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AT-HOME ASSESSMENT OF USABILITY AND DATA COLLECTION FROM A WEARABLE BIOELECTRONIC MONITORING DEVICE

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ABSTRACT

Development of wearable devices that are easy to use and comfortable for the wearer enhances their ability to be used in settings where clinical management and support is limited, such as rural communities. This study gathered data that measured the usability of a multimodal wearable bioelectronic device to reliably and accurately monitor vital signs in real time. The participants (n=13) reported that the device was comfortable and adhered well during a 24-hour period, as well as easy to put on. Feedback was also collected to understand how the device might be improved, and participants shared concerns over the ability to expose the device to water (bathing, perspiration related to exercise), the size of the device, and ability to sleep wearing the device. Participant responses were consistent across collection methods (text survey during the 24 hour study period, follow-up paper survey, and follow-up phone survey). These results will inform the continued development and refinement of the device to enhance participant comfort to increase the feasibility of long-term remote management of chronic disease conditions, resulting in improved health outcomes, reduced costs, and improved quality-of-life.

Keywords: Wearable electronics, remote monitoring, whole person health

1. INTRODUCTION

Wearable devices are increasingly used for early detection and prevention of disease and illness [1]. Continuous, real-time monitoring of biometric measures such as heart rate, blood oxygenation, airflow, and gait can support enhanced performance of these wearable devices [2]. While portable medical monitoring devices are available, many existing devices are cumbersome to apply or manipulate, are perceived as bulky [3], or are unable to transmit data in real-time, resulting in diagnostic delays [4]. More recently, smart watches, such as the Apple Watch (Series 4), can check heart rhythms for irregularities. However, these devices are not suited for continuous monitoring and recording occurs at the wrist, resulting in poor quality ECGs and misinterpretations [5,6]. Despite strong evidence that early diagnosis and treatment is effective in reducing morbidity and hospitalization [7], the lack of validated wearable technologies that can continuously measure clinical data and track health status prevents remote assessment and prompt diagnosis [8]. This gap impedes the development of inexpensive and reliable tools to continuously monitor vital signs, detect abnormalities, and track treatments. Significant challenges exist to enable remote, in-home

continuous measurement of high-quality clinical data that promises early, more predictive diagnosis and personalized interventions [9]. Further, studies suggest that comfort and usability is associated with wearer compliance especially in non-clinical or remote settings [5,7,10]. The goal of this study was to gather data that would support the development of a soft wearable bioelectronic device to reliably and accurately measure clinical data that would continuously monitor vital signs and activity, detect physiological and metabolic changes, and track treatments in real time. Such a system would enhance capacity for remote management of chronic disease conditions resulting in improved clinical outcomes, reduced costs, and improved quality-of-life [9].

2. MATERIALS AND METHODS

Participants were recruited via posted signage on a local University campus. Participants were screened and consented before enrollment. Eligible subjects were required to meet the following inclusion criteria: able to walk freely within their home, free from any musculoskeletal or cardiac pathology that significantly affects gait, and free of any skin conditions that could be aggravated from wearing the device. Exclusion criteria included having a body mass index (BMI) greater than 35 kg-m^2 or having back or lower extremity injury or surgery, and neurological, musculoskeletal, or metabolic disease that may affect walking patterns. Participants with self-reported cardiac disease, sensitivities to adhesives, existing implantable medical device(s), and volunteers who are pregnant were also excluded. Potential subjects with any self-reported cardiac disease or any implantable medical device(s) were also excluded from the study.

A subject was considered to have withdrawn from the study if they decided not to wear the device for the full 24-hours for reasons that do not deal with the device (e.g. it does not match their outfit, if visible), or if they didn't respond to 2 text message prompts in a row (i.e. 8 hours without a response). Data collected from text surveys would still be used in the study if subjects did not complete the feedback form or telephone interview.

2.1 Device

The wearable device incorporates a 1) system-on-a-chip module with Arm Cortex processor and Bluetooth low-energy 5 transceiver for signal processing and data communication, 2) non-volatile flash data storage, 3) rechargeable battery, power regulation, and battery management circuit, 4) fit-for-purpose sensors including an electrocardiogram, three-axis accelerometer, and digital temperature sensor to continuously measure physiological and activity signals to access whole person health, and 5) a real-time clock with temperature compensated crystal oscillator to provide an ultra-accurate clock reference with time zone offset. The device is adhered to the skin using commercially available long-term electrocardiogram electrodes (EL502, BioPac Systems Inc.) that snap into the wearable device and are disposed after use. Data is collected from the sensors at a frequency of 200 Hz, secured on the wearable device using 128-bit AES encryption, and then stored locally until downloaded upon return.

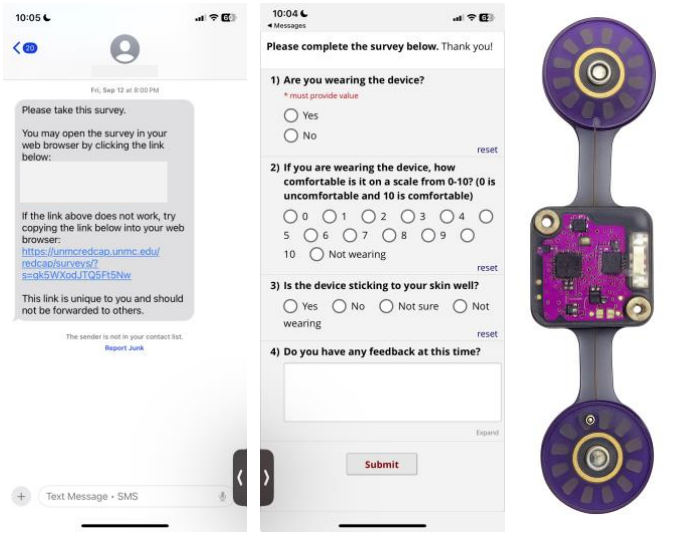
Devices were assembled and prepared, including inspection and testing for functionality by turning the device on and validating data collection from both sensors prior to being cleared for deployment in the study. Devices were issued a serial number for record keeping.

2.2 Study Design

After participant consent and eligibility was confirmed, a device was given to the subject with instructions on use and contact information. Subjects were instructed to wear the device for 24-hours after applying the device, usually immediately after enrollment. Subjects were also added to the RedCap survey tool using their cell phone number, and a test text message was sent to confirm receipt ability at the enrollment appointment. Participants were sent 4 text messages via RedCap during the 24-hour period they were instructed to wear the device at the following times: 8:00AM, 12:00pm, 4:00pm, and 8:00pm. The first message time depended on the enrollment appointment time (i.e. if a participant received their device at 10:00am, their first text would be at 12:00pm, with the remaining following at 4:00pm, 8:00pm, and 8:00am the next day). The RedCap survey asked if the participant was (1) wearing the device, (2) if it was comfortable, (3) if it was sticking to their skin well, and (4) if there was additional feedback. An example of the text message used to solicit survey responses as well as the survey itself are shown in Figure 1. The text survey was used to collect data from the participant and as a reminder to wear the device during the 24-hour period. Upon completion of the 24-hour data collection, participants received an email invitation to complete a feedback form regarding their experience as well as a reminder to drop off their device at the designated spot. If desired by the subject, they were also invited to schedule a time with the study coordinator to give feedback on their experience via phone call/Zoom. After use, devices were decontaminated with PDI Q55172 Super Sani Cloth Germicidal Disinfecting Wipes according to the instructions on the product. Devices were cleared of data and then re-charged for next use in the study.

2.3 Data Management

Data from surveys distributed via text message was stored on the University of Nebraska Medical Center RedCap system for collection. Once the devices were returned, the study coordinator removed mini-SD card from the devices and downloaded the data to a secure cloud environment for shared team collaboration. Additional data (written form feedback, phone/Zoom call feedback, and contact information for participants) was stored on a separate secure cloud server by the study coordinator.



(a) (b) (c)

FIGURE 1: (A) SURVEY TEXT INVITATION EXAMPLE. PARTICIPANTS RECEIVED THIS TEXT WITH A LINK TO COMPLETE A SURVEY ABOUT DEVICE COMFORT. (B) THE SURVEY PRESENTED WHEN CLICKING THE LINK ASKS THE PARTICIPANT ABOUT DEVICE COMFORT AND ADHESION IF THEY ARE WEARING IT AT THE TIME OF COMPLETION. (C) A PICTURE OF THE DEVICE.

3. RESULTS AND DISCUSSION

A total of 14 subjects were enrolled in the study. One subject withdrew via failure to respond to 2 consecutive survey texts (Subject 3). All other subjects successfully completed the study. One objective of the study was to measure the comfort of the device over the 4 timepoints while the subject was wearing it. To measure this, we used data collected from the text survey question "*If you are wearing the device, how comfortable is it on a scale from 0 to 10? (where 0 is uncomfortable and 10 is very comfortable)*". Subjects reported the device as comfortable across all timepoints; with average values for each of the timepoints during the 24-hour period at or above a score of 8 and median at or above a score of 9. Data is shown in Table 1 and Figure 2. Responses in Figure 2 are plotted relevant to their initial survey submitted during the consent process (i.e. if a participant was consented at 11:00am, their first survey for comfort would be received at 12:00pm. If a participant consented at 12:15pm, their first survey for comfort would be received at 4:00pm). Some participants missed a survey but then completed it much later, closer to the next scheduled survey (ex. Subject 5, surveys 3 and 4). Others completed surveys late (Subject 6). Subject 2 completed their initial survey and then submitted their first survey 5 within 10 minutes of the consent survey.

TABLE 1: COMFORT LEVEL RATINGS. WITHDRAWN PARTICIPANT DATA FOR SUBJECT 3 NOT SHOWN.

	Device Comfort Response (0=Uncomfortable, 10=Comfortable)			
Subject	Survey 1	Survey 2	Survey 3	Survey 4
1	N/a	9	7	8
2	9	7	10	10
4	10	10	10	10
5	10	10	10	10
6	N/a	8	9	7
7	9	10	10	10
8	9	10	9	7
9	10	10	10	10
10	5	4	4	5
11	9	9	10	10
12	10	10	9	10
13	9	9	9	10
14	8	9	7	8
MEAN	**8.91**	**8.93**	**8.77**	**8.85**
MED	**9**	**9.5**	**9**	**10**
MIN	**5**	**4**	**4**	**5**
MAX	**10**	**10**	**10**	**10**

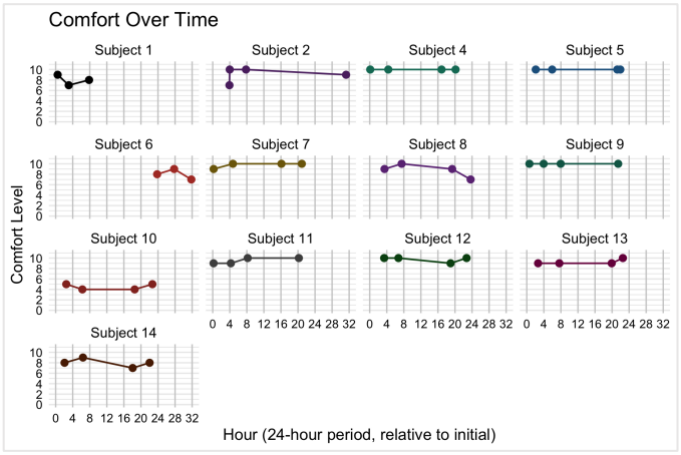


FIGURE 2: COMFORT OVER TIME BY PARTICIPANT IN THE 24 HOUR STUDY PERIOD.

Another metric of device usability was a record of whether the device was being worn when participants received a text survey (Table 2) and whether it was adhered well (Table 3). Subjects were asked to wear the device for an entire 24-hour period, only removing it to bathe. Subjects did report removing the device during workouts or physical activity due to device discomfort or concerns about it falling off. Other subjects reported being unable to sleep wearing the device.

TABLE 2: SUMMARY OF RESPONSES TO "*ARE YOU CURRENTLY WEARING THE DEVICE?"*. ONE PARTICIPANT REPORTED THAT THEY WERE NOT CURRENTLY WEARING THE DEVICE BUT ALSO REPORTED A NON-ZERO DEVICE COMFORT RATING AND THAT THE DEVICE WAS STICKING WELL. THIS COULD BE AN ERROR IN SURVEY INPUT OR REPORT OF PERCEIVED COMFORT AND DEVICE ADHESION DURING PRIOR WEAR.

	Text Survey 1	Text Survey 2	Text Survey 3	Text Survey 4
Yes	10 (77%)	13 (100%)	13 (100%)	12 (92%)
No	3 (23%)	0	0	0
Incomplete	0	0	0	1 (8%)

TABLE 3: SUMMARY OF RESPONSES TO "*IS THE DEVICE STICKING WELL?"* ONE PARTICIPANT DID NOT RESPOND TO TEXT SURVEY 4.

	Text Survey 1	Text Survey 2	Text Survey 3	Text Survey 4
Yes	11 (85%)	12 (93%)	12 (93%)	12 (100%)
No	0	1 (7%)	0	0
Not Sure	0	0	1 (7%)	0
Not Wearing	2 (15%)	0	0	0

While the device was worn at the time of the RedCap survey, text survey feedback indicated that subjects did remove the device at other times due to discomfort, especially during sleep:

- "I couldn't fall asleep with the device on me, so I removed it around 11pm. It was difficult to remove the device, it stuck so well. After removing, I am seeing a little redness and experiencing itchiness."
- "I felt skin stretching while I was sleeping. So I had to remove it (at) midnight"
- "Movement during sleep caused device to detach one of the adhesive strips"
- "When I sleep on the side it's kind of uncomfortable"
- "Other than sleeping it's comfortable you can't even notice it"

3.1 Follow-Up Paper Questionnaire

Feedback from the follow-up paper questionnaire was collected from 8 out of 13 participants and was similar to the comments recorded from the RedCap surveys. Participants found the device easy to put on. They were asked *"How easy was it to put the device on yourself?" on a scale from 0 (Very easy) to 10 (I required assistance every day)* and responses included: Average 0.375, Median 0.0, Minimum 0, Maximum 2 with all 8 participants recording values. Participants varied in their awareness of the device during the study period when asked *"Once the device was on, how often did you notice you were wearing the device?" with a scale from 0 (I never noticed the device) to 10 (I constantly noticed the device)*. For all 8 participants, Average score for this response was 4.375, Median was 4, Minimum was 0 and Maximum was 9. We also asked participants if they had any problems with the device that were not reported. Seven respondents reported No, and one respondent reported they had problems with the electrode adhesive (with no additional information given). When asked about improvements that could be made to the device, three respondents reported "None", two reported that reduction in size of the device would increase its comfort, two reported that making the device waterproof or sweat resistant would be an improvement, and another reported that making the device more comfortable for sleep would be an improvement. These feedback improvements echo findings of other usability/wearability studies [11,12].

3.2 Follow-Up Phone Call

Feedback from 7 out of 13 participants was collected via phone or Zoom call based on participant preference. The feedback was similar to the comments from the RedCap surveys. Six out of seven (85.7%) of participants reported a positive overall experience with the device ("*What was your overall impression of the device?*") and all participants to the phone follow-up reported that the device was easy to put on and easy to use. Two of the seven reported minor skin redness/irritation ("*Did the device cause skin itchiness, redness, or irritation*?") and one reported that the device was uncomfortable during the 24-hour period of wear. Five of the phone call follow-up participants (71%) reported being able to sleep with the device on. Of the remaining two respondents, one reported being able to fall asleep after some trouble with finding a comfortable sleeping position. The last respondent reported no issues.

Finally, we asked participants in the follow-up phone call if they had any additional feedback to improve the device: two reported no feedback (28.5%), and the remaining 5 recommended:

- Making the device waterproof
- Changing the location of wear or reducing the number of electrodes needed (also found in [13])
- The device was uncomfortable on larger breasts
- LED flashing on the device was distracting
- Reducing the overall size of the device

4. CONCLUSION

This study aimed to collect data on the usability and comfort of a soft wearable device to be worn at home during a 24-hour period from n=13 participants. Participants wore the device as tolerated through a 24-hour study period where they were contacted four times via text message survey to ask about the device comfort, adhesiveness, and additional feedback, as well as optional follow-up surveys via paper and phone. Generally, participants reported the device as comfortable with limited discomfort other than minor skin irritation, sleeping, and bathing/exercising. These results suggest that development and refinement of the device could be used to enhance participant comfort and ultimately compliance when wearing the device for clinical management and decision support.

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