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Challenges and Solutions for Monitoring Alcohol Use in Patients with Alcohol Related Liver Disease: Pilot Study of a Wearable Alcohol Biosensor

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Abstract

Objectives: Early alcohol use identification can prevent morbidly/mortality for alcohol-associated liver disease (ALD). Innovative wearable alcohol biosensors (biosensors) that identify alcohol use through perspiration are an emerging technology with potential application for patients with ALD. Our primary aim was to determine biosensor acceptability and feasibility for patients with ALD. We describe participant acceptance and challenges using biosensor technology in a pilot study of biosensors with patients with ALD.

Design: Participants had a recent diagnosis or hospitalization for decompensated ALD, had to be drinking within the past three months and be followed at our center. Participants wore the biosensor daily for 3 months. Quantitative data using the Technology Acceptance Model 2 (TAM2) measure were collected at intake and study conclusion. The TAM2's 13 items cover 4 scales; perceived usefulness, ease of use, attitude towards technology and intention to use on a 7-point Likert scale. Lower scores indicate higher acceptance. Participants were asked open-ended questions about issues wearing the biosensor.

Results: Among 27 participants, 60% were women, average age 45±10, and 89% were white. TAM2 subscales indicated initially high acceptance (mean scores 1.2–2.2) and remained high

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(mean scores 1.3–2.3) without statistically significant decline at study conclusion. From open-ended questions, several themes regarding problems with device wear emerged: a) uncomfortable or cumbersome to wear, b) problems with biosensor appearance, and c) issues with useability. Challenges to biosensor usage included data being lost when devices were damaged and devices being lost during the study.

Conclusions: Alcohol biosensors appear to be acceptable to ALD participants. However, improving the appearance, comfort, durability and functionality of biosensor devices is critical to clinical deployment.

Keywords

Alcohol related liver disease; wearable alcohol biosensors; feasibility; acceptability

INTRODUCTION

Of the 14 million US persons with alcohol use disorders,10–20% (1.4–2.8 million) develop alcohol related liver disease (ALD) and 5–7% (70,000–100,000) experience serious liver-related complications each year.(1,2,3) ALD accounts for ~45% of US (20,000/year)(4) and up to 80% of UK (5) liver disease deaths. ALD is the primary indication for 30% of all liver transplants in the US and Europe.(6)

For many patients with ALD the disease is relatively silent with few symptoms until a medical crisis such as a hospitalization for decompensated ALD. Decompensated ALD is defined by development of intestinal bleeding, jaundice, ascites, or encephalopathy. (7–10) Although medical therapies are used to stabilize liver functions, only total abstinence can stop the progression of ALD. During these clinical encounters patients with ALD are instructed to maintain complete abstinence to prevent disease sequela or worsening of their liver disease. However, despite the positive impact serious illness resulting from alcohol use can produce on the intent to stop drinking, sobriety after ALD decompensation is poor. After an index ALD hospitalization, relapse occurs in 40–70% of patients. Most patient relapse within months after discharge and drinking is the strongest predictor of readmission and mortality. (11–14) With continued drinking, decompensated ALD has a predictable deteriorating fatal course making it a compelling disease for identifying improved treatment approaches.

Currently monitoring of patients with ALD' alcohol use is primarily done through clinical interview and conventional laboratory alcohol testing. Optimally, patients would be interviewed frequently and randomly tested, although in real-world clinical settings this is difficult to accomplish. Studies of patients with ALD monitored by self-report and biochemical monitoring (e.g., alcohol breathalyzers, ethyl glucuronide) show self-reports identified virtually no drinking while biochemical markers revealed 32–57% positive values indicating use(15–17) and liver biomarkers had low specificity.(17,18) From our prior work (19) we determined that most discoveries of alcohol use in patients with ALD were not made until months after resumed consumption and were largely captured based on prospective, repeated, multi-method research measures not routinely employed in a clinical setting. The lack of precision in identifying if and when actual alcohol use occurs

is a significant barrier to early identification and assisting patients to access appropriate treatment when alcohol use occurs. The complete abstinence requirement in this patient population makes ALD a critical disease in which to test new strategies for efficient monitoring of patient alcohol use.

We explored the use of an emerging technology, wearable alcohol biosensor monitors (biosensors) for an ALD population. Prior pilot studies have demonstrated the feasibility and acceptability of biosensors in healthy populations (20). We chose patients who were recently diagnosed and/or hospitalized with decompensated ALD as these patients were the specific population in which we envisioned this technology to be the most clinically impactful. Continuous monitoring of alcohol use by wearable biosensors is possible but to date these devices have not been used in clinical medical settings to monitor adherence to medical directives. For patients with ALD such devices could facilitate monitoring of alcohol abstinence, providing both patients and clinicians with real-time information that may be critical for development and adjustment of alcohol treatment plans.

The convenience, feasibility and acceptability of such devices requires input by patients as key stakeholders in evaluating these elements. These process considerations are essential to guide the development of a full-scale trial and future translation into clinical practice. Thus, our main goal was to examine the integration of this technology in a real-world ALD patient population. We examined the potential for biosensor integration with health care, identified barriers to biosensor implementation, and determined longer-term wearability of biosensor devices in a clinical cohort. We additionally report on the challenges to implementation of biosensors and provide lessons learned with strategies for future biosensor use in a clinical cohort.

METHODS

Ethics statement

This study was approved by the University of Pittsburgh Human Research Protections Office (PRO 18010209). All participants signed written informed consent prior to any study-related testing procedures.

Overall study design and primary aim

We designed a 3-month randomized control trial (RCT) to examine the feasibility of an alcohol biosensor monitor for patients with decompensated ALD. All participants were instructed to wear the device 24 hours a day 7 days a week for three months and were randomized to either receive feedback on alcohol use data from the biosensor (summarized into days of drinking, average drinks per episode, peak and average alcohol levels and days of binge drinking) or receive no biosensor feedback. All participants, regardless of randomization, received information on the risks of drinking alcohol with liver disease and referral sources for finding treatment help (both their hepatologist's contact information and addiction treatment resources). The research, overall, was designed to examine acceptability and also to test receipt of feedback on the device data through the RCT. In this paper we report on our primary aim which was to determine usability, acceptability, and feasibility

of biosensor use for patients with ALD. The effectiveness of the RTC will be reported in a separate paper pending future analyses.

Participants

We chose patients who had a recent diagnosis or hospitalization for decompensated ALD and were followed at the University of Pittsburgh Center for Liver Diseases. Participants decompensated ALD was determined by a hepatologist (JB, MD, and RB). Although we did not use a Model of End-stage Liver Disease (MELD) cutpoint to determine eligibility, we excluded those with unresponsive acute alcohol related hepatitis, multi-organ failure, and fulminant hepatic failure (all with 3-month mortality ≥20%). (21,22) Participants were approached and enrolled between September 2018 and February 2020. Participants had to be drinking within the past three months, i.e., we excluded individuals who were already stably abstinent. Participants had to be willing to wear the biosensor for three months. Participants had to score >26 on the Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES) problem recognition subscale (scores ≤26 indicate very low recognition). (23–25) We instituted this requirement because individuals with low recognition in the face of secondary alcohol complications may have pathological denial or cognitive impairment and are unlikely to intend to stop use. (25) We did not use exclusion criteria for ambivalence or taking steps (the other 2 SOCRATES subscales) as we believed these characteristics would be representative of most of the ALD patient population. Potential participants were excluded if they had current overt hepatic encephalopathy or moderate cognitive impairment (scoring <21 on the Montreal Cognitive Assessment). (26)

Alcohol biosensor device

Alcohol's presence in the body can be determined through bodily specimens, typically blood, urine or breath, but also saliva and sweat. (27) Alcohol Biosensors are electrochemical devices that measure alcohol vapor secreted transdermally in perspiration which indirectly measures blood alcohol content (BAC), and thus, by inference, alcohol consumption.(27) At the time of our study only two types of wearable biosensor devices existed. Of the two we chose, the wrist transdermal alcohol sensor (WrisTAS™ Giner/SmartStart, Newton MA) for its more discreet appearance like a wristwatch, ultra-lightweight design, location of wearing on the wrist, and the ability to remove it in an emergency. The other device, the SCRAM® (SCRAM Systems US), has the appearance of a house arrest ankle device, is used in law enforcement, is worn on the ankle which is problematic for patients with ALD with peripheral edema, and is locked on and difficult to remove by users which is dangerous for patients.(28) The validity, precision, and accuracy of WrisTAS was evaluated by the National Highway Traffic Safety Administration under laboratory testing demonstrating a high rate of true positives, ≥ 82%, across a range of BAC and had accuracy down to 0.02 g/dL BAC (27,29,30) with virtually no false positives, even in liver disease. (27,31). The accuracy of WrisTAS meets law enforcement and justice system standards. The WrisTAS™ continuous sampling interval can be set from every 10 seconds to every 10 minutes. For our purposes we chose a 10-minute sampling interval. For data retrieval a USB interface downloads WrisTAS™ data to a computer (participants cannot "see" or download device data). The WrisTAS™ captured data for one month on a single battery but required monthly servicing by the research staff to change the battery and

hardwire the biosensor device to a computer to download the monthly data. WristTAS™ also detected and recorded removal via skin conductance and temperature sensors. (27,29) At the time of our study, WrisTAS devices cost $2500 per device and each device was covered by a $1875 eighteen-month service agreement.

The device was worn on the wrist with a Velcro strap that was adjustable and easily removed (see Figure 1A and B). Participants were fitted with the biosensor and instructed on its use, with demonstration of how to put it on, adjust it to make sure it was snug and remove it. A biosensor device wearing brochure was created and provided to participants with written instructions and pictures showing proper wearing of the device (location on arm and orientation) as well as restrictions (e.g., not wearing during showering/swimming as device is not waterproof). The brochure stated they did not need to perform any maintenance functions and were told not to tamper with the device or attempt to open it or it would be severely damaged. They were told the device was delicate but could withstand normal wear. Participants were instructed to wear the device at all times (except when in water). They were informed that study staff would retrieve the device once a month to download the data and replace the battery. The device has no visible sensors or display. Participants were instructed to contact study staff with any concerns over size or fit rather than try to fix it themselves. They were compensated $25 for each month of wear.

Assessments

Baseline characteristics—At intake, participants were surveyed on the Project Match Form 90 AI which provides detailed statistics for self-reported alcohol consumption, related health problems/health care utilization, and days in addiction treatment. (32) The measure has excellent test-retest reliability for core alcohol variables (r's>0.90). Participants were also interviewed using the M.I.N.I. Neuropsychiatric Interview for DSM5 Alcohol Use Disorders module (validated diagnostic interview) (33) to categorize the severity of their alcohol use disorder.

Measures of acceptability, useability, feasibility—The Technology Acceptance Model 2 measure (TAM2) includes 13 items covering four subscales (perceived usefulness, ease of use, attitude toward use, and intention to use) (subscale alphas=.80-.98). (34) Each item is scored on a 7-point Likert scale from 1=very likely to 7=very unlikely. Lower scores indicate better acceptance. Participants completed the TAM2 at intake and 3 months later at study completion.

Monthly questions on issues with biosensor wear—Each month participants were asked an open-ended question worded as "Did you have any problems wearing the device?" A list of any noted problems was kept. Participants were also asked how often and for how long they took off the device and whether they removed it to drink alcohol. A monthly assessment was chosen to align with the monthly device downloads and feedback sessions.

Measure of biosensor wear – Proximity sensors on the biosensor devices—WrisTAS™ biosensors have a proximity sensor, measuring skin conductivity, that along with temperature and humidity sensors can determine when the device is being worn. Based on

every 10-minute proximity sensor readings, the WrisTAS™ software program provides a summary of the total time in days the device was not worn over each month of wear. We calculated the total time in days the participant had the biosensor and removed the time in the hospital from the days of expected wear as participants were instructed to remove the devices during hospitalizations. We calculated the percent of time the participant wore the device for each month and summed this for the total percent wear time for the three months of study participation.

Statistical Analysis

Baseline characteristics are reported as percentages for categorical variables and mean and standard deviation for continuous variables. The four TAM2 subscales were scored as a summary of the subscale items and analyzed with paired t tests across pre- to post-study assessments. We also analyzed independent samples t tests between the biosensor feedback group and the control group that did not receive feedback to see if receiving feedback had any impact on biosensor device acceptance. Responses to the monthly questions on problems with the biosensor device were listed and categorized by content. The number of participants who endorsed taking the device off to drink was counted.

RESULTS

Baseline characteristics of the study cohort

Of 54 patients approached for participation in the study, 67% agreed to be screened for eligibility (i.e., screening with SOCRATES and MOCA). Of 18 patients who declined screening, the primary reason for not being interested was the appearance of the device (n=5). Three patients were interested but lived too far from the center and/or had transportation issues and could not return for follow-up. One was afraid wearing the device would trigger thoughts to drink. One patient was concerned that the device would break due to their rugged lifestyle. Of the 36 patients screened 34 were eligible – one did not achieve an adequate score on the MOCA and one did not intend to stop drinking. No potential participant was screened out due to low recognition subscale score on the SOCRATES.

Of those determined eligible (n=34), 97% were enrolled, and one person declined at the consent stage. There were no sex or race/ethnicity differences between enrollees and those who chose not to be screened or were not enrolled, but enrollees were significantly younger (45±11 vs. 55±19, t(df)= −2.3(49), p=0.026).

Participants were mostly white women who were not married or with a partner. The mean alcohol use severity score was 8 indicating a severe alcohol use disorder. In the past three months they had spent an average of two weeks in a hospital for ALD. Less than 50% were participating in alcohol rehabilitation (see Table 1 for cohort characteristics).

Twenty-seven participants completed the time 1 interview and 21 completed the time 2 interview 3 months later at the end of the study (3 withdrew - 2 at the beginning of the COVID-19 pandemic shut-down, 2 died, 1 was too ill). One participant did not complete the 3-month TAM2. During the study the largest loss of participation of those enrolled was due to serious illness or death (22% including both arms of the study), We had purposely chosen

a cohort of individuals with decompensated liver disease as we felt they would be the most in need for complete alcohol cessation and careful monitoring for return to use. As shown in Table 1, the average Model for End Stage Liver Disease (MELD) score, a validated measure of severity of decompensated liver disease, of our cohort was 20, indicating severe liver disease, as patients with MELD scores ≥20 have a 20% or greater three-month mortality risk. (35,36)

Useability and acceptability

Quantitative results—At intake, acceptance across all TAM2 subscales was high (mean scores ranging 1.2–2.2, indicating very to quite likely). Only one participant rated the perceived usefulness worse (score=4.75) than the scale midpoint (4) and intent to use biosensor as quite unlikely (score=6). By the end of the 3-month biosensor wearing period, perceptions and attitudes had not changed and remained highly positive (mean scores ranging 1.3–2.3) Thus, there were no statistical differences between pre- to post-TAM2 subscale scores (df=19, Ps 0.3–0.8) (see Table 2). Of the four TAM2 subscales, ease of use had lowest ratings pre- to post-study although this was still rated favorably high with mean scores indicating the participants felt slightly to quite likely to find the biosensor easy to use. The single participant who rated the biosensor technology poorest at intake improved their views with subscale scores of 2–3 at study end. We examined whether there were differences by arm of the study such that receiving feedback or not had any impact on technology acceptance but found no statistical difference between the two groups (see Table 2.)

Device wearing—From the proximity sensors, we determined 46% of the participants wore their biosensor devices ≥ 90% of the total time. The amount of time off would be consistent with taking the device off to shower/bathe or wash dishes during a three-month period. Fifteen percent of participants wore it a significant but slightly lesser amount of time (77–81% of the three months of wear). Thirty one percent wore it between 25% to 53% of the time. For these participants we commonly noticed a day-night cycle where the device was taken off for sleep. In some cases, the device would not be put back on for several days. The remainder 8% (n=2) barely wore the device (only 7% and 13% of the three months, respectively). Both of these individuals met criteria for a severe alcohol use disorder (11 and 10 respectively) and reported heavy consumption patterns prior to study enrollment (≥20 drinks/day). The participant wearing the device 7% of the time noted the strap was itchy and the foam padding caused skin irritation (see below).

Open ended questions about wearing the biosensor device—Most participants reported wearing the biosensor faithfully, and only removing it for showering, washing dishes, swimming, or hospitalizations/procedures. Some participants reported taking it off to sleep. However, some noted forgetting to put it on in the morning or after showering and not discovering their mistake for hours or days. Several reported taking it off for travel/vacations due to concerns over breaking the device. One participant noted he went on a kayaking trip for several weeks and left the device at home for fear of getting it wet. One participant with 56% wearing reported that in addition to taking it off for sleep, he would also take it off when he worked out at the gym several times a week for fear of sweating too much and getting it wet.

As for removing the device to avoid detection of alcohol use, two participants reported taking the device off to drink. One stated she took it off because she was embarrassed for others to know she drank but quickly put it back on as she knew the research team would know she drank anyway. Some participants expressed concern if they used alcohol-based hand sanitizer or perfume on their skin it would look as if they were drinking.

Open ended questions about problems wearing the device—In response to the question, “Did you have any problems wearing the device?”, the most commonly noted problems were minor inconveniences while wearing the device. Many reported the Velcro strap felt itchy, or hot, or the device was bulky, annoying, and uncomfortable to wear (see Table 3). Others noted it was like a watch and had no issues with comfort. Several participants noted they put it on and forgot about it. Some experienced issues with skin irritation or developed an indentation or mark on the skin from the device. One participant had a latex allergy and developed a rash to the foam backing on the sensor. For the participant the foam was removed from the device, but this appeared to influence the accuracy, potentially due to issues related to contact with the skin. A common complaint was that the device was uncomfortable to sleep with and some participants had to take it off at night while sleeping. Some of the issues with comfort could be resolved with adjusting the strap or allowing a brief period without device wearing.

Others complained about issues with device use such as the Velcro strap caught or snagged on clothing. Even if the strap was snug it could slip down the wrist and become loose. Several participants noted that despite the strap being snug, the strap twisted so the sensor was rotated and was not making contact with the wrist. Some participants noted it was cumbersome to take off and put on the biosensor for activities such as washing dishes or showering. Some noted wearing the device made taking shirts on/off difficult or that it caught on the cuff of a sleeve. Others noted it got in the way of doing tasks such as typing or working at a desk.

Another common issue was the appearance of the device. Many commented on the appearance not being optimal and described the device as bulky and unattractive. One participant noted that other people commented on it and one participant was asked if they were on probation which was embarrassing. Others noted trying to hide it under their sleeves while others noted wearing it with short sleeves without problem.

Lessons learned about implementation of biosensors in a patient population —We developed a priori, detailed plans for the implementation of the study including device deployment and retrieval, servicing of the devices, and analysis of the data. Nevertheless, as the study progressed, we needed to make adjustments to accommodate unanticipated problems or issues. We review these issues briefly below and in Table 4.

Device deployment and retrieval—Although we planned to meet patients face to face in the clinic for biosensor data downloads, this was not possible because our tertiary hepatology specialty clinic served patients from a wide geographic location. Many participants were unable to return long distance on a monthly basis and we needed to develop procedures for mailing devices.

Device losses—Following the loss of a device in the mail we changed our mailing procedure to include a sturdier double packaging, labeled interior and exterior packaging with instructions on how to contact us for return of the device if found. Although we had considered purchasing insurance on all device mailings, due to the high volume of mailing and the high cost of insuring a package at a level consistent with the cost of the device this was impractical.

We also lost a device when a participant was hospitalized (hospital staff removed the device and then lost it). We subsequently updated our device wearing brochure for participants with instructions to remove the biosensor for any procedures or hospitalizations and to leave it at home for safekeeping. One device was lost when a participant died at home. Although we discreetly asked the family whether they could locate the device they were unable to do so. Approaching families at such a difficult time requires great sensitivity. If it were not for the substantial expense of these devices, in such cases the research team may have forgone attempting to recover a device.

Issues with data loss and data interpretation—On a few occasions data capture was lost due to the battery stopping during wear. Even if a battery stopped during wear, data stored until that point were retained and could be retrieved once a new battery was installed. Only a few months data capture was lost when the sensors broke or malfunctioned during the wearing period. Data captured prior to sensor failure could be retrieved.

With the WrisTAS™ set to take readings every 10 minutes, it generates over 20,000 datapoints/month including date/time stamp, alcohol reading, proximity and other sensor data. The manufacturer created a software program to analyze the data. However, after the data are analyzed by the program additional visual examination of the data is required to make sure drinking episodes and wearing periods are being accurately identified. This additional examination of raw data can be very labor-intensive.

We observed that hand sanitizer containing ethyl alcohol could produce a transient spike in the alcohol sensor although this is easily distinguishable from actual alcohol consumption on visual inspection of the data.

Issues with device damage and tampering—Despite instructions in the brochure provided to all patients, we had multiple devices that sustained water damage and/or developed moisture corrosion requiring repair. Although we did not keep a log of the numbers of participants who damaged their devices, we were aware of damage due to reports from the manufacturer during servicing or damage we observed when devices were returned to us. Several participants told us they shortened the straps to make them fit better by cutting the ends off the straps which damaged the strap requiring repair. Some appeared to have tampered with and severely damaged devices by breaking or cutting wires and one participant returned a device with screws removed, leaving open the sensor electronics. In addition, the research team also inadvertently damaged a few device casings by over-tightening screws during the battery change resulting in cracks in the device casing.

DISCUSSION

We examined the acceptability of the biosensor technology from the perception of the patient in a population of patients with ALD. Interestingly perceived patient acceptance was high at the start of the study even before participants had a chance to wear the device. Participants gave high scores for perceived usefulness, ease of use, overall acceptance of biosensor technology, and intent to wear. Importantly, acceptance remained high after three months of device wearing. Even the participant who scored the device less favorably, noting their intention to use the biosensor as quite unlikely at the start of the study, changed their view to slightly likely to use the biosensor device by the end of the study. Additionally, this participant wore the biosensor device 77% of the time, suggesting that device wearing improved rather than worsened perceptions of the device.

We examined whether it was feasible in a clinical population for participants to wear a biosensor across a period of three months of wear. While by self-report most participants reported consistent biosensor wearing this may have been biased by a desire to please the researchers. Nevertheless, the proximity sensors demonstrated 61% of participants wearing the device 77% of the time or more. While the use beyond the observation period cannot be determined, there were factors observed that may impact long-term feasibility of wearing the biosensor device such as the fragility of the device and the damage that apparently occurred from participants' daily activities.

Prior field studies and studies of healthy participants drinking at unhealthy levels have found similar adherence to wearing biosensor devices. A field study using both the WrisTAS™ and SCRAM® worn concurrently for 4 weeks in 22 financially compensated healthy participants had good compliance and no dropouts. (29) A study of 29 healthy "at-risk" drinkers demonstrated the ability to wear the SCRAM® for a 12-week financial contingency study with none withdrawing due to the device. (37) In another study 13 healthy participants drinking at unhealthy levels wore the SCRAM® for three weeks in a contingency management with financial reinforcement study. Two withdrew from the study due to the device and one participant cut the device off and could not be located. (28). One study examining the feasibility of the WrisTAS™ in 57 healthy adolescents and young adults found high adherence to a one month wearing. (38) Two adolescents were excluded from analyses due to large amounts of missing data but all of the young adults completed the trial with less than 50% of data missing. (38) A two-week field study of healthy participants (n=12) who were binge drinking used a newer lightweight biosensor that has the appearance of a fitness tracker (see BACtrack Skyn® below) and found a high degree of acceptability and feasibility. (20)

In all studies researchers noted there would be expected differences in the acceptance of biosensor devices between paid participants and patients. In this regard contingency management models reinforcing positive behavior such as abstinence, as described above for some of the biosensor studies, may not represent real world patient acceptance. We chose a low level of payment to compensate participant participation but not serve as an inducement. We had hoped the participants intention to stay abstinent was the motivation to using a biosensor.

We also found the appearance of the device is a critical consideration for wearers. Indeed, nearly 10% of those approached who did not participate cited the appearance of the device to be a reason for declining. Additionally, it caused some participants to temporarily remove the device in settings where they felt uncomfortable with its appearance or while in public if it could not be hidden. Appearance is an essential issue to patient acceptance and critically such a device must not look like a law enforcement device to prevent embarrassment to the patient. In a prior study using the SCRAM®, which is used as a law enforcement device, participants experienced moderate embarrassment wearing the device. (28) Since our study, the WrisTAS™ has been redesigned to the next iteration, the BARE™ (SmartStart, Newton MA) which has both sensor and electronics in a single casing that appears more like a watch. SmartStart is currently focusing on its new law enforcement device ORBIS® (39)(see below) and the BARE™ is not available for research. In addition, another device, the BACtrack Skyn®, has been developed which has an appearance like a Fitbit® and measures alcohol use over a week period. However, with this device the wearer is responsible for downloading data and charging the device.

Comfort was another common issue with the device, such as the composition of the strap, and with the device itself. Some participants found it uncomfortable to wear for daily activities like typing and others needed to remove at night while sleeping due to discomfort. We chose a monthly interval to assess issues with the device wearing both to align with the monthly feedback session and to minimize participant burden. A possibility of recall bias exists which a more frequent interval of assessment could have alleviated.

We believed patients who had decompensated ALD to be those most in need of continuous alcohol use monitoring to ensure complete alcohol abstinence with the intent of preventing further decompensation. From a physiologic perspective, while it is true that these individuals have the most to benefit from complete abstinence or early identification of alcohol use, from a practical perspective many individuals with decompensated ALD are often too ill to drink and some will continue to decompensate and die despite being abstinent. Identifying individuals earlier on in the disease process would be an important strategy. However, at an earlier point in the disease process patients may be less inclined to acknowledge the potential severity of their situation. In fact, many patients may be asymptomatic until the later stages of liver disease. Such individuals may not appreciate the significant risk of ongoing drinking nor have the insight or motivation gained from a serious medical encounter. We felt the strong personal motivation that can develop from a hospitalization for serious liver disease made this a good population in whom to study biosensor monitoring. We recognize the choice of a cohort of patients with decompensated ALD was a limitation as in our study 22% dropped out due to serious illness or death. However, there are tradeoffs between choosing the population most at need versus those most capable of completing the study. Thus, the timing of technology deployment in the course of an illness requires careful consideration of the medical fragility and stability of the patient population as well as the goals of the technology use.

The field of biosensor technology is rapidly advancing with improvements in appearance as noted above and functionality. However, the functionalities of the available biosensor devices have merits and purposes for which they are best suited. In this field the

development of many of these devices (e.g., SCRAM®, ORBIS®) are driven by law enforcement needs such as inability to tamper with or circumvent alcohol use detection which can lack sensitivity to patient and research participant needs (such as comfort, appearance, etc). Newer more appealing devices developed since our study have beneficial functions such as the direct transmittal of data through a smartphone app or a personal device-computer dock. The BACtrack Skyn® is one such device that can upload data through an app. Wang et.al., found most participants reported using and syncing with the app was easy after training and practice. (20) This type of technology could avoid loss of data as we experienced when our devices were lost. Nonetheless the more technically complex a device is or the more responsibilities a patient has to maintain the device or download data, the less likely some patients will be able to use the device correctly. For our patient population, we felt safety, ease of use, and duration of use were priorities. The less they needed to be responsible for with regards to maintenance and data management, the more likely we felt they would be to use the biosensor and use it correctly. The WrisTAS™ does not require any maintenance or interaction by the wearer. There are no sensors or displays to read. The WrisTAS™ can be worn continuously for one month without requiring a battery change. Participants do not need to remember to charge it. There are no data downloads required by the user, all data are stored in the device for the one month of wear. However, time is required on the part of researchers, or in the future clinicians, to perform maintenance, download data, and provide data interpretation.

Finally, although not an aim of the study, it is important to consider the labor and financial costs of using these devices. It is not uncommon that the extensive resources required to conduct a research study cannot be replicated in clinical practice making translation challenging. Biosensor devices are expensive and require servicing for breakage or sensor failure by the manufacturer. Devices such as the SCRAM®, with real time internet connectivity, have substantial monthly usage fees. To use biosensors in a clinical setting clinical staff would need to be trained on the use, internal servicing and maintenance of these devices and staff time would need to be dedicated to these tasks. Whether health insurance plans would pay for these services as part of clinical care requires consideration. Nevertheless, although the costs to purchase, maintain, and service these devices may seem large, these costs are consistent with costs of other types of therapies such as pharmaceutical therapies.

Potential limitations to our study resulted from our participant cohort which was small and we had attrition from baseline to study conclusion (22% did not complete the final assessment due to death or serious illness). The small sample size may not have allowed us to distinguish differences between groups with respect to perceived usefulness and acceptability of the biosensor. Our cohort lacked racial and minority diversity (only 11% black, 4% hispanic). Our cohort also may have been more accepting of their alcohol use disorder and more ready to commit to abstinence. Additionally, although participants were largely agreeable and able to wear the biosensor for three months, for a chronic disorder such as an alcohol use disorder longer periods of wear could be required to ensure stable abstinence. Thus, our findings should be interpreted cautiously and further research in larger, more diverse patient samples is warranted.

CONCLUSIONS

In conclusion, a research study of patients with decompensated ALD demonstrated high acceptance of biosensor technology. Despite their significant medical illness and other medical care priorities, their largely consistent wearing pattern, and findings that they did not remove it to avoid alcohol use detection implies that patients may have similar acceptance of this technology. However, personal factors that lend to sustained use of wearable devices include adoptability, fit/comfort, user experience, lifestyle compatibility, and overall utility.(39). Thus, a comfortable, discreet appearing, durable, waterproof device would be essential if the intent is for daily biosensor wearing. Additionally for biosensors to be clinically useful the burden of time and effort for clinical staff to maintain, service and deploy biosensors needs to be reduced. These issues are being addressed with newer iterations of biosensor devices which will enhance translation to clinical practice.

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Acronyms:

ALD	Alcohol related liver disease
BAC	Blood alcohol content
MELD	Model of End Stage Liver Disease
SD	Standard deviation
IQR	Interquartile range
US	United States
UK	United Kingdom
USPS	United States Postal Service
USB	Universal serial bus
WrisTAS™	Wrist Transdermal Alcohol Sensor

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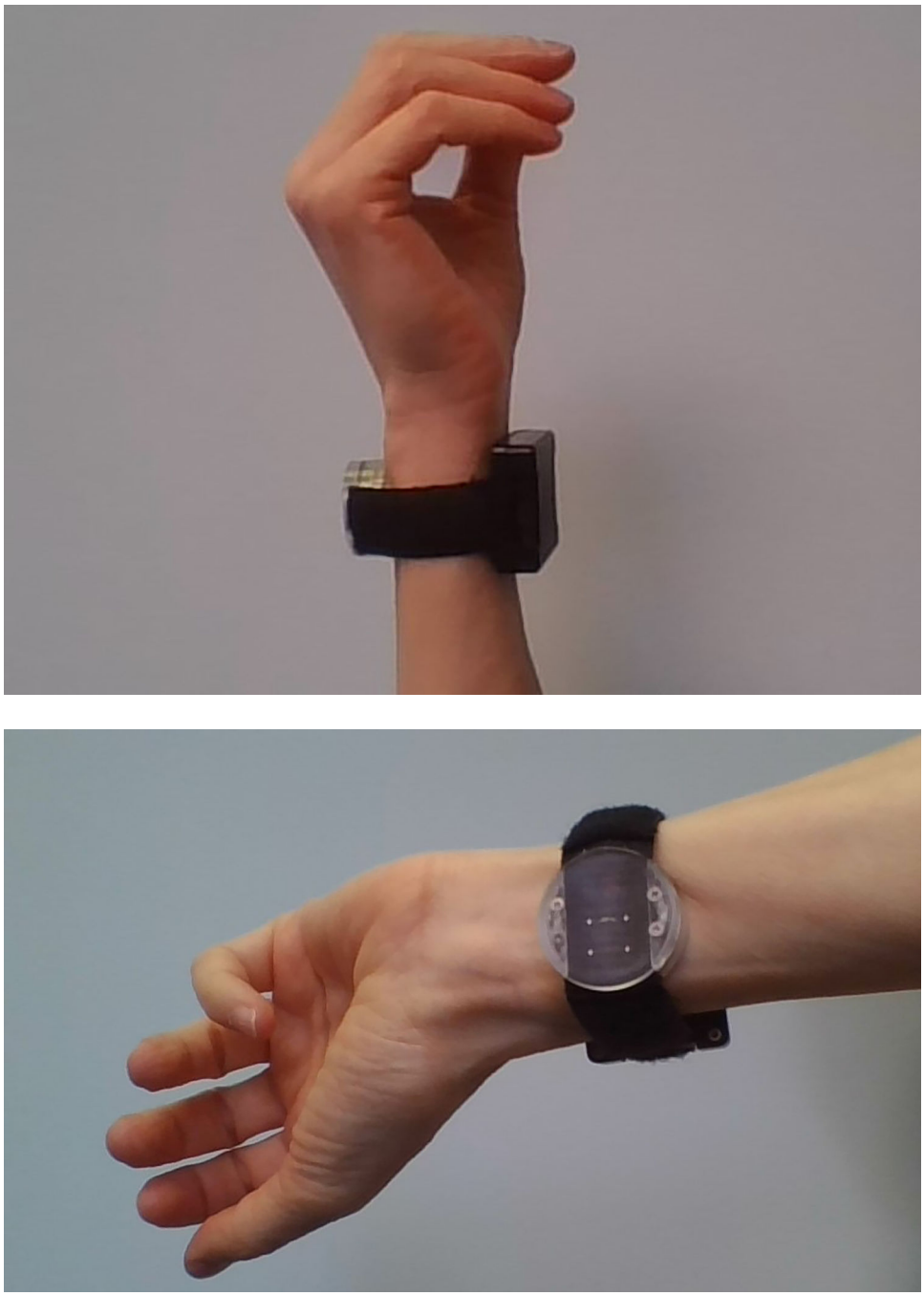

Figure 1.
Pictures of WrisTAS™ being worn on wrist: clear disc contains the sensors; black box contains electronics and battery.

Table 1.

Comparisons between intervention and control groups on baseline characteristics

	Assignment		Group Comparison: Test Statistic, p[†]
	Feedback n=14	No Feedback n=13	
Demographics			
Sex, % men	36	46	0.30, 0.70
Age in years, M (SD) range	43 (10), 30–59	47 (11), 31–69	−0.94, 0.36
Race, % white	100	73	3.13, 0.21
Ethnicity, % non-Hispanic	100	92	0.48 [*]
Occupation, % clerical/semi-tech/unskilled	43	54	0.33, 0.71
Marital status, % married/with partner	36	23	0.67 [*]
Residence distance from medical center in miles, M (SD), range	27(21), 3–68	29(33), 1–117	−0.20, 0.42
Medical Variables			
Days in medical hospital in past 90 days M (SD) range	15 (18), 0–66	15 (14), 0–47	−.01, 0.90
MELD score M (SD)	22 (9)	19 (7)	0.87, 0.39
Alcohol Use History			
Alcohol Use Disorder severity (# criteria endorsed), M (SD), range	9 (2), 6–11	8 (3), 3–11	1.8, 0.08
Time from last drink in days, M (SD), range	57(26), 16– 91	50(36), 0–104	0.32, 0.56
When drinking average drinks/day, M (SD), range [+]	13(5), 7–20	11(5), 4–18	0.66, 0.52
Attendance at a 12-step meeting in prior 90 days, % yes	61	31	2.5, 0.24
Participating in formal addiction treatment, % yes	28	15	0.38 [*]

M-mean, SD-standard deviation, IQR-interquartile range

MELD – Model of End-stage Liver Disease

[*] Fisher's exact test

[+] half of participants could not quantify exact amount or it fluctuated

Table 2.

Total Group and Arm of Study Group Comparisons on Technology Acceptance Model Across Assessments

	Intake	3 Month	Group Comparison Test Statistic, p*	Intake			3 Month		
				Feedback n=14	No Feedback n=13	Group Comparison Test Statistic, p†	Feedback n=11	No Feedback n =9	Group Comparison Test Statistic, p†
Perceived usefulness	1.7 ± 1.1	1.9 ± 0.8	−0.67, 0.507	1.8±1.2	1.4±0.7	0.95, 0.351	1.7±0.7	2.1±0.9	−1.2, 0.248
Ease of use	2.0 ± 0.93	2.3 ± 1.4	−1.0, 0.313	2.3±0.87	2.0±1.1	0.79, 0.438	2.3±0.9	2.3±1.9	−0.04, 0.967
Attitude toward tech	1.3 ± 0.72	1.3 ± 0.53	0.17, 0.864	1.5±0.82	1.0+0.0	2.0, 0.054	1.4+0.6	1.2±0.3	0.80, 0.435
Intent to use	1.5 ± 1.2	1.5 ± 0.89	0.27, 0.789	1.6±1.3	1.1±0.5	1.0, 0.308	1.5±0.8	1.4±1.0	0.03, 0.981

* paired t test

† t test

Table 3.

Issues with Biosensor Device Wearing

Specific Issue	Feedback	No Feedback
Skin irritation / indentation *	7/14 (50%	7/13 (54%)
Strap felt itchy / was scratchy	2/14(14%)	4/13 (31%)
Wearing device was uncomfortable (sleeping or otherwise)	4/14 (29%)	2/13 (15%)
Uncomfortable with device appearance	1/14 (7%)	2/13 (15%)

* participants typically noted this was from wearing the device too tight - strap was adjustable and most reported issues resolved with adjustment.

Table 4.

Challenges and Solutions

Issues	Problem or challenge	Solutions
Device deployment and retrieval	• Participants did not come to clinic at research assessment points	• Developed procedures for packing, mailing, and tracking devices. Tracking dates for device delivery and retrieval was especially critical to the interpretation of data on wearing time
	• Costs associated with insuring devices while in transit in the mail	• We were unable to insure devices at a level consistent with their replacement cost and made every effort for in person retrieval, meeting up with participants at any medical encounter within our system
Device loss	• Inability to locate lost loose items in the mail	• Created sturdier double packaging, labeling of all parts of packaging interior and exterior with toll free number and instructions on how to contact study team if found with payment for return postage
	• Ability to track packages	• Applied tracking labels and created a tracking database for all device mailings, monitored tracking labels for location
	• Participants hospitalized with device and device was lost	• Rewrote device brochure to instruct removing device for any hospitalization or procedures
	• Participants who became too ill or died during study and device was lost	• Required a contact person who is aware of participants involvement in the study and aware of the device to facilitate return if a participant is unable to do so. Provide return packaging with postage
Data interpretation and data loss	• Needed to consider the time a device was in transit to analyze the data	• Developed a system to match tracking labels and sensor readings to identify when a device was with the participant
	• On a few occasions data capture was lost due to the battery stopping during wear.	• Used a voltmeter to check that batteries contained a full charge prior to deployment
	• On a few occasions data were lost when a device malfunctioned during deployment	• Made sure to have routine servicing and if possible start up and allow a device to run for a few days prior to deployment to observe the sensors
	• Ethyl alcohol containing skin products (e.g., perfume, hand sanitizers) can produce a transient alcohol reading	• Rewrote device brochure to recommend participants avoid ethyl alcohol containing products (e.g., hand sanitizer, perfumes) close to the sensor especially on the skin under the sensor
Device damage	• Biosensor device is fragile, cannot withstand water contact and cannot be tampered with	• Rewrote the device brochure and verbally reminded participants with each device deployment about not tampering with device and taking off for any activities with water