

Communication

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A Novel Shoulder-Mounted Pulse Oximeter in Patients with Suspected Sleep Apnea: Design and Patient Perceptions

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Highlights

- Shoulder-based monitoring may be a feasible form factor to use for pulse oximetry
- Shoulder-based pulse oximetry is more comfortable than traditional finger-based pulse oximetry

What are the main findings?

- Shoulder-based pulse oximetry results in decreased noisy data compared to traditional finger-based pulse oximetry
- Shoulder-based pulse oximetry is more comfortable than traditional finger-based pulse oximetry, resulting in fewer device removals and decreased self-reported sleep disruption.

What is the implication of the main finding?

- New medical devices targeting the shoulder for respiratory monitoring in sleep-disordered breathing patients will be well received by patients
- It is feasible to get high accuracy from shoulder mounted devices

Abstract

The shoulder may be an effective central site for continuous oxygen saturation (SpO₂) monitoring but studies of shoulder-mounted pulse oximetry technology are limited. We hypothesized that a shoulder-based biosensor device would be similar in function and user acceptance to a standard FDA-cleared finger-based pulse oximeter. We conducted a quantitative and descriptive pilot study of two prototype biosensor designs in patients with clinical suspicion of hypoxic episodes at an outpatient sleep center. Participants wore two prototype biosensors—the first a shoulder-mounted adhesive and the second a combination ring-bracelet—in addition to a control FDA-approved finger-based pulse oximeter. We assessed SpO₂ agreement among the devices as well as the comfort of the devices based on a survey. We monitored 27 patients during an overnight polysomnography study. The prototype shoulder pulse oximeter SpO₂ readings agreed with the control values of the commercial finger-based pulse oximeter with a 0.72% mean absolute error. Participants rated the shoulder-mounted device more highly than the control device on a Likert-scale survey of comfort (4.6 out of 5 versus 3.1 out of 5). Open-ended questionnaires showed that the two major criticisms of the control and ring devices were devices falling off and disruption to sleep while only one participant commented on the shoulder device, specifically. This study confirms that alternative configurations for SpO₂ monitoring offer potential as accurate and well-tolerated devices. Problems with traditional pulse oximetry, such as false readings of hypoxia due to device removal or noisy data, were encountered less frequently in shoulder-mounted pulse oximetry than in the commercial finger-based device. Future directions include studies of additional populations that are at risk of

respiratory collapse and surveys to elicit specific feedback on the configurations, whether positive or negative.

Keywords: pulse oximetry; wearable biosensors; user acceptance; sleep apnea; respiratory monitoring

1. Introduction

Introduction

Wearable continuous monitors technologies are increasingly common in healthcare [1,2]. Continuous pulse oximetry would benefit several high risk populations including patients with chronic lung disease, sleep-disordered breathing, and patients with active opioid use [3–5]. Conventional pulse oximeters limit use of the hands, but alternate pulse oximeter probe sites range from the forehead to the toes sometimes with smartphone interface [6–10]. Motion artifacts in ambulatory patients limit accuracy, potentially resulting in delayed detection of hypoxemia [1,11]. Wearable biosensor technologies in the outpatient setting must be designed with user acceptability, device effectiveness, and hold the potential for additional features such as integrated respiratory monitoring [4,12,13].

Studies of shoulder-mounted pulse oximetry technology are limited [14,15]. Our group developed a shoulder-mounted device with a high level of acceptability in certain populations [16]. We sought to investigate the feasibility and acceptability of a shoulder-based pulse oximeter among a convenience cohort undergoing diagnostic polysomnography.

2. Materials and Methods

We conducted a quantitative and descriptive pilot of two prototype biosensor designs at the Penn Sleep Medicine Diagnostic Program, an outpatient sleep center in Philadelphia, Pennsylvania, USA. The study protocol was approved by the University of Pennsylvania IRB and was performed in compliance with relevant laws and institutional guidelines. Inclusion criteria included clinical suspicion for sleep-disordered breathing and age >21. Exclusion criteria included pregnancy.

Patients wore a standard pulse oximeter (EMAY EMO-80 Sleep Oxygen Monitor, Figure 1a) and two prototype biosensors: Prototype-ring (Figure 1b) and Prototype-shoulder (Figure 1c). Prototype-ring (Figure 1b) consisted of a ring worn on the index finger to assess oxygen saturation as well as a wristband containing a battery and data storage hardware. Prototype-shoulder (Figure 1c) was an adhesive armband worn over the deltoid.

We assessed the prototypes based on FDA guidelines for pulse oximeters [18]. We trained the model using an 80-20 train-test split on a 5-fold cross validation. We then tested the R2 score, mean absolute error, and standard deviation of the mean absolute error to ensure the model was not overfit (Supplemental Methods). No adjustments were made for known confounders such as skin tone, positioning, or sleep stage. We also evaluated the comfort via a 5-point Likert scale and an open-ended qualitative questionnaire. Independent patient-level variables included demographics and participant BMI. Differences in mean results were assessed with a two-sided t-test with alpha 0.05.

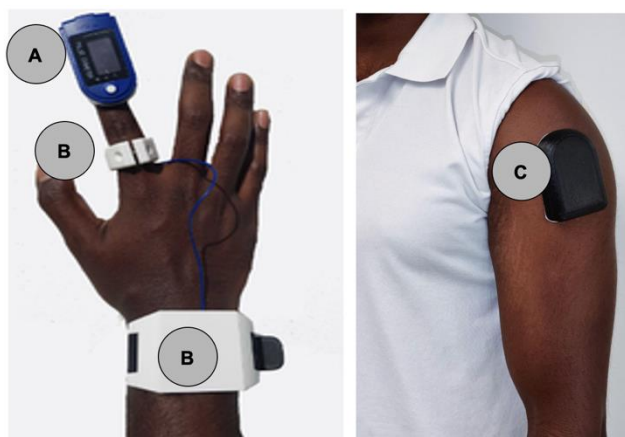


Figure 1. A) Commercial pulse oximeter control B) Prototype-Ring configuration C) Prototype-Shoulder configuration.

3. Results

3.1. Study Participants

Participant demographic information is described in Table 1. The patients sampled were majority white (57.1%) and male (58.3%). Participants had a median BMI of 28.5 (IQR 26.5 - 35.1). Participant demographics are described in Table 1. The patients sampled were majority white (57.1%) and male (58.3%). Participants had a median BMI of 28.5 (IQR 26.5 - 35.1). A consort diagram is shown in Figure 2. Data from the shoulder was unusable for 3 patients due to corrupted data files (2) and SD card unavailability (1). The FDA cleared control device had 8 patients with unusable data. All patients with interpretable finger pulse oximetry data had interpretable shoulder-mounted data.

Agreement among the 19 patients with data from both devices is shown in Figure 3. The Prototype-shoulder pulse oximeter had a 0.72% mean absolute error from the control values of the commercial finger-based pulse oximeter (Figure 3). Participants removed the prototype 0 times, and the control device a mean 4.6 (sd 3.7) times (Figure 4a), and the time removed is shown in Figure 4b. 5 point Likert Scale feedback on comfort showed a mean rating of 4.6 for the shoulder, 4.5 for the ring and 3.1 for the finger mounted control (Figure 5). Both the shoulder and ring were rated higher than the control de-vice ($p < 0.01$).

Themes were identified in open-ended questions regarding the comfort or fit of the study-provided devices: Many participants reported that their control devices fell off either before falling asleep or during the night. One participant noted that the finger-based “commercial device came off a few times before sleeping” which caused “restless sleep”. Several participants also noted that the control devices either fell off or were purposefully re-moved throughout the night. Participants cited irritation, fit, and using the restroom as reasons for control device removal. One person noted that the wristband portion of the Prototype-ring fell off in the middle of the night. None complained of comfort worsened by the shoulder mounted device. Several participants complained that one or multiple devices disrupted their sleep. These devices included the Prototype-ring and commercial pulse oximeter. Tightness of fit was the most commonly problematic factor among these devices. One participant specifically cited the plastic shell that encased the data hardware in Prototype-ring as causing pain. Other participants removed the control device due to discomfort of a “burning sensation” or complaints that the device “was getting hot.” There was only one participant who specifically commented on Prototype-shoulder. This person stated that they slept on their side but there was “not much movement [to the device] while sleeping.”

Table 1. Patient demographic information.

Age [median (IQR)]	55 (38.5 - 69.5)
Male (%)	58.3
Race (%)	
White	59.3
Black	29.6
Asian	7.4
Native Indian/Native Hawaiian/Other	0
BMI [median (IQR)]	28.5 (26.5, 35.1)

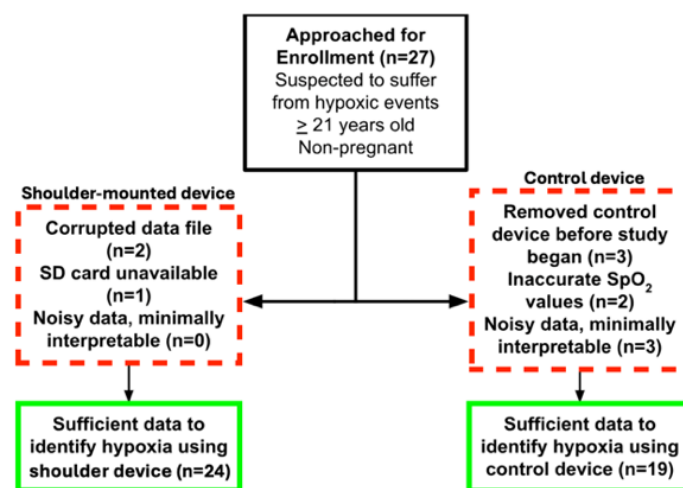


Figure 2. Proportion of devices with sufficient data to identify hypoxia.

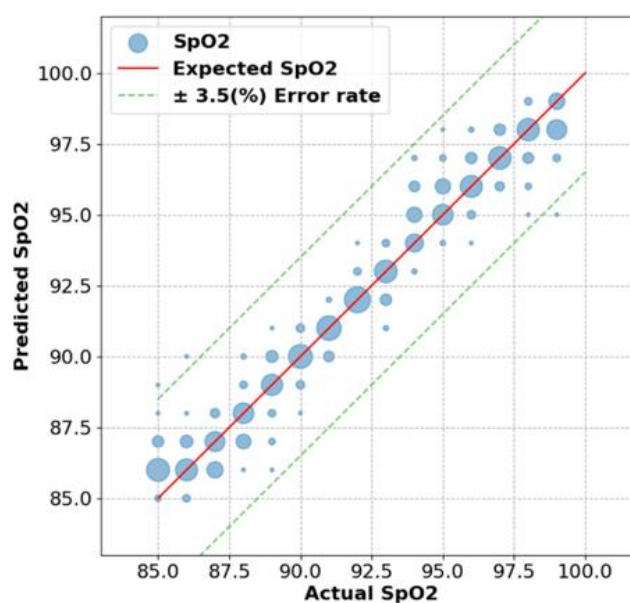


Figure 3. Pulse oximetry data quality comparing commercial pulse oximeter (actual SpO₂) to investigational predicted SpO₂ with Prototype-shoulder.

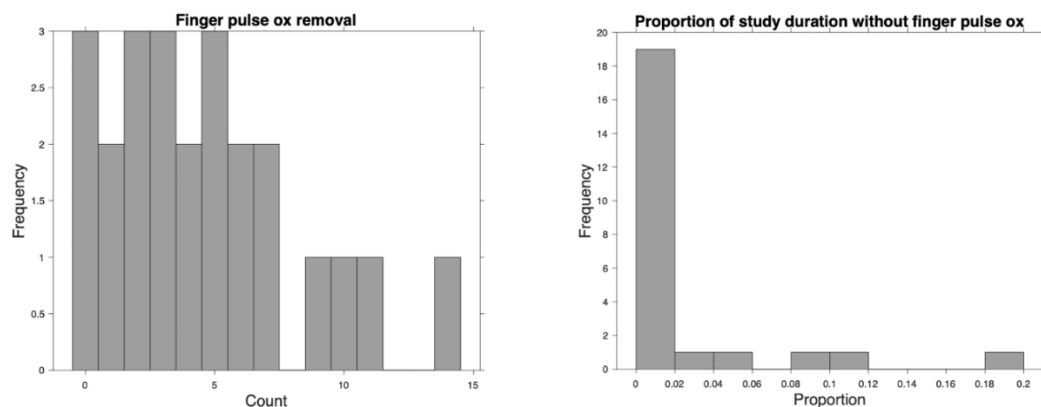


Figure 4. a. Number of commercial pulse oximeter removals. Figure 4b. Proportion of study duration during which the finger pulse oximeter was removed.

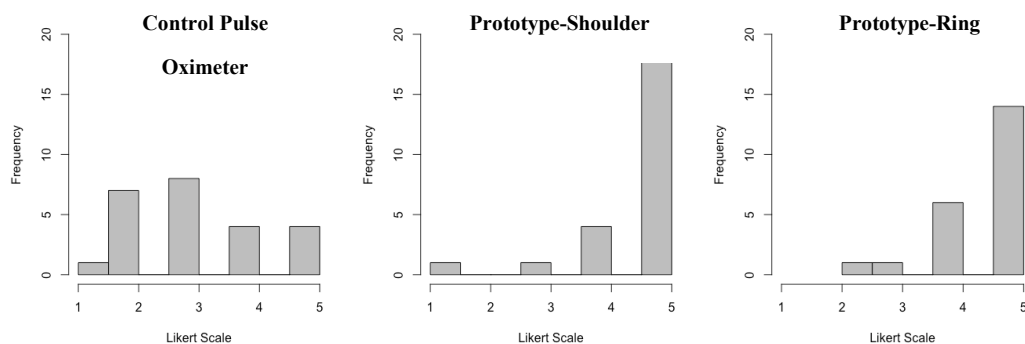


Figure 5. quantitative Likert Scale feedback regarding the comfort of the study-provided devices, 1 is very uncomfortable, 5 is very comfortable.

Discussion

This study demonstrated a shoulder-based investigational SpO₂ monitor prototype was accurate to within FDA-defined guidelines. Additionally, both shoulder-based and ring devices measured SpO₂ with fewer interruptions to continuous monitoring than a traditional commercial finger pulse oximeter. Also, participants noted improved comfort compared to a commercial finger pulse oximeter. The open-ended questionnaire revealed this stemmed from issues with security to the finger, fit, and temperature. Participants reported accidental or purposeful removal of the commercial device both before and during their sleep studies, as well as interference with sleep from the control and ring devices. By contrast, the shoulder prototype did not carry the same reports. Collectively, these results support the concept that a shoulder-mounted pulse oximeter is a viable and potentially preferable configuration for SpO₂ monitoring in patients receiving polysomnography.

Shoulder-mounted pulse oximetry is also pertinent as an alternative to current finger-based wearables because it offers the opportunity to combine SpO₂ monitoring with additional features, such as accelerometry, to detect apneic motion [4,12,15]. These applications are important for people with sleep-disordered breathing at the highest risk of respiratory compromise [13,19]. This study demonstrates that shoulder-mounted pulse oximeters may be more comfortable and less disruptive than traditional finger-based pulse oximetry.

There were multiple limitations to this pilot. Firstly, the control pulse oximeter is an imperfect gold standard as its accuracy may be limited. Secondly, most participants did not provide constructive qualitative feedback for all study-provided devices, so it is difficult to evaluate the

characteristics that drove improvements in Likert-scale score. Additionally, we did not collect sufficient data to correlate data quality with the participants' sleep position. While participants were able to recollect removal and/or repositioning of the study-provided devices, the accuracy of their subjective reports is limited in the absence of a real-time record of behavior from the center's technicians. Finally, this study was not powered or designed to assess meaningful clinical outcomes, nor for generalizability to more ill populations.

Conclusions:

Overall, this study confirms that alternative configurations for SpO₂ monitoring offer potential as accurate and well-tolerated devices. Problems with traditional pulse oximetry, such as false readings of hypoxia due to device removal or noisy data, were encountered less frequently in Prototype-shoulder than in the commercial finger-based device. Users not only tolerated the shoulder-based form factor but also preferred this configuration relative to the traditional finger pulse oximeter.

Supplementary Materials: The following supporting information can be downloaded at the website of this paper posted on Preprints.org, Figure S1: Sample of Motion vs SpO₂ Over Time; Supplemental Methods S1: Processing of motion and SPO₂ data.

Author Contributions: Conceptualization, KK, JB, CB, and AL.; methodology, JB, CB and IG.; software, AL.; validation, AL., OO, and JB.; formal analysis, KK and CB.; investigation, AW, DG, AS, AL, and IG.; resources, JB and IG.; data curation, AL.; writing—original draft preparation, KK.; writing—review and editing, CB, OO, IG, DG, and JB.; visualization, KK.; supervision, JB and CB.; project administration, AW and KK; funding acquisition, JB and OO. All authors have read and agreed to the published version of the manuscript.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study

Data Availability Statement: Anonymized analyzed datasets available on request

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Abbreviations

The following abbreviations are used in this manuscript:

SpO₂ Peripheral Saturation of Oxygen

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