Design and Preliminary Evaluation of a Wearable Device for Mass-Screening of Sleep Apnea*

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***Abstract*— Between 7–18 million Americans suffer from sleep disordered breathing (SDB), including those who suffer from obstructive sleep apnea (OSA). Despite this high prevalence and burden of OSA, existing diagnostic techniques remain impractical for widespread screening. In this study, we introduce a new model for OSA screening and describe an at-home wearable sleep mask (named ARAM) that can robustly track the wearers' sleep patterns. This monitoring is achieved using select sensors that enable screening and monitoring in a form-factor that can be easily self-instrumented. Based on feedback from sleep doctors and technicians, we incorporate the most valuable sensors for OSA diagnosis, while maintaining ease-of-use and comfort for the patient. We discuss the results of preliminary field trials, where both our sleep mask and a commercially available device were worn simultaneously to evaluate our device's robustness. Based on these results, we discuss next steps for the design of the screening system, including analyses techniques that would provide more efficient screening than existing systems.**

I. INTRODUCTION

Normal physiological functions, including neurological and cardiovascular function, rely critically on adequate sleep duration and quality [1]. One of the most prevalent sleep disorders, sleep disordered breathing (SDB), is associated with mood disorders including depression, as well as chronic diseases such as hypertension, diabetes, heart failure, and stroke [2], [3]. According to the National Commission on Sleep Disorders Research, SDB affects 7-18 million adults in the US. SDB comprises disorders characterized by abnormalities in respiratory pattern (cessation of breathing) or ventilation (obstruction of airflow), with obstructive sleep apnea (OSA) being the most common disorder. Given this prevalence, the economic impact of OSA is substantial, estimated at $10 billion annually in direct costs alone [4].

The current gold standard for OSA detection is overnight polysomnography (PSG), which is an exam typically conducted in a hospital or sleep testing facility. Additional options for at-home sleep testing are also available, however they still require the support of a trained technician at the residence of the patient. A typical PSG includes at least 12 channels, of which few channels are critical in determining the most common OSA cases.

To reduce complexity, discomfort, and cost of screening, a number of medical device companies have created PSG devices that incorporate a smaller number of channels for at-home diagnosis of OSA [5], [6], [7], [8]. Additionally, there have been specific efforts to implement unobtrusive sleep apnea diagnostic devices such as non-contact Doppler radar [9], pressure sensors arrays embedded within a mattress [10], ballistocardiography [11], and finger-based pulse-oximetry devices [12]. However, many at-home devices offer poorer diagnostic quality and patients do not always prefer them to lab-based PSGs [13]. Furthermore, many of these devices still require a trained technician to install and analyze the data and do not always offer the same quality of data as a full overnight PSG, in many cases because of their indirect measures of respiration. As such, they are not designed for multiple nights of monitoring to help screen with statistically valuable amounts of data, nor do they offer ways for patients to longitudinally monitor their condition as they seek behavior improvements during treatment.

In order to address these problems, we consider a new model for OSA screening built around a simplified screening device embedded in a sleep mask. Within our model, a simplified, patient-operated device designed for its efficacy in screening and longitudinal monitoring could perform individual screening at home. While less detailed than a full PSG, the data collected overnight by this sensory mask would provide a determination of a patients OSA risk on a three-tiered system: not at risk, mild, severe. This simplified screening system would provide an effective framework that can clear those who are not at risk without imposing the costs or time commitment of a full PSG. While the data collected would not provide the same breadth as PSGs performed in a sleep lab, the ability to robustly collect the same signals night after night would provide valuable indicators of progress if the appropriate sensors are chosen.

In this paper, we evaluate the performance of such a device, named ARAM: Apnea & Rest Analysis Mask, in its first stage of design. We focus on the comfort, ease-of-use, and signal-quality of a custom-built, at-home, OSA screening device for use without a trained physician. We compare the installation process and measurement quality of our device to those of existing screening solutions as a preliminary stage in developing a broader platform for mass-screening and monitoring of OSA.

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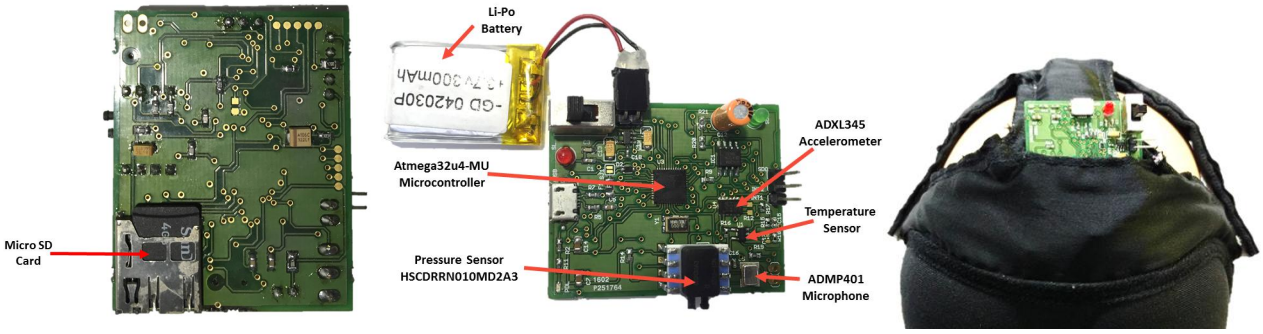

Fig. 1. *ARAM's* Custom built PCBs. (Left) Back of the PCB including the MicroSD card slot. (Middle) Front of the PCB including all sensors and battery. (Right) The entire circuit was housed inside the cloth pocket at the top of the ARAM mask.

II. Materials and Methods

A. Sensor Selection and Implementation

Our screening device is a sleep mask with embedded sensors that can track a users respiratory activity and motion throughout the night. The sensors were chosen based on discussions with sleep clinicians and technicians. Through these discussions, we identified a core group of signals that are used when (manually) making OSA diagnoses in sleep labs. These core signals include air pressure, respiration rate, and pulse oxygenation.

Of these signals, those that lent themselves to the most straightforward integration into our sleep mask were air flow (measured by air temperature fluctuations), nasal air pressure, and actigraphy (motion). We also include a microphone on the mask to measure ambient noise levels throughout the night. Although pulse oxygenation is often used as an important marker to detect OSA events, we decided not to include a pulse oximeter because of difficulties with proper skin contact in the current form factor.

The sensors that we chose can be broken into two categories of physiological monitoring: respiratory activity (airflow and nasal air pressure) and sleep behavior (motion and noise). The respiratory sensors directly indicate abnormalities and cessations in airflow through a simple nasal cannula. The microphone records patient snoring and ambient noise. The accelerometer measurements can be used to infer sleep stage through movement as well as the orientation of the wearer. Our ultimate goal is for these sensors to be analyzed together to provide a more detailed picture of a patients sleep, e.g. when they are aroused from sleep because of loud external noises as opposed to an apneic event. This way, we expect to be able to classify the wearer into a screening category.

The sensors are integrated into a sleep mask that consists of four parts: an eye-cover, an electronics pocket, an overhead strap, and a rear strap. The mask is made of padded cotton-polyester fabric sewn onto a set of polyester straps. The straps fasten with Velcro in order to hold the system in place during sleep, while remaining adjustable for different patients' use. For a measurement, the patient puts on the mask, fastens the straps, and toggles a switch to begin recording.

A custom-built PCB collects sensor data, uses an on-board timer to timestamp each measurement, and then saves the data to the internal SD card. As shown in Fig. 1 the PCB includes subsystems for sensing, power regulation, operating status indication, and data storage. Pressure data is collected using a pressure sensor and thermistor (Pressure Sensor HSCDRRN010MD2A3), actigraphy from an accelerometer (ADZL345), and ambient noise from an on-board microphone (ADMB401). The cannula routes air from the patient's nose and mouth up into the thermistor and pressure sensor. The data is saved onto an on-board SD card in a custom timestamp-value format, which can be readily converted into the standard PSG data format (EDF+) [14]. The storage (4 GB) and battery (300 mAh) capacities are designed to last for two nights without needing to be recharged or cleared of the data.

Fig. 2. *ARAM's* cloth housing including Velcro straps around the patient's head. The device is designed to look and feel like a sleep mask so as to simplify installation for the patient, while still offering secure support for the sensors and cannula.

B. Data Collection Procedure

In order to evaluate the performance of our device (ARAM), clinicians at a collaborating college performed field trials with the device[1]. Participants ranged from 44-70 years old, and all were identified as 'at risk' for OSA by a physician. Our prototype was tested alongside an FDA-approved at-home diagnostic device, the ResMed ApneaLink Air [15]. The two devices were worn simultaneously: the ARAM device worn on the head, and the ResMed device strapped to the chest during sleep. Because both devices monitor air flow using a

[1]This study was approved by the ethical review board of K.J. Somaiya Medical College (IRB Title "ARAM – Sleep Apnoea Measurement").

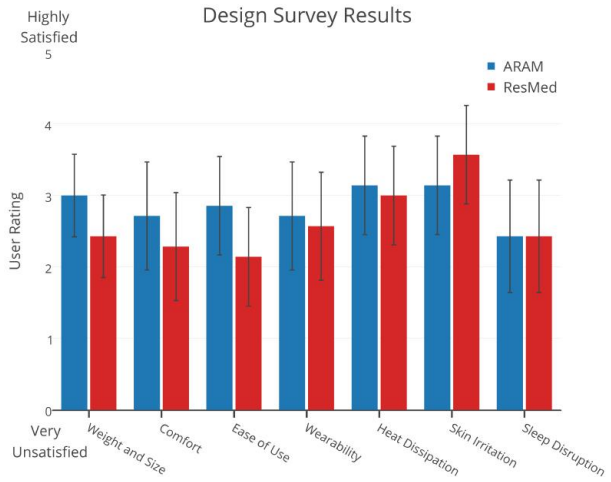

Fig. 3. *ARAM's* Results of the design survey designed to evaluate patient comfort using the ResMed device versus our ARAM device.

nasal cannula, the two cannulas were bound together before and worn by the patient.

Although some of the ResMed measurements cannot be directly compared to the ARAM device, their measurements can be used for both automated and manual OSA labeling, which can in turn be used to infer the meaning of certain trends in the ARAM sensor data. In future work, we plan to validate the effectiveness of our solution by comparing it to the diagnosis from the ResMed device's own sensor suite.

III. Evaluation Procedure

To evaluate the device design, we sought participant feedback via a survey after each of our clinical tests. The survey asked users to compare the ARAM device with the ResMed device in 7 key areas: (1) weight and size, (2) general comfort, (3) ease to put on, (4) ease to wear, (5) discomfort from heat dissipation, (6) skin irritation (mask material selection), and (7) disturbance to sleep. Participants rated each metric on a scale of 1-5, 1 indicating poor performance or extreme dissatisfaction, 5 indicating exceptional performance or satisfaction, and 3 indicating an average performance or satisfaction. Although we had a limited number of participants able to test both devices (N=6), their feedback in these areas provides useful guidance for future iterations of such a device design and for this preliminary evaluation.

In order to quantitatively assess whether our device can detect OSA events, we compare the pressure sensor readouts for the ARAM device with those of the ResMed device. In this preliminary evaluation, we focus on the pressure sensor data because both devices collect similar measurements and airflow was identified as one of the most valuable measurements to indicate OSA events. In future work, we plan to analyze the accelerometer data for qualitative evaluation of sleep stage and body position.

Direct comparison of the pressure sensor readings is complicated by the lack of direct time-synchronization between the two devices, as well as the differences in sensor calibration, recording and processing. However, because the pressure sensors are used to identify changes and cessation in respiration, we focus on the frequency content of the pressure signals using a short-time windowed Fourier-transform (spectrogram), with a 60 sec window. This approach allows us to track how a patient's respiratory rate changes with time. Additionally, if breathing ceases briefly (functionally resembling a step function), we should see a large spike in the frequency domain data followed by a temporal period with no significant pressure frequency content. By comparing the spectrograms of the two diagnostic systems, we evaluate how well the ARAM device can track changes in respiration for efficacy in OSA screening.

IV. Results, Analysis & Discussion

A. Design Feedback

The results of the user survey (shown in Fig. 3) generally indicate that the simplicity of our device improves the user experience for patients. Across most of the metrics we focused on, our device outperformed the ResMed device. Users consistently preferred the size, weight, feel, and ease-of-use of the ARAM device. One area where we were consistently rated below the ResMed device was on our mask material selection, given by the lower experience due to minor skin irritation because of thickness of the material.

Moving forward, mask materials will be selected for better skin compatibility, in order to not irritate a users skin due to friction or material allergies. Additionally, the impact of the device on sleep can be reduced by streamlining the design and incorporating flexible circuitry to reduce the devices presence on the users head. This improvement will also reduce the size and weight of the device, and should increase comfort.

B. Sensor Performance

As preliminary tests, we evaluate how well our device would able to identify an OSA event using only the pressure sensor readings (see Fig. 4). Since the ResMed device is an approved diagnostic device, our assumption is that if we can track the same respiratory behavior as the ResMed device, then our device can be used to evaluate airflow-dominated OSA events as well as the ResMed device.

In some of our tests, the ARAM pressure sensor stopped recording data in the middle of the night because the cannula came off of the user overnight. This failure represents an important design issue that will be addressed in future iterations of the device. In other tests, both air devices lost air-flow signals, presumably because of changes in patient posture. In the following analysis, we analyze two patients.

We focus on how the frequency content of the pressure measurement evolved throughout the night, as plotted in the spectrograms in Figure 4. Time through the night progresses along the x-axis, and the signals frequency content increases along the y-axis. Color represents the spectral power density at a given frequency and time.

A number of similarities and differences can be identified in the spectra of Fig. 4. It is apparent that power in the ARAM spectra is more widely distributed, indicating a lower signal to noise ratio. The slightly different color scales on

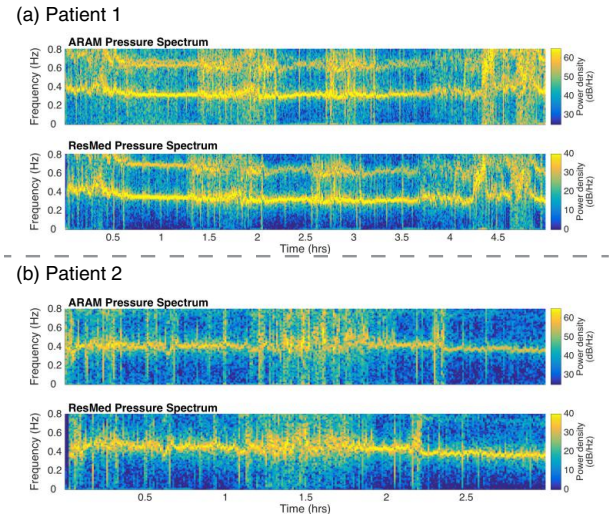

Fig. 4. Spectrograms showing the evolution of the respiratory signal throughout parts of the night for two different patients in our clinical trials. The same was observed in all patients but only two representative spectrograms were chosen for this figure in the interest of preventing redundancy.

the two plots can be explained because data acquisition and processing differences between the devices. An offset in times also appears between the graphs, which arose because the ResMed device was turned on before the ARAM device.

Despite these minor inconsistencies between the two measurements, the structure of the spectrograms look remarkably similar for both devices.The respiratory signal appears strongest around 0.4 Hz in both patients, exhibiting small fluctuations in this frequency throughout the night. The same respiratory events are apparent in the ARAM data as the ResMed data. For example, in Patient 2, the respiratory frequency suddenly drops just after 0.5 hrs. Additionally, both the ARAM and ResMed devices similarly track the sudden and prolonged periods of more variable respiratory activity for both patients ($\sim$4.5 hrs for patient 1; $\sim$1.5 hrs for patient 2). In addition to large changes in respiration rate, both devices similarly track small fluctuations in respiration, such as those from 2.25 hrs onward in Patient 2. All of these examples indicate that different kinds of changes in respiratory patterns can be adequately picked up by the ARAM device.

Ultimately, full verification of the devices efficacy requires observation and categorization of OSA events. However, these preliminary similarities in the data indicate that our device should perform comparably to the ResMed device for events that manifest in the respiratory signal.

V. Conclusions

In this paper, we presented ARAM, a new self-administered device for at-home OSA screening and longitudinal monitoring. We evaluated the design of our device, as well as the ability of our pressure sensor to capture the same respiratory events as a clinically-approved OSA diagnostic device. In the next iterations of the device, we aim to improve the mechanical design and ease of use, as well as automate data analysis and screening so that the device can be evaluated in larger screening studies. When used together with survey-based evaluations (as discussed by [16]), devices like ARAM may offer a much lower-cost and more accessible device for mass-screening of OSA because of their simplicity [7].

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