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RESEARCH ARTICLE

In-hospital and home-based long-term monitoring of focal epilepsy with a wearable electroencephalographic device: Diagnostic yield and user experience

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Abstract

Objective: The aim is to report the performance of an electroencephalogram (EEG) seizure-detector algorithm on data obtained with a wearable device (WD) in patients with focal refractory epilepsy and their experience.

Methods: Patients used a WD, the Sensor Dot (SD), to measure two channels of EEG using dry electrode patches during presurgical evaluation and at home for up to 8 months. An automated seizure detection algorithm flagged EEG regions with possible seizures, which we reviewed to evaluate the algorithm's diagnostic yield. In addition, we collected data on usability, side effects, and patient satisfaction with an electronic seizure diary application (Helpilepsy).

Results: Sixteen inpatients used the SD for up to 5 days and had 21 seizures. Sixteen outpatients used the device for up to 8 months and reported 101 focal impaired awareness seizures during the periods selected for analysis. Focal seizure detection sensitivity based on behind-the-ear EEG was 52% in inpatients and 23% in outpatients. False detections/h, positive predictive value (PPV), and F1 scores were 7.13%, .11%, and .002% for inpatients and 7.77%, .04%, and .001% for outpatients. Artifacts and low signal quality contributed to poor performance metrics. The seizure detector identified 19 nonreported seizures during sleep, when the signal quality was better. Regarding patients' experience, the likelihood of using the device at 6 months was 62%, and side effects were the main reason for dropping out. Finally, daily and monthly questionnaire completion rates were 33% and 65%, respectively.

Significance: Focal seizure detection sensitivity based on behind-the-ear EEG was 52% in inpatients and 23% in outpatients, with high false alarm rates and low PPV and F1 scores. This unobtrusive wearable seizure detection device was well received but had side effects. The current workflow and low performance limit its implementation in clinical practice. We suggest different steps to improve these performance metrics and patient experience.

KEYWORDS
focal seizure, machine learning, real-world data, seizure detection, wearable devices

1 | INTRODUCTION

Wearable devices (WDs) could become an important tool in the management of people living with epilepsy.[1,2] Nevertheless, the current use of these devices in patients with focal seizures is still in its infancy, and there is a lack of data about the impact on clinical outcomes such as morbidity and mortality.[3] Furthermore, according to the clinical practice guidelines for automatic seizure detection using WDs issued by the International League Against Epilepsy and the International Federation of Clinical Neurophysiology (IFCN),[4] there is high-quality evidence only in the detection of focal to bilateral or generalized tonic–clonic seizures (GTCS).[4]

Most published research on electroencephalogram (EEG)-based WDs in focal seizures has focused on evaluating the devices in the epilepsy monitoring unit (EMU)[5–7] or by using subscalp EEG,[8,9] which is invasive. Only a few studies have been carried out in outpatient scenarios for short periods,[10–12] and another study used a wearable EEG device to derive a novel biomarker of seizure propensity.[13] On the other hand, patients' desires have been extensively studied,[14–18] but there is less information about their experience during/after WD use outside the EMU.[4,5,9,19]

Finally, seizure diaries are widely used despite their low reliability due to seizure underreporting.[20,21] They remain the primary tool for patient monitoring and are currently the main instrument for seizure counting in clinical trials.[22] Therefore, other complementary tools are needed to improve patient follow-up.

From the second quarter of 2021, we have been recording different biosignals with the Sensor Dot (SD; Byteflies) in a cohort of patients with focal impaired awareness (FIA) seizures, using replaceable dry electrode patches, and more recently, hydrogel electrode patches (Plug 'nPatch, NCT04642105). These patients also used an electronic seizure diary application, Helpilepsy (Neuroventis), to answer daily and monthly questions about their well-being and emotional state. In this study, we investigated the diagnostic yield of automated EEG-based seizure detection using the SD and dry electrode patches in patients admitted for a 5-day presurgical evaluation and outside the hospital until December 31, 2021 (up to 8 months). We also present patients' adherence to the daily questionnaires using Helpilepsy and their experience during hospital admission and long-term use of the WD.

Key points

- Focal seizure detection sensitivity based on behind-the-ear electroencephalogram (EEG) was 52% in inpatients and 23% in outpatients; however, positive predictive values and F1 scores were low due to a high false alarm rate.
- Patients with refractory epilepsy were willing to use a behind-the-ear wearable scalp EEG device at home; nonetheless, the likelihood of using the device decreased to 62% at 6 months, mainly due to side effects.
- To improve the performance metrics, we need better wearable EEG electrodes with good signal quality, measures to avoid and handle artifacts, and the integration of other biosignals in addition to EEG.
- The current workflow and low performance limit its use in clinical practice; personalized algorithms are likely to have better performance.

2 | MATERIALS AND METHODS

2.1 | Patients and device setup

We recruited adult (≥18 years old) inpatients and outpatients with a confirmed diagnosis of focal refractory epilepsy and at least one FIA seizure per month in the previous 6 months before inclusion. Patients with cognitive limitations were included if they had a caregiver who could manage the SD and provide information about the patient's seizures.

The inpatient group consisted of individuals admitted for presurgical evaluation in the EMU of the University Hospital Leuven (UZ Leuven). They underwent video-EEG monitoring using a Schwarzer EEG amplifier (OSG) and Ag/AgCl cup electrodes (Ambu Neuroline Cup, Ambu), placed according to the standardized array proposed by the IFCN,[23] hereafter referred to as full montage EEG. The SD measured two EEG channels (same side [ipsilateral to the presumed or documented seizure focus], top to bottom electrodes; cross head, top electrodes [left to right]) at a sample rate of 250 Hz with dry electrode patches that we placed on the mastoid bone bilaterally (Figure 1), hereafter referred to as SD EEG. The closest corresponding electrodes on the full montage EEG were T7 and T8 for the top

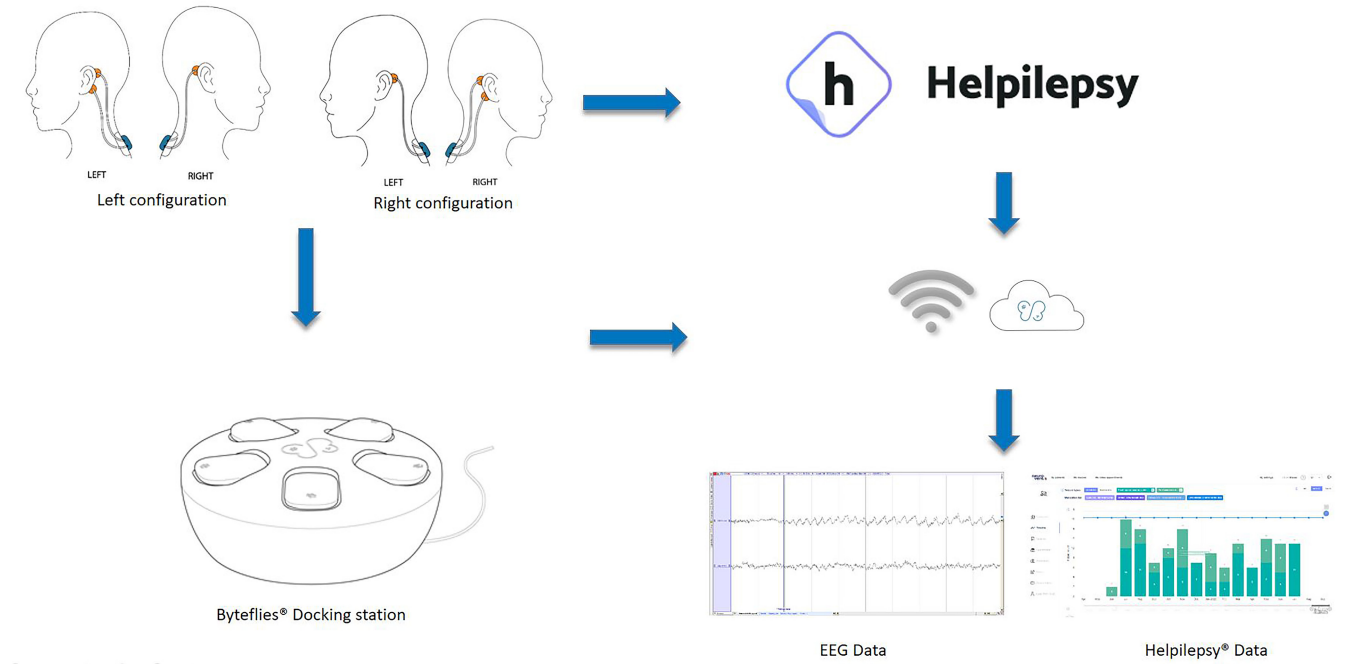

FIGURE 1 Clinical study workflow. Patients measured the two-channel electroencephalogram (EEG) with dry electrode patches placed on the mastoid bone. The Sensor Dot was replaced every 24 h for data transmission to a secure web cloud, and battery charging was done through the Byteflies Docking Station. Patients reported their seizures and responded to daily and monthly questionnaires via Helpilepsy. The research team accessed the data from both servers.

and P9 and P10 for the bottom electrodes. We changed the patches every 24–48 h. The SD was replaced every 24 h due to its memory storage limit (2 gigabytes) and battery life (approximately 30 h for this configuration).

Patients filled in the Quality of Life in Epilepsy V1 (QOLIE-31) scale,[24] and we measured seizure severity through the National Hospital Seizure Severity Scale (NHS3).[25] On their last day of admission, patients filled in a 10-point Likert-type questionnaire about the future usability of the device. Patients could choose between paper forms or Helpilepsy.

The outpatient arm was selected from our database of patients who underwent presurgical evaluation, in whom the habitual seizures were recorded. We preselected 80 patients starting from the most recent evaluation (December 2021) going back in time. We did not exclude patients with seizures originating outside the temporal lobe to evaluate the performance in all possible focal seizure types. One participant in the outpatient arm had also participated in the inpatient arm. This group used the SD at home for at least 16 h per day, wearing the dry electrode patches with the same configuration as the inpatient group. The focal channel was placed ipsilateral to the seizure focus or the most affected hemisphere in the case of multifocal epilepsy. Unfortunately, we could not measure patch impedance in this group. During the first study visit, we measured seizure severity with the NHS3 scale and patients filled in the QOLIE-31. In addition, patients received instructions about the correct use of the device, the need to swap the SD and patches every 24 h, and the transfer of collected data to a secure web-based cloud using the Byteflies docking station (Figure 1).

Furthermore, via Helpilepsy, outpatients received daily notifications to fill in questions about how active, happy, and stressed they felt (AHS questionnaire). Through the application, they also reported their seizures, perceived quality of sleep, and mood. Finally, monthly in-person or online follow-up assessed side effects and the reasons for not using the device. We used QOLIE-31 to evaluate their quality of life while using the SD every month. After the evaluation period, we gave all patients a detailed report about the number of seizures recorded and the device's general performance.

Written informed consent was obtained from every participant or their caregiver. The study was approved by the ethics committee of UZ/KU Leuven.

2.2 | Seizure detection

In both groups of patients, we used a support vector machine classifier to flag seizures in the SD EEG. The algorithm was trained with several features previously calculated on EEG data obtained in the hospital using Ag/AgCl cup electrodes (SeizeIT1).[26] The following metrics evaluated the algorithm's performance:

1. Sensitivity: TP/(TP + FN), where TP = true positives, FN = false negatives;
2. False alarm rate per hour: false positives (FP)/duration of recordings (in hours);
3. Positive predictive value (PPV): TP/(TP + FP); and
4. F1 score: 2 × (sensitivity × PPV)/(sensitivity + PPV).

In the inpatient group, first, the algorithm identified and annotated regions of possible seizures on the SD EEG, as seizure start – seizure stop. Then, we aligned the SD EEG data with the similarly clinically annotated full montage EEG, which was the gold standard. Overlapping seizure annotations on both datasets were considered TP. Seizure annotations on the full montage EEG without a corresponding annotation in the SD EEG were considered FN. Finally, annotations on the SD EEG without a seizure annotation on the full montage EEG were deemed FP. We evaluated the performance automatically with a custom-made program using MATLAB v9 (R2019b).[27]

In the outpatient group, the seizures reported via Helpilepsy were considered the ground truth. We followed this procedure: the first author, a neurologist, inspected all the measurements to exclude low-quality EEG segments due to incorrect patch positioning and electronic artifacts. We did not exclude segments with movement artifacts to evaluate the impact of daily activities on the algorithm performance. Then, the seizure detector algorithm flagged possible seizures on the selected data. Finally, the first author reviewed all the flagged regions to determine the algorithm's performance. We considered TP those flagged segments that occurred within 20 min before or after a reported seizure. We selected this time window considering the disruptions in attention and memory patients experience during and after seizures.[28] The EEG segments flagged by the algorithm as seizures that did not correspond to an electrographic pattern were deemed FP. FN corresponded to FIA seizures reported by the patients but not detected by the algorithm. We also noted seizures detected by the algorithm that were not reported in the seizure diary.

2.3 | Adherence and quality of life: Outpatients

We evaluated SD and questionnaire adherence as a percentage of the probable days of use and response from the first day of EEG measurements up to December 31, 2021. In addition, we assessed the differences in QOLIE-31 between the inclusion and the last month of SD use, that is, the month of dropout or December 2021, with the Wilcoxon signed-rank test.[29]

MATLAB v9 (R2019b)[27] was used to test the classifier. Statistical analysis was done in RStudio v2021.9.1.372[30] based on R v4.1.2.[31] We calculated the retention likelihood in the outpatient group using Kaplan–Meier survival analysis with the *survival* package V 3.2-13.[32]

3 | RESULTS

3.1 | Patients characteristics

Tables 1 and 2 show the clinical characteristics of the 16 inpatients and an equal number of outpatients included between March and December 2021. The median age of the inpatients was 30 years (interquartile range [IR] = 26–35), with a median age of seizure onset of 13 years (IR = 9–23). Most of them used three antiseizure medications (ASMs) and had a median of five seizures (IR = 3–11) in the previous month. QOLIE-31 ranged between 33.12 and 80.5, with moderate to high FIA seizure severity (median = 9, IR = 8–13) measured by the NHS3.

Of 80 patients prescreened in the outpatient group, 40 were excluded after reassessment for several reasons (seizure freedom after introducing new ASMs, they had both epilepsy and psychogenic nonepileptic seizures, etc.), 24 declined the invitation, and 16 patients agreed to participate. The median age was 38 years (IR = 28–48), with a median age of seizure onset of 20 years (IR = 11–24). Most patients also used three ASMs (IR = 2–3), and their QOLIE-31 ranged from 32.51 to 79.83. The median FIA seizure severity was 8 (IR = 6–15).

3.2 | Seizure detection

3.2.1 | Inpatient group

Twenty-one FIA seizures were recorded in 10 patients during 1379 h of measurements. Patients reported 15 of the 21 recorded FIA seizures (71%) in their seizure diary. The seizure detector had an overall sensitivity of 52%, and was higher for seizures originating in the temporal versus the frontal lobes (70% vs. 33%). The total F1 score was .002 (range = 0–1; Table 3), and the algorithm had a mean of 7.13 (standard deviation [SD] = 3.51) false detections per hour.

TABLE 1 Inpatient clinical characteristics.

Subject	Sex	Age, years	Age at onset, years	SD configuration	Affected lobe	Etiology	Current ASMs	Previous ASMs	QOLIE-31	NHS3 (FIAS)
Inpat_01	F	42	26	Right	Temporal	Hippocampal sclerosis	LTG, BRV	CBZ, LCM, LEV, TPM, VPA	33.12	9
Inpat_02	M	61	4	Right	Temporal	Hippocampal sclerosis	BRV, CZP, PHT, OXC	CBZ, LCM, LTG, LEV, PER, PGB, RTG, TPM, VPA	53.96	16
Inpat_03	M	35	15	Right	Frontal	Focal cortical dysplasia type IIb	LEV, CLB, PGB	BRV, CBZ, CZP, LCM, OXC, PER, TPM	37.78	7
Inpat_04	F	24	16	Left	Temporal	Hippocampal sclerosis	LEV, LTG, VPA	NA	52.51	16
Inpat_05	M	29	19	Right	Frontotemporal	Unknown	CBZ, LTG, VPA	LEV	28.99	16
Inpat_06	M	31	10	Left	Frontal	Resected fibrillary astrocytoma (WHO II)	CBZ, BRV, LEV, PGB	PER, TPM, VPA	61.38	9
Inpat_07	F	24	21	Left	Temporal	Malformation of cortical development	LCM	BRV, LTG, LEV	45.66	14
Inpat_08	M	32	12	Right	Temporal	Unknown	BRV, LCM, VPA	LEV	61.58	9
Inpat_09	F	57	54	Right	Temporal	Unknown	BRV, LCM, PER	CBZ, LTG, VPA	29.17	5
Inpat_10	M	23	9	Right	Temporal	Unknown	LCM	Null	80.5	11
Inpat_11	F	26	4	Right	Frontal	Focal cortical dysplasia	LEV, LTG	CBZ, GBP, TPM	75.14	NA
Inpat_12	F	26	9	Right	Multifocal	Rett syndrome–*MECP2* duplication	LTG, PER, VPA	BRV, CBZ, CBZ, LCM, LEV, RFM, TPM	22.54	6
Inpat_13	F	34	20	Right	Temporal	Malformation of cortical development	CBZ, LCM, LTG	BRV, LEV, TPM, VPA	70.87	5
Inpat_14	M	25	15	Left	Frontal	Unknown	LEV	LCM, LTG, VPA	38.52	12
Inpat_15	M	30	7	Left	Temporal	Focal cortical dysplasia	BRV, LCM, LTG, PER	CBZ, LEV, VPA	61.9	10
Inpat_16	M	36	11	Right	Frontal	Unknown	LTG, LEV	CBZ, LCM	73.61	8

Abbreviations: ASM, antiseizure medication; BRV, brivaracetam; CBZ, carbamazepine; CLB, clobazam; CZP, clonazepam; F, female; FIAS, focal impaired awareness seizures; GBP, gabapentin; LCM, lacosamide; LEV, levetiracetam; LTG, lamotrigine; M, male; *MECP2*, methyl-CpG binding protein 2; NA, not applicable; NHS3, National Hospital Seizure Severity Scale; OXC, oxcarbazepine; PER, perampanel; PGB, pregabalin; PHT, phenytoin; QOLIE-31, Quality of Life in Epilepsy V1; RFM, rufinamide; RTG, retigabine; SD, Sensor Dot; TPM, topiramate; VPA, valproate; WHO, World Health Organization.

TABLE 2 Outpatient clinical characteristics.

Subjects	Sex	Age, years	Age at onset, years	SD configuration	Lobe	Etiology	Current ASMs	Previous ASMs	QOLIE-31	NHS3 (FIAS)
Outpat_01	M	33	14	Right	Temporal	Unknown	LEV, VPA, CBZ, CZP	LTG, LCM	32.51	7
Outpat_02	M	29	11	Right	Occipitoparietal	Focal cortical dysplasia	LCM, VPA, BRV	LEV, CBZ	79.83	4
Outpat_03	M	46	42	Right	Temporal	Hippocampal sclerosis, bilateral	BRV, LCM, CZP	LTG	59.95	6
Outpat_04	M	51	24	Left	Temporal	Unknown	PER, LTG, BRV, PGB	CBZ, LEV, TPM, RTG	76.93	17
Outpat_05	M	28	24	Left	Temporal	Hippocampal sclerosis	LCM, BRV, CZP	LEV	35.34	10
Outpat_06	M	28	22	Right	Temporal	Unknown	BRV, LTG, LCM	LEV, VPA, TPM	61.27	8
Outpat_07	F	36	23	Left	Temporal	Autoimmune limbic encephalitis (anti-GAD)	LEV, LCM, CZP	TPM, VPA	72.58	9
Outpat_08	F	31	3	Left	Temporal	Hippocampal sclerosis	LTG, BRV	LEV, CBZ, TPM, LCM, PGB	61.84	4
Outpat_09	F	39	31	Left	Temporal	Periventricular heterotopia	BRV, LCM	LEV, LTG, CBZ, PGB	41.47	17
Outpat_10	M	56	9	Right	Frontal	Polymicrogyria	LTG, LCM, CLB	PHT, LEV, OXC, PGB, VGB	46.72	19
Outpat_11	M	23	8	Left	Parietotemporal	Grade II astrocytoma	LTG, BRV, LCM, VPA	PB, CBZ, LEV	45.93	6
Outpat_12	F	53	18	Right	Temporal	Unknown	BRV, CBZ, VPA	LEV	71.48	7
Outpat_13	F	57	24	Right	Temporal	Periventricular heterotopia	LEV, BRV	RTG, PER, CBZ, VPA, PHT, TPM, LTG	71.31	4
Outpat_14	F	24	23	Left	Temporal	Focal cortical dysplasia	LCM	LEV, LTG, BRV	–	14
Outpat_15	F	26	14	Left	Multifocal	Rett syndrome–duplication of *MECP2* gene	PER, VPA, LTG	LEV, CLB, CBZ, LCM, TPM, BRV, RFM	34.12	6
Outpat_16[a]	F	47	11	Generalized	Temporal	Focal cortical dysplasia	BRV, CBD	CBZ, LEV, PB, VPA, VGB, TPM, LTG, CZP, LCM, PER	–	21

Abbreviations: –, not obtained; ASM, antiseizure medication; BRV, brivaracetam; CBD, cannabidiol; CBZ, carbamazepine; CLB, clobazam; CZP, clonazepam; F, female; FIAS, focal impaired awareness seizures; GAD, glutamate decarboxylase; LCM, lacosamide; LEV, levetiracetam; LTG, lamotrigine; M, male; *MECP2*, methyl-CpG binding protein 2; NHS3, National Hospital Seizure Severity Scale; OXC, oxcarbazepine; PB, phenobarbital; PER, perampanel; PGB, pregabalin; PHT, phenytoin; QOLIE-31, Quality of Life in Epilepsy V1; RFM, rufinamide; RTG, retigabine; SD, Sensor Dot; TPM, topiramate; VGB, vigabatrin; VPA, valproate.

[a]Deceased due to sudden unexpected death in epilepsy.

TABLE 3 Algorithm performance for FIAS inpatients.

Subject	Total hours analyzed	Alarms	Gold standard: FIAS visible on full montage EEG	FIAS detected by algorithm on SD-EEG (TP)	FIAS not detected by the algorithm (FN)	Incorrect detections (FP)	Sensitivity, % [range = 0–100]	PPV, % [range = 0–100]	F1 score [range = 0–1]	False detections/h
Inpatient_01	93.27	1418	2	2	0	1416	100	.14	.003	15.18
Inpatient_02[a]	23.03	158	0	0	0	158	NA	0	NA	6.86
Inpatient_03	89.66	452	3	0	3	449	0	0	NA	5.04
Inpatient_04	89.68	381	0	0	0	381	NA	0	NA	4.25
Inpatient_05	112.48	610	0	0	0	610	NA	0	NA	5.42
Inpatient_06	63.37	311	0	0	0	311	NA	0	NA	4.91
Inpatient_07	90.41	480	3	3	0	477	100	.63	.01	5.28
Inpatient_08	93.5	716	2	2	0	714	100	.28	.01	7.64
Inpatient_09[a]	65.69	924	2	0	2	922	0	0	NA	14.07
Inpatient_10	92.77	402	0	0	0	402	NA	0	NA	4.33
Inpatient_11	69.17	636	0	0	0	636	NA	.79	NA	9.12
Inpatient_12	98.4	154	5	2	3	152	40	1.30	.03	1.54
Inpatient_13	73.60	611	0	0	0	611	NA	0	NA	8.3
Inpatient_14	92.62	563	1	0	1	562	0	0	NA	6.08
Inpatient_15	114.83	1254	1	0	1	1254	0	0	NA	10.92
Inpatient_16	116.81	782	2	2	0	780	100	.26	.01	6.68
Total	1379.29	9852	21	11	10	9841	52	.11	.002	7.13
Temporal lobe	736.77	4792	10	7	3	4785	70	.15	.003	6.49
Frontal lobe	431.63	1797	6	2	4	1795	33	.11	.002	4.16
Other localization	210.88	764	5	2	3	762	40	.26	.002	3.61

Abbreviations: EEG, electroencephalogram; FIAS, focal impaired awareness seizures; FN, false negatives; FP, false positives; NA, not applicable; PPV, positive predictive value; SD, Sensor Dot; TP, true positives.

[a]Dropped out.

3.2.2 | Outpatient group

Sixteen outpatients used the device for 32 526 h, the equivalent of 1355 days. We excluded 20 934 h (872 days, 64%) of the analysis due to low signal quality. During the remaining 483 days, 12 patients reported 101 FIA seizures (Table 4). Twenty-three of 101 reported seizures were detected by the algorithm (sensitivity = 23%). It was higher for seizures originating in the temporal (28%) versus the frontal lobe (0%) and other locations (13%). The total PPV and F1 scores were .04 and .001, respectively (Table 4). Figure 2 shows an example of a detected episode.

On the other hand, the algorithm identified 19 nonreported electrographic seizures during sleep, and two seizures reported as focal aware (auras) by one patient.

The first author spent 15.5 min (SD = 4.2 min) reviewing every 24 h of flagged SD EEG, compared to approximately 85 min when reviewing a nonflagged file.

3.3 | Inpatients: Experience and future use

All inpatients used the device for at least 1 day of admission. One patient with a history of contact dermatitis stopped participating in the study due to patch allergy. Another patient dropped out on Day 4 because the device was uncomfortable during sleep. Five more adverse events occurred, namely skin irritation and patch imprinting, which did not preclude the completion of the study.

After using the patches and SD, patients reported a median score of 7 (IR = 6–8) for future daily usability (future usability: zero = very unlikely, 10 = very likely) for up to 4 weeks. The worriedness about how they looked wearing the device had a median score of 3 and a maximum of 5 (zero = completely not worried, 10 = completely worried). They considered the SD and patches comfortable to use during the day (median score = 7; 0 = very uncomfortable, 10 = very comfortable) and during the night (median score = 8, IR = 6–8).

TABLE 4 Algorithm performance for FIAS outpatients.

Subject	Total hours analyzed	Alarms	Gold standard: FIAS reported by the patient[a]	FIAS detected on SD-EEG (TP)	FIAS not detected (FN)
Outpat_01	1933.23	21 585	0	NA	NA
Outpat_02[b]	823.27	6774	4	0	4
Outpat_03[b]	676.24	4093	0	NA	NA
Outpat_04	1707.20	11 928	13	6	7
Outpat_05[b]	136.37	979	0	NA	NA
Outpat_06	833.54	6619	1	1	0
Outpat_07[b]	425.60	2641	0	NA	NA
Outpat_08	1243.91	12 450	18	3	13
Outpat_09	1673.51	10 714	31	9	22
Outpat_10	88.79	439	3	0	3
Outpat_11	467.55	1882	11	1	10
Outpat_12	941.68	7712	4	0	4
Outpat_13	51.09	293	1	0	1
Outpat_14	17.00	160	0	NA	NA
Outpat_15	570.48	1848	15	3	12
Outpat_16[c]	2.54	15	0	0	NA
Total	11 592	90 132	101	23	78
Temporal lobe	9641.91	79 189	68	19	49
Frontal lobe	88.79	439	3	0	3
Other localization	1861.3	10 504	30	4	26

Abbreviations: EEG, electroencephalogram; FIAS, focal impaired awareness seizures; FN, false negatives; FP, false positives; NA, not applicable; PPV, positive predictive value; SD, Sensor Dot; TP, true positives.

[a]During the segments selected for analysis.

[b]Dropped out.

[c]Patient died due to sudden unexpected death in epilepsy.

3.4 | Outpatients: Device and seizure diary app use

Of 1891 days of possible recordings, patients did not wear the SD and patches for 531 days (Table S1). Side effects occurred in all but one patient and contributed to the WD nonuse on 236 of 1891 days (13%) of expected recordings. These side effects were skin irritation, itch, and patch imprinting, which usually disappeared after stopping use of the device between 1 day and 1 week. During summer, skin irritation and itching increased. Also, one patient with a history of migraine reported headaches when using the patch. Furthermore, on 295 of 1886 days (16%), patients did not wear the device for several reasons (e.g., during social events, sporting, holidays, weekends, and work-related activities).

The median device use was 74 days (IR = 45–123) for all participants, except for one patient who died of sudden unexpected death in epilepsy after a seizure during the first day of the study. The likelihood that a patient kept using the device after 1, 3, and 6 months was 93%, 73%, and 62%, respectively (Figure S1). The reasons for dropping out included side effects in four of five cases, being the main reason in three of five cases. One patient lost interest after 2 months of measurements, and another found that the system interfered with his daily work routine and stopped his participation in the study.

Regarding Helpilepsy use, the AHS questionnaire was filled in an average of 59 (SD = 49) days, corresponding to 33% of all possible days. On the other hand, QOLIE-31 was answered 39 of 60 times, corresponding to 65% (Table S1).

QOLIE-31 data were available for 12 patients at baseline and the last month of measurements. The median global QOLIE-31 was 53.33 (IR = 42.61–71.35) and 55.29 (IR = 48.40–65.30), respectively, without a statistically significant change (p = .97) after the SD and patch use. Additionally, no differences were seen in any of the subscores of the QOLIE-31 (Table S2).

Incorrect detections (FP)	FIAS not reported & detected on SD-EEG	Sensitivity, % [range = 0–100]	PPV, % [range = 0–100]	F1 score [range = 0–1]	False detections/h
21 580	5	NA	0	NA	11.17
6774	0	0	0	NA	8.23
4093	5	NA	0	NA	6.05
11 922	1	46	.05	.001	6.98
979	0	NA	0	NA	7.18
6618	2	100	.01	.0002	7.94
2641	0	NA	0	NA	6.2
12 447	4	17	.02	.0004	10.0
10 705	1	29	.08	.002	6.40
439	0	NA	0	NA	4.94
1881	0	9	.05	.001	4.02
7712	0	0	0	NA	8.19
293	0	0	0	NA	5.73
160	0	NA	0	NA	9.41
1845	1	20	.16	.003	3.23
15	0	NA	0	NA	5.90
90 109	19	23	.04	.001	7.77
79 170	18	28	.02	.0004	8.21
436	0	0	0	NA	4.91
10 500	1	13	.04	.001	5.64

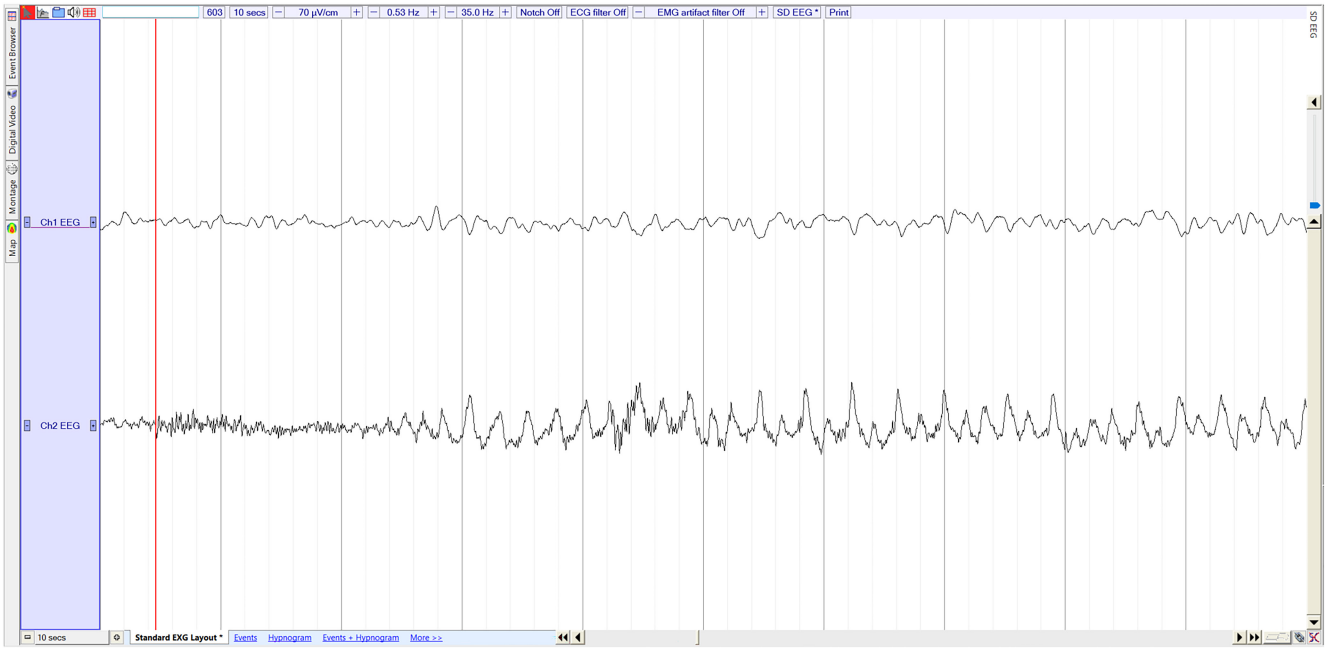

FIGURE 2 Seizure detected in an outpatient with temporal lobe epilepsy due to hippocampal sclerosis. Low-amplitude fast activity is followed by a delta-theta evolving rhythm. The seizure stopped 35 s later (not shown). Ch1, crosshead channel, between top left and top right electrodes; Ch2, same side bipolar channel, between the top and bottom electrodes. Sensitivity = 70 µV/cm, high-frequency filter = 35 Hz, low-frequency filter = .53 Hz, time base = 10 s.

4 | DISCUSSION

In patients with focal refractory epilepsy, we showed that an EEG WD could detect FIA seizures during hospital admission (sensitivity = = 52%) and long-term monitoring at home (sensitivity = 23%). This system's main advantages were its ease of use and discrete appearance. We also evaluated the patients' experience using the SD and a seizure diary app, confirming that patients are willing to try new devices and keen to continue using them at home. Nevertheless, when adverse events occurred frequently, the patient's motivation declined. Furthermore, after long-term monitoring, there were no differences in the quality of life (QOLIE-31 = 53.33 vs. 55.29).

4.1 | Seizure detection performance metrics

Previous studies on WDs in epilepsy were based on seizure detection in the hospital or for short periods at home.[7,10,11,33,34] Other authors used subscalp EEG, which is wearable but invasive,[8,9,35] but only a few algorithms have been tested on long-term home-acquired data.[35,36] To our best knowledge, this is the first study to investigate the diagnostic yield of long-term monitoring with reduced-montage scalp EEG.

Although seizure detection on reduced-montage EEG is difficult,[37–40] scalp EEG WDs are imperative for patients whose seizures are difficult to detect through other biosignals (e.g., seizures with low body motion or subtle autonomic changes).

Our study found fair to low sensitivity, high false detection rates, and low PPV and F1 scores. Analyzing the data, we found some reasons that might explain these metrics. First, dry patch electrodes produced low signal quality, mainly due to high impedances (up to 100 kΩ in the hospital setting). Additionally, incorrect patch positioning led us to discard several days of recordings. Second, we trained the seizure detector with data obtained in the hospital with cup electrodes, which have a better signal-to-noise ratio when compared to the patches. Third, the EEG signal became contaminated when clinical seizure manifestations preceded EEG changes, obscuring the expected evolving EEG pattern. Fourth, there was heterogeneity in the EEG seizure trace between patients and sometimes between seizures of the same patient. Finally, most false detections originated from movement artifacts resembling seizure patterns and baseline jump artifacts.

To overcome the exposed challenges, we believe further scalp EEG developments should consider the following. First, better quality patches with lower impedance and higher biocompatibility are needed.[41] Furthermore, appropriate patient and caregiver training are necessary for long-term acquisitions to reduce low signal quality

caused by incorrect use. Second, patient-specific EEG patterns, that is, seizure signature,[26,42] should be used to train the seizure detectors. Third, algorithm pipelines should include a library of artifacts to reduce FP. The library can be used during the postprocessing phase, as demonstrated in patients with absence epilepsy.[43] Another important topic for future studies is to evaluate specific movement patterns during focal seizures. Finally, the integration of different biosignals (e.g., heart rate, electrodermal activity) must be assessed, especially in patients whose EEG signal becomes easily obscured at the beginning of the seizure.[44,45] In a previous study by our group, integrating the heart rate increased seizure detection by 11% and 8% in the SeizeIT1 and Epilepsiae-Freiburg databases.[46]

Finally, our study found that signal quality was better at night, leading to lower FP and the detection of 19 unreported seizures during sleep that were unlikely to be captured otherwise. Nighttime use of the SD could increase seizure detection and counting when they are more likely to be missed.[20]

4.2 | Home gold standard and review time

Seizure diaries are the standard suggested and used in the literature for clinical purposes and new ASM trials.[22,47] Nevertheless, we confirmed that these diaries have limitations due to patients' lack of recall.[20,21] Therefore, WDs could be a complement to the diary, especially during the night.

On the other hand, review time was significantly reduced from approximately 1.15 h to <20 min for every 24 h of recording using the algorithm. Nevertheless, decreasing false detections is still essential to avoid human reader fatigue, especially because we foresee the need for human intervention in accurate focal seizure detection tasks during long-term monitoring.

4.3 | Patient experience

As shown previously,[14,16,17,48] patients want to try new WDs for seizure monitoring while admitted to the EMU, resulting from their need for appropriate follow-up as outpatients.[5] In our study, participants did not feel particularly worried about their appearance while using the SD, and the overall comfort was acceptable despite wearing patches and wires, both considered a limitation in previous studies.[5,6]

Nevertheless, we identified specific moments when patients are unwilling to use the device, which might affect seizure counts. In our study, patients wanted days without the WD, especially during holidays, weekends, and outside their usual environment. In the same direction, a qualitative study of Danish patients with epilepsy who wore, among others, an EEG WD for a short period at home found that patients felt "being placed in the spotlight" while using the device.[11] In addition, WD use at home might increase other people's perception of the severity of their disease.[11] In contrast, smartwatchlike devices or devices worn only during the night have higher retention rates (.84) and more prolonged use.[19]

On the other hand, skin-related side effects were the main reason to stop participating, and adverse events hindered using the device during 13% of the days of expected recordings. Therefore, hypoallergenic and breathable fabrics must be considered during device production to prevent these side effects.

Finally, we did not find a significant change in the patient's quality of life after using the device. Moreover, the design of our study cannot disentangle the effects on quality of life of frequent follow-ups, the use of a seizure diary, and the WD itself.

4.4 | Seizure diaries and questionnaires

Seizure diaries have been used for patient follow-up, documenting seizures in clinical trials and daily practice,[18] discovering seizure clusters,[49] and forecasting.[50,51] In our study, the use of the seizure diary to answer well-being measures was inconsistent despite daily reminders and declined with time. The main reasons stated by our patients included forgetting to answer the questions and the high frequency of queries (daily questions), something to be considered to avoid fatigue in users of the diaries.

4.5 | Limitations

Our study has two significant limitations. First, we had a low, highly selected sample size, which is not representative of all patients with epilepsy. Second, we obtained low signal quality on the SD EEG data, which depended not only on the dry patch but also on movement and daily activities, which became the main reason for our study's low PPV and F1 scores.

Nevertheless, this study is the first step toward long-term monitoring with a wearable scalp EEG device. Furthermore, we have proved its feasibility and identified drawbacks that need to be addressed, such as better patch quality and artifact treatment.

5 | CONCLUSIONS

In the past decade, interest in WDs has increased among patients living with epilepsy, caregivers, and physicians.[14,17,18] Future uses include seizure counting in clinical trials and medication titration, differentiating epileptic from nonepileptic events, detecting periods with higher seizure risk, and forecasting.[2,52,53] Currently, different devices are used by patients with GTCS,[4] and others are under development.[54] However, detecting focal seizures at home with WDs is still in its infancy, and more research is imperative for this group of patients.[12,53,55] Individual characteristics and use case scenarios are critical when selecting a WD device, because not all patients will be suitable or willing to use minimally invasive approaches, which have shown the best performance after intracranial devices.[35] In addition, patients now have access to customer-based applications and nonmedical devices with unclear interpretability and reliability, which might create false expectations regarding their use and diagnostic capabilities. Therefore, further developments should be evaluated in a reproducible framework that includes the diagnostic yield, patient experience, and changes in the clinical outcomes.[47]

AUTHOR CONTRIBUTIONS

Study design: Jaiver Macea, Wim Van Paesschen. Patient recruiting and follow-up: Jaiver Macea, Victoria Broux. Data acquisition Jaiver Macea. Data analysis: Jaiver Macea, Miguel Bhagubai. Funding acquisition: Wim Van Paesschen, Maarten De Vos. Manuscript drafting: Jaiver Macea. Manuscript edition and final approval: all authors.

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CONFLICT OF INTEREST STATEMENT

W.V.P. and M.D.V. have consultancy agreements with Byteflies, outside the scope of this research. None of the other authors has any conflict of interest to disclose. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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