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SCIENTIFIC INVESTIGATIONS

Evaluation of a novel device to assess obstructive sleep apnea and body position

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Study Objectives: Obstructive sleep apnea is a prevalent disease with well-known complications when left untreated. Advances in sleep-disordered breathing diagnosis may increase detection and appropriate treatment. The Wesper device is a recently developed portable system with specialized wearable patches that can measure respiratory effort, derived airflow, estimated air pressure, and body position. This study sought to compare the diagnostic ability of the novel Wesper device with the gold standard of polysomnography.

Methods: Patients enrolled in the study underwent simultaneous polysomnography and Wesper device testing in a sleep laboratory setting. Data were collected and scored by readers blinded to all patient information, and the primary reader was blinded to testing method. The accuracy of the Wesper device was determined by calculation of the Pearson correlation and Bland-Altman limits of agreement of apnea-hypopnea indices between testing methods. Adverse events were also recorded.

Results: A total of 53 patients were enrolled in the study and 45 patients were included in the final analysis. Pearson correlation between polysomnography and Wesper device apnea-hypopnea index determinations was 0.951, which met the primary endpoint goal ($P = .0003$). The Bland-Altman 95% limits of agreement were −8.05 and 6.38, which also met the endpoint goal ($P < .001$). There were no adverse events or serious adverse events noted.

Conclusions: The Wesper device compares favorably with gold-standard polysomnography. Given the lack of safety concerns, we advocate for further study regarding its utility in diagnosis and management of sleep apnea in the future.

Keywords: obstructive sleep apnea, sleep diagnostics, polysomnography, sleep testing

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BRIEF SUMMARY

Current Knowledge/Study Rationale: This study sought to compare detection of apnea-hypopnea index by gold-standard polysomnography with detection by the novel Wesper device, a new portable testing system.

Study Impact: Novel diagnostic tools like the Wesper device have the potential not only to identify patients with disease but also to assist with monitoring therapy response in the future.

INTRODUCTION

Obstructive sleep apnea (OSA) is a pattern of sleep-disordered breathing characterized by recurrent upper airway collapse and is thought to affect up to 1 billion people worldwide.[1] OSA has well-established neurocognitive and cardiometabolic sequelae but is still underdiagnosed and undertreated.[2,3] At present the gold standard for testing for OSA is polysomnography (PSG); however, PSG can be perceived as cumbersome as well as expensive. PSG is typically conducted for a single night, giving a "snapshot" in time. However, OSA is known to be somewhat dynamic with changes night-to-night based on sleep stages, body position, alcohol intake, nasal congestion, etc. In the longer term, OSA can change based on changes in body weight, titration of therapy, and other factors. Thus, a diagnostic technique that allows serial assessment over time would have clear value. Furthermore, in-laboratory sleep testing does not allow assessment of real-world conditions in the home and thus may be regarded as an artificial evaluation. In recent years, home sleep testing has increased in popularity, but existing devices also have limitations including rudimentary position sensing and cumbersome/uncomfortable impedance belts, etc.[4–6] Thus, there is a well-established need for more efficient and accessible diagnostic tools.[7,8]

In theory, a diagnostic test that allows reliable evaluation of sleep and breathing including body position could be used on a large scale to evaluate patients longitudinally with OSA as well as those at risk of this condition.[9] The Wesper technology has been developed to allow for the assessment of OSA including continuous position monitoring. In addition, tests on multiple nights can easily be conducted. The Wesper device is a portable device with specialized sensors attached to the patient via wearable

patches that can measure respiratory effort, derived airflow, and estimated air pressure. Although initial testing has been encouraging, definitive data from multicenter studies are lacking.

This study evaluated the Wesper device vs PSG in a large multicenter study. We sought to test the hypothesis that the Wesper device would compare favorably to gold-standard PSG during concurrent assessments. The demonstration of the utility of the new device could be used in the design of subsequent studies to monitor the response to therapy, including titration of oral appliances, positive pressure, weight loss, or pharmacotherapy.[10] The goal was to evaluate whether the Wesper device could be used to assist health professionals in determining the apnea-hypopnea index (AHI; number of apneas and hypopneas per hour of sleep) of a patient.

METHODS

The study was conducted at three clinical sites in the United States in compliance with Good Clinical Practice guidelines and all applicable local regulatory requirements. A total of 53 patients (21 women and 32 men, mean age 48.8 ± 15.2 years) were enrolled in the study (**Table 1**).

Eligible patients were at least 21 years of age and were referred by a physician to the study to complete an overnight PSG for the evaluation of OSA. Patients meeting the following criteria were excluded from participation: patients who were pregnant or actively trying to conceive, actively breastfeeding, had major cardiorespiratory disease, were suspected to have respiratory muscle weakness, had known or suspected awake hypoventilation or sleep-related hypoventilation, used opioid medications chronically, had known history of stroke, had known history of severe insomnia, or had any known health condition that, in the opinion of the investigator, should warrant exclusion from the study. The study was approved by the Institutional Review Board (no. 20212459) and participants provided written informed consent.

Each patient underwent an overnight PSG while simultaneously wearing 2 Wesper device patches and a paired pulse oximeter cleared by the Food and Drug Administration for a single night at the designated sleep clinic. All patients were observed by trained sleep technicians. Potential adverse events were assessed via phone communication within 5 days of the sleep study completion.

All sleep data were read by certified sleep technologists who completed a training program on analysis software used in the study. Scoring was done manually in accordance with the American Academy of Sleep Medicine scoring manual version 2.6 using the 3% hypopnea rule. No study readers were part of data collection or enrollment in study. Both Wesper and PSG studies were interpreted using the same scoring platform, and readers were blinded to all patient identification information and data collection devices (Wesper device vs PSG).

The Wesper device (**Figure 1**) is a novel piece of sleep test equipment made up of 2 wireless adhesive patches with embedded sensors and a compatible pulse oximeter. The patches themselves were attached with coated medical-grade adhesive.

Table 1—Summary of demographics and characteristics of the analysis population (n = 45).

Parameter Statistics	Enrolled Population (n = 53)	Analysis Population (n = 45)
Sex, n (%)		
Female	21/53 (39.6%)	18/45 (40.0%)
Male	32/53 (60.4%)	27/45 (60.0%)
Age (years)		
Mean (± SD)	48.8 (15.2)	48.8 (14.7)
Median	49.0	49.0
Minimum, maximum	21, 76	22, 76
Race, n (%)		
Asian	1/53 (1.9%)	1/45 (2.2%)
Black or African American	10/53 (18.9%)	9/45 (20.0%)
White	36/53 (67.9%)	29/45 (64.4%)
Other	4/53 (7.5%)	4/45 (8.9%)
Multiple	2/53 (3.8%)	2/45 (4.4%)
Ethnicity, n (%)		
Hispanic or Latino/a	9/53 (17.0%)	8/45 (17.8%)
Not Hispanic or Latino/a	44/53 (83.0%)	37/45 (82.2%)
Body mass index (kg/m^2)		
Mean (± SD)	34.2 (10.0)	33.6 (9.5)
Median	30.4	30.3
Minimum, maximum	23.0, 61.0	23.0, 56.1
Fitzpatrick type, n (%)		
II	16/53 (30.2%)	12/45 (26.7%)
III	14/53 (26.4%)	12/45 (26.7%)
IV	12/53 (22.6%)	11/45 (24.4%)
V	5/53 (9.4%)	5/45 (11.1%)
VI	6/53 (11.3%)	5/45 (11.1%)
Hair under thorax, n (%)		
None	38/52 (73.1%)	31/45 (68.9%)
Moderate	9/52 (17.3%)	9/45 (20.0%)
Heavy	5/52 (9.6%)	5/45 (11.1%)
Hair under abdomen, n (%)		
None	30/52 (57.7%)	25/45 (55.6%)
Moderate	16/52 (30.8%)	14/45 (31.1%)
Heavy	6/52 (11.5%)	6/45 (13.3%)

The device measures total recording time, sleep position, oxygen saturation (SpO_2), pulse rate, respiratory effort, derived airflow, sleep position, and estimated air pressure using proprietary sensors and algorithms. Data collected from the device were transmitted via Bluetooth in real time to a smartphone application and then uploaded to a cloud server.

The primary endpoints were agreement of AHI determination between the Wesper device and PSG signals as measured by Pearson correlation and Bland-Altman 95% limits of agreement using significance levels of 2.5% and 5%, respectively. An additional primary endpoint was incidence of adverse

Figure 1—Wesper patches.

events and serious adverse events associated with Wesper device assessments. Secondary endpoints were as follows: estimation of Deming regression parameters of Wesper device AHI on PSG AHI, estimation of interrater reliability for Wesper device AHI, estimation of agreement of severity of sleep apnea (none, mild, moderate, or severe) between methods, and estimation of the Bland-Altman 95% limits of agreement of Wesper device and PSG AHI by position (supine vs nonsupine).

RESULTS

As shown in **Figure 2**, of the 53 patients enrolled in the study 1 patient withdrew, 1 experienced protocol deviation due to operator error, and 6 had unusable data due to malfunction of the paired accessory oximeter device. Additionally, 2 patients were lost to follow-up after the study and were unable to complete the follow-up phone communication for the safety endpoint. Therefore, paired PSG and Wesper device data from 45 participants were scored and included in the analyses.

In the primary analysis, the Pearson correlation between PSG and Wesper device AHI determinations was 0.951 with a one-sided lower 95% confidence interval of 0.919. This value met the primary endpoint goal for agreement of greater than 0.862 ($P = .0003$).

The Bland-Altman 95% limits of agreement were −8.05 and 6.38, which also met the endpoint goal (−30.6 and 28.4, $P < .001$) consistent with good agreement (**Figure 3**).

There were no adverse events or serious adverse events noted in the primary safety analysis.

Regarding the secondary analyses, Deming regression of the Wesper device against PSG indicated good concordance between the 2 methods (**Figure 4**). Interrater reliability was 0.94 (95% confidence interval 0.90–0.96), demonstrating excellent consistency between raters. OSA severity classifications of none, mild, moderate, and severe between the Wesper device and PSG methods showed overall agreement of 82.2%.

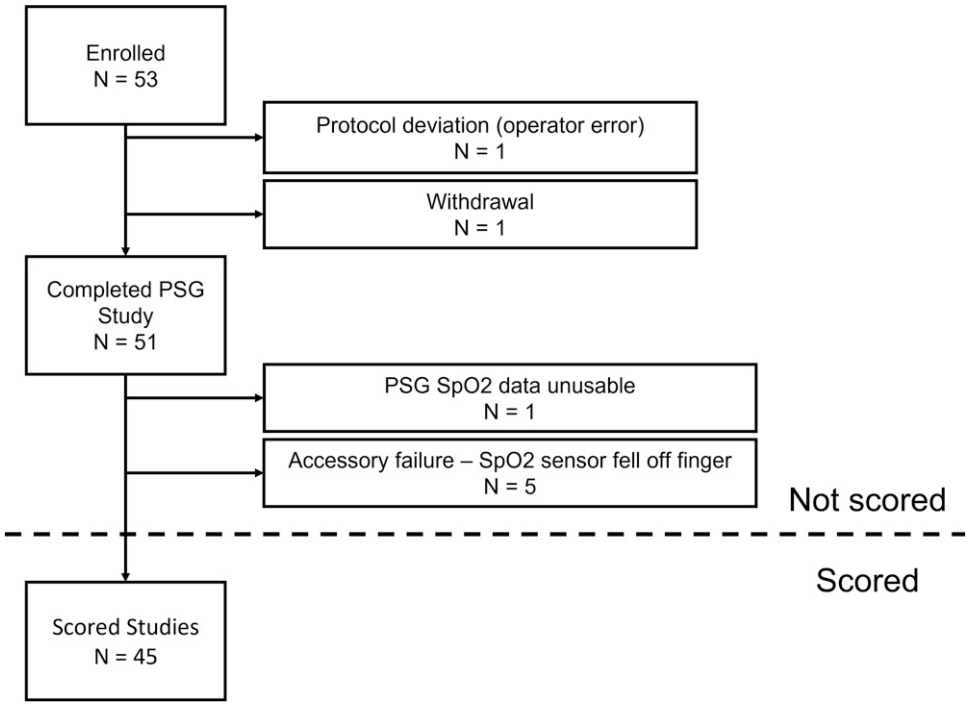
Positional dependency was assessed by Bland-Altman plot. For the supine position lower and upper 95% limits of agreement were −12.82 and 11.66, respectively, with a mean difference of −0.58 events/h. For the nonsupine position, the lower and upper 95% limits of agreement were −8.49 and 9.69, respectively, with a mean difference of 0.6 events/h. Of note, central apneas were relatively infrequent, but **Figure 5** provides some anecdotal reassurance regarding their detection through the direct measurement of respiratory effort.

DISCUSSION

Our study is important for a number of reasons. We provide validation of the Wesper device, which compares favorably with gold-standard PSG.[11] We evaluated real-time position sensing and were able to identify body position (supine vs nonsupine) using the Wesper device. Of note, body position during traditional home testing is often unreliable or not available, giving this feature a potential advantage over some of the available technology.

The underdiagnosis of OSA is likely multifactorial.[12,13] A general lack of awareness of the importance of sleep health still exists among patients and providers.[14] Thus, many do not prioritize sleep evaluation for overall health. Some regard sleep evaluation as cumbersome, even though such comments are rarely made about other diagnostic procedures such as elective cardiac catheterization or computed axial tomography imaging, which may have associated risk. Although PSG is somewhat labor-intensive

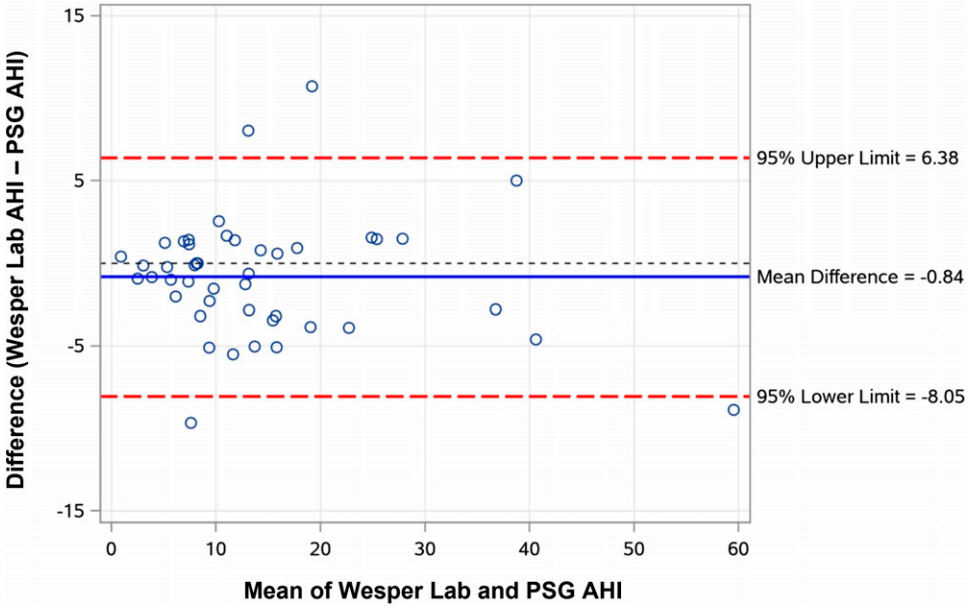
Figure 2—Subject flow.



PSG = polysomnography, SpO_2 = oxygen saturation.

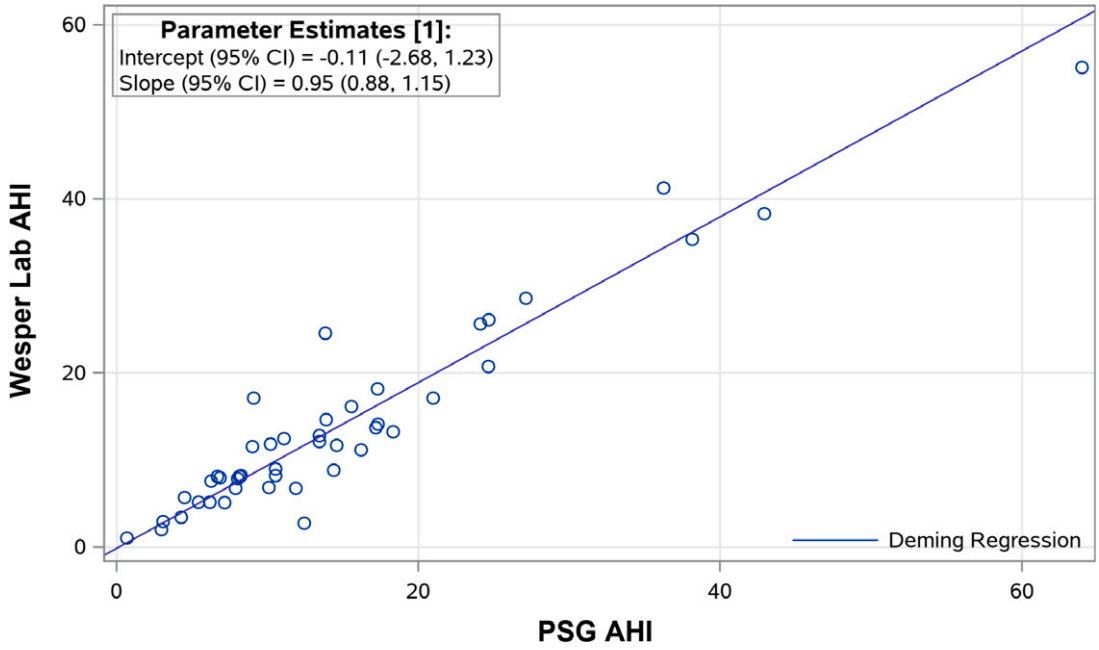
and time-consuming, simplified diagnostic tests are being developed that provide adequate sensitivity and specificity and may obviate the need for PSG in at least a subset of individuals. Home testing has many advantages because it provides real-world examination in the patient's natural environment and surroundings.[5] However, its limitations include a lack of evaluation of total sleep time, instead relying on total recording time. In addition, position sensors are variably available and prone to inaccuracy, and thus therapies for positional apnea are not able to be assessed routinely.[15] Finally, many home sleep tests do not

Figure 3—Bland-Altman plot of Wesper Lab and PSG AHI.



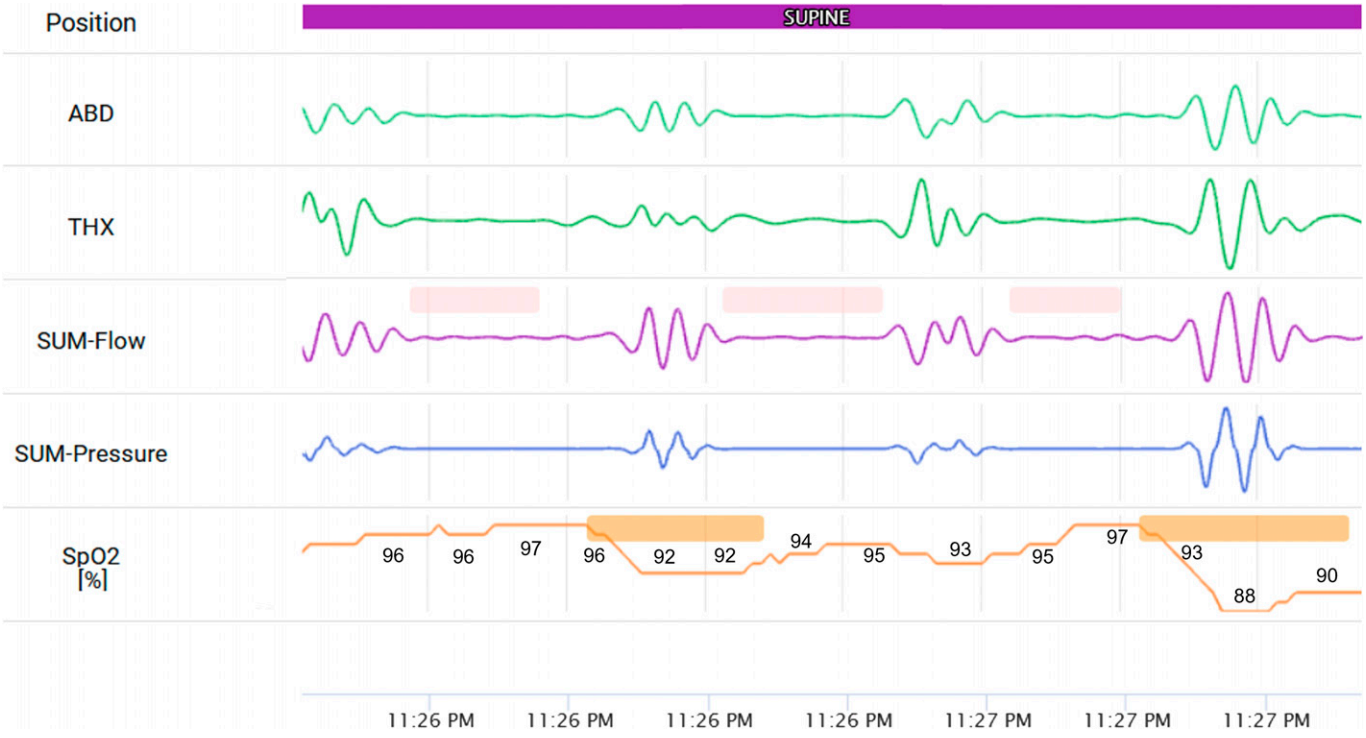
AHI = apnea-hypopnea index, PSG = polysomnography.

Figure 4—Deming regression of Wesper Lab and PSG AHI analysis population (n = 45).



[1] Confidence intervals were calculated using bootstrap resampling method. AHI = apnea-hypopnea index, CI = confidence interval, PSG = polysomnography.

Figure 5—Abdominal (ABD) and thoracic (THX) effort, derived airflow and pressure, and SpO_2 during a run of automatically detected central apnea.



SpO_2 = oxygen saturation, SUM-Flow = derived airflow, SUM-Pressure = derived pressure.

conveniently allow assessment of multiple nights of data, which would have clear advantages, particularly for patients with dynamic disease. Thus, we view the Wesper device as a step forward, although we acknowledge the need for further data. We found no safety issues and reasonable efficacy, suggesting that further study is warranted.

Of note, skin color has become a major topic of discussion in light of a prominent *New England Journal of Medicine* paper and a Food and Drug Administration warning regarding the use of pulse oximeters in people of color.[16] Many diagnostic devices have been evaluated in largely Caucasian populations, making the utility of the technology questionable in the broader population. One advantage of our study was the inclusion of 20% African Americans and 15% of participants of other/multiple races. Distribution of participants' skin phototypes was measured by the Fitzpatrick classification, which grades skin phototypes (degree to which an individual is susceptible to sunburn) from grade I to VI (sunburns easily/pale to never burns/deeply pigmented).[17] Thus, we are optimistic that our findings will be generalizable to the broader OSA population and those at risk. We also noted that prevalence of hair distribution on the abdomen and chest, which poses a risk of malfunction of the Wesper device's adhesive patches, was also distributed equally between treatment groups and therefore unlikely to limit the device's efficacy.

Despite our study's clear strengths, we acknowledge a number of limitations. First, we had a modest sample size and some dropouts largely related to the pulse oximetry. We believe that this issue can be easily addressed with improved oximetry devices but acknowledge further data would be helpful. Nonetheless, we completed a multicenter study with good racial/ethnic diversity, suggesting our findings are both "portable" and generalizable. Second, although we used gold-standard PSG, we relied on total recording time rather than total sleep time for comparison to the Wesper device. This decision was by necessity based on regulatory authorities, but we acknowledge that this approach may differ from usual practice. Patients with OSA and comorbid insomnia or more complex sleep disorders were not the focus of our investigation, but we support further research in this area.[18,19] Furthermore, we focused on our comparison of our device with gold-standard PSG and did not pursue a head-to-head comparison with other home sleep testing devices. We see the findings of favorable comparability with the gold standard as a strength but cannot comment specifically on our device in comparison to other home tests. Finally, although we view the Wesper technology as appealing to patients, we did not formally assess patient-reported outcomes or preferences. These data would be helpful in strategizing the optimal use of this technology in the future.

CONCLUSIONS

The Wesper device compared favorably with gold-standard PSG. Given the lack of safety concerns, we advocate for further study regarding its utility in diagnosis and management of OSA in the future.

ABBREVIATIONS

AHI, apnea-hypopnea index
OSA, obstructive sleep apnea
PSG, polysomnography

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SUBMISSION & CORRESPONDENCE INFORMATION

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DISCLOSURE STATEMENT

All authors have seen and approved this manuscript. Dr. Janna Raphelson is supported by an ATS Aspire Fellowship. Dr. Imran M. Ahmed is the principal investigator of the Wesper study. Dr. Sonia Ancoli-Israel is a consultant for Eisai, Idorsia, Merck, and Wesper. Dr. Joseph Ojile is the Founder of Clayton Sleep Institute, LLC. Mr. Nathan Bennett and Dr. Chelsie Rohrscheib are employed by Wesper Co. and have equity in the company. Dr. Malhotra is funded by the National Institutes of Health; he reports income related to medical education from Livanova, Wesper, Eli Lilly, and Zoll. ResMed provided a philanthropic donation to the University of California San Diego. Ms. Suzanne Pearson and Mr. Matthew Uhles report no conflicts of interest.