USER EXPERIENCE OF WEARABLE INFANT SLEEP MONITORING SYSTEM FOR MEDICAL RESEARCH AND DIAGNOSTICS

Ilén E[1], Acosta Leinonen N[2], Ranta J[2], Airaksinen M[4,5], Haataja L[3,4], Vanhatalo S[2,4]

[1] *AALTO University, School of Arts, Design and Architecture, Department of Design, Espoo, Finland*

[2] *Department of Clinical Neurophysiology, Children´s Hospital, University of Helsinki and Helsinki University Hospital (HUH), Helsinki, Finland.*

[3] *Pediatric Neurology, Children´s Hospital, University of Helsinki and Helsinki University*

[4] *BABA center, Pediatric Research Center, University of Helsinki, Helsinki, Finland*

[5]*AALTO University, School of Electrical Engineering, Department of Signal Processing and Acoustics, Espoo, Finland*

elina.ilen@aalto.fi

ABSTRACT

A large proportion of infants have frequent sleep-related issues, and some of them may also have an underlying medical adversity, such as preterm birth or neonatal infections. While infant sleep is currently only studied in hospitals using labor-intensive polysomnography measurements, there would be a clear need for recording in patient's home as well. Here, we describe a newly developed mobile wearable system designed for such purpose, consisting of pull-up pants, with integrated motion sensor and textile ECG-sensors. The paper presents our preliminary findings of product user's experience; a parent, a nurse and a doctor.

Key Words: Smart Textiles, Wearable Technology, Sleep Monitoring, Mobile Health

1. INTRODUCTION

According to caretaker reports, nearly half of infants have sleep-related issues. Some of them are related to physiological immaturity of sleep-wake rhythmicity, however some issues may also be exacerbated by a possibly underlying medical adversity, such as preterm birth, neonatal infections, or birth asphyxia. These conditions often need a prompt diagnosis and treatment. However, the current diagnostic procedure is resource intensive being only available for infants with most severe disorders, and most infants hence remain without objective sleep monitoring. In many cases, monitoring of infant's sleep could significantly alleviate concerns, but it would be logistically possible only if performed out of hospital, preferably in patient's native environment, the home. The wider interest to monitor sleep stems from the reasoning that rhythmicity of sleep serves as a surrogate marker of physiological stability, which may carry diagnostic and/or prognostic information of its own. [1]

Wearable technology, which combines textile and electronics, has an implicit potential for medical research and diagnostics. Many textile integrated wearable products have been introduced to surveillance of infant life activities [2]. However, very little has been developed for their medical validation. Characteristics to infant medical wearables is that they have multiple coexistent users whose experience and perceived added value have to be factored in. The user groups include infant as a product wearer, a nurse or parent as a dresser of the product, and a medical doctor as a validated data utilizer. The product should meet the requirements by all users, such as safety, reliability and willingness to use.

The aim of study was to investigate the user experience of a novel wearable system for monitoring infant sleep, consisting of textile pants with integrated motion and ECG detector, and mobile phone app for data logging. In this case, we had two user groups: a parent or nurse as a product dresser and a doctor as a data utilizer. The dresser's user experience study culminated in easy-to-dress aspect and emotions of product comprehensive acceptability; product design, materials and willingness to use. Whereas, the user experience of the doctor

aimed to identify the three states of sleep, quiet sleep, light sleep and awake. The goal was to validate the infant textile pants for a high enough fidelity detection of these sleep states. We compared the results to the co-registered clinical benchmark, a polysomnography (PSG) study.

2. CURRENT METHOD: SLEEP MONITORING, POLYSOMNOGRAPHY (PSG) IN HOSPITAL

The current *lege artis* infant sleep study system, polysomnography (PSG), is always performed by the dedicated sleep laboratories. PSG consists of recording multiple physiological parameters, where the detectors are cable-connected to the recording device (see Figure 1). The full PSG includes at least electroencelograph (EEG) for recording brain activity, electrocardiograph (ECG) for recording heart, electooculogram (EOG) for recording eye movements, electromyogram (EMG) for detecting muscle tone, sensors for recording respiratory effort and nasal air airflow, as well as recordings of blood gas balance, especially pulse oximetry and transcutaneous (or end-tidal) CO2 measurements.

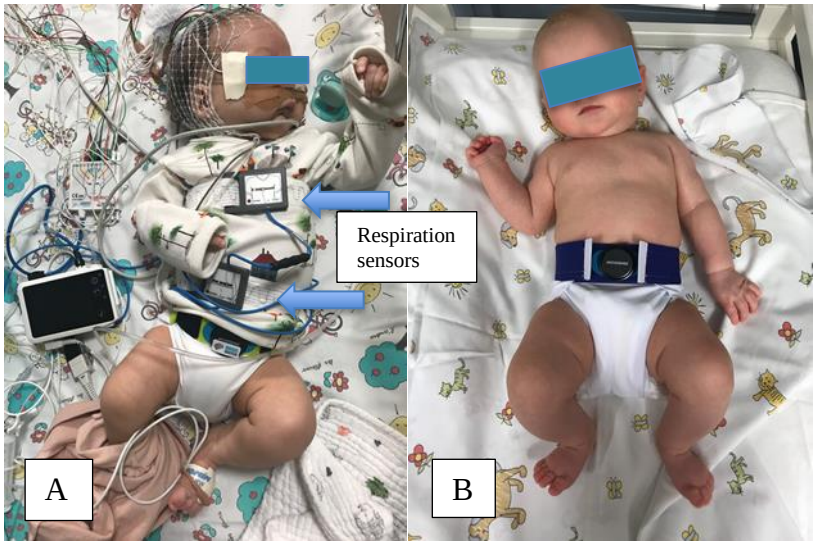

Figure 1. Comparison of the full PSG and sleep pant recordings. A: An infant with the full PSG setup and the sleep pants in tandem. B: Infant wearing the sleep pants only.

PSG is a resource intensive measurement, thus it is only used if a significant medical issue is suspected. The multi parameter study of PSG is justified clinically because severe sleep-related disorders have issues with many of those body functions. However, the majority of infants with parentally reported sleep issues would not benefit from the full PSG setup, and showing the sleep rhythmicity could be possible decently from respiration and/or heart monitoring alone.

3. A NOVEL SLEEP MONITORING PANTS FOR HOME USE

The pants are designed to be worn over the diaper, where the sensor technology is integrated to the waist band. This mobile and wireless system includes the textile ECG electrodes, which require a proper skin contact and the motion sensor, which has to stay close to the abdominal wall, near the belly button. See Figure 1. The gathered data is transmitted in real time via Bluetooth Low Energy (BLE) connection [3, 4] to a custom-scripted mobile app. The pants use Movesense sensor that embeds three tri-axial motion sensors (IMU; accelerometer, gyroscope, magnetometer) and an ECG module [5]. The rationale is that abdominal movement records respiration, and the textile-ECG-sensors monitor heart rate (see Figure 2), which together could allow identifying the sleep states.

Figure 2. Mobile sleep pants with Movesense sensor and textile electrodes. A: skin side and B: the face side. *Images: Natalia Acosta Leinonen.*

The system allows objective sleep rhythm assessment to supplement parent's subjective perception of infant's sleep. In comparison, a PSG study is limited in time to only a few hours, often during day-time sleep, whereas home use sleep pants could readily enable overnight recordings, and even several nights or even weeks in a row. Recording in infant's native environment may bring particular ecological validity that is unavailable in the sleep laboratory.

In the previous literature, mobile monitoring of infant respiration has been done with external sensors, such as optical fibers [6, 7], or monitoring mattress integrated in the bed [8]. The pants' development process applies user centered design approach, focusing on the product user experience. They are simple to set up and adjust to fit on top of diaper without disturbing or limiting spontaneous movements. Our recent work has suggested that combination of linear accelerometer and gyroscope might be very sensitive in observing respiratory and movement changes related to sleep states in the infant [9].

4. USER'S EXPERIENCE OF SLEEP STATE MONITORING

User experience (UX) is understood as a holistic approach to product usability, not only how to get the task done, but it strongly leans on user's emotions, attitudes, perceptions and values occurring before, during and after the use of product. It is a subjective view of utility, ease of use and efficiency influenced by system properties, user itself and context of use. The principle of UX studies is to understand the users' and their relationship, thus, the interaction with product. [10,11].

The infants as product wearers, have no voice of their own. Thus, a parent or nurse as a product dresser must first accept the idea of product feasibility and second, identify its usability for an infant. The user experience of medical doctors instead, relates to their role as a qualified data user. Their key interest is to obtain enough data with sufficient signal quality in order to allow reliable study interpretation.

5. RESULTS

The pants were applied by the parents at home according to instructions given the same day in the hospital, and the actual recordings lasted for at least one overnight period. A second patient series was recorded while the infants underwent a PSG study as a part of their volunteering in another research project. The user experience of the product was conducted by interviewing the parents via questionnaire. The quality and reliability was analyzed from measuring signal quality over time, and as compared to the clinical benchmark, PSG measurement.

5.1 User experience of a product dresser, parent or nurse

Eight users filled in the user experience questionnaire after having used the sleep pants. We asked about the ease of use -aspect, their possible willingness to participate a full week study, and their feelings about infant comfort; if they considered the sleep pants to disturb infant sleep or if they had noted any dents or irritation on infant's skin after use. Their opinions of product outlook and materials were also enquired.

All respondents felt the pants had been easy to use, and they could think of going through a longer study periods as well. None of users had observed any disturbance of infant sleep by the pants. Three of eight user's commented on uncertainty with correct tightness of waist band. *"The thick belt did not feel good, as all the time I needed to think, if it is tight or loose enough to avoid dents on skin."* commented a parent. Notably, no skin dents or lesions could be observed in objective physical exams after pants use. The signal quality in non-invasive skin contact sensors is strongly dependent on proper skin contact to avoid motion artefacts. The appropriate tightness is adjusted with hook-and-loop fasteners on the elastic waist band. One infant had atopic skin and the parent had observed some dents on the skin under the waist band. In addition, one of respondents mentioned about challenges in positioning diaper and pants so that the ECG sensors would still remain in a proper skin contact. As the Movesense sensor is located on the middle of abdomen, one parent speculated, that in case of an older infant sleeping in prone position, the sensor may cause pressure to the abdomen.

The warp knit fabric of the pants is made from polyester elastane blend, which has a high elasticity and fast-drying property. It is smooth and easy-to-clean, but slightly slippery on top of the diaper. Two of eight respondents pointed out that the slippery fabric thrusted against the diaper. All users found overall appearance of the product pleasant.

The results indicate that sleep pants are easy to dress, i.e. use, and they can be worn over longer time periods in infant's home environments. This was expected as the overall design was aimed to mimic the style of ordinary diapers and their pull-up covers. Further development will be needed in the selection of textiles and the shape, which could still be improved to ensure the optimal skin contact, the prerequisite for both movement (respiratory) detection and especially the ECG recordings. For instance, the friction between textile material and diaper could be increased either with laminating additional friction layer on fabric or changing the textile material structure. We acknowledge that the interviewed group size (n=8) is rather low and further user studies are needed, however the findings are supported by the high concordance across the informants.

5.2 User Experience of a Doctor, visually perceived readability of the signal

Here, we show that signal quality does not deteriorate over longer time epochs, and we also show that most of the signal is readily readable. Our mathematical analyses showed that gyroscope signals are able to show respiratory rhythm respectively (see Figure 3). These results suggest that textile electrodes and the Movesense sensor are sensitive and reliable enough for supporting sleep cycle detection in home recordings.

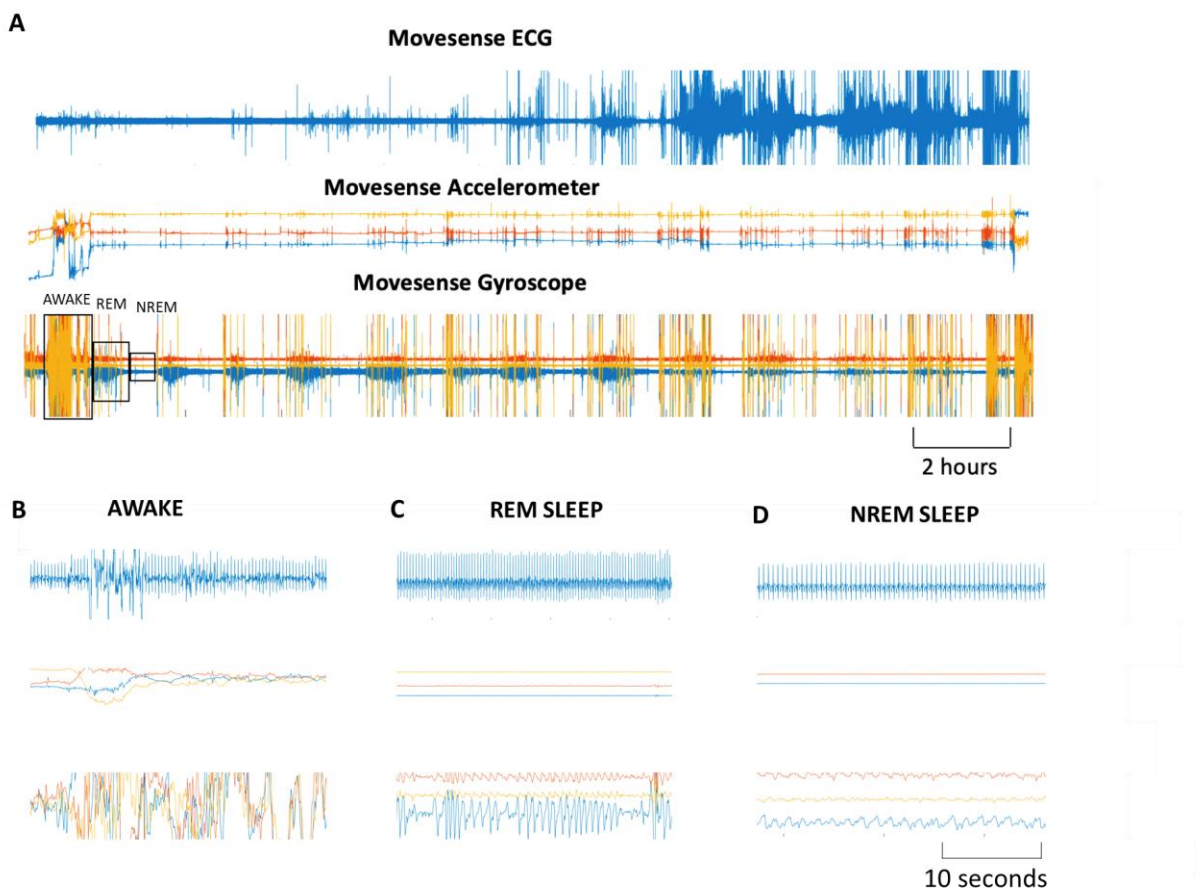

Figure 3. Example of the Movesense signals from an overnight home recording (10.5hrs). A) The individual raw signals from the ACC, GYRO and ECG channels. Awake states and REM & NREM sleep states were identified based on visual analysis of the signals, and the proposed sleep classes are currently the best guess based on experience from co-registered Movesense + PSG studies. B) Outputs of the same signals with shorter time epochs as depicted in the figure labels. Note the robustly different patterns of respiration in different sleep states. [9]

6 DISCUSSIONS AND CONCLUSIONS

The preliminary results indicate that overnight recordings can be performed reliably using the novel wearable system, and that the signals are clear enough to allow putative detection of different sleep states, *NREM, REM, awake.* While this Internet-of-Things (IoT) solution based on smart textiles cannot fully replace the conventional polysomnography conducted in hospitals, it could allow monitoring of sleep rhythmicity with high fidelity. This method is quantitative and objective, and it offers an attractive alternative to the widely employed parent questionnaires that are known to be unreliable. The developed pants are mobile, wireless, and easy-to-use at home in the infant's native environment. However, some details will need further development, such as determining the correct tightness for the sensor contacts, and increasing the friction between fabric and diaper to avoid possible motion artifacts. The monitoring system includes also a mobile application which will benefit from a user center design development as well as user experience studies in the future. The applied electronics raise emotional opinions, beliefs and perceptions, which must be further studied together with clinical validation of product system and long-term product usability and durability in home use. The comprehensive

understanding of user experience in the area is essential. In addition to sleep state monitoring, the sleep detection pants could also be employed for detection of periodic breathing.

7 ACKNOWLEDGEMENTS

This research was supported by the *Academy of Finland Health from Science (TERVA) Academy Program* under Grant 314572 RIB and *the Finnish Brain Foundation* and *the Foundation for Pediatric Research*: Rhythms in Infant Brain: Wearables for Computational Diagnostics and Mobile Monitoring of Treatment.

8 REFERENCES

1. Van Den Hooken, A., Teunis, C.J., Shellhaas, R.A., Pillen, S., Benders, M., Dudlink, J., How to Improve Sleep in a Neonatal Intensive Care Unit: A Systematic Review, *Early Hum. Dev.*, 2017, Oct. No.113, 78-86.
2. Zhu, Z., Liu, T., Li, G., Li, T., Inoue, Y., Wearable sensor systems for infants. *Sensors*, 2015, Vol. 15, 3721-3749
3. Klingeberg, T., Schilling, M., Mobile Wearable Device for Long Term Monitoring of Vital Signs, 2012, Computer Methods program in Biomedicine, Vol. 106, no.2, 89-96.
4. Zhou, C., Tu, C., Tian, J., Feng, J., Gao, Y., Ye, X., A Low Power Miniaturized Monitoring System of Six Human Physiological Parameters Based on Wearable Body Sensor Network, *Sensor Review*, 2015, Vol35, No. 2, 210-218.
5. Movesense [online]. 2019. [Accessed on 12.4.19]. Available at https://www.movesense.com/wp-content/uploads/2017/11/Movesense-Sensor-Datasheet-_-20171109.pdf
6. Ciocchetti, M., Massaroni, C., Saccomandi, P., Caponero, M.A.,Polimadei, A., Formica, D., Schena, E., Smart Textile Based on Fiber Bragg Grating Sensors for Respiratory Monitoring: Design and Preliminary Trials, *Bionsensors*, 2015, No. 5, 602-615.
7. Krehel, M., Schmid, M., Rossi, R.M, Boesel, L.F., Bona, G-L., Scherer, L.J., An Optical Fibre-Based Sensor for Respiratory Monitoring, *Sensors*, 2014, Vol.14, No. 7, 13088-13101
8. Chang, W-Y., Huang, C-C., Chen, C-C., Chang, C-C., Yang, C-L., Design of a Novel Flexible Capacitive Sensing Mattress for Monitoring Sleeping Respiratory, *Sensors*, 2014, Vol.14, No.11, 22021-22038.
9. Acosta Leinonen, N., *Monitoring Infant Respiration and Heart Rate with a Wearable Motion Sensor*. Master's Thesis. Helsinki University, Helsinki (Unpublished), 2019.
10. International Organization for Standardization (2009). *Ergonomics of human system interaction - Part 210: Human-centered design for interactive systems (formerly known as 13407). ISO F±DIS 9241-210:2009.*
11. Law, E., Roto, V., Hassenzahl, M., Vermeeren, A., Kort, J. Understanding, Scoping and Defining User Experience: A Survey Approach. *Proceedings of Human Factors in Computing Systems conference*. CHI'09. Boston, MA, USA, 2009.