WESPER

Apnea/Hypopnea Index (AHI) Accuracy of Wesper Lab

Obstructive sleep apnea (OSA) is a common but serious medical condition associated with significant adverse health and economic consequences. Despite the growing use of home sleep testing for OSA, there are significant barriers that make the OSA diagnostic process difficult for patients.

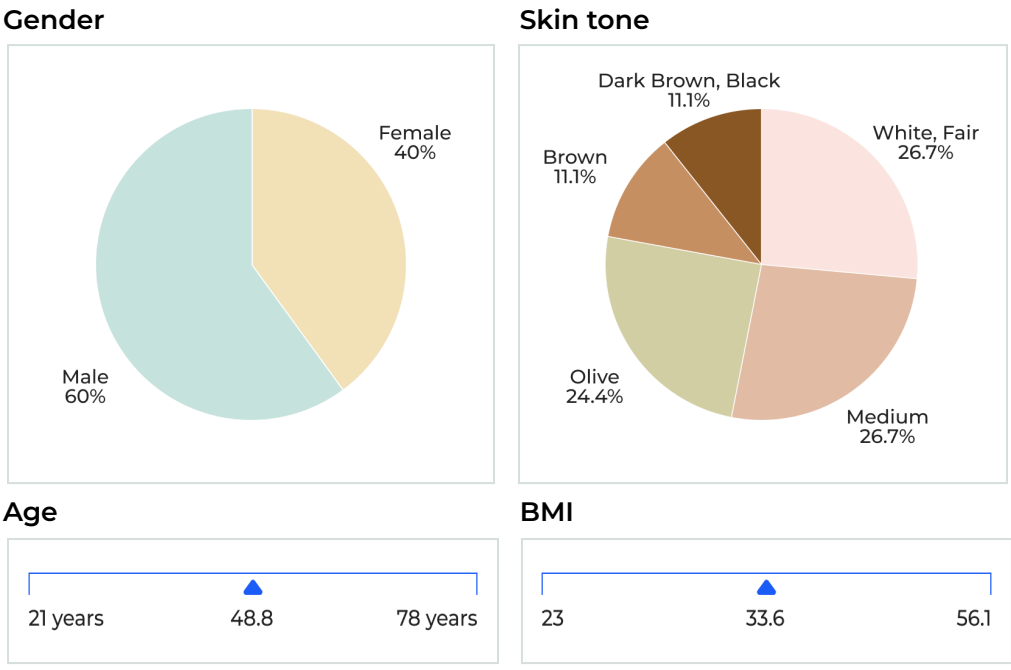
Wesper Inc is making home sleep testing more accessible and comfortable by creating a novel in-home sleep test (Wesper Lab) consisting of a set of thin, flexible and wireless wearable adhesive patches containing embedded sensors that measure sleep position, pulse-rate, respiratory effort, flow and air pressure using proprietary sensors and algorithms.

This clinical study aimed to evaluate Wesper Lab for the detection of OSA as compared to polysomnography (PSG) respiratory signals. Accuracy across a wide range of body types was also evaluated. The study demonstrated high correlation (95.1%) between Wesper and PSG for predicting AHI.

Methods

Adult patients from three sleep clinics across the United States (Figure 1) already scheduled to undergo a PSG evaluation for OSA were asked to wear two Wesper patches and a fingertip pulse oximeter in addition to the PSG equipment during their sleep study. Wesper patches measured respiratory effort, derived airflow and nasal pressure, body position and movement for the duration of the PSG study. The pulse oximeter measured blood oxygen saturation and heart rate.

Figure 1: Study Subject Demographics



Body Hair	Analyzed Population (45 Subjects)
Under Abdomen Patch	None: 25 (55.6%) Moderate: 14 (31.1%)

Body Hair	Analyzed Population (45 Subjects)
	Heavy: 6 (13.3%)
Under Thorax Patch	None: 31 (68.9%) Moderate: 9 (20%) Heavy: 5 (11.1%)

The two sets of simultaneously recorded, independent respiratory and pulse oximetry data were scored by an outside Registered Polysomnographic Technologist who was not involved in data collection. Studies were scored in a randomized order, and the scorer was blinded to both subject and collection device for each study.

Analysis was performed to determine:

1. The accuracy of AHI measured using Wesper as compared with PSG
2. Wesper sleep data remained accurate across a range of body characteristics including skin tone, level of body hair, and level of adipose tissue.
3. The accuracy of positional AHI using Wesper as compared with PSG

Pearson correlation was calculated to evaluate the concordance between the AHI-Wesper and AHI-PSG. Variability in the Wesper indices was evaluated against the in-laboratory PSG using a Bland-Altman plot analysis showing the mean and limits of agreement of the Wesper-AHI bias.

Results

Analysis of the collected sleep data established a 95.1% correlation between the AHI derived from PSG signals and the AHI derived from Wesper signals, with strong equality between the two measures (Slope, Intercept; 0.95, -0.11). No degradation in accuracy was noted for supine vs non-supine AHI. This demonstrates that Wesper signals are accurate for determining AHI as compared with PSG signals. Wesper signals were also shown to be accurate for measuring positional AHI in both supine and non-supine positions (Table 1). No adverse events were reported during or after testing.

Table 1: Agreement between Wesper AHI and PSG AHI

Parameter	Pearson Correlation
Apnea-Hypopnea Index (AHI)	95.1%

Analysis also found that the diagnostic quality of Wesper remained high across the range of body characteristics tested, demonstrating that different body characteristics don't affect the accuracy of AHI measurement.

Summary

This study demonstrated that Wesper is safe and is able to measure respiratory dynamics with comparable accuracy to PSG for the purpose of computing an AHI and body position. This will provide an alternative to the less comfortable home sleep apnea tests and could lead to improved patient comfort and compliance.