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ABSTRACT Home sleep apnea testing (HSAT) without electroencephalography (EEG) recording is increasingly used as an alternative to in-laboratory polysomnography for the diagnosis of obstructive sleep apnea (OSA). However, without EEG, electrooculography (EOG), and chin electromyography (EMG) recordings, the OSA severity may be significantly underestimated. Although several ambulatory EEG systems have been recently introduced, no patient-applied systems including EEG, EOG, and chin EMG suitable for home polysomnography are currently in clinical use. We have recently developed and pre-clinically tested a self-applied ambulatory electrode set (AES), consisting of frontal EEG, EOG, and EMG, in subjects with possible sleep bruxism. Now, in this clinical feasibility study, we investigated the signal scorability and usability of the AES as a self-administered sleep assessment approach supplementing the conventional HSAT device. We also investigated how the diagnostic parameters and OSA severity changed when utilizing the AES. Thirty-eight patients (61 % male, 25-78 years) with a clinical suspicion of OSA conducted a single-night, self-administered HSAT with a portable polysomnography device (Nox A1, Nox Medical, Reykjavik, Iceland) supplemented with AES. Only one AES recording failed. The use of AES signals in data analysis significantly affected the median apnea-hypopnea index (AHI), increasing it from 9.4 to 12.7 events/h ($p < 0.001$) compared to the conventional HSAT. Also, in eight patients, the OSA severity class changed to one class worse. Perceived ease of use was well in line with that previously found among healthy volunteers. These results suggest that the AES provides an easy, clinically feasible solution to record EEG as a part of conventional HSAT.

INDEX TERMS Bioimpedance, biomedical electrodes, biomedical monitoring, electroencephalography, obstructive sleep apnea.

I. INTRODUCTION

Home sleep apnea testing (HSAT) is increasingly used as an alternative to in-laboratory full polysomnography

(PSG) [1], [2] which is the standard clinical test for diagnosing sleep disorders such as obstructive sleep apnea (OSA) [3]. The increasing popularity of HSAT can be explained by indisputable facts: estimated 1 billion people suffer from OSA [4], but the majority remain untreated and PSG is too labor-intensive and expensive for diagnosing the increasing number of patients [5]. Furthermore, hospitals with full PSG facilities are not available everywhere. Due to the limited availability and high costs of the clinical PSG, suspected OSA patients are primarily referred to HSAT instead of the standard full PSG.

As severe untreated OSA causes health consequences such as the increased risk for hypertension, stroke, heart attack, diabetes, and depression [6], [7], an accurate diagnosis is highly important. Currently, the diagnosis is mainly based on the apnea-hypopnea index (AHI) which is the count of complete (apnea) and partial (hypopnea) breathing cessations per hour of sleep [8]. An apnea in adults is scored when the airflow signal drops 90 % or more from the baseline for at least 10 seconds [3]. A hypopnea is scored when at least a 30 % airflow drop for at least 10 seconds is followed by a 3 % drop in blood oxygen saturation and/or a cortical arousal [3]. Whereas the full PSG comprises electroencephalogram (EEG), electrooculogram (EOG), electromyogram (EMG), and cardiorespiratory signal recordings, HSAT does not typically include EEG, EOG, or chin EMG [1] due to the lack of self-applied, multichannel electrode sets designed for home sleep studies [9]. However, EEG, EOG, and chin EMG recordings are crucial for the accurate assessment of total sleep time (TST) and sleep structure [3]. Especially sleep stage dependent OSA phenotypes [10] such as REM-predominant OSA cannot be diagnosed if EEG is not recorded. In addition, hypopnea events that lead only to cortical arousals are totally missed. This may lead to a significant underestimation of the severity of OSA [5], [11].

To enable EEG, EOG, and chin EMG signal recordings in the current HSAT, we have previously introduced a self-applied forehead electrode set which was designed to supplement the conventional home sleep recording device [12]–[14]. This ambulatory electrode set (AES) includes screen-printed flexible Ag/AgCl electrodes for EEG, EOG, and chin EMG recordings as well as the electrocardiogram (ECG) electrodes for heart rate recording. The major advantages of the AES are minimally sleep disturbing design, easy assembly by a patient, and minimal skin preparation required (only gentle swiping with alcohol). To the best of our knowledge, the AES is currently the only multi-channel, self-applied EEG, EOG, and EMG sensor which can be attached to any modern EEG/PSG amplifier and is suitable for sleep studies. It has been used to accurately determine sleep stages and total sleep time in comparison to the standard in-laboratory PSG [12] and to detect sleep bruxism (i.e. teeth grinding) events [14]. The AES has been demonstrated to be easy to apply among test subjects with possible sleep bruxism [13], [15]. Due to the reported sweat artifact in recordings [13], and to further develop the AES electrodes, we recently conducted an electrode comparison study in vitro [16] and in vivo [17]. In these previous studies, electrochemical properties and electrode-skin impedances of different screen-printed electrodes were investigated aiming to improve the sweat artifact tolerance of the AES electrodes. Differences in sweat artifact tolerance between electrode materials were found, and the most sufficient materials for the AES were suggested [17].

Previous studies concerning the AES were conducted with healthy, working-age volunteers. However, the feasibility results based on this previous population group cannot be directly applied to more demanding patient groups. In the present study, we focused on the clinical feasibility of the AES in clinical OSA patients including individuals from different age groups. To ensure that the AES system provides adequate additional data for OSA diagnostics, we aimed to compare the diagnostic parameters between the conventional HSAT and the HSAT supplemented with the AES. We also investigated the scorability of the nocturnal recordings and the usability of the AES in a clinical cohort of 38 patients with suspected OSA. We hypothesized that the AES is simple enough for self-application by patients at their homes and provides high-quality signals for sleep assessment enabling more advanced diagnostics in HSAT.

II. MATERIAL AND METHODS
A. FOREHEAD AES
The forehead AES (Fig. 1) prototypes were manufactured by Screentec Oy (Oulu, Finland). In the present study, the electrode materials of the AES were updated based on the results of previous studies [16], [17]. The Ag/AgCl electrodes were screen-printed on a flexible polyethylene terephthalate (PET) film (MacDermid Autotype Ltd, Wantage UK). Two layers of conductive ink were printed on the electrode area: the first (i.e. the bottom) layer with silver (Ag) ink and the second (i.e. the top) layer with silver chloride (AgCl). The total thickness of the printed layers was 30 μm. The electrodes were covered with an adhesive hydrogel membrane (AG602, Amgel Technologies, Fallbrock, CA, USA) which acts as an electrolyte and improves the electrode-skin contact. All electrodes were surrounded by non-conductive, adhesive medical foam (Venture 7432M, Venture Tape, MA, USA). Printed insulation paste was used to cover the conduction traces. The manufacturing process of the AES is described in detail in the previous study [16]. AES consists of three parts (Fig. 1). The forehead part had four EEG electrodes Af7, Fp1, Fp2, and Af8, two EOG electrodes F8 and F7, one ground electrode Gnd, four masseter EMG electrodes (two MassL and two MassR) and two mastoid reference electrode T9 and T10. The chin part of the AES consisted of three submental EMG electrodes S1, S2, and Sf. The chest part had two ECG electrodes, HR1 and HR2, which were placed
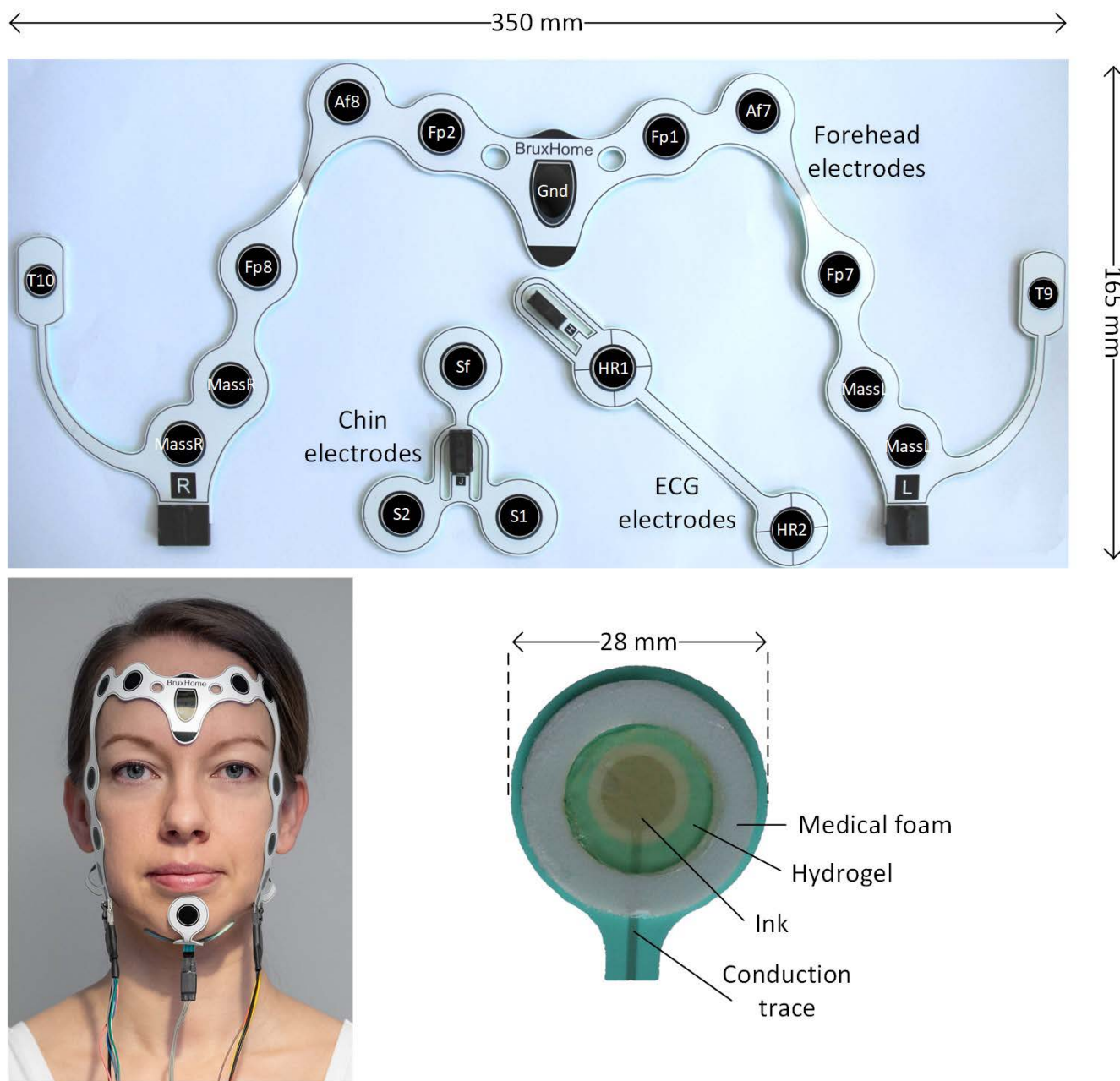
FIGURE 1. The forehead ambulatory electrode set (AES) worn by the author (LK) and the structure of the electrodes. The AES is a disposable, self-applied sensor that enables multichannel EEG, EOG, EMG, and ECG recordings with the screen-printed silver/silver chloride (Ag/AgCl) electrodes embedded in a flexible polyester film. Electrodes and conduction traces were printed using Ag and Ag/AgCl inks. The electrodes were covered by an adhesive hydrogel membrane and the hydrogel circles were surrounded by adhesive medical foam. The AES consists of three parts: the forehead, chin, and chest parts [16].

on top of the heart at a 45° angle to the horizontal line. The AES had lockable connectors and 1.5 mm touch-proof safety sockets suitable for any modern EEG amplifier.

B. HOME SLEEP RECORDINGS

23 male and 15 female suspected OSA patients, aged 25-78 years, were recruited to this study (Table 1) during 2016-2020. All patients had been referred to the outpatient clinic of the Otorhinolaryngology at Kuopio University Hospital (Kuopio, Finland) due to a clinical suspicion of

OSA. The Research Ethics Committee of the Northern Savo Hospital District reviewed the study protocol and issued a favorable statement (126/2016). Permission to use the AES as a non-CE marked sensor prototype was obtained from The National Supervisory Authority for Welfare and Health (Valvira, 220/2013).

All patients conducted a single-night self-administered sleep recording with a portable PSG device (Nox A1, Nox Medical, Reykjavik, Iceland) at their home. The sampling frequency of the recorded EEG, EOG, and EMG signals

TABLE 1. Demographic and polysomnographic data of 33 patients. Data is shown as median (range) or as a number of the patients. AHI and TST/TRT are based on the HSAT. N1, N2, N3, REM, and ARI are based on HSAT+AES.

Gender (male/female)[a]	23/15
Age[a]	45.5 (25-78)
BMI (kg/m^2)[a]	27.7 (22.0-37.2)
AHI (events/h)	9.4 (0.4-64.0)
TST/TRT (h)	7.4 (3.1-9.6)
ESS (scores)[a]	6.5 (0-17)
N1 (% of TST)	13.8 (4.8-40.2)
N2 (% of TST)	40.3 (23.0-60.5)
N3 (% of TST)	17.8 (0.0-37.5)
REM (% of TST)	26.0 (14.2-38.5)
ARI (events/h)	16.6 (6.8-65.7)

AHI = apnea-hypopnea index, TST = total sleep time, TRT = total recording time, REM = rapid eye movement, HSAT = home sleep apnea testing, ARI = arousal index, AES = ambulatory electrode set, BMI = body mass index, ESS = Epworth sleepiness scale, [a]n=38, 5 recordings were consider as failed and thus, only included to the usability analyses

was 200 Hz. Before sleep staging, EEG and EOG signals were band pass filtered from 0.3 to 35 Hz, EMG from 10 to 100 Hz. The Nox A1 PSG device measured continuously electrode impedances during the recording. Besides the AES, the sleep recording setup included respiratory inductance plethysmography (RIP) belts (thorax and abdomen), oronasal thermistor, nasal pressure sensor, pulse oximeter, and leg EMG electrodes. The Nox A1 PSG device also recorded position, activity, and audio with embedded sensors. The recording was conducted according to the current clinical practice at the Kuopio University Hospital.

All patients first received written and oral information about the study and then signed an informed consent form. The recording devices with illustrated instructions were provided to the patients by a skilled nurse from the Department of Clinical Neurophysiology of Kuopio University Hospital. In addition, the study instructions were carefully explained to the patient. The patients were asked to fill out three forms: the Epworth Sleepiness Scale (ESS) questionnaire and a questionnaire including questions concerning the sleep time, possible wakeups during the night, sleep quality, and the sleep-disturbing factors. In addition, to evaluate the usability of the electrode set, an additional patient questionnaire concerning the ease of applying the AES and other equipment was given to the patient. The response scales were from 1 (easy) to 10 (difficult) or yes/no. The patients were also encouraged to report any problems encountered with the recording devices.

C. DATA ANALYSIS

The respiratory events and leg movements of the HSAT recordings were first scored by an experienced physician at the Department of Clinical Neurophysiology in Kuopio University Hospital with Noxturnal software (Nox Medical, Reykjavík, Iceland) following the American Academy of Sleep Medicine (AASM) guidelines [3]. The 3 % limit for blood oxygen desaturation was used to score hypopneas [3]. The scorer estimated sleep time based on activity and breathing signals and marked the analysis stop and start times based on this estimation of the TST. Thus, in HSAT recordings,

TST equals total recording time (TRT). HSAT recording was considered as failed if the pulse oximeter signal or all respiratory signals (RIP, thermistor, and nasal pressure) were missing.

The HSAT with the AES recordings were then reanalyzed blindly to first scorings using 30-s epochs with the same criteria by a skilled sleep technologist at Reykjavík University. The EEG recording montage had four derivations (Af8-T9, Fp2-T9, Fp1-T10, Af7-T10), two EOG derivations (F7-T10, F8-T9) two submental EMG derivations (S1-SF, S2-SF), two bipolar masseter EMG derivations from MassR and MassL electrodes, and ECG (HR1-HR2) (Fig. 1). Because the AES did not include occipital electrodes, the posterior dominant alpha rhythm could not be detected. According to the AASM guidelines, the sleep stage N1 is usually detected based on the occurrence of the alpha rhythm [3]. However, all individuals do not generate an alpha rhythm, and alternative phenomena including eye movements, vertex waves, and other EEG activities, can be applied in scoring [3]. This alternative scoring criterion for non-alpha-producing subjects was also used in scorings of the AES recordings.

The percentage of clinically feasible data was determined by visually evaluating the scorability of the recordings by a clinical expert scorer. If the scorer could determine the sleep stage of an epoch, it was marked scorable. If an epoch was not scorable due to the artifacts or missing signals it was marked as non-scorable. To analyze the quality of the recordings, the percentage of scorable signal for each recording was calculated. The non-scorable data and related respiratory and leg movement events were excluded from further analyses. If artifacts or signal losses occurred, the possible reasons were analyzed utilizing the recorded data and the patient questionnaires. An HSAT recording with AES was considered as failed if all EEG, EOG, or EMG signals were lost throughout the night, or they were non-scorable. The mean impedance values of the EEG electrodes of each patient were calculated at the beginning and at the end of the recording.

The usability of the AES as well as the other PSG equipment was evaluated based on the previously developed patient questionnaires [13]. We also evaluated whether the patient succeeded in self-assembly. The statistical and data analyses were conducted using Matlab R2017b (Mathworks, Natick, Massachusetts, USA). Wilcoxon signed rank-sum test was used to compare PSG parameters between the HSAT and the HSAT with the AES. A *p*-value of less than 0.05 was considered to indicate a statistically significant difference.

III. RESULTS
A. AES SIGNAL SCORABILITY
Due to missing pulse oximeter data, five of the 38 recordings were considered as failed and were excluded from the subsequent signal scorability analysis. After this exclusion, the percentage of scorable AES data of total recording time (TRT) was 92.3 %. Out of 33 recordings, the proportion of scorable data of 23 recordings was more than 90 %, in four recordings

TABLE 2. The mean impedances (standard deviation) of the EEG electrodes of each patients at the beginning ($Z_{BEGINNING}$) and at the end (Z_{END}) of the recording and the percentage of scorable data of the total recording time.

Patient	$Z_{BEGINNING}$ (kΩ)	Z_{END} (kΩ)	Percentage of scorable data (%)
1	16.5 (±10.2)	14.8 (±8.1)	100.0
2	6.8 (±4.7)	7.1 (±4.7)	100.0
3	12.5 (±1.5)	13.4 (±13.5)	100.0
4	6.2 (±1.4)	7.2 (±2.1)	100.0
5	25.6 (±33.8)	30.3 (±37.1)	100.0
6	12.3 (±2.0)	12.2 (±1.6)	100.0
7	91.6 (±116.5)	77.4 (±123.4)	100.0
8	16.3 (±15.3)	127.6 (±155.7)	100.0
9	13.7 (±3.5)	19.8 (±13.9)	100.0
10	11.1 (±10.2)	12.8 (±7.8)	100.0
11	14.7 (±8.3)	14.2 (±8.4)	100.0
12	9.9 (±5.4)	10.1 (±9.6)	99.8
13	7.0 (±4.7)	6.9 (±3.0)	99.8
14	11.9 (±3.5)	13.5 (±14.0)	99.5
15	19.1 (±10.7)	20.6 (±12.3)	98.8
16	10.4 (±1.0)	11.0 (±3.4)	98.7
17	6.2 (±1.4)	6.4 (±2.6)	98.5
18	10.8 (±8.0)	14.9 (±11.5)	98.4
19	30.8 (27.8)	41.4 (±48.4)	96.5
20	22.6 (±13.2)	26.4 (±21.0)	96.3
21	57.1 (±55.0)	94.8 (±129.4)	95.6
22	13.8 (±2.3)	13.7 (±2.3)	95.2
23	124.0 (±158.0)	123.8 (±158.2)	91.5
24	320.2 (±18.2)	117.7 (±162.6)	87.0
25	176.5 (±93.8)	82.7 (±123.4)	87.0
26	8.3 (±3.2)	14.8 (±24.4)	84.0
27	56.0 (±10.2)	56.7 (±9.9)	81.0
28	23.1 (±9.4)	27.4 (±21.0)	78.0
29	8.7 (±4.1)	7.5 (±2.4)	75.0
30	16.3 (±4.3)	12.8 (±7.8)	74.0
31	88.5 (±124.6)	119.5 (±161.3)	70.0
32	14.9 (±6.1)	12.1 (±3.7)	67.0
33	12.3 (±7.8)	10.5 (±7.0)	47.1

No correlations between the average impedances ($Z_{BEGINNING}$ or Z_{END}) and the percentage of scorable data were found (Spearman's rank correlation coefficients $\rho = -0.26$ and $\rho = -0.15$).

TABLE 3. Median (range) values of the polysomnographic parameters (n = 33).

Parameter	HSAT	HSAT + AES	p-value
AHI (1/h)	9.4 (0.4–64)	12.7 (0.3–68.2)	<0.001
ODI (1/h)	9.1 (0.4–56.5)	9.6 (0.3–64)	<0.001
TST (min)	452.2 (183.4–579.3)	369.0 (85.0–538.5)	<0.001
AI (1/h)	1.2 (0.0–62.6)	1.8 (0.0–67.4)	0.004
OAI (1/h)	0.7 (0.0–21.5)	1.7 (0.0–19.8)	0.002
MAI (1/h)	0.0 (0.0–39.1)	0.0 (0.0–47.8)	0.240
CAI (1/h)	0.2 (0.0–9.9)	0.1 (0.0–11.1)	0.510
HI (1/h)	7.7 (0.2–18.6)	10.7 (0.1–22.8)	<0.001
PLMI (1/h)	11.9 (0.0–174.5)	6.7 (0.0–125.6)	0.050

HSAT = home sleep apnea testing, AES = ambulatory electrode set, AHI = apnea-hypopnea index, ODI = oxygen desaturation index, TST = total sleep time, AI = apnea index, OAI = obstructive apnea index, MAI = mixed apnea index, CAI = central apnea index, HI = hypopnea index, PLMI = periodic limb movements index
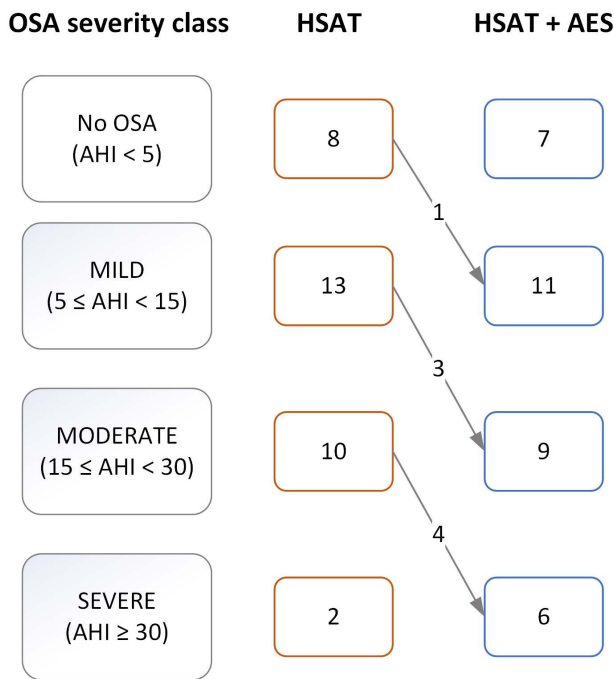
The median values of oxygen desaturation index (ODI), apnea index (AI), obstructive apnea index (OAI), and hypopnea index (HI) were also significantly higher ($p < 0.05$) when the AES was included in recordings, whereas the median value of TST was significantly smaller ($p < 0.001$). However, the non-scorable data was excluded from the median TST with AES. If non-scorable data would be included, the difference between the TST with and without AES was still significant ($p = 0.037$). The differences in median values of mixed apnea index (MAI), central apnea index (CAI), and periodic limb movement index (PLMI) between the HSAT and the HSAT with AES were not significant.

The number of patients in each OSA severity class is presented in Fig. 2. The OSA severity class changed in eight patient cases if HSAT with AES was used to define the severity of OSA instead of the HSAT. These changes were from no OSA to mild (one patient), from mild to moderate (three patients), and from moderate to severe (four patients).

C. USABILITY
Results of the usability questionnaires are presented in Table 4 and Fig. 3. Out of all 38 patients (including the five patients with missing pulse oximeter data), 35 patients (92 %) considered that the forehead ambulatory electrode set fitted properly on their face whereas three patients had difficulties wearing it. The reported difficulties were the unsuitable size of the electrode set (two patients), hair under the electrodes (one patient), and inability to attach the electrode set symmetrically (one patient).

All 38 patients succeeded in self-assembly. In 32 cases (84 %), all electrodes remained firmly attached over the night, whereas four patients (11 %) reported that at least one electrode was detached, and two patients did not answer this question. According to the analyses of the recorded data, one or more detached electrodes were detected in four patient cases.

80-90 %, and one recording remained below 50 % (Table 2). In four patient cases, one electrode was detached (either T9, Af7, or Af8) during the night, but scorings were conducted using the EEG data from the remaining electrodes. In two cases the scorer marked one or more electrode connections bad (i.e. signals were only partially scorable during the night). Sweat artifact was detected in nine recordings. The TST of two patients was < 3 h (85 and 124 minutes) and the proportion of scorable data was also the two lowest (47.1 and 67.0 %, Table 2). The mean EEG electrode impedance values at the beginning of the recording varied from 6.2 kΩ to 320.2 kΩ and at the end from 6.4 kΩ to 127.6 kΩ (Table 2), but no correlation between the impedance values and the percentage of the scorable data was found.

B. PSG PARAMETERS
Table 3 shows the median PSG parameters based on the conventional HSAT and the HSAT with the AES. The median AHI value based on the conventional HSAT was 9.4 events/h, whereas the median AHI based on the AES supplemented HSAT was 12.7 events/h. This difference in AHI between recordings was statistically significant ($p < 0.001$).

OSA severity class	HSAT	HSAT + AES

FIGURE 2. The number of patients in each OSA severity class. Following changes occurred when the AES signals were added to analysis: from no OSA to mild (one patient), from mild to moderate (three patients), and from moderate to severe (four patients). OSA = obstructive sleep apnea, AHI = apnea-hypopnea index, HSAT = home sleep apnea testing, AES = ambulatory electrode set.

TABLE 4. The results of the usability questionnaire (n = 38). Results are presented as mean (range) or as the number of answers.

How easy was the electrode attachment, 1 (easy)-10 (difficult)?	
ECG electrodes	2.4 (1-8)
Chin electrodes	2.2 (1-7)
Forehead electrodes	3.5 (1-8)
Other devices	2.1 (1-5)
Did all electrodes remain attached over the night? (yes/no)	32/4
Did the forehead and chin electrodes fit properly on the face? (yes/no)	35/3
Did the recording affect the sleep quality? (yes/no/do not know)	21/8/9
Did the recording disturb sleeping? (yes/no/little)	10/7/16
Sleep quality compared to usual? (better/no difference/worse)	1/17/15

ECG = electrocardiogram

On a scale from 1 (easy) to 10 (difficult), 27 patients (71 %) graded the ease of use of the electrode set from 1 to 4, ten patients (26 %) from 5 to 8, and one patient did not answer this question. Ten (26 %) patients reported that the recording noticeably disturbed sleeping. According to the questionnaire, patients reported the following issues concerning the AES (free text): the adhesive membrane was too tightly attached to the skin and was difficult to detach (two patients), the set-up of the measurement devices (including all devices) took too much time (two patients), the edge of the AES electrode behind ear was too sharp (one patient), and the chin electrodes did not attach properly (two patients).

IV. DISCUSSION

In this study, 38 patients with a clinical suspicion of OSA conducted a conventional HSAT supplemented with a novel self-applied forehead ambulatory electrode set (AES). We investigated the scorability of recordings and the usability of the AES. We also compared the diagnostic parameters between the conventional HSAT and the HSAT with the AES approach. The proportion of scorable data of all TRT was 92.3 %. Using the response scale from easy (1) to difficult (10), most patients (71 %) graded the ease of use of the electrode set from 1 to 4. The diagnostic parameters (excluding MAI, CAI, and PLMI) differed significantly between the HSAT and the HSAT with AES (Table 3). The OSA severity class changed to worse in eight patient cases (Fig. 2).

The number of failed HSAT recordings was 5 out of 38 (13 %), which is consistent with the failure rates (4-20 %) reported in the literature [18], [19]. All failed HSAT recordings were due to the oximeter malfunctions. The total loss of the AES signals (EEG, EOG, or EMG) did not occur. There are no general criteria for technically adequate home-EEG, but according to the grading system used in previous studies [13], [20], [21], recordings with less than 2 hours of usable data are considered as failed. When this grading system is used, the failure rate of AES only is 3 % (one failed out of 33 recordings). The percentage of scorable data of all TRT was lower than previously reported with the AES (92.3 % vs. 96.9%) [13]. This was, however, expected due to the differences in study populations. In the present study, the study subjects were patients with clinically suspected OSA whereas the previous study was conducted with healthy, mostly highly educated, working-age volunteers with possible sleep bruxism [13].

A common disadvantage of the home-EEG devices is that the electrode-skin contacts are not typically checked after the assembly or monitored during the night [9], [19]. Even though the successful self-application was demonstrated in this study, in six recordings at least one electrode was fully or partially detached during the night. No particular reason for insufficient electrode contacts was found in the corresponding recordings or the patient questionnaires. In general, the initially high electrode-skin-contact impedance due to the individual skin properties, movement, insufficient swiping with an alcohol swab, hair under the electrode, and sweating may affect the quality of electrode-skin contact [22], [23]. The mean EEG electrode impedance values ranged from 6.2 kΩ to 320.2 kΩ at the beginning of the recordings (Table 2). Traditionally, electrode-skin impedances below 5 kΩ have been considered clinically acceptable [3]. However, modern EEG/PSG amplifiers with high input impedances can tolerate much higher
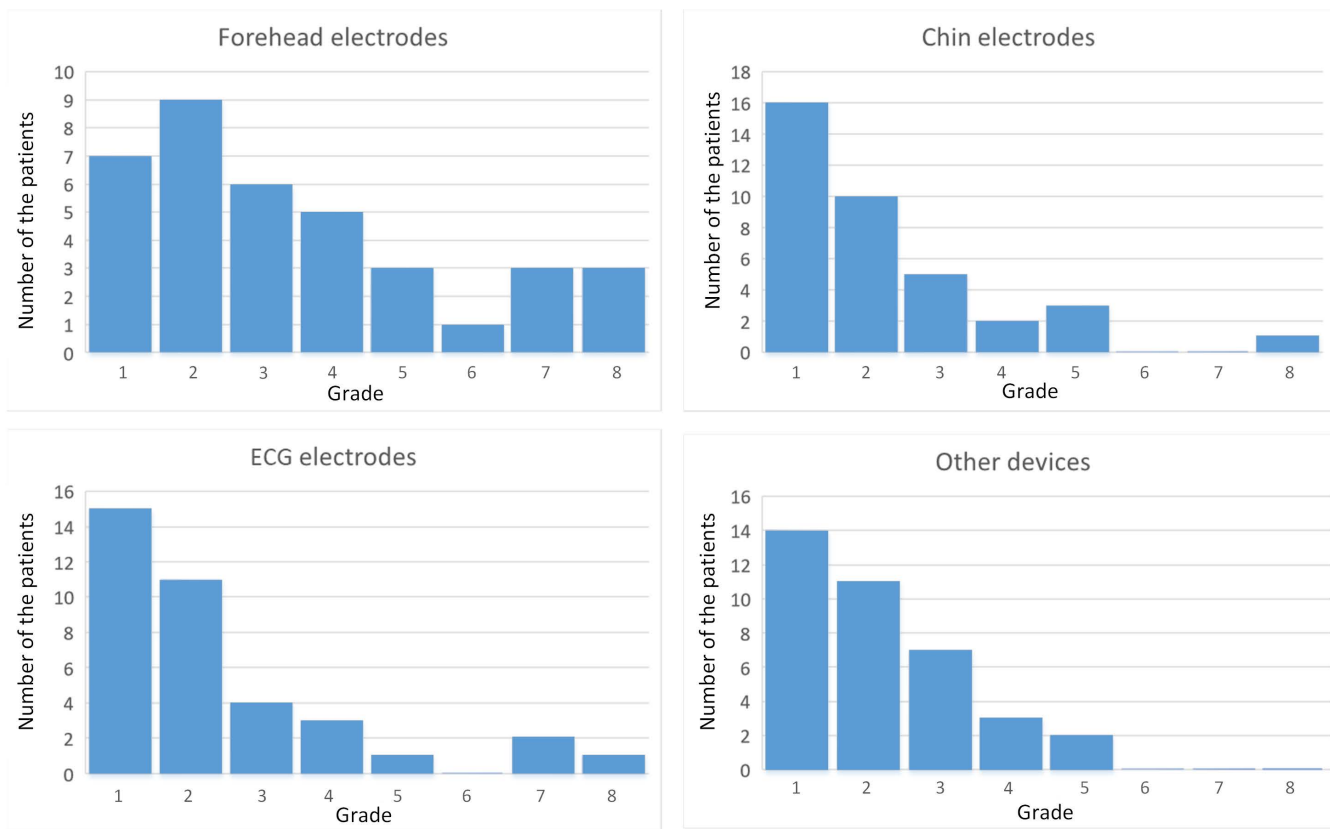
FIGURE 3. Ease of applying the electrodes and other sleep recording devices (n = 38). Grading: 1 (easy)–10 (difficult). The study subjects did not select grades 9 and 10 in any cases.

electrode-skin impedances without significant decreases in signal quality [24], [25].

Nocturnal sweating is common among OSA patients [26] and related sweat artifacts might be a problem especially in home recordings. To improve the sweat-induced artifact tolerance in this study, the AES electrodes were updated for eight recordings (starting from 2019) based on electrode development in the previous studies [16], [17]. Sweat artifacts were visible in nine recordings (three of them conducted with updated AES electrodes), but due to the limited number of recordings, correlations between sweat artifacts and updated/original electrodes were not further investigated in this study.

The usability of the AES was evaluated according to the patient questionnaires and based on success in self-assembly. The mean grades for the easiness of assembling the forehead electrodes were 3.5 and 2.1-2.4 for other devices (Table 4) which are in line with the respective grades of 3.3 and 2.0-2.1 previously reported [13]. Thus, perceived ease of use among healthy volunteers in the previous study [13] and among suspected OSA patients now, is quite similar. In addition, all patients succeeded in the self-assembly of the AES regardless of age. In this study, 92 % of patients considered that the AES fitted properly, but in three cases the size of the AES was unsuitable. Currently, only one size of the

AES is available and more sizes need to be manufactured to ensure the proper fit for all patients. It should be noted that patients were not asked if they were assisted (e.g. by a spouse or a relative) in self-assembly. Received assistance might certainly affect the grades given in the questionnaires. Furthermore, the average assembly time was not measured. To further evaluate the usability of the AES, patients should perform self-assembly under controlled conditions.

In addition to the usability of the AES, the PSG parameters between the conventional HSAT and the HSAT with AES recordings were compared. The median estimated TST in HSAT recording was 452.2 minutes whereas in HSAT with AES the median TST was significantly shorter, 369.0 min. In general, HSAT without EEG overestimates the TST compared to the recordings with EEG [21]. This is due to the more accurate determination of wake/sleep epochs in the recordings with EEG. When EEG is included, all wake epochs detected during the night are excluded from the TST [3]. In this study, non-scorable epochs and related respiratory and leg movement events were removed from the HSAT with AES recordings. This might further increase the difference in TST between recordings when the percentage of non-scorable data is high. Hence, a uniform rule for the limit for scorable data should be determined and recordings below this limit should be considered failed. In addition to a significant increase of

AHI, ODI, AI, OAI, and HI in HSAT with AES recordings, the OSA severity class of eight patients changed to worse (Fig. 2). This was not a surprise, because the false negative rate of the HSAT is known to be high and HSAT is known to underestimate the OSA severity [27]. It should be, however, noted that the number of patients participating in this study was limited, and further research might be needed to improve the statistical strength of the results. Despite the limitations of this study discussed above, the change of the OSA severity class of 8 patients (out of 33) is remarkable. In one patient case, the positive diagnosis was totally missed in the HSAT recording and the underestimation of the OSA severity in seven cases might have affected the treatment given to the patient.

Recently, several home-based wearable sleep monitoring devices, such as single-channel EEG devices, have been introduced to find cost efficient alternatives to PSG [9], [28]–[30]. However, to our knowledge, there are no other studies concerning multi-channel, self-applied EEG, EOG, and EMG sensor which can be attached to any modern EEG amplifier. The major advantage of single-channel EEG devices is usability, but there is also an increased risk of the total loss of EEG data [18]. Also in the present study, the success rate would have been notably worse if the alternative EEG channels would not have been available when artifacts occurred. Multi-channel devices are often considered more difficult to use [9], but in the present study, no total loss of the AES signals due to the mistakes in self-assembly occurred. We also demonstrated that the self-application of the AES is possible not only for healthy volunteers but also for clinically suspected OSA patients having variable educational background and age range.

To further improve the quality of the recordings, the percentage of scorable data should be increased. Thus, interferences such as sweat-induced artifacts and misplaced electrodes due to the unsuitable size of the electrode set should be minimized. Previously reported methods to increase the electrode tolerance to sweat artifacts [16], [17] were implemented to a few electrode sets in present study, but more recordings with these updated electrodes are planned to investigate comprehensively whether the better sweat-tolerance is achievable.

The previous studies have shown that the sleep parameters such as TST recorded with the AES were highly consistent with the corresponding parameters recorded with in-lab PSG [12]. Good reliability and easy patient-applicability have also been demonstrated among young and healthy volunteers [13]. The impedance characteristics and stability of the AES electrodes have been investigated and their artifact-tolerance has been improved [16], [17]. Together with these previous studies, this current clinical feasibility study showed that the AES has potential to enable an easy and accurate home PSG. In addition, we have recently developed a deep learning-based automated sleep staging approach that accurately determined sleep stages based on EEG channels measured with AES [31, 32]. This recent study also demonstrates that the AES signals can be used as a reliable input for this automatic scoring algorithm.

To conclude, we investigated the clinical suitability of the forehead AES for OSA diagnostics with 38 suspected OSA patients. This study demonstrates that the forehead AES is simple enough for self-application and enables more advanced OSA diagnostics compared to conventional HSAT.

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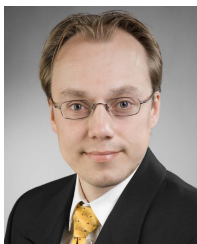
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