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Screening for obstructive sleep apnea using a contact-free system compared with polysomnography

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DISCLOSURE STATEMENT

Megahealth Medical, Inc. supplied the contact-free portable devices and the dedicated software, had no other involvement in the study. All of the authors have indicated no financial conflicts of interest. Work for this study was performed at Peking University People's Hospital.

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ABSTRACT

Study Objectives: To evaluate the utility of a contact-free device in screening for obstructive sleep apnea (OSA).

Methods: 359 participants (mean age was 46 ± 13 years old, BMI was 26.1 ± 4.2 kg/m^2, and 67.7% were male) underwent an overnight monitoring using a contact-free device, OrbSense, and polysomnography (PSG) in the sleep lab simultaneously. The OrbSense recordings were analyzed automatically, and PSG was scored based on recommended guidelines.

Results: The REI from OrbSense were lower than AHI from PSG (25.5 ± 20.7 vs 27.0 ± 25.2 events/h ($p=0.007$); (2) REI was significantly correlated with AHI (Pearson's coefficient=0.92, $p<0.0001$). Bland-Altman analysis showed a mean difference of 1.5 events/h, limits of agreement was -18.6 to 21.5 events/h. OrbSense results in larger underestimates AHI and lower negative predictive value at higher AHI values (especially when AHI ≥ 30 events/h). (3) Using a PSG diagnostic criteria of AHI over 5 events/h, the optimal diagnostic cut-off value from OrbSense was 8 events/h, with a sensitivity of 90.4%, and a specificity of 77.6%, 94.6% positive predictive value, and 65% negative predictive value. For moderate to severe OSA patients, whose AHI are over 15 events/h, the OrbSense cutoff was 16.6 events/h, with a sensitivity of 87.1%, and a specificity of 89.7%. (4) Among 359 participants, 250 subjects (69.6%) had totally the same OSA severity division classified by both PSG and OrbSense.

Conclusions: The contact-free device OrbSense can detect respiratory events during sleep and has close agreement with in-lab PSG in screening for OSA. Further studies are warranted to test its utility in community-based setting and at home.

Keywords: contact-free monitor; obstructive sleep apnea; apnea hypopnea index; polysomnography

BRIEF SUMMARY

Current Knowledge/Study Rationale: New bio-motion contact-free devices (e.g. OrbSense), have been developed to assess, sleep disordered breathing. It is important to thoroughly understand the accuracy of this new technology as compared with PSG. The purpose of this study was to evaluate the diagnostic value of this device for obstructive sleep apnea.

Study Impact: The results demonstrate that the contact-free device has close correlation and agreement with the results of in laboratory PSG when both are measured simultaneously in a sleep laboratory. The optimal diagnostic cut-off value of the OrbSense was REI ≥ 8 events/h compared to PSG. This contact free device could be a useful screening tool and complementary for PSG. Further studies are needed to assess the utility of OrbSense in home sleep apnea testing.

INTRODUCTION

Obstructive sleep apnea hypopnea syndrome (OSAHS) is a common chronic disorder affecting more than 5% of the general population. It is a risk factor for cardiovascular and metabolism diseases[1, 2] of OSAHS patients in the population. Worldwide, it is estimated that there are more than 936 million adults aged 30–69 years of OSA patients in the population.[3] In China, the patients with AHI over 15 events/h is more than 50 million, however, the proportions of diagnosis and treatment are both less than one percent, mostly due to the limited capacity of sleep service.[4] Using emerging validated technologies to detect sleep apnea at home might be a solution to the problem. Contact-free sleep devices with less effect on sleep have been developed to monitor sleep/wake duration,[5, 6] however, few contact-free techniques were validated to monitor for obstructive sleep apnea (OSA).[7] A new contact-free device (OrbSense) was designed to assess respiratory events using an ultrawideband (UWB) radar system without any electrodes attached to the subjects. The goal of the study was to use in-lab polysomnography (PSG) testing to validate this new technique in detecting respiratory events, and its clinical utility in screening for OSA.

METHODS

Participants and protocols

Adults with suspected OSA and had no previous experience for sleep testing or treatment were recruited from the Sleep Disorders Center at the Peking University People's Hospital, Beijing, China. Three hundred and fifty-nine adults were enrolled to the study. Individuals were excluded from the study for the following reasons: prior diagnosis of chronic heart failure (CHF) with possible central sleep apnea/Cheyne-Stokes respiration (CSA/CSR), obesity hypoventilation syndrome, narcolepsy, rapid eye movement behavior disorder, chronic obstructive pulmonary disease (COPD), jet lag or shift worker by history over the past 3 months; under oxygen therapy; or a clinically unstable medical condition, such as recent hospital admissions in previous month or acute myocardial infarction, acute exacerbation of chronic obstructive pulmonary disease, thyroid disease, untreated depression, surgery, or untreated cancer.

During routine in-laboratory PSG sleep testing, the sleep technologist installed the contact-free device (OrbSense, Megahealth Medical, Inc. Zhejiang, China) on the table beside the patient's bed; the distance to the patient was within 100 cm. The recording was initiated when the device turned on. The start and stop of recording time during OrbSense monitoring were defined the same as lights off and lights on time during PSG testing. All the data from OrbSense testing and PSG study was conducted simultaneously and collected to be analyzed.

The study was approved by the Ethics Committee of Peking University People's Hospital, and informed consents were obtained from all patients.

The working principle of OrbSense contact-free monitor system

OrbSense is a non-contact respiratory movement-monitoring device using Impulse Radio Ultra-Wide Band (IR-UWB) radar, sending and collecting the radio signals toward and from the chest wall of body (**Figure 1**). Because of its high resolution and penetration power, it can recognize minor movements of human body parts. The IR-UWB radar sensor is able to detect objects using the ultra-wide band frequency without interference from other sensors. The radar module has a central frequency of 7.29 GHz and a bandwidth of 1.5 GHz using low power of approximately -41.3 dBm/MHz, which meets the US Federal Communications Commission (FCC) standards.[8] The average power emitted by the OrbSense is 0.1 mW (about 1000 times lower than a standard Wi-Fi router). The OrbSense uses impulse waves of a duration as short as 1 ns.

The OrbSense was placed on a patient's bedside table with the antenna pointed toward the patient's chest. Typically, respiration causes chest displacements up to several millimeters.[9] The OrbSense transmits the pulse wave to the body; the radiated pulse is reflected by the subject and detected by the

receiver antenna. The signal was processed automatically by the software algorithm inside the OrbSense. Acquired data includes respiration rate, respiration movement amplitude, heart rate and body movement. When respiratory events including sleep apnea or hypopnea occur, breath amplitude will change significantly compared with the normal respiration. Based on the correlation analysis, through proprietary algorithms, OrbSense can define all the respiratory events (obstructive apnea-hypopnea events， central sleep apnea and mixed sleep apnea). In the current algorithm of OrbSense software, both obstructive apnea and hypopnea were classified as obstructive events as both of them have same clinical significance. The total analyzed time representing a close estimation of the total sleep time is automatically calculated by the sleep/wake analytic software designed in the OrbSense algorithm (**Figure 1**) and employed in the final calculation of respiratory event index (REI, total respiratory events*60/ total analyzed time in minutes). An example of OrbSense respiration signal versus PSG sum channel demonstrating a series of apneic events is displayed in **Figure 2**.

Polysomnography

Polysomnography (Alice6, Philips Respironics, Inc, Murrysville, Pennsylvania, United States) was performed according to the recommendations of the American Academy of Sleep Medicine (AASM).[10,11] The following signals were recorded: electroencephalogram (F3M2, F4M1, C3M2, C4M1, O1M2, and O2M1), bilateral electrooculogram, chin muscle electromyogram, oronasal thermistor, nasal pressure, rib cage and abdominal movement, electrocardiogram, snoring, body position, bilateral anterior tibialis electromyograms, and heart rate and oxygen saturation by pulse oximetry. Using the AASM scoring criteria,[11] PSG was scored manually with the aid of computer software by an experienced sleep technologist without knowledge of the results of the OrbSense. Apneas were scored when there was ≥ 90% reduction in airflow from baseline for ≥ 10 seconds on the oronasal thermistor signal. The same criteria used to identify obstructive, central, and mixed apneas on the portable monitor recordings were used to score those events on PSG. Hypopneas were defined by a ≥30% reduction in a respiratory signal for at least 10 seconds associated with a ≥3% reduction in oxygen saturation or an arousal. AHI on PSG was calculated as the average number of apneas and hypopneas per hour of sleep.

Statistical analysis

Means and standard deviation (SD) was used to summarize continuous variables, while counts and percentages for categorical variables. We used the paired t test, Pearson's correlation coefficient and Bland-Altman plot to analyze respiratory parameters from different monitoring methods to evaluate the level of correlation and agreement between the OrbSense and PSG.[12, 13] We examined the diagnostic characteristics of the contact-free sleep apnea monitor by calculating the sensitivity, specificity, positive predictive value, and negative predictive value at the cutoff values of AHI thresholds of ≥ 5, ≥ 10, ≥ 15 and ≥ 30 events/h, respectively. Receiver-operator characteristics (ROC) curves were built for 4 different PSG diagnostic thresholds to identify the cutoff-values to clinical decision of OrbSense. A convenience sample of 119 participants from the 359 subjects were chosen to evaluate the performance of OrbSense in identifying the specific type of individual respiratory events, including hypopnea, obstructive sleep apnea, central sleep apnea and mixed sleep apnea. The 119 patients were the most recently tested cases during the study period, their demographic data and comparison with the whole group were shown in **Table S1**. Although the 119 cases had lower AHI, they had similar proportion of obstructive, central or mixed sleep apnea (or hypopnea). The scoring of respiratory events from PSG was done by the sleep technicians, who were blinded to OrbSense.

Statistical analyses were performed using MedCalc Version 19.0.5 (MedCalc Software, Ostend, Belgium), and $p<0.05$ is considered as significant.

RESULTS

Sample characteristics

Among the 359 patients included in the study, all patients were Han Chinese, 67.7% were male, with mean BMI of 26.1 ± 4.2 kg/m^2, and mean age of 46.3±13.3 years. Patients were moderately sleepy, with an average Epworth Sleepiness Scale (ESS) score of 11.5±5.4. During the PSG testing, participants slept 6.7 ± 1.1 hours on average with a mean sleep efficiency of 82.2±12.9%. The demographic data of participants in subgroup and all samples is presented in supplemental material (**Table S1**).

Comparison of respiratory parameters between two techniques

Total respiratory events, total analyzed time and REI from in-laboratory OrbSense were compared to total respiratory events, total sleep time and apnea-hypopnea index from PSG, respectively. There was no difference between OrbSense and PSG in the number of total respiratory events per night (179.2±174.5 vs 173.1 ± 138.6, respectively, P=0.1746). The total sleep time was half an hour shorter on the in-laboratory PSG than total analyzed time in the OrbSense recording (401.3±68.6 vs 434.6±75.0 min，p< 0.0001). Therefore, the AHI on the PSG was slightly higher than REI on OrbSense (27.0±25.2 vs 25.5±20.7 events/h, P=0.007).

When the respiratory parameters in a subgroup of 119 patients were analyzed (**Table 1**), as that of the total patient sample, the number of total respiratory events per night was not different between in the two systems. OrbSense is able to identify obstructive events almost as accurately as the PSG (125.0±102.8 by OrbSense vs 121.9 ± 137.7 events by PSG, respectively, P=0.756). However, compared with PSG, OrbSense recognized fewer central (9.4 ± 29.0 vs 1.0 ± 4.6, p=0.001) and mixed events (11.3 ± 32.8 vs 1.0 ± 4.6, p=0.001). Since central and mixed events were much less frequent than obstructive events, the overall AHI (PSG) and REI (OrbSense) were similar (21.6 ± 21.8 vs 21.8 ± 18.7 events/h, p=0.886).

Correlation and agreement between the two monitoring methods

As shown in **Figure 3A**, AHI and REI had high correlation (r=0.92, p<0.001). The Bland-Altman analysis demonstrated a mean difference of 1.5 (95% confidence ranging from −18.6 to 21.5 events/h) **(Figure 3B)**. After calculating, 97.2% points located within the limits of agreement and its 95% CI, which means a high agreement between overall REI in OrbSense and AHI from PSG. Based on different PSG AHI thresholds of <5, ≥ 5, ≥ 15 and ≥ 30 events/h, participants were divided into four groups with no OSA and mild, moderate, and severe OSA. Correlation and agreement between the two techniques in four groups were conducted as well (**Figure S1**, supplemental material). We noted that there was evidence for a significant negative correlation between the difference and mean, suggesting that at higher AHI values (especially when AHI ≥ 30 events/h), OrbSense results in larger underestimates of the PSG AHI. Similar results were observed on AHI and REI between the two techniques in subgroup (N=119) analysis (**Figure S2**, supplemental material).

Diagnostic accuracy of the OrbSense

Table 2 indicated the comparisons of the diagnostic characteristics of REI based on cutoffs value of AHI derived from PSG with different severity criteria at 5, 10, 15, and 30 events per hour. Accordingly, receiver-operator characteristics curves are shown in **Figure 4**. Using a threshold of AHI ≥5 events/h, the in-laboratory OrbSense recording had 96% sensitivity, 56% specificity, 0.904 area under the curve (AUC). Similar results were observed at AHI cutoffs of ≥10 and ≥15 events/h, with specificity increasing to 81%, AUC increasing to 0.942 with only a small decrease in sensitivity (90%) at an AHI cutoff ≥15 events/h.

Using a PSG diagnostic criterion of AHI over 5 events/h, the optimal diagnostic cut-off value from OrbSense was 8 events/h, with a sensitivity of 90.4%, and a specificity of 77.6%. For moderate to severe OSA patients, whose AHI is over 15 events/h, the OrbSense cutoff was 16.6 events/h, with a sensitivity of 87.1%, and a specificity of 89.7%, as shown in **Table 3**.

OrbSense versus PSG based on OSA severity

Figure 5A illustrates the percentage of subjects with no OSA and mild, moderate, and severe OSA based on the AHI on PSG and in-laboratory OrbSense recording. As suggested given the strong agreement between the PSG for the AHI using the 3% hypopnea criteria and simultaneous in-laboratory OrbSense, based on a four-severity division into normal (AHI<5), mild(5≤AHI<15), moderate(15≤AHI<30) and severe OSA(AHI≥30), the proportions within each of the clinical groupings were similar between these two techniques. **Figure 5B** shows the classification of subjects by polysomnography (PSG) against the classification of cases by OrbSense. The data demonstrates that among 359 participants, 250(69.6%) subjects in this study had totally the same OSA severity division classified by both PSG and OrbSense, nighteen of 193 patients (9.8%) with moderate or severe OSA on PSG were scored as REI < 15 events/h on OrbSense testing.

The percentage and classification of subgroup subjects based on OSA severity were presented in **Figure 5C** and **Figure 5D**. For moderate to severe OSA patients whose AHI≥15 on PSG, the cutoff of REI≥15 on OrbSense showed a sensitivity of 0.90, a specificity of 0.81, a false positive rate of 3.5%, and a false negative rate of 9.8%. Although in the subgroup sample, participants predominated with normal and mild OSA group, the proportions within each of the clinical groupings and OSA severity classification were similar between PSG and OrbSense.

DISCUSSION

Wearable devices assessing sleep are widely used. This study is one of the few clinical validation studies of contact-free sleep apnea monitoring devices comparing the findings to simultaneously acquired PSG data. In this clinic-based patient cohort, obstructive events detected by OrbSense were not different than those acquired by PSG. OrbSense screens OSA with high sensitivity and specificity. Using a cutoff value of AHI≥5 events/h, 81.1% of subjects had a diagnosis of OSA both on OrbSense and on PSG. At a cutoff value of AHI ≥15 events/h, 57.1% of subjects received a diagnosis of OSA on OrbSense and 53.8% on PSG.

OrbSense was designed to detect subject's body motion due to respiratory movement by specific algorithm. Unlike other wearable devices, it was not used for sleep/wake duration monitoring. In the current study, we focused on the respiratory event monitoring. Data showed a close agreement between REI and AHI (p=0.886), and high sensitivity and specificity when specific cutoff values reflecting OSA severity were assessed. Although subgroup analysis demonstrated that in-lab OrbSense generated a total monitoring time similar to TST from PSG (p=0.4965). OrbSense overestimated half an hour of sleep duration than PSG in the whole group of patients, and underestimated PSG derived AHI by 1.5 events/h, a larger difference occurred when the AHI≥30, which might be due to severe cases had more movement time which was not classified as sleep time. However, this difference did not have major influence on the clinical decision-making, as OrbSense only missed few patients with AHI≥15. This was particularly so when a lower diagnostic threshold of moderate–severe OSA was used. For example, when OrbSense REI≥13 events/h was applied as a cutoff, the rate of missing was 5.2% (10/193 patients with moderate-severe OSA). The utility of OrbSense in screening for OSA was further illustrated by the ROC for OrbSense using this threshold, with an area under the curve of 0.94. Our results are consistent with the finding from SleepMinder,[15,] another bio-motion non-contact device using low-power radio frequency, which was correlated strongly with polysomnographic measurement ($r = 0.90$; $P < 0.0001$). As reported by Zaffaroni and his colleagues, when a diagnostic threshold of moderate–severe (AHI≥15 events/h) OSA was used, SleepMinder displayed a sensitivity of 90%, a specificity of 92% and an accuracy of 91% in the diagnosis of sleep-disordered breathing.[15,] In summary bio-motion signals collection can be used to detect respiratory events during sleep, either by low-power radio frequency in SleepMinder, or by IR-UWB radar in OrbSense.

One of the advantages of OrbSense system is that it is a contact-free sleep apnea monitor device, with no electrodes or sensors attached to the subject. This largely reduced the influence on the subject's

sleep and potentially allows more normal sleep than traditional diagnostic modalities. Moreover, it requires minimal set-up, and hence has the potential to allow for convenient testing of sleep-disordered breathing at home, which facilitates ambulatory diagnosis and enlarge diagnostic capacity.[14] This contact free device when used in sleep lab is comparable to, at least not inferior to the classic type 3 out-of-center devices and other contactless systems for sleep apnea testing (OCST) in detecting respiratory events (**Table 4**).

The current study has several limitations. First, the study was conducted in sleep laboratory, the data may not apply to home testing, as different environment at home may interfere with the UWB radar signals. Positioning the receiver by patients themselves may differ too. Second, the current study focused on Han Chinese with lower BMI, the generalization of the findings from the current report to other populations is limited. Finally, the studied population was those without major comorbidities such as COPD or CHF, its utility in detecting CSA/CSR events warrants further study.

CONCLUSIONS

This study validated the use of the in lab OrbSense as a contact-free device in detecting sleep apnea in suspected OSA patients. This system could be used as a screening test and complementary for PSG with less interruption of sleep. Further studies are warranted to test its utility in community-based setting and at home.

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All the authors have seen and approved the manuscript, Dr. XS Dong and Dr. F Han contributed to the study design; R ZHAO, JB XUE, H ZHI and JN CHEN contributed to the data collection and data analysis; R ZHAO and JB XUE contributed to coordinating this project; XS DONG is the guarantor of the manuscript and take responsibility for the integrity of the data; R ZHAO, H ZHI, XS DONG, F HAN and T Penzel contributed to the writing and editing of the manuscript.

ABBREVIATIONS

AASM, American Academy of Sleep Medicine
AHI, apnea-hypopnea index
AUC, area under the curve
BMI, body mass index
COPD, chronic obstructive pulmonary disease
CHF, chronic heart failure
CI, confidence interval
CSA, central sleep apnea
CSR, Cheyne-Stokes respiration
ESS, Epworth Sleepiness Scale
HSAT, home sleep apnea testing
IR-UWB, impulse radio ultra wide band
LB, lower bound
NPV, negative predictive value
OCST, out-of-center devices for sleep apnea testing
OSA, obstructive sleep apnea
OSAHS, obstructive sleep apnea hypopnea syndrome

PAP, positive airway pressure
PPV, positive predictive value
PSG, polysomnography
REI, respiratory event index
ROC, receiver operator curve
SD, standard deviation
TST, total sleep time
UB, upper bound
UWB, ultra-wide band

REFERENCES

1. Young T, Peppard PE, Gottlieb DJ. Epidemiology of obstructive sleep apnea; a population health perspective. *Am J Respir Crit Care Med* 2002; 165:1217–39.
2. McNicholas WT, Bonsigore MR. Sleep apnoea as an independent risk factor for cardiovascular disease: current evidence, basic mechanisms and research priorities. *Eur Respir J*. 2007; 29(1): 156–78.
3. Benjafield AV, Ayas NT, Eastwood PR, et al. Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis. *Lancet Respir Med* 2019; 7: 687–98.
4. Han F. Development of sleep medicine in China. *Chin Med J*, 2009,122(12): 1462-1463.
5. Tal A, Shinar Z, Shaki D, Codish S, Goldbart A. Validation of contact-free sleep monitoring device with comparison to polysomnography. *J Clin Sleep Med.* 2017; 13(3): 517–522.
6. Schade MM, Bauer CE, Murray BR, Gahan L, Doheny EP, Kilroy H, affaroni A, Montgomery-Downs HE. Sleep validity of a non-contact bedside movement and respiration-sensing device. *J Clin Sleep Med.* 2019; 15(7): 1051–1061.
7. Zaffaroni A, Kent B, O'Hare E, et al. Assessment of sleep- disordered breathing using a non- contact bio- motion sensor. *Journal of Sleep Research, 22*(2), 231–236.
8. Federal Communications Commission, Electronic Code of Federal Regulations: Title 47, Part 15, Subpart F, American National Standards Institute C63.10: 2013.
9. A. Lazaro, D. Girbau, R. Villarino. Analysis of vital signs monitoring using an IR-UWB radar. *Progress in Electromagnetics Research*, PIERv100, 2010; 265–284.
10. Kushida CA, Littner MR, Morgenthaler T, et al. Practice parameters for indications for polysomnography and related procedures: an update for 2005. *Sleep*. 2005; 28(4): 499–521.
11. Berry RB, Brooks R, Gamaldo CE, et al.; for the American Academy of Sleep Medicine. *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical specifications. Version 2.6.* Darien, IL: American Academy of Sleep Medicine; 2020.
12. Flemons WW, Littner MR. Measuring Agreement Between Diagnostic Devices. *Chest*. 2003 124(4): 1535-42.
13. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986; 1:307-310.
14. Kuna, ST, Badr MS, Kimoff RJ, et al. An official ATS/AASM/ ACCP/ERS workshop report: research priorities in ambulatory management of adults with obstructive sleep apnea. *Proc Am Thorac Soc*, 2011, 8: 1–16.
15. Zaffaroni A, De Chazal P, Heneghan C, Boyle P, Mppm PR, McNicholas WT. SleepMinder: an innovative contact-free device for the estimation of the apnoea-hypopnoea index. *Conf Proc IEEE Eng Med Biol Soc*, 2009: 7091–7094.
16. Xu L, Han F, Keenan BT, et al. Validation of the Nox-T3 portable monitor for diagnosis of obstructive sleep apnea in Chinese adults. *J Clin Sleep Med.* 2017; 13(5): 675–683.
17. Morales CR, Hurley S, Wick LC, et al. In-home, self-assembled sleep studies are useful in diagnosing sleep apnea in the elderly. *Sleep.* 2012; 35(11): 1491–1501.
18. Chai-Coetzer CL, Antic NA, Rowland LS, et al. A simplified model of screening questionnaire and home monitoring for obstructive sleep apnoea in primary care. *Thorax.* 2011; 66(3): 213–219.
19. Gjevre JA, Taylor-Gjevre RM, Skomro R, Reid J, Fenton M, Cotton D. Comparison of polysomnographic and portable home monitoring assessments of obstructive sleep apnea in Saskatchewan women. *Can Respir J.* 2011; 18(5): 271–274.
20. Norman MB, Middleton S, Erskine O, Middleton PG, Wheatley JR, Sullivan CE. Validation of the Sonomat: a contactless monitoring system used for the diagnosis of sleep disordered breathing. *Sleep* 2014; 37(9):1477-1487.
21. Agatsuma T, Fujimoto K, Komatsu Y, et al. A novel device (SD-101) with high accuracy for

screening sleep apnoea-hypopnoea syndrome. *Respirology* 2009; 14:1143-50

Table 1—Comparison of respiratory parameters observed in PSG and OrbSense.

	PSG (n = 119)	**OrbSense (n = 119)**	***P***
AHI or REI (events/h)	21.6 ± 21.8	21.8 ± 18.7	0.886
Numbers of respiratory events			
Total events	147.7 ± 151.9	133.3 ± 110.1	0.123
Obstructive	121.9 ± 137.7	125.0 ± 102.8	0.756
Central	9.4 ± 29.0	1.0 ± 4.6	0.001
Mixed	11.3 ± 32.8	1.0 ± 4.6	0.001

AHI = apnea-hypopnea index, PSG = polysomnography, REI = respiratory event index.

Table 2—Prevalence, sensitivity, specificity, and PPV, NPV for different cutoff of the in-laboratory OrbSense recording versus polysomnography.

AHI (events/h)	Prevalence (%)	Sensitivity	Exact 95% CI		Specificity	Exact 95% CI		PPV	NPV
			LB	UB		LB	UB		
≥ 5	0.81	0.96	0.93	0.98	0.56	0.44	0.68	0.90	0.77
≥ 10	0.66	0.95	0.91	0.97	0.69	0.60	0.77	0.86	0.88
≥ 15	0.54	0.90	0.84	0.93	0.81	0.74	0.87	0.85	0.87
≥ 30	0.35	0.89	0.81	0.93	0.94	0.90	0.97	0.89	0.94

AHI = apnea-hypopnea index, LB = lower bound, NPV = negative predictive value, PPV = positive predictive value, UB = upper bound.

Table 3—Best cutoffs for different OSA severity.

AHI (events/h)	OrbSense Cutoff (events/h)	AUC	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
≥ 5	8.0	0.90	90.4	77.6	94.6	65.0
≥ 15	16.6	0.94	87.1	89.7	90.9	85.5
≥ 30	31.6	0.97	88.7	95.7	91.7	94.1

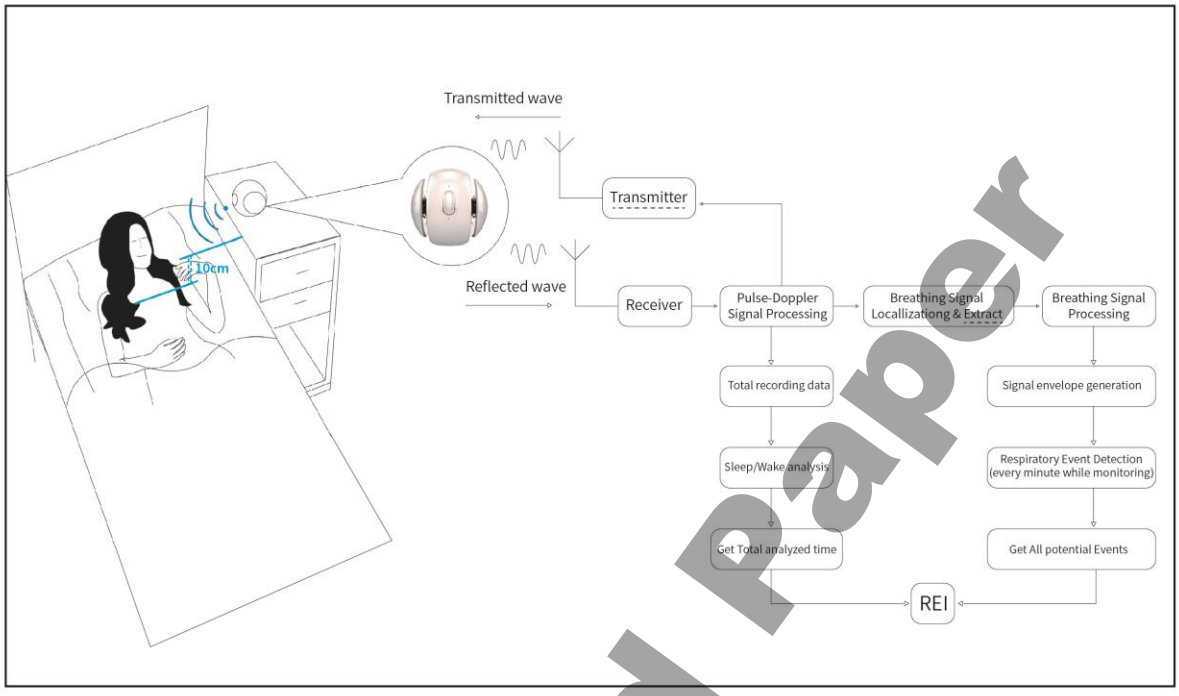
AHI = apnea-hypopnea index, AUC = area under the curve, NPV = negative predictive value, OSA = obstructive sleep apnea, PPV = positive predictive value.

Table 4—The performance of reported type 3 out-of-center devices for sleep apnea testing in detecting OSA.

Study	Portable Monitoring	OSA Comparison	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Xu et al, 2017[16]	Nox T3	AHI > 5	97	75	95	82
		AHI > 15	100	94	95	100
Morales et al, 2012[17]	ResCare AutoSet	AHI ≥ 30 uAHI > 20.9	84	74.3	NR	NR
Chai-coetzer et al, 2011[18]	ApneaLink oximetry	AHI ≥ 15 3%ODI ≥ 16	88	82	56	96
Gjevre et al, 2011[19]	Embletta	AHI > 5 AHI > 15	90.6 62.5	60 93.3	82.7 95.2	75 53.9
Norman et al, 2014[20]	Sonomat	AHI > 5	94	77	NR	NR
Agatsuma et al, 2009[21]	SD-101	AHI ≥ 5 AHI ≥ 15	100 96.6	32.5 60.0	NR NR	NR NR

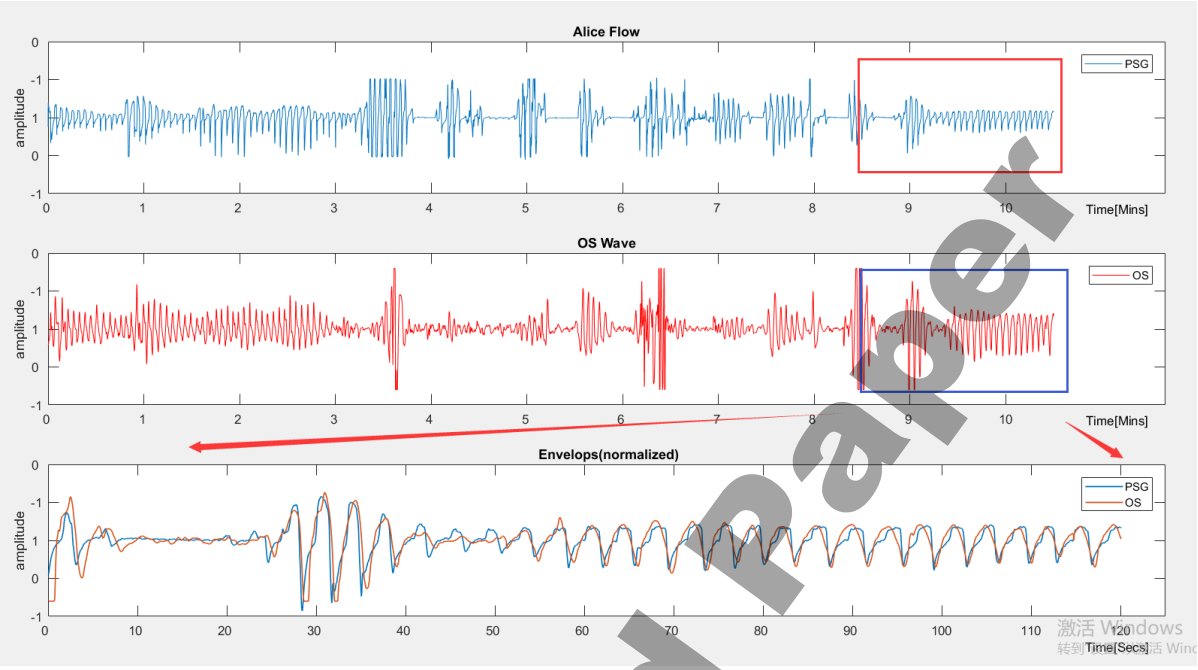
AHI = apnea-hypopnea index, ODI = oxygen desaturation index, uAHI = estimated unattended AHI, NR = not reported, NPV = negative predictive value, OSA = obstructive sleep apnea, PPV = positive predictive value.

Figure 1—A setting example of contact free device, and schematic diagram of the UWB radar and respiratory events detection algorithm.



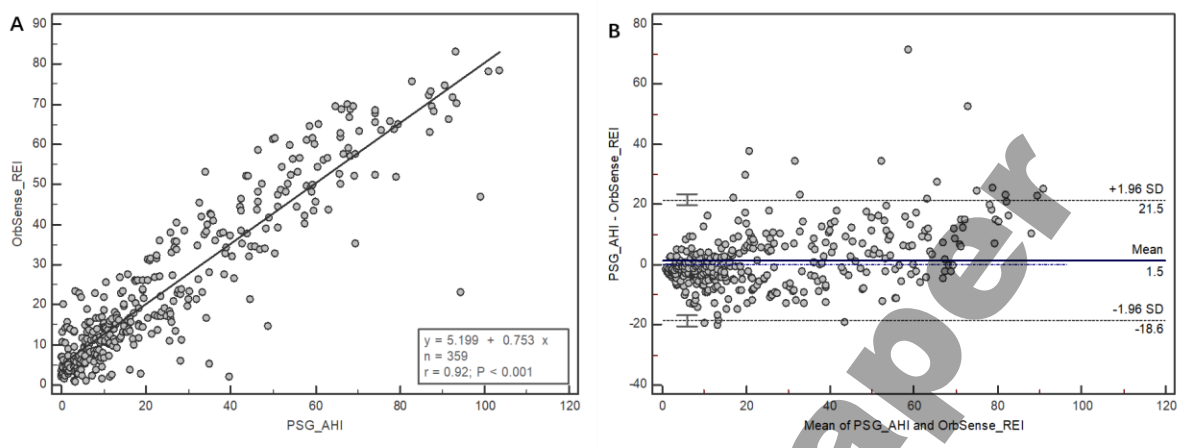
The OrbSense is placed beside the patient's bed with no more than two meters in the distance and no less than ten centimeters in height. Potential events are identified and then processed by the event morphological analysis to determine detected events. Finally, they are matched against epoches of sleep and the REI value calculated.

Figure 2—An example of a comparison of the OrbSense respiration signal and the polysomnography sum signal, demonstrating a series of apneic events in a patient with severe OSA.



The amplitude of both signals has been normalized.

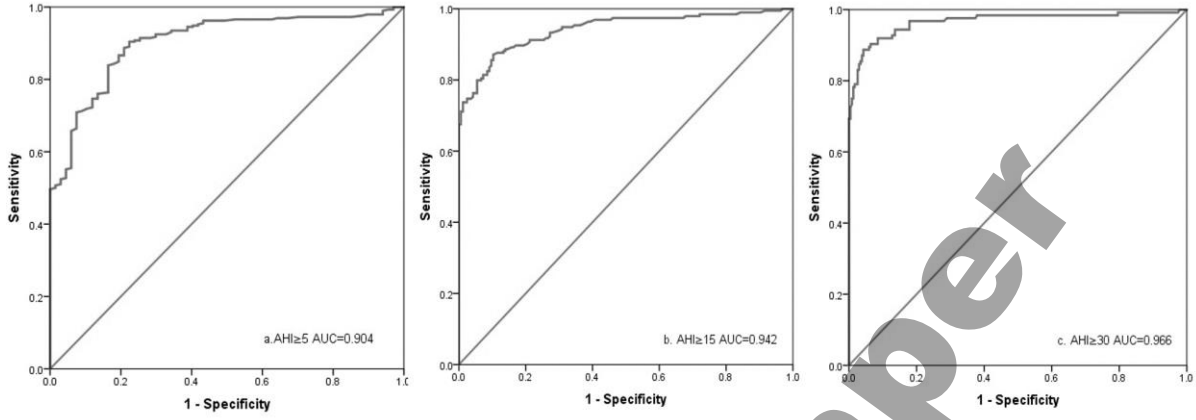
Figure 3—Comparison of manually edited AHI on PSG and OrbSense recording.



(A) Scattered plot of AHI on PSG compared to OrbSense.

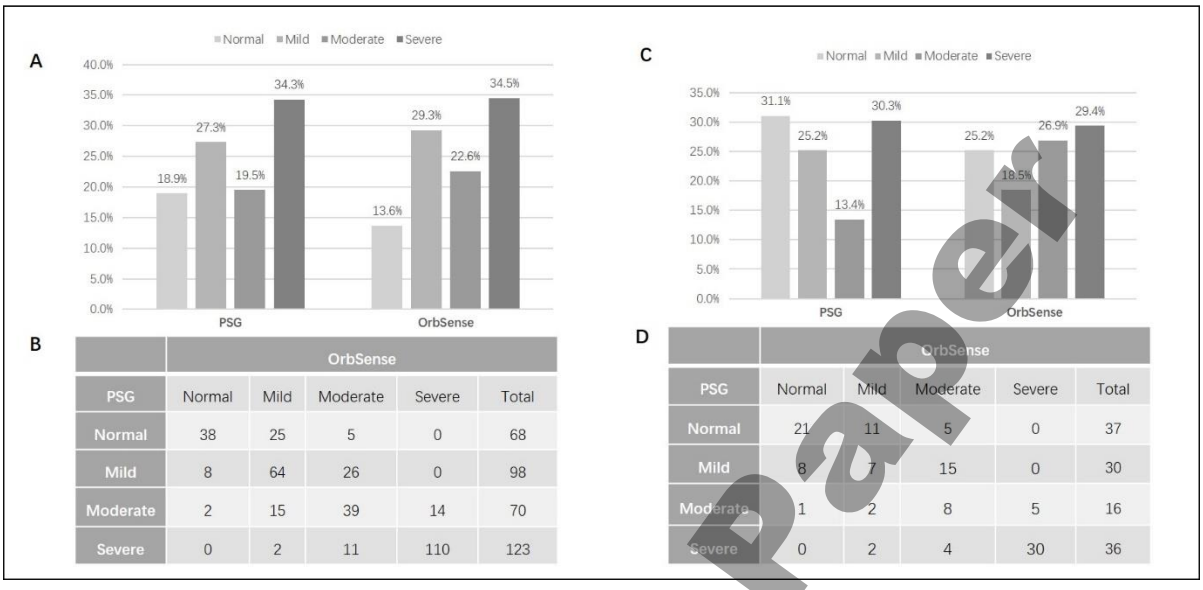
(B) Bland-Altman plot of AHI on PSG compared to in-laboratory OrbSense.

Figure 4—Receiver-operator characteristics curves for the OrbSense estimated respiratory event index versus the PSG AHI.



The three curves refer to a diagnostic threshold of the expert annotated AHI≥5 (AUC = 0.904), AHI≥15 (AUC = 0.942), AHI≥30 (AUC = 0.966), respectively.

Figure 5—Diagnostic performance of OrbSense versus PSG based on OSA severity.



B

	OrbSense				
PSG	Normal	Mild	Moderate	Severe	Total
Normal	38	25	5	0	68
Mild	8	64	26	0	98
Moderate	2	15	39	14	70
Severe	0	2	11	110	123

D

	OrbSense				
PSG	Normal	Mild	Moderate	Severe	Total
Normal	21	11	5	0	37
Mild	8	7	15	0	30
Moderate	1	2	8	5	16
Severe	0	2	4	30	36

(A) Percentage of total patients falling into different OSA groupings with 2 techniques.
(B) Distribution of total subjects evaluated by polysomnography (PSG) against OrbSense.
(C) Percentage of subgroup sample falling into different OSA groupings with 2 techniques (N=119).
(D) Distribution of subgroup samples evaluated by polysomnography (PSG) against OrbSense (N=119).
OSA severity was defined as normal (AHI<5), mild (5≤AHI<15), moderate(15≤AHI<30) and severe OSA (AHI≥30) with both PSG and OrbSense. For Orbsense, AHI means REI (respiratory event index).