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EMERGING TECHNOLOGIES

Belun Ring Platform: a novel home sleep apnea testing system for assessment of obstructive sleep apnea

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Study Objectives: The objective of the study is to validate the performance of Belun Ring Platform, a novel home sleep apnea testing system using a patented pulse oximeter sensor and a proprietary cloud-based neural networks algorithm.

Methods: The Belun Ring captures oxygen saturation, photoplethysmography, and accelerometer signals. The Belun Ring total sleep time is derived from features extracted from accelerometer, oxygen saturation, and photoplethysmography signals. The Belun Ring respiratory event index is derived from Belun Ring total sleep time and features extracted from heart rate variability and oxygen saturation changes. A total of 50 adults without significant cardiopulmonary or neuromuscular comorbidities and heart rate affecting medications were evaluated. In-lab sleep studies were performed simultaneously with the Ring and the studies were manually scored using the American Academy of Sleep Medicine Scoring Manual 4% desaturation criteria.

Results: The Belun Ring respiratory event index correlated well with the polysomnography-apnea-hypopnea index (AHI; r = .894, $P < .001$). The sensitivity and specificity in categorizing AHI ≥ 15 events/h were 0.85 and 0.87, respectively, and the positive predictive value and negative predictive value were 0.88 and 0.83, respectively. The Belun Ring total sleep time also correlated well with the polysomnography-total sleep time (r = .945, $P < .001$). Although the Belun Ring Platform has a good overall performance, it tends to overestimate AHI in individuals with AHI under 15 events/h and underestimate AHI in those with AHI over 15 events/h. **Conclusions:** In this proof-of-concept study, the Belun Ring Platform demonstrated a reasonable accuracy in predicting AHI and total sleep time in patients without significant comorbidities and heart rate-affecting medications.

Clinical Trial Registration: Registry: ClinicalTrials.gov; Name: Validation of a Novel Device for Screening Patients With Symptoms of Obstructive Sleep Apnea; URL: https://clinicaltrials.gov/ct2/show/NCT04121923; Identifier: NCT04121923.

Keywords: obstructive sleep apnea, home sleep apnea testing, photoplethysmography

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BRIEF SUMMARY

Current Knowledge/Study Rationale: In this initial proof-of-concept study, we evaluated the performance of Belun Ring Platform, a new home sleep apnea testing system based on oxygen saturation, pulse rate, photoplethysmography, actigraphy, and its proprietary deep learning algorithm through neural networks.

Study Impact: We report that the Belun Ring Platform has a good overall accuracy in predicting obstructive sleep apnea in individuals without significant comorbidities and medications known to affect heart rate. The Belun Ring Platform may be a promising clinical tool in the assessment of obstructive sleep apnea.

INTRODUCTION

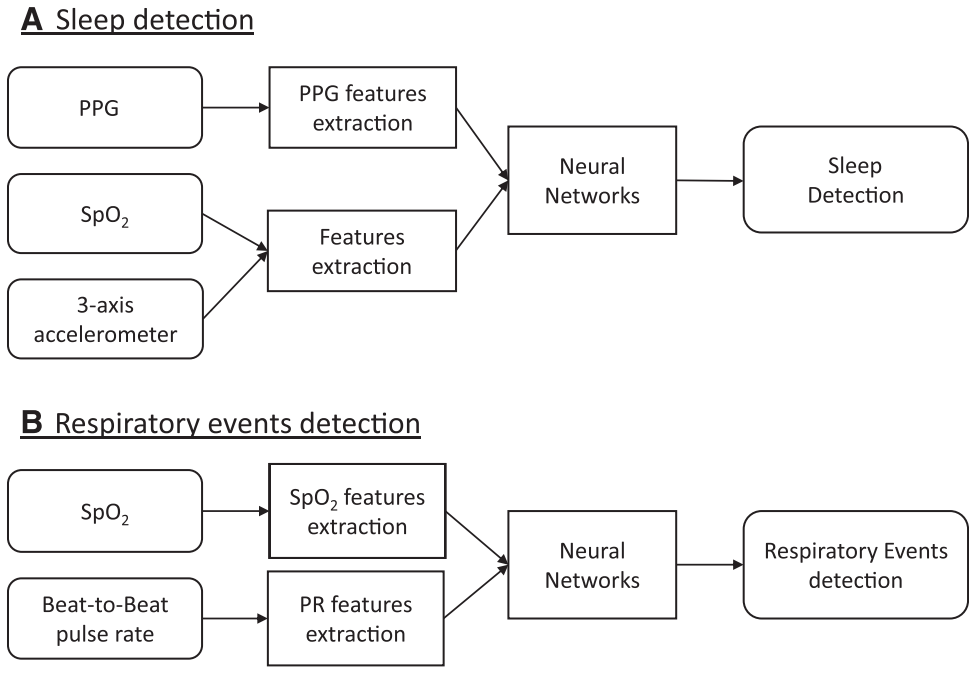
Obstructive sleep apnea (OSA) is a disorder characterized by recurrent collapse of the upper airway during sleep. It is highly prevalent in the adult general population, and severe OSA is associated with increased adverse health outcomes, including cardiovascular, metabolic, cerebrovascular morbidities, neurocognitive impairment, and mortality.[1–7] Currently, attended overnight in-lab polysomnography (PSG) is the gold standard for the diagnosis of OSA but is costly and labor intensive. Limited access to sleep labs continues to be an issue in many remote areas of the United States.

The American Academy of Sleep Medicine (AASM) has recommended that a technically adequate home sleep apnea testing device may be used for the diagnosis of OSA in uncomplicated adult patients exhibiting signs and symptoms that indicate an increased risk of moderate to severe OSA.[8] Type 3 home sleep apnea testing devices (minimum of 4 channels, including airflow, chest movement, pulse oximetry, and heart rate or electrocardiogram), although with limitations, have been widely accepted. WatchPAT (Itamar Medical, Caesarea, Israel), a device that monitors and analyzes peripheral arterial tone signal, is also considered as adequate.[9] More recently, sophisticated "oximeter-plus" devices that incorporate pulse oximetry, photoplethysmography (PPG), accelerometer, and heart rate variability (HRV) have been developed for identifying OSA.[10–12] Compared with the peripheral arterial tone technology that uses a more sophisticated

Figure 1—Belun Ring and accessories.

(**A**) Belun Ring securely worn on the proximal phalanx of the index finger; (**B**) Belun Ring sitting on the charging cradle; (**C**) Paper ring selector; (**D**) Measuring finger size with the paper ring selector.

Figure 2—Sleep and respiratory events detection algorithm using neural networks.



(**A**) Sleep detection; (**B**) Respiratory events detection. PPG = photoplethysmography, PR = pulse rate, SpO_2 = oxygen saturation.

finger-mounted pneumo-optical sensor for continuous measurement of the arterial pulse wave volume of the finger, PPG operates based on simple optical technology to detect blood volume changes in the tissue microvascular bed.[13,14]

The Belun Ring Platform (Belun Technology Company Limited, Hong Kong, People's Republic of China) consists of 3 components: a patented novel ring pulse oximeter that can be securely placed on the proximal index finger, a charging cradle, and a cloud-based software. The Ring sensor (the Ring) is an FDA-cleared pulse oximeter and is specifically designed to minimize sensor motion artifacts and sleep interference. The Ring acquires pulse oximetry, PPG, and 3-axis accelerometer signals from the proximal phalangeal radialis indicis artery of the index finger (**Figure 1A**). The Belun Ring Platform proprietary algorithm was built using neural networks (**Figure 2**) and trained with a data set of 5,783 patients and 8,417 records of overnight sleep studies scored with the 4% desaturation hypopnea criteria.[12] The Belun Ring total sleep time (Ring-TST) is derived from features extracted from 3-axis accelerometer, oxygen saturation, and PPG signals, including HRV and PPG amplitude changes. The Belun Ring respiratory event index (Ring-REI) is derived from Ring-TST and features extracted from HRV and oxygen saturation changes. The cradle of the Ring (**Figure 1B**) is used for charging and uploading data to the cloud for calculation and data storage.

In this proof-of-concept study, we assessed the performance of Belun Ring Platform, specifically the accuracy of Ring-REI and Ring-TST, by comparing them directly to concomitant in-lab PSG-apnea-hypopnea index (AHI) and PSG-TST.

METHODS

Belun Ring data collection protocol

There are 6 different Ring sizes (sizes 5, 7, 9, 10, 11, and 13) with circumferences ranging from 15.7 mm to 22.2 mm. A 2-step approach was adopted to optimize signal quality: 1) a sleep technician first measures the proximal index finger of the nondominant hand using a paper ring selector as shown in **Figure 1, C** and **D**; 2) the sleep technician then places the Ring selected in step 1 on the proximal index finger of the nondominant hand and runs a personal computer software program for ring size optimization. In step 2, patients are asked to keep the testing hand "absolutely still" for signal quality assessment. This step can take up to 60 seconds, and those who fail to keep their hands still to pass the arbitrary high-pass signal strength threshold are excluded from the study. (Notably, we now believe the step 2 is largely unwarranted as Belun Ring signals are adequate in over 90% of the patients used the Ring so far.) Once the ring selection is optimized, the Ring is securely placed on the finger and left in place overnight. At the conclusion of the sleep study, the Ring is removed and placed back on the cradle connected to a personal computer laptop using a USB cable. The acquired data are then uploaded to the cloud via the internet. The proprietary algorithm automatically calculates and generates a report that can be downloaded immediately.

To assess the accuracy of Ring-TST, the sleep stages in 30-second epochs from PSG were extracted according to the valid sleep period of Belun Ring Platform for comparison with the PSG-TST. The Ring-REI is defined as the number of respiratory events estimated by the Belun Ring software divided by the Ring-TST. The Belun staff involved in the study were blinded to the attended in-lab PSG scoring results.

Participants

Seventy participants consented to the study and twenty among them were excluded due to difficulty achieving an arbitrarily preset high-pass signal strength threshold. Fifty consecutive participants who passed the step 2 ring size optimization were enrolled and underwent Belun Ring testing with simultaneous overnight PSG at the Mountain Sleep Diagnostics Sleep Lab in Louisville, CO. Inclusion criteria were age ≥ 18 years who were referred to the sleep lab for sleep study and consented to wear the Ring during PSG. Exclusion criteria included the use of oxygen or noninvasive ventilation, history of chronic obstructive pulmonary disease, heart failure, atrial fibrillation, status post pacemaker, neuromuscular disorders, insomnia, parasomnia, narcolepsy, and those on medications known to interfere with heart rate, such as beta-blockers, digoxin, or calcium receptor antagonists. In this study, the type of sleep study was not restricted to diagnostic studies. Split night studies and continuous positive airway pressure titration studies were allowed. The study protocol was approved by the Salus Institutional Review Board (Austin, TX).

PSG data acquisition and scoring

Attended in-lab PSG (Philips-Respironics G3, Murrysville, PA) was performed in all patients in a standard fashion. The montage for diagnostic sleep study includes electroencephalograph leads (O1M2, O2M1, C1M2, C2M1, F1M2, F2M1), right electro-oculogram, left electro-oculogram, chin electromyogram, nasal pressure airflow, thermistor airflow, chest and abdominal respiratory effort, pulse oximetry, left leg electromyogram, right leg electromyogram, and electrocardiogram. continuous positive airway pressure flow was also monitored for split night and positive airway pressure titration studies. All studies were manually scored in 30-second epochs according to the AASM Scoring Manual version 2.4.[15,16] An obstructive apnea event is defined as a decrease in the thermistor airflow to < 10% of baseline for ≥ 10 seconds with continued respiratory effort. A hypopnea event is defined as a decrease in nasal pressure signal excursions by 30–90% of baseline for ≥ 10 seconds accompanied by oxygen desaturation ≥ 4%. The PSG scoring technicians were blinded to the results of the Belun software analysis.

Statistical analysis

Statistical analysis was performed using MATLAB (MathWorks, Natick, MA) to assess the accuracy of Belun Ring Platform in predicting OSA. The overall accuracy, sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio (LR+), negative likelihood ratio (LR−), Cohen's kappa coefficient (kappa), and the area under the receiver operator curve were computed at PSG AHI cutoffs of 5, 15, and 30 events/h. The correlation coefficient was calculated to evaluate the concordance between the Ring-REI and OSG-AHI as well as between the Ring-TST and the PSG-TST. The Bland-Altman plot was also used to analyze further the agreement between Ring-REI and PSG-AHI as well as between Ring-TST and PSG-TST.

RESULTS

Patients characteristics

A cohort of 50 patients was included, of which 27 (54%) were men. Demographic and clinical data showed a mean age of 54.9 years, a mean body mass index of 30.5 kg/m^2, and a mean AHI of 18.5 events/h. There were 7 patients with AHI < 5 events/h, 16 patients with AHI in the range of 5 to 14.9 events/h, 18 patients with AHI of 15–29.9 events/h, and 9 patients with AHI ≥ 30 events/h as summarized in **Table 1**. Race was not recorded.

Ring-REI and Ring-TST estimation

The Ring-REI correlated well with the PSG-AHI (r = .894, $P < .001$) as shown in **Figure 3A**. The Ring-TST also correlated well with the PSG-TST (r = .945, $P < .001$) as shown in **Figure 3B**. The Bland-Altman plots illustrating the difference between Ring-REI and PSG-AHI and the difference between Ring-TST and PSG-TST are shown in **Figure 4**. The mean difference between Ring-REI and PSG-AHI was −2.3 and the standard deviation was 7.6. Receiver operator curve (n = 50) is plotted at 3 different PSG-AHI thresholds of 5, 15, and 30 events/h in **Figure 5A**. The overall performance of Belun Ring Platform including accuracy, sensitivity, specificity, positive predictive value, negative predictive value, LR+, LR−, kappa, and area under the receiver operator curve is summarized in **Table 2**. The variability of kappa estimation observed at different PSG-AHI thresholds in this study may be due to the small

numbers of patients with AHI < 5 events/h (7 patients, 14%) and AHI ≥ 30 events/h (9 patients, 18%). The 95% confidence interval of kappa was (−0.092, 0.675) for AHI < 5 events/h and (−0.024, 0.662) for AHI ≥ 30 events/h. Error matrix comparing Ring-REI vs PSG-AHI at 3 different AHI cutoffs of 5, 15, and 30 events/h is shown in **Table 3**.

Among the 50 patients undergoing sleep studies, there were 20 diagnostic studies, 14 split night studies, and 16 positive airway pressure titration studies. The duration of the split night diagnostic portion averages 3.1 hours. When the results of the diagnostic portion of the split night studies were combined with the results of the diagnostic sleep studies, the overall accuracy was 0.85, sensitivity 0.86, specificity 0.85, positive predictive value 0.900, negative predictive value 0.786, LR+ 5.571, LR− 0.169, kappa 0.693, and area under the receiver operator curve 0.883 at PSG-AHI cutoff of 15 events/h. Of the 16 continuous positive airway pressure titration cases, 3 had central apnea index ≥ 15 events/h. When these 3 patients were excluded, the accuracy was 0.89, sensitivity 0.92, specificity 0.87, positive predictive value 0.880, negative predictive value 0.909, LR+ 7.028, LR− 0.096, kappa 0.787, and area under the receiver operator curve 0.920 for PSG-AHI ≥ 15. Receiver operator curve (n = 47) is also plotted at PSG-AHI thresholds of 5, 15, and 30 events/h in **Figure 5B** after the exclusion of the 3 patients with central apnea index ≥ 15.

Table 1—Summary of patient characteristics.

Patient Characteristics (n = 50)	
Men/Women	27 (54%)/23 (46%)
Age, y	54.9 (16.3)
BMI, kg/m^2	30.5 (7.7)
AHI, events/h	18.5 (15.4)
AHI range, events/h	
< 5	7 (14%)
5–14.9	16 (32%)
15–29.9	18 (36%)
≥ 30	9 (18%)

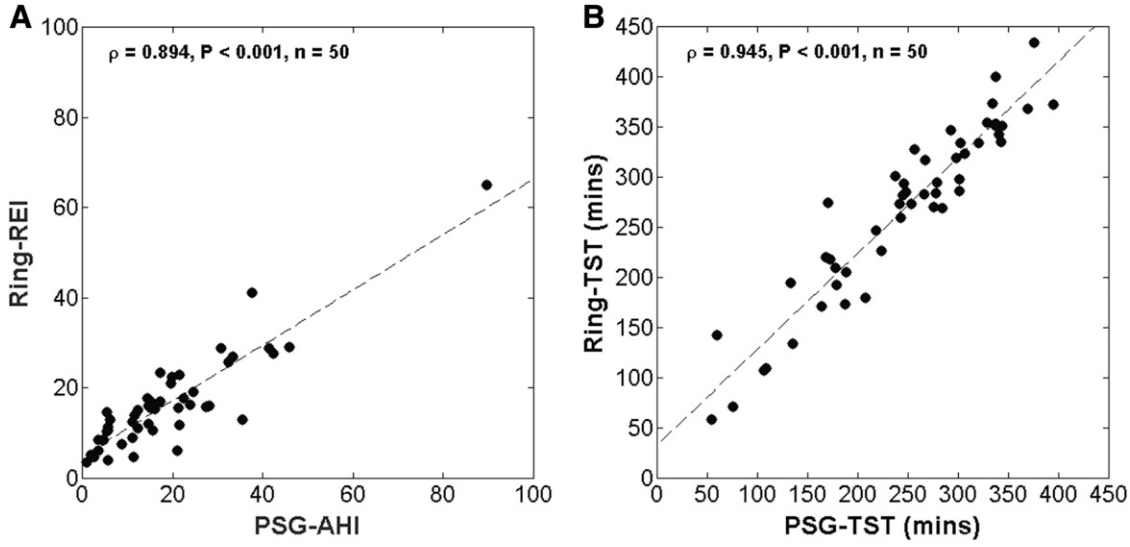
Data are presented as number of patients (percentage of cohort) or mean (SD). AHI = apnea-hypopnea index, BMI = body mass index.

DISCUSSION

Validation studies have been performed on various PPG-based home sleep apnea testing devices.[10,11] Romem et al[10] evaluated the Morpheus Ox system for the detection of OSA and found a positive correlation between PPG-derived and PSG-derived AHI. More recently, Massie et al reported the development of the NightOwl system which also showed a good correlation between NightOwl-REI and PSG-AHI.[11]

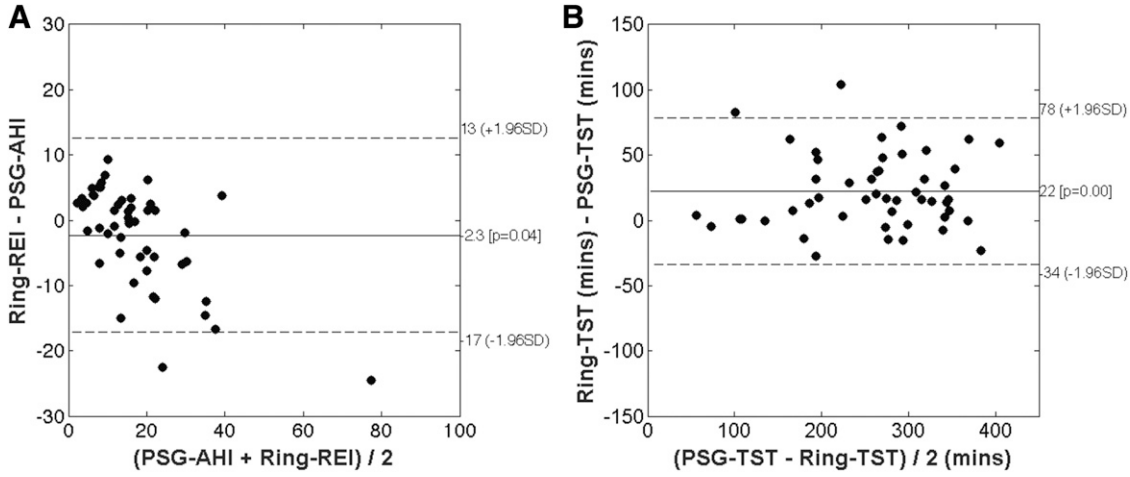
In this proof-of-concept study, we evaluated the performance of Belun Ring Platform in individuals without significant comorbidities and medications known to affect heart rate. There is a good correlation between the Ring-REI and PSG-AHI as well as between the Ring-TST and PSG-TST. Although the Belun Ring Platform has a good overall performance, it tends to overestimate AHI in individuals with AHI under 15 and underestimate AHI in those with AHI over 15 (**Table 3**). This observed discordance between PSG-AHI and Ring-REI is not entirely unanticipated and has been reported in other PPG and peripheral arterial tone-based devices.[11,14,17,18] Massie et al[11] observed that NightOwl overscores AHI in patients of the mild OSA category with AHI of 5–15 events/h and underscores when AHI is above 50 events/h. Ayas et al[14] speculated that the overestimation of AHI in the low AHI range by WatchPAT may be due to the detection of respiratory effort-related arousals and sleep fragmentation. It is plausible that the overestimation of AHI in the

Figure 3—Scatterplots.



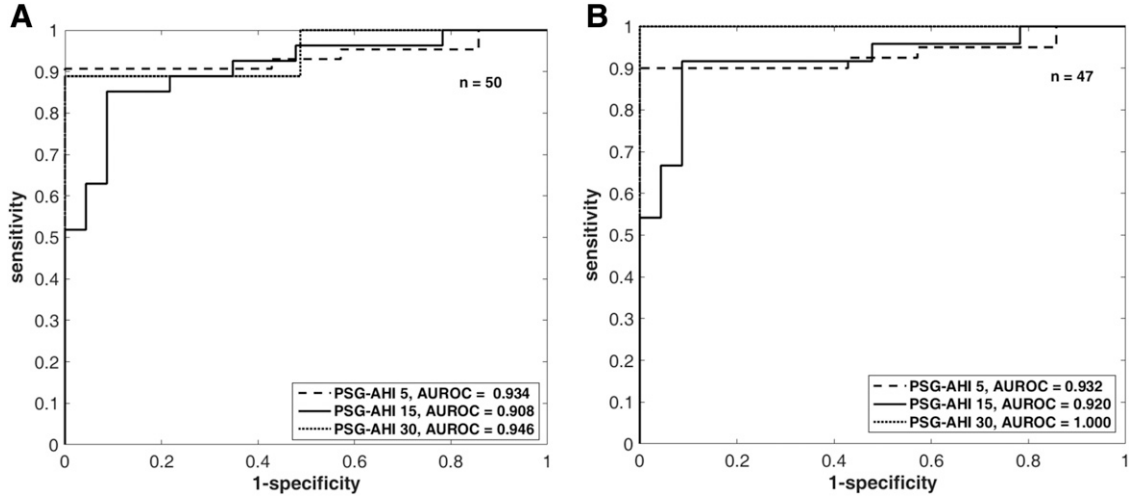
(**A**) Scatterplot comparing Ring-REI to PSG-AHI; (**B**) Scatterplot comparing Ring-TST to PSG-TST. AHI = apnea-hypopnea index, PSG = polysomnography, REI = respiratory event index, TST = total sleep time.

Figure 4—Bland-Altman plots.



(**A**) Bland-Altman Plot of Ring-REI vs PSG-AHI; (**B**) Bland-Altman plot of Ring-TST vs. PSG-TST. AHI = apnea-hypopnea index, PSG = polysomnography, REI = respiratory event index, TST = total sleep time.

Figure 5—ROCs for Ring-REI vs PSG-AHI.



(**A**) ROCs with PSG-AHI thresholds at 5, 15, and 30 events/h (n = 50); (**B**) ROCs with PSG-AHI thresholds at 5, 15 and 30 events/h when 3 cases with central apnea index ≥ 15 were excluded (n = 47). AHI = apnea-hypopnea index, PSG = polysomnography, ROC = receiver operator curve.

Table 2—Performance metrics of Ring-REI at PSG-AHI thresholds of 5, 15, and 30 events/h.

n = 50	Accuracy	Se	Sp	PPV	NPV	LR+	LR−	kappa	AUROC
AHI ≥ 5 events/h	0.86	0.95	0.29	0.891	0.500	1.334	0.164	0.292	0.934
AHI ≥ 15 events/h	0.86	0.85	0.87	0.885	0.833	6.553	0.170	0.719	0.908
AHI ≥ 30 events/h	0.86	0.22	1	1	0.854	+∞	0.778	0.319	0.946

AUROC = area under the receiver operator curve, kappa = Cohen's kappa coefficient, LR− = negative likelihood ratio, LR+ = positive likelihood ratio, NPV = negative predictive value, PPV = positive predictive value, Ring-REI = Ring-respiratory event index, Se = sensitivity, Sp = specificity.

low AHI range noted in this study may be due to the identification of respiratory effort-related arousals and autonomic arousals from other causes by the Belun Ring neural networks algorithm.

On the other hand, the underestimation of AHI in those with AHI above 15 events/h in this study is at least, in part, attributed to the Ring's incapability in capturing central apneas. It is important to realize the Belun Ring Platform was not specifically trained to recognize the HRV pattern of central sleep apnea. Szollosi et al[19] reported that the HRV pattern in central sleep apnea is different from that in OSA in patients with heart failure. It is our observation that the Ring REI tends to "underestimate" the overall PSG-AHI in patients with prominent

Table 3—Error matrix of Ring-REI vs PSG-AHI.

PSG-AHI, events/h	Ring-REI			
	REI ≤ 5	REI 5–14.9	REI 15–29.9	REI ≥ 30
AHI ≤ 5	2	5	0	0
AHI: 5–14.9	2	11	3	0
AHI: 15–29.9	0	3	15	0
AHI ≥ 30	0	1	6	2

AHI = apnea-hypopnea index, Ring-REI = Ring-respiratory event index.

central sleep apnea. In one specific case, the Ring-REI approximated the difference of overall PSG-AHI and central apnea index while being more precise in reflecting true obstructive AHI. Another feasible explanation is that some of the consecutive respiratory events may be missed by the Belun Ring neural networks when multiple respiratory events occur over a short period of time. This was previously observed in WatchPAT and may explain the PSG-AHI and Ring-REI discordance in patients with severe OSA who have few central events.[14,17] Lastly, as observed in the NightOwl study, the underestimation of AHI in the high AHI range may also be attributable to the rejection of motion artifact-related poor PPG signals by the algorithm in patients with very severe OSA.[11]

The main limitation of this study is that the studied population has no significant cardiopulmonary or neuromuscular comorbidities and are not on medications known to affect heart rate. Further validation is warranted in patients with comorbidities and/or on medications affecting heart rate. Also, this study was not performed in an unattended home setting but rather in a sleep lab with trained sleep techs helping patients apply the device. Consequently, we are uncertain how the Ring will perform in the unattended home setting void of staff assistance. Additional investigation in the unattended home setting in comparison to established HST devices should be conducted. It is also crucial to realize that this study cohort is selected from an in-lab sleep study population. Thus, it is likely to recruit those with higher risk for OSA and its performance metrics may be different in a population with a lower OSA prevalence. Lastly, we recognize that the aggregation of diagnostic, split night, and continuous positive titration studies made the interpretation of study results challenging. Future in-lab validation research should focus on comparison with diagnostic sleep studies.

The primary advantage of Belun Ring Platform for OSA testing is its ease of use. Another is that the analysis algorithm can be further refined through neural networks to improve its accuracy with the collection of more data. The main clinical application limitation of this device is in patients with significant arrhythmias or pacemaker use. It should be cautioned that the Belun Ring Platform was not trained to identify central apneas and that patients with high probability of central apnea are likely poor candidates for Belun Ring testing.

In summary, in this proof-of-concept trial, the Belun Ring Platform demonstrated a reasonable accuracy in predicting AHI and TST in patients without significant comorbidities and medications known to affect heart rate. It may be promising as a clinical tool in the assessment of OSA.

ABBREVIATIONS

AASM, American Academy of Sleep Medicine
AHI, apnea-hypopnea index
HRV, heart rate variability
kappa, Cohen's Kappa coefficient
LR+, positive likelihood ratio
LR−, negative likelihood ratio
OSA, obstructive sleep apnea
PPG, photoplethysmography
PSG, polysomnography
REI, respiratory event index
TST, total sleep time

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SUBMISSION & CORRESPONDENCE INFORMATION

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DISCLOSURE STATEMENT

All authors have seen and approved this manuscript. The sleep studies and simultaneous Belun Ring testing were performed at the Mountain Sleep Diagnostics Sleep Lab, an American Academy of Sleep Medicine-accredited independent testing facility, in Louisville, Colorado. This study was funded by the Belun Technology Company Limited, Hong Kong. Wenbo Gu is a PhD student at the Department of Computer Science, National Chiao Tung University, Hsinchu, Taiwan, and is also an engineer of Belun Technology. Drs. Lydia Leung and Ka Cheung Kwok are Belun Technology employees. Dr. I-Chen Wu is a professor of Computer Science at National Chiao Tung University in Hsinchu, Taiwan. Dr. Wu received a research grant from Belun for Belun Ring software algorithm development but has no other financial conflicts of interest. Dr. Rodney Folz has no financial conflicts of interest. Dr. Ambrose Chiang is an unpaid voluntary scientific advisor to Belun. Dr. Chiang has received a research grant from Belun for conducting another Belun Ring validation trial at University Hospitals Cleveland Medical Center but has no other financial conflicts of interest. The Belun Ring sensor has obtained FDA 510(k) clearance as a noninvasive and stand-alone pulse oximeter, intended to be used for spot checking and/or data collection and recording of oxygen saturation and pulse rate of adult patients through index finger in hospital and home environment (K191417). The Belun Ring Platform software for analyzing the respiratory event index and total sleep time is not yet FDA-cleared.

EDITOR'S NOTE

The Emerging Technologies section focuses on new tools and techniques of potential utility in the diagnosis and management of any and all sleep disorders. The technologies may not yet be marketed, and indeed may only exist in prototype form. Some preliminary evidence of efficacy must be available, which can consist of small pilot studies or even data from animal studies, but definitive evidence of efficacy will not be required, and the submissions will be reviewed according to this standard. The intent is to alert readers of *Journal of Clinical Sleep Medicine* of promising technology that is in early stages of development. With this information, the reader may wish to (1) contact the author(s) in order to offer assistance in more definitive studies of the technology; (2) use the ideas underlying the technology to develop novel approaches of their own (with due respect for any patent issues); and (3) focus on subsequent publications involving the technology in order to determine when and if it is suitable for application to their own clinical practice. The *Journal of Clinical Sleep Medicine* and the American Academy of Sleep Medicine expressly do not endorse or represent that any of the technology described in the Emerging Technologies section has proven efficacy or effectiveness in the treatment of human disease, nor that any required regulatory approval has been obtained.