG machines are trusted and assumed to always work. It is the usage what determines the quality of the registrations. The caregivers have to be skilful to find the baby and to distinguish a proper FHR registration from noise. Furthermore, there is no automated data analysis; it is always up to trained professionals to give their best diagnostic. These interpretations assume that when good registrations are achieved and the FHR looks normal, it is almost sure that the baby is doing well. However, if the CTG outcome is odd, then the situation is unknown and further assessments are required.

In conclusion, the areas of opportunity identified to improve the monitoring process are the following: (1) objective indication of distress levels; (2) effective alarm system; (3) improved sensor sensibility to avoid intermittent registration; (4) informed use of CTG systems by untrained users to avoid stress if they cannot find the location of the baby.

5.2. Mothers-to-be

Pregnancy is a whole new experience, especially for women having their first child. It is accompanied with uncertainty, body changes and even pain. Therefore, they do not want to be troubled by additional nuances of monitoring systems. Ideally, accurate monitoring and timely identification of possible complications have to be provided, whilst ensuring the comfort of the mother. What are the most important aspects to ensure comfort? What characteristics should the garment have to be well received by the mothers-to-be? In a previous study, these questions were investigated using user research and multiple textile garments (Perusquía-Hernández et al. 2014). Figure 2 and Figure 3 provide a graphical representation of the user requirements obtained in that study and the relationship among them. These requirements fall into comfort, reassurance and play categories. This research also shed light on the difficulty for the users to decide on the best qualities of the garment without having seen it and tried it on. Therefore, subsequent studies would require the use of both fabric prototypes and a method that promotes the user's involvement in the design process. Hence, the authors also proposed several garment options, from which relevant characteristics for the monitoring garment were defined. These included the type of garment preferred by the mothers-to-be, and an ergonomic shape for a flexible PCB to be integrated in the garment. By using already made prototypes, an iterative design process is also started. In section 6, this design process is continued with a specific design. This design further explores the ideal characteristics of a garment for pregnancy monitoring.

5.3. Recommendations for design

The requirements obtained from literature and user research are outlined in Table 1.

6. Case study of a wearable pregnancy monitoring system

6.1. SEBAN project

Smart Energy Body Area Sensor Network (SEBAN) is an ongoing four years project funded by the Dutch Technology Foundation STW. It is also supported by partners within the SEBAN Consortium, namely, the Máxima Medisch Centrum, IMEC, Philips and TMSi. Its ultimate goal is to build crucial parts of a wearable with an integrated fully wireless electronic system which permits to monitor continuously the progress of pregnancy at home.

The wearable is battery-powered, to ensure safety and portability. In order to be worn for long periods of time, the wearable uses an energy efficient amplifier (Song et al. 2013). Furthermore, it uses five solid-gel electrodes optimally arranged to maximize the quality of the FECG and EHG acquisition in third-trimester pregnancies (Rooijakkers et al. 2014). Such arrangement is similar to a star, where the distance between sensors is fixed. This would allow a more robust signal acquisition, which deals with constant foetal movement.

The data gathered with this arrangement is sent to the mobile phone of the user using low-power Bluetooth 4.0 technology. Using the mobile phone, the future mother would be able to get information about the status of the unborn baby. Besides its functions as a tool to provide feedback, the phone will be used as forwarding point for the data. The data will be transferred to a back-end server where additional signal processing will be performed. The outcome of the monitoring can be accessed by terminals at the hospital, so that caregivers can professionally assess it and take the necessary actions in case of an emergency (Perusquía-Hernández et al. 2014). This system would offload the healthcare system while providing better information to the patients. Furthermore, it would help to pave the road for future research on assessment of foetal distress.

6.2. Garment design for an ambulatory pregnancy monitoring system

Within the SEBAN project, user requirements were considered to inform the design, especially that of the wearable and the system feedback elements. As mentioned in section 5, suggestions for a wearable design can be drawn from user research, but without a textile prototype, it is difficult for the users to decide on specific qualities of the garment. The iterative design of a garment for the SEBAN project will be described in the following subsections, starting with a description of the design focus and its elements.

6.2.1. Design Focus

Even though technology can grant future mothers the ability to closely monitor their babies, if they do not have enough motivation (e.g., an explicit risk factor), they are less likely to use the system. Indeed, the Fogg Behaviour Model (FBM) (Fogg 2009) describes that in order to achieve a target behaviour, a good combination of ability and motivation are required. Furthermore, a trigger is necessary to increase the likeliness to perform such behaviour.

Applying the FBM, the monitoring system should not only be technically accurate and provide good measurements, but also the motivation to wear the garment should be increased, and a trigger should be provided. The ability is provided by a functional portable device and the trigger could be medical recommendation starting from 22 to 24 weeks of pregnancy. Furthermore, motivation can be increased by different qualities. These include improved comfort, good interactions and appropriate feedback that increase the bond with the baby and avoid unnecessary worries, among others.

Therefore, the design focus of the SEBAN garment is to provide an ambulatory monitoring for extended periods of use; which facilitates monitoring and research on the interpretation and decision making based on the data gathered; and includes persuasive elements to reach the target behaviour of continuous usage.

6.2.2. Design Elements

To reach the aforementioned goal of constant monitoring, three design elements are considered: (1) a smart garment to take measurements, (2) a phone App to provide feedback, and (3) a package for the garment to provide extra information.

Persuasive elements (Kaptein & van Halteren 2012) are integrated in these design elements as follows:

1. Increased ability is provided by facilitating functional technology with good usability. Furthermore, all information and materials are gathered in a single place (package).
2. Increased motivation is provided with:

a. **A social factor.** The phone App provides empathy with other pregnant women by showing the relationship of the current monitoring with others. Furthermore, it provides contact with the caregivers, who provide constant support.

b. **Rich explanations.** The package includes information about the system, how to use it, and outlines its advantages. Furthermore, the App provides appropriate feedback on the system and the foetal status at the moment and over time; and it includes timely, noticeable alarms in case of distress.

c. **Increasing liking by providing a good experience.** The system as a whole is understandable, comfortable, it allows movement, and it has a good look-and-feel.

3. Includes an authority trigger in the right moment: the caregivers' advice to use the monitoring system.

Although the persuasive dimension of the design expands to elements other to the garment itself, the following sections will concentrate in the garment design.

According to previous research (Perusquía-Hernández et al. 2014), a belly band approach is preferred by users. From the two types of closure, an open one was selected. Although an open structure is not clearly preferred, it is more difficult for the users to close open garments. Therefore, open versions have more areas of opportunity to be tested in future iterations. Finally, the users had more troubles using the garments without the simple instructions. Therefore, it is recommended to add some guidance on how to use the wearable.

6.2.3. Design and evaluation

A garment was designed and prototyped. The PCB was designed as described by (Perusquía-Hernández et al. 2014). Additionally, a package was designed following the characteristics outlined in section 6.2.2. Furthermore, both the garment and the package were evaluated.

Garment

The garment design was a belly belt closed with hooks and eyes on the back. As seen in Figure 4, the belt is wider on top of the belly, and thinner at the back. The belt has a fabric cover to avoid the contact of the PCB with the skin.

This cover includes several holes to allow the connection between the PCB and the electrodes. The PCB is kept in place with help of a small fabric band. Furthermore, the belt can be decorated on the outer side.

The material for the prototype on the outside is thick Lycra, and on the inside and the cover thin cotton jersey. Furthermore, the band to hold the PCB is made with a patch of non-stretch cotton fabric. Finally, the dummy PCB was sealed with fabric, using Copolyamide as glue. The seal had the intention to cover the metal-looking PCB, as women complained of the sharp edges in previous iterations. Moreover, the PCB is kept visible to avoid having the users mindlessly bend it.

Package

The package consisted of a 45x30x6 cm box decorated as shown in Figure 5a. It included a 3V coin battery, three sets of five electrodes, the garment, the PCB, and a piece of paper with the instructions and more information about the system (Figure 6). The layout of the box is shown in Figure 5b. On top of this arrangement, the sheet of instructions was placed. In other words, when users open the box, the first things they see are the instructions, and they have to lift the booklet to reach the garment, electrodes and battery. This was intended to reduce the number of people that will miss the instructions.

Evaluation

Methods

Participants

Six pregnant women (average gestational age = 28.83 weeks, SD=4.57, average age = 30.5, SD=5.68) participated in the evaluation. Three of them evaluated the prototypes at the hospital (high-risk), and three of them (low-risk) did the evaluation in a home-like environment.

Procedure and analysis

The evaluation was divided in two parts. The first part was a usability evaluation (Frokjaer et al. 2000; Nielsen 1993) assessing efficiency, effectiveness, and satisfaction. Participants were given the task of wearing the garment for the first time. They received the package with all the materials included, and the task was considered complete when they wore the garment in the correct position.

The time they used to complete the task was a measure of efficiency. The number of deviations from the ideal number of steps (i.e., the number of missed steps) were counted as a measure of effectiveness (Frokjaer et al. 2000; Nielsen 1993). Finally, satisfaction was assessed with self-report questionnaires. The questions included the Post Study System Usability Questionnaire (PSSUQ)(Lewis 2002); five questions about the quality of the wearable; and four questions including the best and worse characteristics of the system, when would they prefer to wear the garment, and additional comments. After the first part was completed, low-risk participants were asked whether or not they would like to take the garment home and try it for a few days. If they agreed, they were provided with enough materials to use the garment for three days, and a semi-structured diary format. The diary included questions about comfort, the activities done while wearing the system, for how long it was used, and awareness of wearing the system. Qualitative answers were analysed using affinity diagrams (Beyer & Holtzblatt 1993). For quantitative questionnaires, plots of the mean scores were created.

Results

The PSSUQ questionnaire included 17 statements related to effectiveness, efficiency, and satisfaction. Figure 7a shows a scatterplot with the distribution of the average scores. Please note that a lower rating means a better usability. In average, the usability of the garment was rated as high. Furthermore, Figure 7b shows the average rating of five garment qualities, including fabric, colour, type of wearable, electronics integration, and how natural to wear the garment is. In this figure, the highest score is related to the best liking of the feature.

As shown in Figure 8a, the average time to wear the garment (efficiency) was 7.71 minutes (SD = 3.11). On the other hand, scores related to efficiency on the PSSQ were about two, meaning that 7 to 8 minutes is considered as a reasonable time to put the garment on.

Figure 8b shows the average effectiveness in completing the task. The most common misunderstandings were related to inserting the battery with the correct polarity (2 participants), and removing the sticker covers from the electrodes

(4 participants). Furthermore, items in the PSSQ related to effectiveness averaged around two, which can be interpreted as the system being perceived as easy to use.

Good acceptability of the garment was also suggested by the fact that two out of the three low-risk participants accepted to take the garment home after the usability test. Additionally, the low-participant that did not accept to keep the garment explained that it made no sense for her to keep it if she could not have feedback. In the long term, one participant started using the system for two hours and then this time decreased to one. The second participant used the garment for an increasing period of time, ranging from 5.5 hours the first day, to 13.5 hours the third day. A possible explanation is that for the second participant the garment fitted better. Both of them used the garment while sitting, and doing housework, and took the garment off when they went to sleep. During the user tests, other women stated that they would prefer to use the system during the day (4 participants), especially when a complain starts or when they are busy (3 participants). Only one participant mentioned her willingness to wear the garment during her sleep.

Over time, the worse experience is to be found if the garment does not fit well, but if it is fitting, it is good enough for long term usage. Fitting problems were mostly related to the top part of the garment, which not always followed the shape of the belly. Also, for some women the size of the PCB was too big, causing the lowest electrode to be in the pelvic zone. Figure 9 shows two examples of good garment fit versus two examples of fitting issues.

In general, the fabric was considered as soft (2 participants), with good colour choice (6 participants). However, the garment itself might be too warm to be used during summer (1 participant). Two participants stated explicitly that the garment is comfortable, two that it feels natural, and two liked the fact that it was a belly band. On the other hand, other two participants stated that the garment felt weird on her belly.

The electrode type was a source of complaint for two participants because it was painful to remove them. Another cause of major complaints was the use of hooks and eyes for garment closure. They were difficult to see, and most women tended to close the garment on the front and then rotate the hooks to the back. This, however, becomes impractical when the electrodes are already stuck on the belly.

Despite these complaints, five participants liked the concept very much, especially the portability. Furthermore, the level of visibility of the garment from the outside was rated as good. In other words, participants were happy that it was not visible for other persons.

Furthermore, some misinterpretations of the instructions were detected. These were mainly related to the correct manner to include the battery, and the instruction to remove the stickers from the electrodes. On the other hand, two participants liked the instruction style and the drawings.

Discussion and conclusions

In general, the garment was well received. The participants of the study liked the SEBAN concept, especially because it reduces the need of being at the hospital. The ratings for the wearable were good, and the instructions clear in most of the cases.

The wearable fulfilled the comfort requirements by being unnoticeable to other people, easy to combine with other clothes, soft, elastic, not heavy, and easy to use. However, the type of closing, and requirements of temperature, and use of textile electrodes are to be solved by future iterations.

Interestingly, colour was rated as good, despite negative reactions towards white in previous iterations. Participants stated that white is best, because it does not show through the clothes, as most pregnancy bands do. Also, although aesthetics was required in previous studies, with a fabric prototype at hand, women were not concern with it. A possible explanation is that it is going to be worn under other clothes. If it would have been a T-shirt, maybe aesthetics would have played a bigger role in the evaluation.

Besides ensuring comfort and usability, the design also presents a simple manner to integrate flexible electronics in the textile. Finally, an ergonomic shape for flexible printed circuit boards was designed to fit the pregnant belly. Encapsulating such PCB in fabric was a successful solution to avoid maternal concerns on the shape of the PCB; as complaints on sharp edges were practically inexistent during this iteration. This PCB has the appropriate characteristics to prove robust FHR acquisition in future iterations. Furthermore, the garment design allows its visibility to avoid mindlessly bending of the PCB.

Although the size and shape of the PCB was determined from previous research, it has been the major determinant of the size of the belly belt. As discovered from this evaluation, this size might prove to be too big for some women. Therefore, it would be better to design it in different sizes. The optimum sizing should be determined in future work, also considering the effects of different sizes on the quality of the measurements.

Another potential source of complains is the use of sticky electrodes. Ideally, these will be changed to textile electrodes. However, the current level of functionality within the SEBAN project did not allow for their use. Therefore, further research on textile electrodes is left for future work.

6.2.4. Suggestions for design improvement

As a follow up from the conclusions of the previous iteration, a new garment was designed (Figure 10). Improvements include a round finish on top of the belt, to improve fitting on top of the belly. Furthermore, the height of the belt was reduced, in order to decrease the area of the belly covered by the garment, and thus, minimize the warmth caused by the garment. The closing of the belt was also changed to Velcro. In this manner, users can close the garment more easily and adjust tightness.

The instructions to use the garment were also changed to make more explicit the correct polarization of the battery and the need to remove the covers of the electrodes (Figure 11).

7. Future Trends

Current smart garment design for pregnancy monitoring is limited by the technology available. In the future, textile-electronics integration will continue to improve, tending to the creation of electronics using textile fibres. Pregnancy monitoring devices will be looking more like the knitted belly band designed in the Shima Seiki Haute Technology Laboratory in Drexel's Expressive & Creative Interaction Technologies (ExCITe) Centre. This band is knitted with a conductive thread that serves as wireless passive radio frequency identification (RFID) tag that sends information about uterine contractions.

The case study presented here can also be improved using knitting technology. The garment could be knitted circularly (Patri-cia Chir-cop n.d.; Spencer 2001), avoiding the need of a closure. If the stretch properties of the knitting are good enough, the garment will adapt itself to the belly shape.

Furthermore, as detection algorithms are improved, electrode-skin contact artefacts might no longer be an issue. This will enable the use of other types of garments that are more beautiful, comfortable, and natural to wear. As discovered during the user research, for some mothers-to-be, it would be better to have a t-shirt instead of a belly band to prevent multiple layers of clothing.

As the smart garments become more comfortable and robust, its acceptance will grow, leading to further research regarding distress patterns and diagnostic algorithms that will improve pregnancy risk management.

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