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- **Title:** Crossover Sleep Testing as a Population Mousetrap for OSA
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Crossover Sleep Testing as a Population Mousetrap for OSA

Introduction: Population level obstructive sleep apnea (OSA) under-diagnosis is attributable in part to sleep testing challenges. Consumer interest has driven the rise of patient wearables as an easy alternative assessment of sleep. Newer home sleep apnea tests have crossover utility between patient wearable and medical grade information. This study assessed patient benefits of crossover sleep apnea testing (XSAT) in a dental clinic.

Methods: A convenience sample of consecutive patients choosing XSAT (N=52) were assessed for sleep testing satisfaction in a retrospective observational study through a phone follow-up survey

Results: Two patients dropped out, 41 completed the survey (82% response). Satisfaction with XSAT was high/very high in 93% of all,100% of Naïve (no past professional sleep test) survey responders with 1.2% technical problems. Failed nights occurred in 5.7% (8/141) test nights with no failed studies. Average sleep test nights were 2.8 (3.0 for Naïve, 2.5 Non-Naïve). Twelve Naïve subjects of 14 (six males, mean BMI 26.9, mean age 48.4) had OSA (6 mild OSA). The night-to-night variability using 3% apnea-hypopnea criteria was 6.3 events/hr for Naïve, 6.0 for all subjects and 6.4 for all patients. XSAT benefit of "no need to return equipment" was important to 85% of Non-Naïve versus 64% of Naïve subjects.

Conclusion: XSAT is an early iteration paradigm shift in patient friendly, professional sleep testing, potentially penetrating the market of undiagnosed OSA and addressing public health objectives.

Clinical Implications: Increasing diagnosis of OSA can be achieved with friendly professional-level technology, enabling patient entry into sleep healthcare.

Keywords – OSA; SRBD; HSAT; XSAT, Crossover sleep apnea testing; Gateway sleep testing: Night-to-Night variability: Multi-night testing: Public Health.

INTRODUCTION:

Increasing the diagnosis of OSA remains a public health directive for sleep health, listed in both the Healthy People 2020 and 2030 health goals from the Office of Disease Prevention and Health Promotion of the U.S. Department of Health and Human Services [1]. OSA is a multifactorial disease related to breathing difficulties during sleep that falls under the classification of sleep related breathing disorders (SRBD). On a world-wide basis OSA prevalence is reported at 936 million individuals ages 30 to 69 years old of which 55% are mild cases [2]. In the U.S., prevalence for the 30-69 age group was reported at >54 million (33.2%) [2] of which a very large proportion (93% of women, 82% of men) with moderate to severe symptomatic OSA remain undiagnosed. There is a greater undiagnosed proportion (98% of women, 90% of men) for mild to severe symptomatic OSA [3]. One review from 2016 [4] indicates 80% of those with OSA remain undiagnosed based upon overly conservative OSA prevalence estimates of 12% of "adults", while epidemiologic studies indicate at least a 26% prevalence rate in the U.S. population between ages 30-70 [5]. The prevalence of OSA continues to rise [6,7] such that 49/193 countries evaluated had at least 50% of their population with OSA, and 48/193 countries had at least 25% of their population with moderate to severe OSA (AHI ≥15) [2].

Untreated OSA is associated with chronic health problems that include cardiovascular disease [8,9], metabolic disorders [10], cognitive impairment [11], memory loss [12], depression [13], workplace and motor vehicle injuries and fatalities [14,15]. Even mild OSA deserves treatment, according to the MERGE multi-center randomized controlled trial, where quality of life measures significantly improved in the mild OSA category with therapy for 3 months [16]. The costs of untreated OSA are enormous [4, 17,18], which combined with the documented association of OSA with numerous adverse clinical outcomes, highlights the need for increased detection as the first step in the pathway to OSA management. One large case-control study of a nationally representative sample of the U.S. Center for Medicare and Medicaid Services (CMS) beneficiaries with OSA was found to have $20,000 / beneficiary in additional healthcare costs the year before OSA diagnosis as compared with matched control patients without OSA [19].

The reasons for OSA under-diagnosis include: unawareness of the disease (both patients and their health care providers), lack of sufficient sleep health education [20,21]; an inconvenient patient diagnostic process (e.g.., lack of readily available screening tools, limited access to sleep facilities and sleep specialists); limited hours of sleep testing; and high costs to diagnose and treat [2, 22]. In 2015 the estimated annual cost of diagnosing and treating OSA in the U.S. was $12.4 billion (Figure 1) based upon a 12% prevalence, with $50 billion needed to diagnose and treat every U.S. adult with OSA, but with a projected saving of over $100 billion from lost productivity, absenteeism, medical comorbidities, motor vehicle and workplace injuries [23].

Clearly health-care systems should seek strategies to raise awareness of OSA in order to diagnose and treat the condition to have a positive impact on population sleep health and health-care expenditures. Diagnostic and delivery-of-care models may be developed so more patients

can receive high-quality and efficient care, without the need for multiple office visits with sleep specialists, coupled with alternative payment models to accommodate more patients [24]. For uncomplicated OSA (no significant health or sleep co-morbidities), models of care without involvement of the very scarce and relative dwindling number of sleep specialists [25,26], are only beginning to be developed that allow excellent clinical outcomes while potentially minimizing costs [27,28].

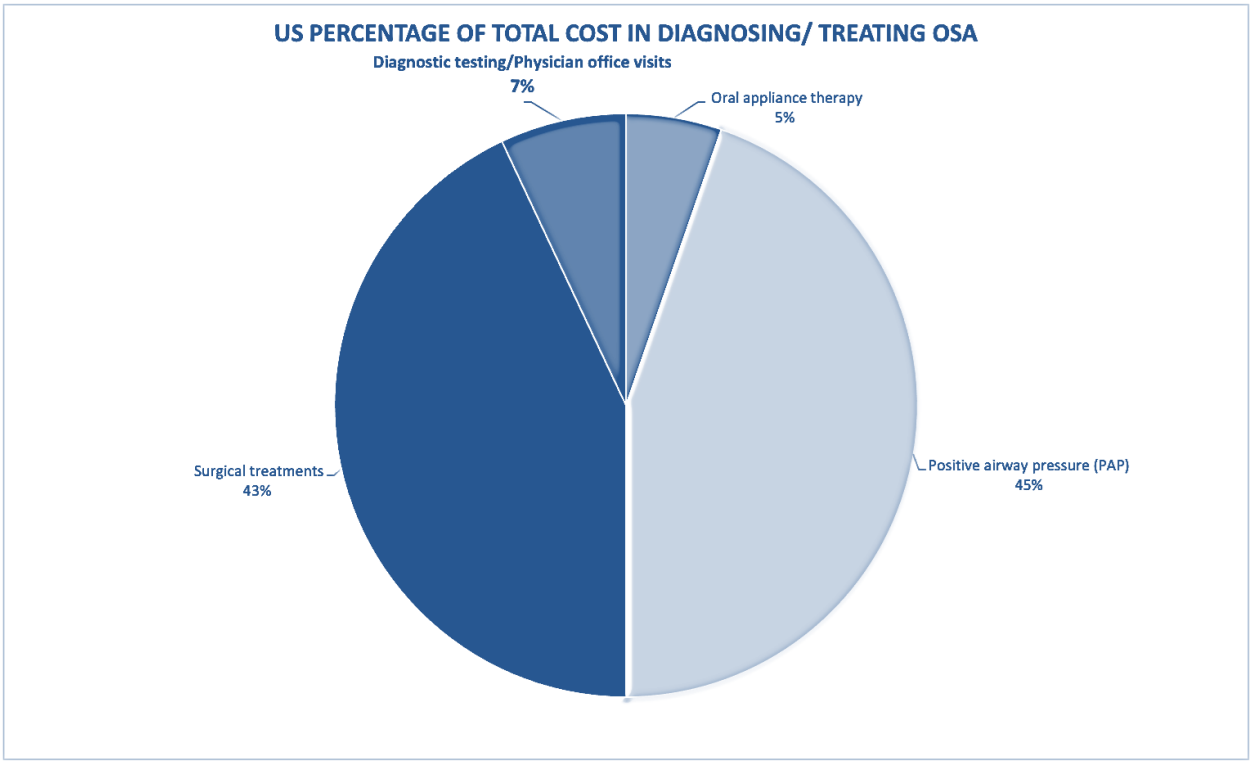


Figure 1 Pie Chart representation of U.S. cost distribution of the primary components of diagnosis and treatment of OSA [4, 17],

In 2008 the CMS acceptance of home sleep apnea testing (HSAT) for OSA diagnosis streamlined the OSA diagnostic process and caused an abrupt paradigm shift from “gold standard” in-lab polysomnographic (labPSG) testing of SRBD to include HSAT [29]. At the same time CMS also approved the innovative use of finger-based plethysmography (PPG) as an acceptable alternative surrogate data set to conventional airflow focused HSAT diagnostic data. HSAT devices were more patient friendly than labPSG sleep testing from a convenience, cost, availability, and access viewpoint, as well as facilitating sleep patterns to be reflected in the patient’s natural sleep environment for multi-night testing.

The rationale for multi-night and more hours of sleep testing is important as it relates to accommodating unsuccessful individual nights of sleep testing, often identified as sleep test failure rate. Failure in diagnosis may also be due to first night testing effects and night-to-night variability [30,31]. Night-to-night variability may address different sleep architecture: between weekdays and weekends; altered work shift schedules; various levels of fatigue; different eating and exercise patterns; intermittent nasal rhinitis contributing to oral breathing; variable sleeping arrangements or body positions; and intermittent use of alcohol, tobacco, tetrahydrocannabinol, other recreational drugs or prescribed medications. Sleep variability may also be impacted by the methods of substance intake such as vaping, inhaling and smoking which may cause transient inflammation of the upper airway structures. Alcohol consumption and/or smoking contributes to low oxygen saturation, respiratory depression, collapse of the oropharyngeal walls worsening severity of snoring and impaired sleep architecture especially in OSA patients [32,33]. In 2018, 2/3 of adults consumed alcoholic drinks, 5.1% heavy (>14 drinks/week for males, > 7 drinks/week for females), 15.5% moderate (4-14 drinks/week for males, 4-7 drinks/week for females) and 45.7% light drinkers (≤3 drinks/wk averaged over the year) [34] with a subsequent 60.14% overall increase in alcohol consumption attributed to the COVID-19 effect [35]. A cross-sectional study showed 35% of the patients who had OSA also smoked cigarettes, noting that smokers have a higher AHI than non-smokers with an estimated 30.8 million adults (12.5%) that smoked in 2020 [36].

Another advantage to home based multi-night sleep testing is the patient can get feedback on the impact of best and worst sleep behaviors and gain insight into sleep health self-efficacy. The clearest understanding is that single night testing in a strange environment represents an under-sampling of potential sleep related breathing pathophysiology, and no number of sensors can capture the needed information for best diagnosis with such limited time of sleep testing. For example, CMS approves labPSG OSA diagnosis in under 2 hours of sleep testing with at least the number of events that would have been required in a 2-hour period (≥10 apnea/hypopnea events) [37]. Single night HSAT may also be insufficient for accurate OSA diagnosis and one study found 20% of subjects were misdiagnosed with a single night HSAT as having no or mild OSA when multi-night testing revealed mild and moderate OSA respectively [31]. Another study of over 47,000 subjects found night-to-night fluctuations in the apnea hypopnea index (AHI) using a HSAT, averaged 5.5 events/hour, resulting in over 1/3 of the subjects having changes between diagnostic cut points [38]. Even gold standard labPSG's have night-to-night variability and first night effects typically result in a second night higher AHI. One labPSG two-night study showed 55/125 (44%) more patients having an OSA diagnosis only in the second night [39]. The first-night effects include decreases in: total sleep time (TST); sleep efficiency; REM, along with increases in: sleep onset latency; wakefulness after sleep onset and number of awakenings.

Recognizing public interest in sleep testing, direct to consumer offerings in wearable sleep trackers include wrist, ring and non-contact technology utilizing Bluetooth communication and smart phone apps which have grown to become commonplace. Sales in the wearable sleep

tracker market grew at a compound annual growth rate of 6.5% between 2013 and 2021 and in 2021, the global market of wearable sleep tracker accounted for approximately 4.5% of the overall wearable health device sales, amounting to around $1.9 billion in sales [40]. Market growth for wearable sleep trackers is predicted to reach $4.2 billion in annual sales within the next 4 years [41]. Many of these devices do not follow professional guidelines for HSAT testing causing confusion and leading to "controversy about their application and validity" [42,43]. Most of these devices collect unnecessary data which have no relevance when assessing sleep apnea. While some of this "smart" technology [44] purportedly gives heart rate, temperature, movement and differentiates light, deep and REM sleep, many of these devices are advertised as "health" or "supplemental" equipment rather than HSAT devices to avoid Food and Drug Administration (FDA) scrutiny. Even so there have been FDA warnings about limitations and accuracy of "over the counter" testing devices such as pulse oximeters due to lack of monitoring of safety and effectiveness [45].

A new paradigm shift is now occurring for HSAT devices that are both professionally monitored using conventional sleep related breathing disorder data and are comparable to patient friendly tracking devices. One HSAT disposable OSA testing device is considered in this study as a XSAT, as it provides data from up to 100 hours of testing over approximately 3 years, individual patient ownership, limited contact with the patient's anatomy, and remote monitoring of professional level data for OSA diagnosis [46,47]. XSAT may provide population level sleep testing in the future. This may be especially helpful in underserved or remote areas. XSAT devices may also be positioned as gateway sleep testing for those unable to access sleep labs and sleep experts, for patients that have irregular and unpredictable sleep cycles, those with a large night to night variability in sleep or those with difficulty falling asleep when attached to conventional sleep testing equipment. From a research perspective an XSAT can be a great equalizer in independently assessing the impact of different medical interventions on OSA objective measures [48].

This study evaluated patient satisfaction with a XSAT. It explores the benefits and short falls of this type of HSAT technology and addresses this new paradigm shift in diagnosing OSA that challenges current population level "gold standard" testing with a more efficient, cost effective, patient friendly and stepped care diagnostic process.

METHODS:

Consecutive patients with high probability of OSA, or under current management of their OSA, presenting to a single California based dental office, were given if indicated, the option to test their sleep using several HSAT devices. Patients that chose an overnight unattended sleep study utilizing the NightOwl XSAT were included in the study. This XSAT is a type IV HSAT device that contains a photoplethysmography (PPG) sensor, pulse oximetry and an accelerometer. The PPG sensor consists of two LED's emitting red (660nm) and infrared (880nm) light which is reflected from the peripheral tissue of the finger onto the photodiodes. The 3-axis accelerometer

picks up motion to provide an indication of activity/movement. Through its PPG sensor, this XSAT records pulsatile volume changes in the fingertip, that reflect changes in sympathetic tone. In order to detect respiratory events, the proprietary software evaluates a decrease in peripheral arterial tone in combination with a drop in SpO2 oximetry, and an increase in heart rate. The resulting estimate of the apnea hypopnea index (AHI) is referred to as the pAHI". Peripheral arterial tonometry (PAT) based technology has a long history of validated use for the diagnosis of OSA and other health disorders and continues to be validated as a HSAT compared to labPSG [29]. More specifically this XSAT has been validated as an OSA testing instrument [46,47]. In this study those patients choosing XSAT were given options as to the number of baseline nights of testing they would like.

Figure 2: Pictures of the disposable XSAT device that is taped to the ventral (palmar) fingertip.

A total of 52 XSAT devices were distributed to patients. The process for set up took less than 5 minutes by an assistant which included helping the patient download the NightOwl Companion app onto their mobile device, reviewing the position and tightness of finger probe placement with device adhesive tape, and confirming receipt of the device access code emailed to the patient. The patient was given an instruction page which outlined testing on multiple nights including a variety of normal weekday and weekend nights and/or nights of alcohol, tobacco, recreational or other drugs use as is typical for each individual. XSAT data along with the patient's comprehensive written medical/sleep history and clinical examination were reviewed by the sleep physician (DN) who produced a diagnostic report consistent with current diagnostic standards. The sleep physician report was forwarded to the patient and their other healthcare provider(s).

One or more phone calls were made to patients by a single research assistant (NH), for permission to ask XSAT follow up phone survey questions, ranging from a week to 10 months after XSAT use. If permission was granted by the patient (now identified as subject) a 2–3-minute phone survey was completed. The phone survey followed a precise order with 6quantitative followed by one qualitative question (Appendix 1). All subjects completed the phone survey. Subjective and objective data was collected and analyzed.

RESULTS:

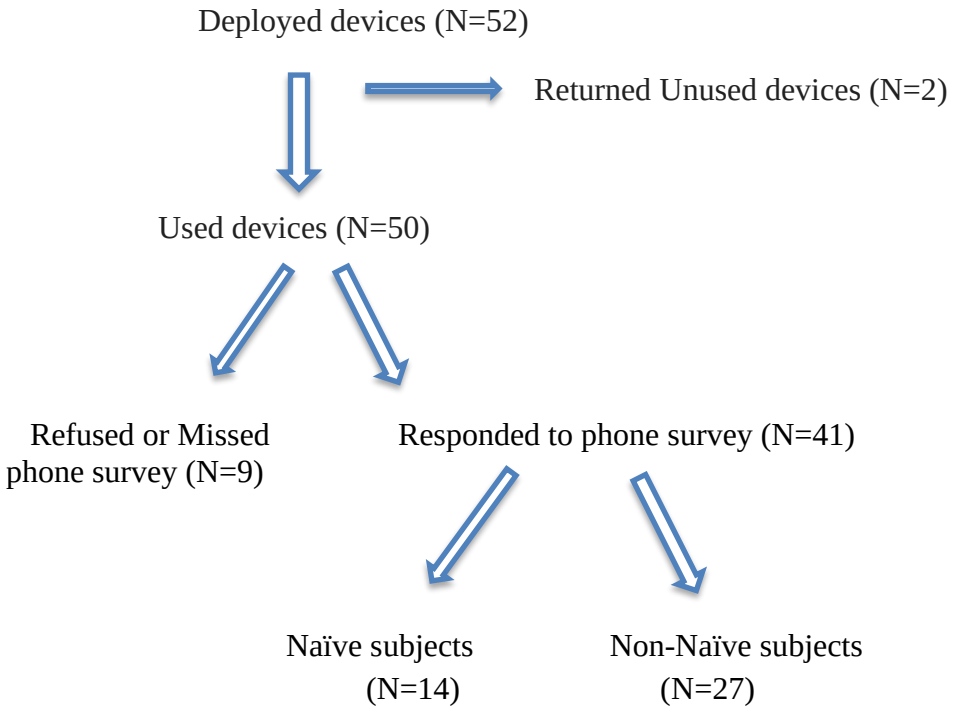
A total of 52 XSAT units were deployed of which two were returned unused and were considered study dropouts. Of the 50 used XSAT devices, 41 subjects responded to the phone survey.

Data collected from all patients was tabulated (Table 1) and broken down into the following groups: "All Subjects" who agreed to answer the phone survey; "Naïve Subjects" (defined as never having a professional sleep study before); "Non-Naïve Subjects"; and "All Patients". There was an 82% (41/50) response rate for all patients, an 87.5% (14/16) response rate for the Naïve patients, and a 79.4% (27/34) response rate for Non-Naïve patients.

Subjective Data:

Subjects (N=41) divided into Naïve (N=14) and Non-Naïve (N=27) groups (Figure 3) endorsed as "important" up to six different attributes of the XSAT. Both the Naïve and Non-Naïve subjects endorsed all survey offered attributes of the XSAT with a minimum of 60% of subjects finding all attributes as important. Highly endorsed attributes, (defined as having more than 85% of subjects endorse as important), included only one attribute by both Naïve and Non-Naïve subjects namely the "minimal connections to your body". Non-Naïve subjects identified two other highly endorsed important attributes including "no return of HSAT' and "Automatic Upload of Data."

Figure 3: Flow of Distributed XSAT devices



Non-Naïve subjects endorsed as important "No need to return equipment "82.6% of the time versus 67% for Naïve subjects ". Non-Naïve subjects endorsed as important "Automatic upload of data" 89% of the time verses 79% for Naïve subjects.

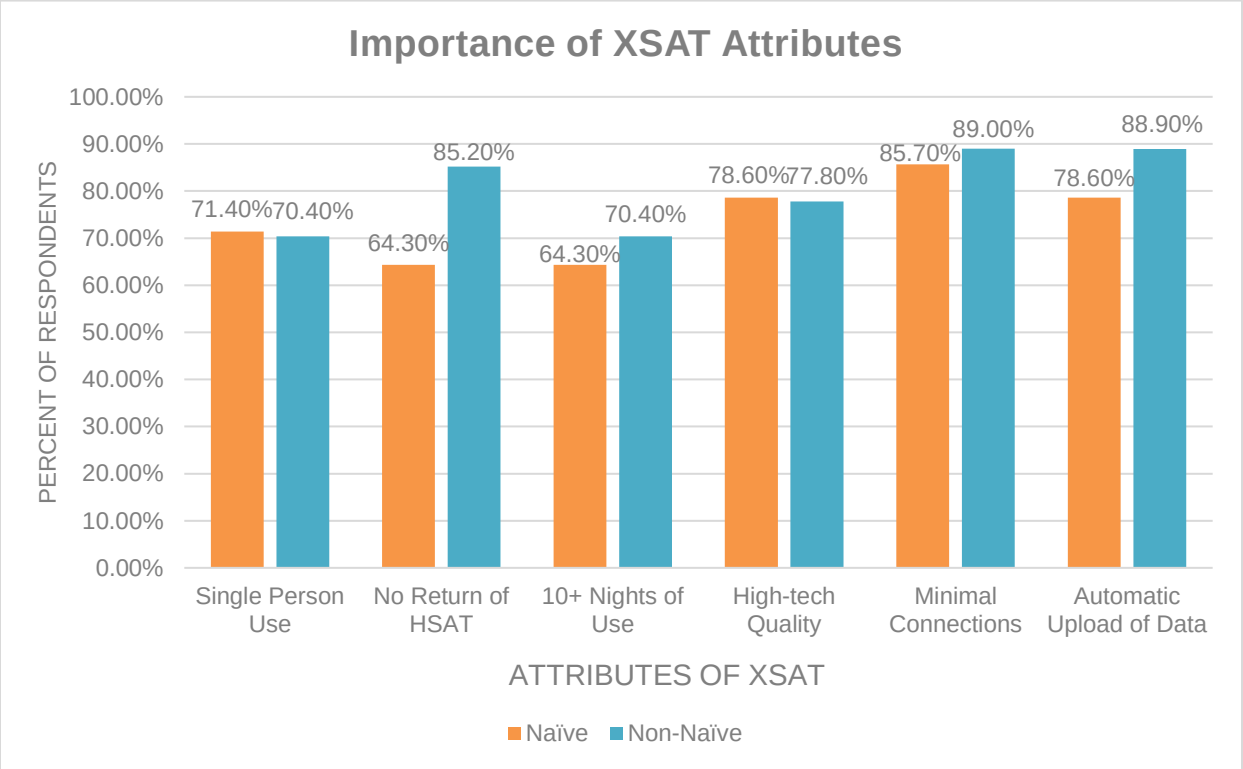


Figure 4: Relative importance of XSAT attributes to Naïve and Non-Naïve Subjects

Technical difficulties can contribute to failed test nights with any sleep test. Question #5 (Appendix 1) of the phone survey gave 7 suggested reasons for technical difficulties that subjects may have had along with one (or more) optional add in reason(s). There were no endorsed technical difficulties reported by the Naïve subjects (N=14) and a total of 4 out of a possible 216 (8x27) endorsed difficulties for the Non-Naïve group making the total endorsed technical issues/difficulties as 1.2% (4/328). These difficulties were hardware (2/41=4.9%), software (1/41=2.4%) and didn't record (1/41=2.4%). There were also 6 possible positive attributes subjects could endorse in the survey Question 4, Appendix 1). Non-Naïve in contrast to Naïve subjects highly endorsed two important attributes of the XSAT "no return of HSAT' and "Automatic Upload of Data." This probably reflects some past frustration with these components of other HSAT experiences and speaks to future approaches to improve repeat testing of OSA.

Historically many patients report that their sleep test did not reflect their typical or problematic sleep cycle. It can be a hit or miss journey and for many a journey of frustration and invalidation. The ability to have feedback on whether the sleep cycle tested is reflective of the patients sleep problems is important but is not usually commented on within sleep test reports. This XSAT companion communication software automatically asks for this information from patients. Results indicated that the sleep cycle was highly representative about half the time (54%) and not representative 6% of the time (Figure 4). This data implies that 6% of sleep studies may miss the mark of catching the patient's sleep complaint and another 40% may be somewhat representative. The advantage of multi-night testing allows for one or more test nights to reflect representative sleep that the patient wants evaluated.

The one open ended phone survey qualitative question (Question 7, Appendix 1) "Is there anything else you would like to add about the NightOwl testing experience" received 7 comments from the Naïve subjects and 17 comments from the Non-Naïve subject group listed in Table 2.

Objective Data:

Classification of all patients OSA severity using the 3% pAHI XSAT criteria indicated 80% (40/50) of the patients had remaining OSA (Table 3). Of those with OSA there were 22.5% (9/40) with severe OSA, 25% (10/40) with moderate and 52.5% (21/40) with mild OSA criteria. The pAHI for 4% was evaluated for the 14 patients age 65+. However, the software only automatically reported pAHI 4% starting in January 2022 so too few patients would have fit this category to report on their OSA severity using the CMS 4% criteria. Comparison data of the patients and subjects is shown in the Figures 5,6 below.

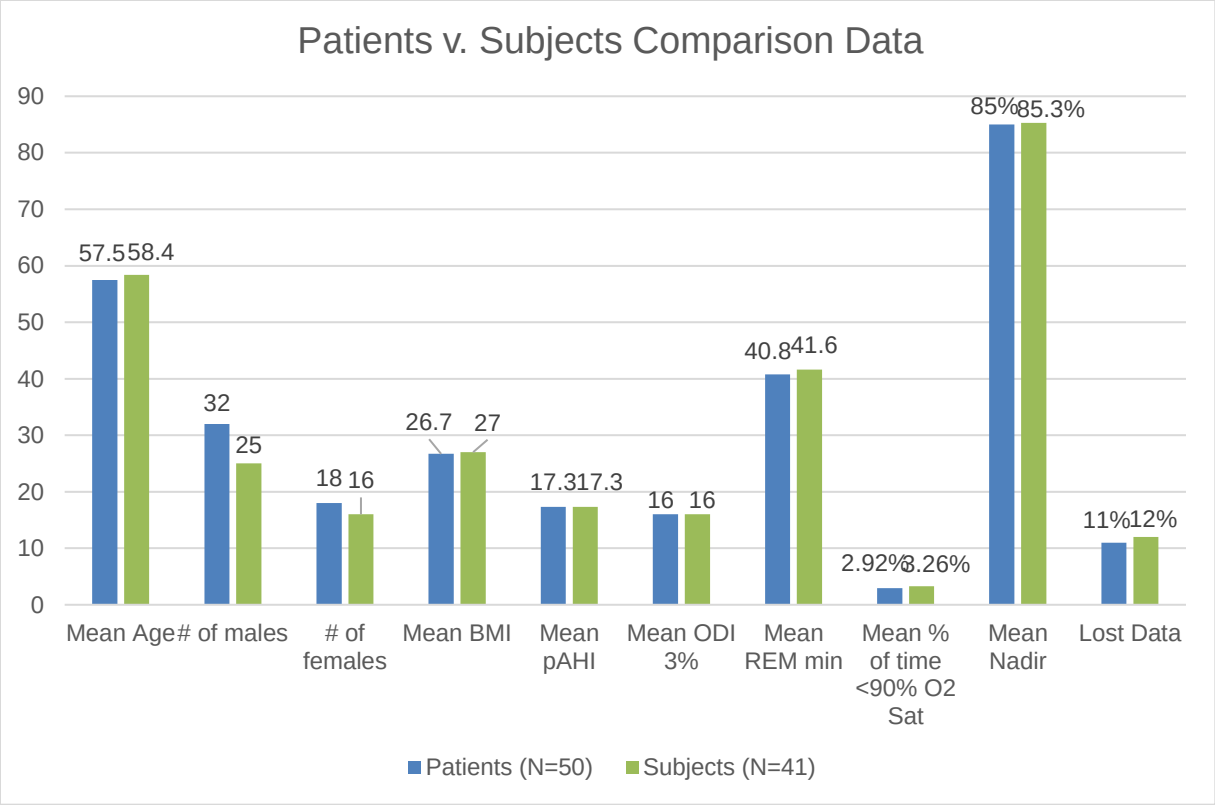


Figure 5: Comparison data of patients and subjects

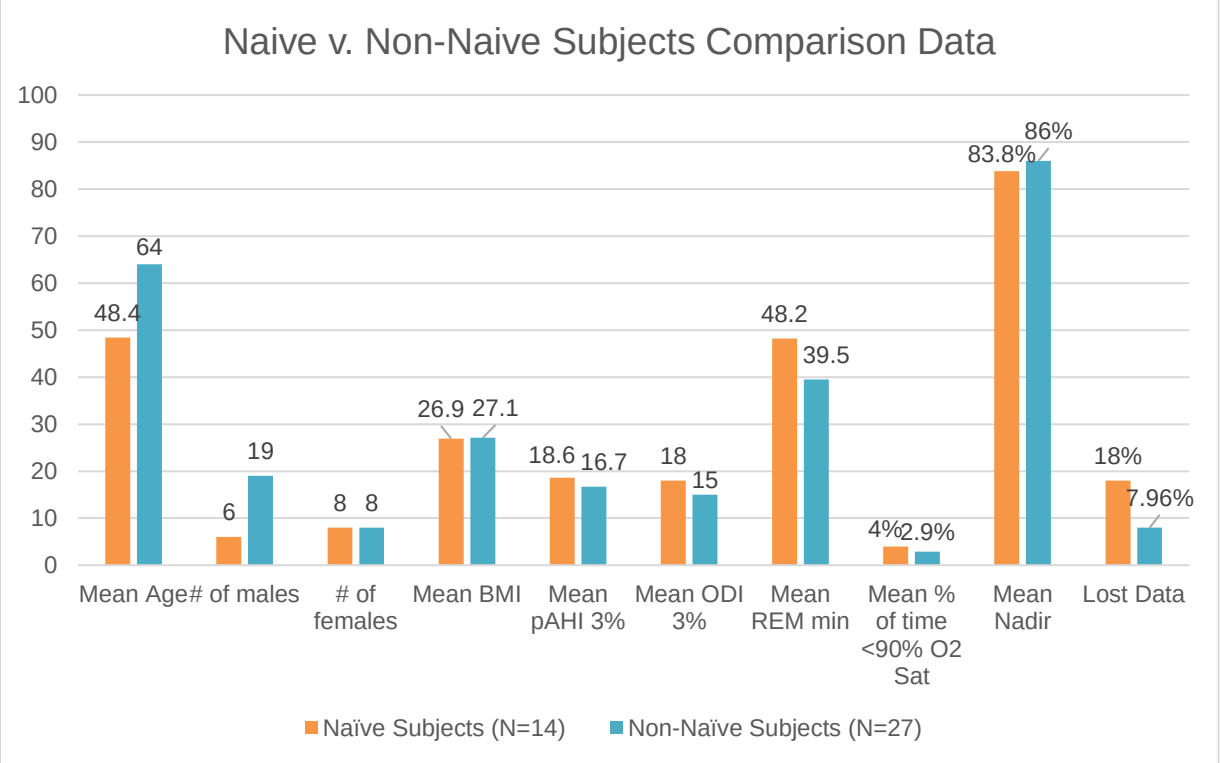


Figure 6: Comparison data of Naïve and Non-Naïve subjects

DISCUSSION:

The 2030 Healthy People sleep directive SH-02 for OSA has the specific goal to "increase the proportion of adults (20+ years old) with sleep apnea symptoms who get evaluated by a **health care provider**" listing a 37.1% target for this population to be evaluated [1]. This represents a sizeable 30% increase from the 2020 Healthy People directive SH-01 target goal of 27.8% of "adults with symptoms of obstructive sleep apnea who seek **medical** evaluation." By changing the "medical" evaluation" to one by a "health care provider" there is greater potential to achieve the directive goal. The goal is enabled by encouraging multiple pathways to diagnosis by others in addition to physicians potentially including: dentists; pharmacists; neuroscientists and other primary healthcare providers (PHP)'s. The engagement of non-physicians in addressing OSA was previously encouraged by the 2006 landmark report on "Sleep Disorders and Sleep Deprivation – An Unmet Public Health Problem" by the Institute of Health [49].

This preliminary study of a dental clinic shows XSAT has high subject satisfaction, similar HSAT night failure rate at 5.7%, zero study failure rate and applicability for diagnosing OSA. Since HSATs track total recorded time (TRT) without specifically determining total sleep time (TST) there is a tendency to under-report apneas and hypopneas per hour of testing. This study showed 88% (12/14) of Naïve patients with a high probability for OSA, were diagnosed with OSA. This speaks to ease and frequency of diagnosis and when paired with a good patient experience can enable future studies once the streamlined process becomes known in the public sector. Naïve subjects were diagnosed with mild OSA in 50% of studies which is similar to large world population studies of OSA showing 55% are mild [2]. Night-to-night variability of the pAHI in this study addresses the impact of first night effects as well as other night-to-night individual variability that may be attributed to many causes. The XSAT companion app allows up to 5 nights in one sleep study. There are several benefits to the multi-night testing in addition to catching more OSA potentially missed in the first night. Some of these benefits include accommodating lost nights due to technical difficulties or specific patient challenges. Two patient (both subjects) challenges in this study accounted for 6 of the 8 failed nights. One patient had early dementia and the XSAT was managed by his spouse. He required all 5 nights for adequate testing and with this opportunity did not have a failed study. A second patient had severe sleep maintenance insomnia and required 5 test nights due to sleeping less than 2 hours at a time. The severe insomnia had associated OSA and sleep data was acquired as a result of multiple nights testing. Moreover, the XSAT served as a gateway for the patient to have the confidence necessary to subsequently attend a split night titration labPSG sleep study. This speaks to the necessity of a stepped care model of sleep testing due to the number of undiagnosed patients. It is likely that more labPSG's will likely be required once penetration of crossover sleep testing is widely available.

The rationale for moving further away from gold standard labPSG testing as a first line test for OSA is that labPSG is not designed specifically for OSA testing but rather to test a wide array of sleep disorders. Population level testing for OSA requires population level solutions, accessible

for general use, highly efficient, cost effective per test which is both patient and clinician friendly. LabPSG is not optimally positioned for diagnosing the increasingly vast number of OSA patients [50]. Since HSAT is the diagnostic procedure of choice by most patients with suspected OSA, the important question becomes which HSAT will have the most penetration into society to identify OSA at optimal sensitivity and specificity. [51]. Since the 2008 CMS approval of HSAT [29] there has been a change in costs and utilization of sleep tests. Reports show CMS had a decreased annual expenditure for sleep tests although the number performed increased by 9.1% since 2010 [52]. These same authors reported that in 2014, labPSG and HSAT accounted for 88%, and 12% respectively of the almost one million total sleep studies as compared to year 2000, when HSAT studies were under 1%. This change in use of HSAT represented a paradigm shift described as "the shot heard around the world" of sleep medicine [53]. The market for HSAT devices subsequently exceeded $576.4 million in 2018 and this is expected to develop over 14.4% in compound annual growth rate between 2019 and 2025 [54]. There has also been an increase seen in HSAT due to COVID-19 when in-lab sleep tests were dramatically reduced, resulting in lengthy wait time lists for labPSGs [55]. An additional COVID-19 concern related to cross contamination through HSAT use resulted in the availability of single patient disposable testing devices with the first FDA approved disposable device released in February 2020 [56]. Disposable HSAT devices remove the patient financial responsibility for safe keeping reusable medical equipment as well as eliminating time and effort spent in returning the device.

According to the American Academy of Sleep Medicine (AASM) labPSG remains the chosen sleep test for specific "complicated" patient groups including: patients with significant cardiorespiratory disease; potential respiratory muscle weakness due to neuromuscular condition; awake hypoventilation or suspicion of sleep related hypoventilation; chronic opioid medication use; history of stroke; or severe insomnia [57]. In the AASM decision flowsheet of recommended sleep testing they also suggest labPSG for symptoms of other significant sleep disorder(s), or environmental or personal factors that preclude the adequate acquisition and interpretation of data from a HSAT [57]. LabPSG is also potentially important for central sleep apnea when an HSAT does not measure breathing effort; some movement disorders of sleep and also for childhood sleep apnea. The AASM recommendations further indicate that HSAT should be reserved for diagnosis of uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA where increased risk is determined by the presence of excessive daytime sleepiness and at least two of the following three criteria: habitual loud snoring, witnessed apnea or gasping or choking, or diagnosed hypertension [57]. This HSAT deployment criteria appears overly restrictive as under 20% of patients with OSA (15.5% male, 22.6% female) endorse excessive daytime sleepiness [58]. In contrast the CMS ruling CAG-00405N indicates HSAT may be used to aid the diagnosis of OSA in all beneficiaries independent of OSA severity and whether or not they are "uncomplicated" [29]. While the 2017 AASM adult sleep testing recommendations [57], including preference of

labPSG use, may be ideal at the individual patient level this approach lacks penetration for population level diagnosis of OSA as evidenced by the continued enormous under-diagnosis of OSA.

There are many economic reasons to increase population level diagnosis of OSA with the estimated increased healthcare spending to treat undiagnosed OSA is between $1950 and $3,899 per patient per year as compared to non-OSA patients [59] and there are in addition many other hidden costs [60]. However, the cost comparison model for labPSG versus HSAT is complex due to the many variables such as: purpose of the study (e.g., diagnostic, baseline, titration, split-night), number of nights tested, HSAT device used, follow up visits/telemedicine, failed study nights, PSG lab space rental and equipment costs and more. One study reported a home-based management pathway for OSA diagnosis is less costly to the payer than a labPSG pathway while both pathways are similar in cost to the provider if delivering "high quality care" [61]. It appears that per night hard costs (sleep technician/overnight stay/testing equipment/disposable supply costs) for a XSAT are about 1% of the labPSG costs independent of follow-up care. This demonstrates a clear population cost advantage to support a XSAT tiered process for diagnosing OSA. As with other HSATs, there is risk that other sleep disorders such as narcolepsy or sleep related movement disorders (SRMD) would not be diagnosed with a XSAT. While SRMD are determined by labPSG, the labPSG would not be diagnostic for narcolepsy without a subsequent MSLT. A thorough sleep and medical history to assess the suspected sleep disorder is therefore important in deciding the correct sleep test to prescribe. The minimal cost of the XSAT is beneficial currently at a population level only to assess for OSA. Future professional level crossover sleep testing may be focused on assessing other sleep disorders and sleep health behaviors.

Failed test nights may be differentiated from a failed sleep study. Failure study rates of the XSAT were considered to be zero due to the number of available testing nights which accommodate one or more individual failed nights of sleep testing without overall sleep study failure. HSAT have been considered to have higher failure rates at 5.3% than labPSGs at 3.1% depending on the population tested [62]. Lower failure may be due in part to the technician placing and correcting displaced sensors during the test. Contrary to some studies, HSAT failure rate may be similar to labPSG at 7.6% depending on criteria for a successful study [63]. Some authors have opined there is no "statistically robust set of parameters to characterize the performance of HSATs in general, and the agreement between HSATs and labPSG in particular" [64]. Other authors pointed out the peril of reliance on correlation coefficients in comparing HSAT and labPSG as opposed to using diagnostic accuracy as a primary clinical performance endpoint [65]. Finally, the importance of increased opportunity to catch OSA with multiple nights HSAT is contrary to the strong recommendation from AASM 2017 clinical practice guidelines stipulate that if a single HSAT test is negative, inconclusive or technically inadequate, labPSG should be performed for the diagnosis of OSA [57].

When Non-Naïve subjects (N=27) were asked to compare their past experience using other professional sleep testing to the XSAT crossover sleep test, using a 5-point Likert scale from much worse to much better, they scored the XSAT as a 4.8/5.0 better experience. This is an important finding that HSAT manufacturers will find of interest as it supports the paradigm shift in sleep testing alluded to in this study. Overall, a large percentage of Naïve and Non-Naïve subjects were "somewhat or very satisfied" with their experience using the XSAT, 100% for Naïve subjects, 87% for Non-Naïve subjects. These satisfaction percentages speak to the potential for more market penetration in professional sleep testing.

The role of the dentist in helping to identify more undiagnosed OSA patients is increasing based upon incidence and prevalence of OSA but must be done in a safe manner involving sleep physicians when possible and minimally the patients treating physician(s). When medical or other sleep disorder co-morbidities exist the sleep physician becomes an integral team member and often team leader. With no medical or sleep comorbidities and mild to moderate OSA the dentist can play an increasingly helpful role in reducing the burden of undiagnosed OSA by channeling patients into diagnosis through use of XSAT. This is important relative to the prevalence of OSA severity where one study of 400 undiagnosed adult subjects (attributed 61% as mild, 32% moderate and 7% as having severe OSA [66].

Limitations to this study include a lack of confirmation of diagnostic accuracy using the XSAT even though the outcomes are very similar to results found in much larger population studies [2] and two studies have verified this specific XSAT accuracy [46,47]. Different time delays between use of the XSAT and the phone survey completion existed and may affect the reliability of the answers. However, there was inherent variability in comparing this XSAT to previous experiences with other sleep testing by the various respondents over their historic testing timelines. The group itself could have bias in that they chose this XSAT versus other HSAT designs which would lead to higher satisfaction ratings but also potentially dissatisfaction if it did not meet with their expectations. This study also compared measures of AHI which may become an obsolete sleep metric since it is not a good reflection of cardiovascular health [67,68,69] and future sleep crossover devices may place more emphasis on desaturation data. The closely guarded proprietary criteria used to define an apnea or hypopnea event with PPG sensor based HSAT technology appear to be evolving as the sensor and interpretive software technology improves. Therefore, background changes in diagnostic algorithms may have happened during this study without clinician end user awareness, potentially affecting consistency of outcomes between patients. In this study additional data showing both 3% pAHI and 4% pAHI were first provided automatically in 2022. The significance of using 3% or 4% criteria may complicate comparisons to labPSG data as one large study of 500 patients having concomitant labPSG and PPG type HSAT (WatchPAT 200) testing found the HSAT device underreported by 6 events/hour using the 4% AHI criteria but overreported prevalence by 4 events/hour using the 3% AHI criteria [70]. Another study limitation is the lack of back-to-back satisfaction comparisons with other emerging professional quality multi-night HSAT devices

including newer ring technology [71], contemporary larger footprint HSAT devices and even comparisons to non-professional sleep tracking technology [72] categorized by delivery platform such as smart phones, wearable devices and devices imbedded into the bed or fixtures in the sleep environment [73]. This merits future research.

CONCLUSION:

Sleep testing for OSA has both evolved and devolved. Evolved in: using novel and more accurate testing devices; using better algorithms that can interface with machine learning and artificial intelligence [74,75]; use of machine level consistency avoiding subjective inter-scorer variability; less cost per test night; increased accessibility; patient friendly interfaces and focus on the underserved. Devolved in reducing the number of hours of sleep within the confines of diagnostic testing, thereby realizing a smaller impact from intra and inter-night variability that compromises accuracy. Periodic reassessment of sleep testing protocols due to technology, cost and convenience had the last major overhaul in 2008 when CMS at the request of the American Academy of Otolaryngology-Head and Neck, allowed for diagnosis of OSA by home sleep testing [29]. At that same time CMS approved novel technology in allowance of plethysmography as an alternative and surrogate data source for diagnosing OSA which continues to evolve.

This XSAT represents the first widely available crossover sleep testing device at the professional level that fulfills many sleep testing advantages and can be considered the first iteration of a patient friendly, cloud-based, mass-produced solution to the lack of population level diagnosis of OSA. There are still many areas of improvement needed such as the ability to distinguish TST from TRT, potentially resolved with add on EEG technology [76] or with newer HSAT technologies [71]; addition of chain of custody information possibly using fingerprint identification technology; incorporation of pulse rate variability information into the algorithm; addition of positional and snoring sound information; and the increased incorporation of artificial intelligence and machine learning into the diagnostic algorithm to improve diagnostic accuracy [77,78]. There will also be challenges to population level deployment of this and other crossover technology as a better mousetrap for the undiagnosed OSA including incorporating XSAT technology in long-term maintenance testing of ongoing OSA therapies. The potential of this technology does not stop with address of sleep disorders but can also contribute to sleep-health education of patients through feedback loops enabling sleep-health self-efficacy. Other needed improvements in the software will include the flexibility to review raw data, explore more specific data of interest and improved outcome reports that meet the interests of both patients and clinicians. Despite these limitations, which will undoubtably improve over time, this crossover technology represents the second paradigm shift and disruption in sleep testing in 5 decades. The opinion that “indiscriminate use of HSAT carries a risk of harm in the form of delayed diagnoses, missed diagnoses, additional financial burden to the patient and health care system, and misallocation of limited diagnostic resources” [75] marginalizes the logarithmically larger

societal damage from missed diagnosis with current OSA testing standards that reach so few of the population.

CLINICAL IMPLICATIONS:

In order to make drastic changes to the bottleneck of diagnosis of OSA a more patient and clinician friendly, efficient and cost saving diagnostic process should be utilized in PHP venues. Following a clearly outlined diagnostic protocol, many more providers will be able to diagnose and manage uncomplicated OSA, using a stepped care model whereby complicated cases can be swiftly referred to sleep specialists. This crossover technology may prove to be the answer in achieving significantly better population-based diagnosis of OSA, fulfilling and potentially exceeding Healthy People 2030 sleep health goals.

DISCLOSURE STATEMENT

The authors have no conflicts of interest to disclose.

ABBREVIATIONS

AHI – Apnea hypopnea index
AI – Artificial intelligence
CMS – Centers for Medicare and Medicaid Services
CPAP - Continuous positive airway pressureFDA - Food and Drug Administration
HSAT – Home sleep apnea test(s)
labPSG – In laboratory polysomnography
ML – Machine learning
OSA - Obstructive sleep apnea
pAHI – NightOwl derived AHI
PAT- Peripheral arterial tonometry
PHP - Primary healthcare provide
PPG - Photoplethsmyography
SRBD – Sleep related breathing disorder
SRMD – Sleep related movement disorder
TRT – Total recorded time (of sleep test)
TST – Total sleep time
XSAT – Crossover Sleep Apnea Testing

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Table 1: Objective data collected and Subjects responses to Phone Survey Questions

Data	Naïve Subjects N=14	Non Naïve – Subjects N=27	All Subjects N=41	All patients N=50
Average age / (Range)	48.4 (17-88)	64 (42-90)	58.7(17-90)	57.5(17-90)
Number Male/Female (%Male)	6 / 8 43%M	19 / 8 69%M	25/16 67%M	32/18 64%M
Mean BMI (Range)	26.9 (19.4–36.5)	27.1 (19.0-39.9)	27 (19-39.9)	26.7(19-39.9)
Mean pAHI 3%	18.6	16.7	17.3	17.3
AHI mean variability 3% / 4%	6.3 / 5.1	5.9 / 1.5	6 / 3.5	6.4 / 3.7
Mean ODI 3% / 4%	18 / 12.9	15.0 / 9.0	16.0 / 10.3	16.0 / 10.0
ODI mean variability 3% / 4%	6 / 4.6	4.1 / 3.3	4.8 / 3.7	5.16 / 3.76
Mean Minutes<90%	4% (0 – 28%)	2.9% (0 – 34%)	3.26% (0-34%)	2.92% (0-34%)
Mean Nadir (Range)	84% (79%–92%)	86% (66% -93%)	85% (66%-93%)	85% (66 -93%)
Mean REM minutes (Range)	48.2 (16 – 98)	39.5 (3 – 113)	41.6 (3-113)	40.8 (3-113)
Failed Nights	3	5	8	8
Lost data % (range)	18% (0 - 66%)	7.96% (0 – 39%)	11.5%(0-66%)	11% (0-66%)
TST Mean & Range	301.5 (104 – 528)	344.4 (73-527)	329.6 (73-528)	329.3 (73-528)
Q1-Ease of use (0-5) 5=Easiest	4.4	4.6	4.5	n/a
Q2- Disruptive (0-10) 0=Least	2.1	1.7	1.9	n/a
Q3 Comparison (0-5) 0=Best	N/A	4.8	4.8	n/a
Q4 Important features (0-6)	62/84 = 74%	130/162 = 80%	192/246 = 78%	n/a
Q5-Technical problems (0-8)	0/98 = 0%	4/189 = 2.1%	4/ 287 = 1.4%	n/a
Q6 High & very highly satisfied	100% -4.6	89% - 4.4	92.7% - 4.5	n/a
Q7 Comments	6 comments	13 comments	19 comments	n/a

Table 2: Comments by Naïve and Non-Naïve subjects when asked the Qualitative question #7: "Is there anything else you would like to add about the NightOwl Testing Experience"

Survey Q7 - Qualitative Comments on Now-HSAT Experience Made by Subjects (N=41)

Naïve	Non-Naïve	Comment
1	0	I wish I could see the sleep data that is collected in a more patient friendly, non-medical way.
1	0	I felt the nights were very variable and am not sure if it was accurate.
1	0	I wish it gave me the ability to cancel during the night because one of the nights I felt my sleep was irregular and I wanted to not have it record.
1	1	I wish I could also see the data to visualize the information.
1	0	It is hard to see the red light for whether the device is on because it is placed against your finger.
1	2	I wish that I wouldn't have to get another sleep test after because I felt that it was not accurate enough.
0	4	I was very happy with this testing experience
0	3	The device was comfortable to use
1	2	I felt that it was not accurate enough
0	1	It still was not comfortable because it caused a tension on my finger when I wore it.
0	1	I am wary if it works or not compared to the in-lab sleep tests I have gotten done.
0	1	I wanted to have more specific information from the test.
0	2	I had a much better experience with this sleep test than my in-lab test.

Table 3. OSA severity by All Patient and sub-groups.

Group (N)	**Severe (≥ 30) events/hr**	**Moderate (15-30) events/hr**	**Mild (5-15) events/hr**	**No OSA ≤ 5 events/hr**
3% pAHI criteria				
All patients (50)	9 (18%)	10 (20%)	21 (42%)	10 (20%)
All Subjects (41)	9 (21.9%)	9 (21.9%)	16 (39%)	7 (17.1%)
Non Naïve (27)	6 (22%)	6 (22%)	10 (37%)	5 (18.5%)
Naïve (14)	3 (21%)	3 (21%)	6 (42.9%)	2 (14.3%)

Appendix 1 Now-HSAT Patient Telephone Survey Questions

Research Id:_____ Date:_____

Hello this is Nina from Dr. Simmons office and we are following up on your sleep testing using the NightOwl finger probe sleep testing equipment. How are you doing?

Dr. Simmons wanted a little feedback from you on this new equipment and wanted me to ask you a few questions that will take a minute or two. Is that okay?

1. How easy was the NightOwl sleep test to use? Was it *(circle)*

   Very difficult Somewhat Difficult Neither Difficult or Easy Somewhat Easy or Very easy to use?

2. How disruptive to your sleep was the NightOwl equipment from 0-10 where Zero is N0 disruption and 10 is the worst disruption possible to your sleep? _#_____

3. Compared to your past experience using other at home professional sleep tests would you say the NightOwl testing experience was (circle)

   Much better Somewhat Better Same Somewhat Worse or Much worse?

4. What features about NightOwl sleep test were important to you *(Circle Yes or No)*

   Single person use **Yes / No**
   No need to return the equipment **Yes / No**
   Up to 10 or more nights of use **Yes / No**
   The high tech quality of the device **Yes / No**
   The minimal connections to your body with the NightOwl **Yes / No**
   The quick automatic upload of data to Dr. Simmons **Yes / No**

5. Did you have any technical issues or difficulties testing with the device? _____

   Problems? ☐ Hardware ☐ Software ☐ Confusing instructions ☐ Device interrupted sleep ☐ Device fell off during sleep ☐ Device turned off and didn't record sleep ☐ Device not activated ☐ OTHER _____

6. What is your overall satisfaction with your experience using the NightOwl device? *(circle 1 of 5 choices)*

   Very or **Somewhat Dissatisfied** **Neither** Satisfied not dissatisfied **Somewhat** or **Very Satisfied**

7. IS THERE ANYTHING ELSE YOU WOULD LIKE TO ADD ABOUT THE NIGHT OWL TESTING EXPERIENCE