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ORIGINAL ARTICLE

A multicenter, video-EEG-based validation of a multimodal wearable device for focal seizure detection in adults: The SeizeIT2 study

Lauren Swinnen[1] | **Miguel Bhagubai**[2] | **Christos Chatzichristos**[2] | **Yvonne Weber**[3] | **Stefan Wolking**[3] | **Ummehan Ermis**[3] | **Elisabeth Schriewer**[3] | **Andreas Schulze-Bonhage**[4] | **Matthias Dümpelmann**[4] | **Nicolas Zabler**[4] | **Nino Epitashvili**[4] | **Benno Mahler**[5] | **Arjune Sen**[6] | **Mkael Symmonds**[6] | **Mark P. Richardson**[7] | **Andrea Biondi**[7] | **Francisco Sales**[8] | **Abuhaiba Sulaiman I**[8] | **Maarten De Vos**[2,9] | **Wim Van Paesschen**[1,10]

[1]Laboratory for Epilepsy Research, KU Leuven, Leuven, Belgium

[2]Department of Electrical Engineering (ESAT), STADIUS Center for Dynamical Systems, Signal Processing and Data Analytics, KU Leuven, Leuven, Belgium

[3]Section of Epileptology, Department of Neurology, RWTH University of Aachen, Aachen, Germany

[4]Epilepsy Center, University Medical Center, Freiburg University, Freiburg, Germany

[5]Department of Neurology, Karolinska University Hospital, Stockholm, Sweden

[6]Oxford Epilepsy Research Group, Nuffield Department of Clinical Neurosciences, University of Oxford, Oxford, UK

[7]Division of Neuroscience, Institute of Psychiatry, Psychology & Neuroscience, King's College, London, UK

[8]Epilepsy Reference Center, Coimbra University Hospital, Coimbra, Portugal

[9]Department of Development and Regeneration, KU Leuven, Leuven, Belgium

[10]Department of Neurology, University Hospitals Leuven, Leuven, Belgium

Abstract

Objective: Currently available wearable devices for detecting focal seizures primarily target major motor seizures or involve semi-invasive subscalp implants. There is a pressing need for accurate, non-invasive methods to detect diverse focal seizures for long-term, out-of-hospital monitoring.

Methods: In this multicenter study (SeizeIT2), people with refractory focal epilepsy undergoing long-term video-electroencephalography (EEG) monitoring were simultaneously recorded with the Sensor Dot, a multimodal wearable device using EEG and electrocardiography (ECG). Wearable recordings were first processed with an offline detection algorithm, after which the algorithm-labeled segments underwent blinded review by a human expert, and results were compared with ground truth video-EEG. Post-hoc analyses were performed to evaluate how specific seizure characteristics, defined by the gold-standard recordings, influenced detection sensitivity.

Results: We recruited 192 adult participants, documenting a total of 616 focal seizures. The mean duration of Sensor Dot monitoring was 5 days. The seizure detection algorithm achieved an overall sensitivity of 0.73, precision of 0.004 and F1 score of 0.01. Following human review, a precision of 0.83 was achieved, albeit with a sensitivity of 0.31, resulting in an F1 score of 0.45. Seizure detection was influenced by the seizure type (focal impaired awareness seizure (FIAS) or focal-to-bilateral tonic–clonic seizures (FBTCS)) and the presence of a distinct ictal pattern on behind-the-ear EEG, constituting mostly temporal lobe seizures.

Maarten De Vos and Wim Van Paesschen—shared last authorship.

Correspondence
Maarten De Vos, Department of Electrical Engineering (ESAT), STADIUS Center for Dynamical Systems, Signal Processing and Data Analytics, KU Leuven, Leuven, Belgium.
Email: maarten.devos@kuleuven.be

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In a post-hoc subgroup analysis of seizures with a clear ictal EEG pattern and ictal tachycardia (as determined by the ground truth), a sensitivity of 0.74 was observed, whereas a sensitivity of 0.60 was achieved when there was visible electrographic seizure activity without tachycardia.

Significance: The overall performance of the Sensor Dot in focal seizure detection was limited in an unselected group of focal seizure types. Our findings suggest that the proposed approach, combining algorithm-based detection with human review, provides detection performance comparable with diary self-reporting, in terms of sensitivity, but with higher precision (0.83 vs. 0.60). Our findings suggest that this multimodal approach may be particularly beneficial for the subset of patients whose seizures are characterized by distinct ictal EEG patterns and tachycardia—features frequently seen in temporal lobe epilepsy. However, the prospective utility of these markers for patient selection requires further validation.

Plain Language Summary: Wearable devices may help improve seizure detection in people with epilepsy, but few non-invasive options exist for detecting focal seizures. We studied a behind-the-ear wearable device (Sensor Dot) using automated analysis combined with expert review. Overall, this approach resulted in detection of seizures with low sensitivity but high precision. Post-hoc subgroup analysis suggested that for seizures characterized by a distinct ictal EEG pattern and tachycardia—features often seen in temporal lobe epilepsy—this multimodal approach achieved a sensitivity of 0.74. Further prospective validation is required to confirm if this performance can be replicated through pre-monitoring patient selection.

KEYWORDS
focal seizures, machine learning, seizure detection, wearable devices

1 | INTRODUCTION

Wearable seizure detection devices can contribute to improved clinical management of people with epilepsy, especially in the 30% of patients who are refractory to treatment.[1] Traditional seizure diaries, although widely used, are unreliable in determining the response to treatment. This is because of seizure underreporting of more than 50% of all seizures, as well as issues related to overreporting and misinterpretation of non-epileptic events.[2–4] Progress in seizure detection technology has been notable, especially for patients experiencing tonic–clonic seizures (TCS),[5] which are a primary risk factor for sudden unexpected death in epilepsy (SUDEP).[6] TCS have a typical motor manifestation, making automatic detection easier. By contrast, focal seizures present in a variety of forms or semiologies, and people with focal epilepsy can experience multiple focal seizure types. These can range from seizures with retained awareness to impaired awareness, and motor or non-motor manifestations.[7] The diversity in focal seizures in terms of clinical signs as well as the subtlety complicates the development of wearable devices for detecting different focal seizure types. Currently, there are discrete wearables, in the form of an arm- or wristband, which can

Key points

- There is a need for non-invasive wearable devices to accurately detect diverse types of focal seizures.
- We studied the use of a multimodal wearable, using EEG and ECG, in people with focal epilepsy.
- Detection performance of the device was limited for unselected focal seizure types.
- A sensitivity of 0.74 was achieved when seizures showed clear EEG patterns and ictal tachycardia, outperforming seizure diaries.

detect focal-to-bilateral tonic–clonic seizures (FBTCS) with a high sensitivity and acceptable false alarm rate.[5,8,9] Additionally, subscalp electroencephalography (EEG)-based devices show potential for detection of non-convulsive focal seizures; however, these devices require surgery for implantation.[10,11] Consequently, semi-invasive subscalp devices are indicated only for those patients who might derive clear added value from the device compared with standard self-reporting in a seizure diary.[10–13] For patients with focal seizures not willing or suitable to use subscalp devices, appropriate alternatives are currently missing. Focal seizure detection devices that are not subscalp rely on alternative modalities. Multimodal approaches could contribute to a higher accuracy in the detection of different focal seizure types.[14–16] As EEG is the gold standard in epileptic seizure detection, incorporating an EEG modality may offer advantages for improving the reliability of a multimodal device.

In this multicenter study, SeizeIT2 (clinicaltrials.gov: NCT04284072), we aimed to validate the multimodal Sensor Dot device (Byteflies, Belgium) for the detection of focal seizures using behind-the-ear two-channel EEG and electrocardiography (ECG). To this end, we used an automatic detection algorithm based on behind-the-ear EEG and ECG[17] followed by expert review of the algorithm-labeled segments.

2 | METHODS

2.1 | Study design and participants

This study was a multicenter, prospective study to validate the performance of the multimodal wearable device, Sensor Dot (Byteflies, Belgium), in adult patients with focal seizures (SeizeIT2; clinicaltrials.gov: NCT04284072). Patients were included in the study if they were 18 years or older, had a history of refractory epilepsy and attended the tertiary epilepsy centers for routine 24-h video-EEG or long-term video-EEG monitoring as part of a presurgical evaluation. They were excluded if they: had a (suspected) allergy to silver-chloride electrodes or medical adhesives, had a (suspected) skin condition that prevented the use of such electrodes and adhesives, or had an implanted device (e.g. pacemaker or neurostimulator). Written informed consent was obtained from all participants. Data were collected between January 10, 2020, and June 30, 2022. The ethical committees of the participating centers approved the study (central ethics committee, UZ Leuven: S63631).

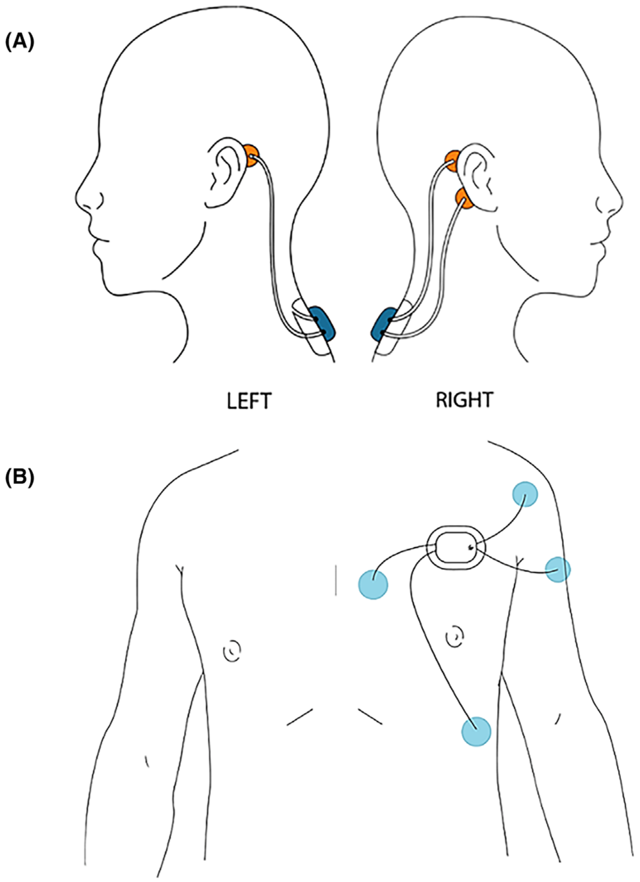


FIGURE 1 Configuration of the Sensor Dot. (A) The set-up for detection of focal seizures requires the attachment of a Sensor Dot to the neck and three electrodes behind the ears: two on the side of (suspected) seizure onset, shown here for a focal right epilepsy, and one electrode on the other side. The upper electrodes on both sides are connected to form a crosshead channel. The two electrodes on the same side are connected to form a second ipsilateral channel. (B) The second Sensor Dot is attached to the chest. EMG is measured from the deltoid muscle and bipolar ECG electrodes are attached to the chest.

2.2 | Data collection

All centers used their own standard equipment for routine video-EEG monitoring. During the monitoring, participants also wore the multimodal wearable device (Figure 1). A Sensor Dot is a recording device that can record two-channel behind-the-ear EEG, ECG, electromyography (EMG), accelerometry and gyroscope (movement data). One Sensor Dot was placed on the participant's neck with the set-up of the electrodes depending on the (suspected) seizure type and onset. When focal seizures were expected to originate from the left hemisphere, two electrodes were positioned behind the left ear (one upper and one lower) and one electrode (upper) behind the right ear. The opposite set-up was applied for focal seizures with a right-sided onset. The upper electrodes from both sides were connected to form a crosshead channel. The electrodes on the same side were also connected to form an ipsilateral channel. When generalized seizures were considered possible, two electrodes were positioned behind each ear and two (one right and one left) ipsilateral channels were created. An additional Sensor Dot was attached to the participant's chest to record ECG and EMG from the deltoid muscle, using adhesive electrodes. All Sensor Dots contain an accelerometer and gyroscope to measure movement. The Sensor Dot has a size of 24.5 × 33.5 × 7.73 mm, weight of 6.3 grams, and a battery life of approximately 24 h. Sampling rate of the Sensor Dot EEG, ECG, and EMG was 250 Hz. Movement data were measured at a sampling frequency of 25 Hz. Impedance was ≤5 kΩ at the beginning and checked throughout.

2.3 | Data analysis

2.3.1 | Data review: Automatic detection followed by human expert review

The full scalp video-EEGs were annotated by the clinicians in the respective centers and these data were used as ground truth. The reporting clinicians were requested to annotate the following: onset and ending of the seizure on video and EEG, seizure type including awareness and potential motor symptoms, whether the participant was asleep or awake before seizure onset and heart rate.

Separately, the Sensor Dot recordings were first analyzed using an offline detection algorithm, which flagged all segments classified as seizures (hereafter referred to as algorithm-labeled segments). The automatic seizure detection algorithm is multimodal, combining the Sensor Dot's behind-the-ear EEG and bipolar ECG, and has been previously described by Bhagubai and colleagues.[17] The algorithm presents seizure events based on the single-segment classification with further post-processing steps. The EEG classification was done to each 2-s segment with a 50% overlap, with subsequent post-processing (a seizure event obtained by the algorithm is retained if, within a window of 10 s of data, at least 8 s have a positive seizure classification). The ECG classification was performed to segments with a duration of 30 s. The seizure segments annotated by the multimodal algorithm thus had a minimum duration of 10 s. Only these algorithm-labeled segments were then presented to the human expert for review. This non-personalized multimodal detection algorithm was trained with the SeizeIT1 dataset[18] and tested on the current SeizeIT2 data.

Algorithm-labeled segments were provided for blinded review to a human expert, L.S., who has several years of experience in reading wearable device data. Although seizure classification by the algorithm was based only on two-channel behind-the-ear EEG and ECG data, the visual review benefited from the full set of signals (two-channel behind-the-ear EEG, ECG, EMG, and movement data) recorded by the wearable. Seizures were annotated by the human reviewer on the Sensor Dot segments, blinded to all clinical and video-EEG data and the number of seizures in the dataset. The duration required to analyze each wearable data recording was systematically documented. Owing to the variation in recording duration, the review time was weighted to 24 h of recording.

2.3.2 | Comparison of Sensor Dot to video-EEG annotations: Performance

The alignment of the Sensor Dot to the video-EEG recordings has been previously described.[19] First, the seizure annotations from the detection algorithm were compared with the ground truth EEG annotations and true positives (TPs), false positives (FPs), and false negatives (FNs) were determined. Second, the annotations of the Sensor Dot segments made by the human expert were compared with the ground truth EEG annotations. If the seizure annotation on Sensor Dot corresponded to a seizure on the ground truth, this was determined a TP. If there was an annotation for a focal seizure on Sensor Dot but not on the ground truth, this was determined a FP. If there was a seizure on the ground truth but not annotated on the Sensor Dot, this was determined a FN.

From these data, we calculated the following performance metrics, with a range of scores between 0 and 1 (poor and excellent):

- Sensitivity: $\frac{\mathrm{TP}}{\mathrm{TP}+\ \mathrm{FN}}$ Sensitivity defines how many seizures were correctly detected by Sensor Dot recordings.
- Precision: $\frac{\mathrm{TP}}{\mathrm{TP}+\ \mathrm{FP}}$ Precision defines how many annotations on Sensor Dot were in fact seizures.
- F1 score: $\frac{2\times(\mathrm{sensitivity}\times\mathrm{precision})}{(\mathrm{sensitivity}+\mathrm{precision})}$ F1 score is the harmonic mean of sensitivity and precision and provides an overall measure of performance.

2.3.3 | Meta parameters

In a post-hoc analysis intended to identify factors influencing detection sensitivity, we collected data on meta-parameters to analyze the effect on detection sensitivity. Therefore, data on seizure duration, state of asleep/awake prior to seizure onset, hemisphere of onset, lobe of onset, and the Sensor Dot set-up were collected. Prior to review of the recordings, we determined if the seizure pattern was visible on Sensor Dot EEG (based on the clinician's annotation of seizure onset and end on the ground truth and a corresponding evolutive pattern on Sensor Dot EEG, that is a clear ictal pattern), contained artifacts or was not visible on Sensor Dot EEG. We documented if motor activity was present on the Sensor Dot EMG and if there was tachycardia (> 20 beats per minute [bpm] compared with baseline) visible on Sensor Dot ECG.

The influence of the meta-parameters on the detection sensitivity was analyzed with a generalized mixed model (binary logistic) using SPSS version 29 (SPSS Inc., Chicago, IL).

3 | RESULTS

3.1 | Participants and seizures

A subset of the SeizeIT2 dataset is publicly available.[20] In this analysis, 192 adult (97 female; 51%) participants were included. Mean age was 38 years (range: 18–78 years) and the total duration of aligned video-EEG and Sensor Dot recording was 11 443 h 33 min 18 s. On average, patients underwent monitoring with the Sensor Dot for 5 days (range: 1–21 days).

The ground truth video-EEG annotated a total of 616 seizures. Of these, 298 were focal impaired awareness seizures (FIAS) (48%), 210 were focal aware seizures (FAS) (34%), 55 were FBTCS (9%), and 53 were focal seizures during which awareness could not be determined (9%). Most seizures had left-sided onset (50%), with relatively fewer demonstrating right-sided onset (18%) or bilateral onset (2%). In 30% of seizures, the hemisphere of onset was unclear. Forty percent of seizures originated from the temporal lobe, 19% from the frontal lobe, 13% from frontotemporal regions, and 28% from the remaining regions. Of all seizures, 321 (52%) showed tachycardia on the gold-standard video-EEG recording. Five seizures showed bradycardia and one seizure involved ictal asystole. For 75 seizures (12%), the ECG contained major artifacts and it was therefore unclear whether tachycardia was present. The mean duration of seizures was 1 min 21 s (median = 1 min 3 s; range: 3 s–16 min 3 s). Further details on seizure characteristics are provided in Table 1.

3.2 | Performance of detection algorithm only

The multimodal detection algorithm based on behind-the-ear EEG and bipolar ECG gave a mean sensitivity per patient of 0.78 (IQR: 0.67–1) and a mean false alarm rate of 6.22 FP/h (IQR: 4.41–7.81 FP/h). The mean duration of the alarms was 22.9 s (range: 10–1882 s). Over the total group of seizures, 447 seizures were accurately detected by the algorithm, achieving a sensitivity of 0.73, precision of 0.004, and F1 score of 0.01.

3.3 | Performance of human review of algorithm output

3.3.1 | Overall performance

Only 193 of the 616 seizures were detected during expert review of the algorithm-labeled segments. This resulted in an overall sensitivity of 0.31. The median sensitivity per patient was 0.38. The overall precision was 0.83 (median = 1.00). Therefore, the overall F1 score was 0.45 (median = 0.86). On average, the review time needed for a 24 h recording was 8 min 17 s (median = 5 min 43 s).

3.3.2 | Influence of seizure type

Further post-hoc analyses were performed. When computing sensitivity for each seizure type individually, we found the following sensitivities: 0.37 for FIAS, 0.82 for FBTCS, 0.14 for FAS, and 0.13 for focal seizures with unknown awareness on seizure level.

On a participant level, stratified by predominant seizure type, median sensitivity (IQR) for FIAS was 0.33 (0.00–1.00), for FAS 0.00 (0.00–0.33), for FBTC 1.00 (1.00–1.00), and for focal seizures 0.00 (0.00–0.5). When computing the F1 scores on a participant level, F1 scores were 0.80 (0.50–1.00) for FIAS ($n = 64$), 0.50 (0.50–0.67) for FAS ($n = 19$), 1.00 (0.92–1.00) for FBTCS ($n = 24$), and 0.55 (0.38–0.75) for focal seizures with unclear awareness ($n = 9$).

When seizures were categorized into motor and non-motor focal seizures (which also included seizures with automatisms as they were not expected to be causing marked artifacts in the recording), the sensitivity was similar for both groups and to the total sensitivity, respectively, 0.32 and 0.31.

3.3.3 | Influence of seizure onset

In the total group, sensitivities were similar for seizures with a left-sided onset (0.39), a right-sided onset (0.41), and bilateral onset (0.42). The sensitivity was highest for seizures from the temporal lobe (0.47) and frontotemporal regions (0.40). Sensitivity was lowest for seizures arising from the frontal lobe (0.06). Sensitivities calculated for seizures from other brain regions either

TABLE 1 Seizure characteristics.

	Total	**FIAS**	**FAS**	**Focal**	**FBTCS**
	616	**298 (48%)**	**210 (34%)**	**53 (9%)**	**55 (9%)**
Hemisphere of onset					
Left	309 (50%)	158	104	23	24
Right	112 (18%)	60	30	11	11
Bilateral	14 (2%)	11	-	-	3
Unknown	181 (30%)	69	76	19	17
Lobe of onset					
Central	11 (2%)	-	11	-	-
Centroparietal	18 (3%)	11	6	-	1
Centrotemporoparietal	5 (1%)	-	4	1	-
Frontal	114 (19%)	43	61	5	5
Frontocentral	8 (1%)	-	-	6	2
Frontocentroparietal	13 (2%)	1	11	1	-
Frontocentrotemporal	6 (1%)	1	3	2	-
Frontotemporal	80 (13%)	20	50	2	8
Insula	15 (2%)	1	13	-	1
Occipital	11 (2%)	4	5	2	-
Occipitoparietal	1 (<1%)	1	-	-	-
Parietal	1 (<1%)	-	-	-	1
Temporal	247 (40%)	181	36	12	18
Temporooccipital	3 (<1%)	3	-	-	-
Temporoparietal	4 (1%)	-	2	-	2
Temporoparietooccipital	7 (1%)	-	-	7	-
Unknown	72 (12%)	32	8	15	17
State					
Awake	333 (54%)	199	104	8	22
Asleep	235 (38%)	70	104	35	26
Unknown	48 (8%)	29	2	10	7
Motor vs. non-motor					
Motor	323 (52%)	127	123	18	55
Non-motor	263 (43%)	154	79	30	-
Unknown	30 (5%)	17	8	5	-

fell within this range or the number of seizures was too low to be representative (Table 1).

3.3.4 | Influence of sleep–wake state

We analyzed sensitivity based on sleep or awake state prior to seizure onset. Seizures originating from awake rendered a sensitivity of 0.34, while seizures from asleep rendered a sensitivity of 0.26. In the asleep state, the largest group (31%) were seizures with a frontal lobe onset (Table S1). In the awake state, nearly half of all seizures were temporal lobe seizures.

3.3.5 | Influence of clinical and neurophysiological characteristics

During human review of the algorithm output, a sensitivity of 0.71 was achieved for focal seizures with distinct ictal EEG patterns on video- and Sensor Dot EEG (Table 2). Seizures with tachycardia on the Sensor Dot's ECG resulted in a sensitivity of 0.74. Most seizures showing distinct ictal EEG patterns and tachycardia originated from the temporal lobe (66%) (Table S2). Temporal lobe seizures with these characteristics were detected with a higher sensitivity (0.76) in the awake state compared to when the seizures occurred from sleep (0.67). In the total

TABLE 2 Seizure characteristics on Sensor Dot biosignals.

Sensor Dot EEG	Sensor Dot ECG	Number of seizures detected by human reviewer	Total number of seizures	Sensitivity
Clear ictal pattern		175	245	0.71
	Tachycardia (>20 bpm)	98 (56%)	132 (54%)	0.74
	No tachycardia	33 (19%)	55 (22%)	0.60
	Artifact	40 (23%)	54 (22%)	0.74
	Bradycardia	1 (1%)	1 (0.4%)	1.00
	ECG N/A	3 (2%)	3 (1%)	1.00
No apparent ictal pattern		4	182	0.02
	Tachycardia (>20 bpm)	4 (100%)	60 (33%)	0.07
	No tachycardia	0 (0%)	81 (45%)	0.00
	Artifact	0 (0%)	33 (18%)	0.00
	Bradycardia	0 (0%)	3 (2%)	0.00
	ECG N/A	0 (0%)	5 (3%)	0.00
Artifact		14	189	0.07
	Tachycardia (>20 bpm)	7 (50%)	59 (31%)	0.12
	No tachycardia	4 (29%)	37 (20%)	0.11
	Artifact	3 (21%)	84 (44%)	0.04
	Bradycardia	0 (0%)	1 (1%)	0.00
	ECG N/A	0 (0%)	8 (4%)	0.00

Note: ECG N/A: Sensor Dot ECG not available. This was due to not applying a Sensor Dot ECG/EMG ($n = 12$) or premature battery depletion of the Sensor Dot ECG ($n = 4$).

group of patients that showed an ictal pattern on EEG and ECG, being asleep (0.71) or awake (0.73) before seizure onset did not notably affect the results. Meanwhile, a clear ictal pattern on EEG but absence of tachycardia resulted in a sensitivity of 0.60.

3.3.6 | Influence of wearable device set-up

As it was hypothesized that the Sensor Dot set-up would affect the results if configured incorrectly, particularly due to the absence of a crosshead channel in the generalized set-up, we performed sub-analyses exclusively on those seizures with a correct set-up.

This gave an overall sensitivity of 0.30 with individual sensitivities of 0.38 for FIAS, 0.82 for FBTCS, 0.13 for FAS, and 0.14 for focal seizures with unknown awareness. Similarly to the full analysis, the sensitivity for seizures originating from the temporal lobe was 0.48 and from the frontotemporal region was 0.41. The sensitivity was again lowest for seizures from the frontal lobe (0.05). Seizures with a bilateral onset gave a sensitivity of 0.46, while those with a left onset or a right onset achieved a sensitivity of 0.40 and 0.41, respectively. Seizures from awake were detected with a slightly lower sensitivity of 0.31, while those from asleep had a similar sensitivity of 0.26.

3.3.7 | Influence of meta-parameters on detection sensitivity

A generalized binary logistic mixed model was performed on the binary variable of seizure detection (i.e. yes/no). Significant effects were only found for seizure types FIAS ($p = 0.004$) and FBTCS ($p < 0.001$), and the clear visibility of the seizure on Sensor Dot EEG ($p < 0.001$). Applying the model with only those seizures recorded with the correct set-up did not influence these results.

4 | DISCUSSION

In this large multicenter study, we evaluated the multimodal Sensor Dot, using behind-the-ear EEG and bipolar ECG, for the detection of focal seizures. Following an initial analysis by a multimodal algorithm on the Sensor Dot data and subsequent review of the algorithm-labeled segments, we achieved an overall sensitivity of 0.31 and a precision of 0.83.

In contrast to TCS,[21,22] only a few wearable devices focus on the monitoring of focal seizures. Most devices attempt to detect motor seizures through movement or EMG, use ECG to detect ictal tachycardia, or are quite invasive procedures.[10,16] Such devices are not suitable for all patients since not all focal seizures are associated with movement or tachycardia.[23,24] In our analysis, we found that 52% of the focal seizures showed tachycardia. In addition, patients could have seizures with varying clinical presentations. Non-invasive multimodal devices have the potential to mitigate these problems, especially when utilized in combination with wearable EEG.

Previously, we found that the performance of our algorithm for focal seizures was optimized by integrating bipolar ECG.[17,18] In the current study, the algorithm achieved an overall sensitivity of 0.73, which is consistent with the performance (0.86) of automatic seizure detection using subscalp EEG data, previously reported by Remvig and colleagues.[25] Although it is sometimes argued that integrating EEG would cause discomfort, this modality seems to play a useful part in achieving a high detection sensitivity. Despite performance improvements, expert visual review of the algorithm output is needed to satisfy the requirements for use in clinical practice due to high FPs/h rates. This combined approach resulted in a precision of 0.83 (median per patient = 1.00). The benefit of a human reviewer is that they can quickly confirm or reject the algorithm-labeled segments, improving precision. Additionally, a neurologist can interpret the data in the context of the patient's medical history, making this step highly valuable for safe and informed clinical decision-making. In the future, feeding this information back to the model could improve its performance.

Nonetheless, in terms of sensitivity, there was a remarkable drop across the total group of seizures following human review. A key factor contributing to this drop was the presence of artifacts, which often masked true seizure activity during visual review. This is a major challenge in wearable seizure detection using limited-channel EEG with dry electrodes. It may be improved by enabling impedance monitoring throughout the recordings, making it possible to correct for poor signal quality. Second, the time needed by the human expert to review a 24 h recording was still relatively long, with an average of 8 min 17 s (median = 5 min 43 s). Although this consists of a significant improvement over reviewing a full 24 h EEG, further enhancements in the algorithm performance, especially in reducing the FPs/h, could lead to a more focused and, consequently, more sensitive review.

To further investigate the performance for the different sub-groups of seizure types, post-hoc analyses were performed. When looking at the EEG and ECG signals, we found that a high sensitivity (0.76) is achieved for those seizures which had clearly visible ictal EEG patterns and tachycardia. The visibility of an ictal pattern on the limited-channel wearable EEG was determined with knowledge of the gold-standard onset, which may overstate the ease of identification in a real-world, blinded expert review. Visibility on the Sensor Dot EEG is largely dependent on the location of seizure onset, due to the particular positioning of the electrodes behind the ears (Figure 1). Second, seizure semiology plays an important role as seizures with major motor activity will also cause muscle artifacts obscuring the signal. This combination perhaps explains why the majority of seizures with a clear ictal pattern (Figure 2) had an onset in the temporal lobe because the onset zone is closer to the behind-the-ear electrodes and they were usually hypomotor. Furthermore, ictal tachycardia is more frequently observed in temporal lobe seizures than in seizures from extratemporal lobes.[24,26] Meanwhile, seizures originating from the frontal lobe likely had an onset either too distant from the electrodes and/or caused artifacts (Figure 3, S1) in the EEG signals due to the typical clinical signs involving pronounced motor activity. Such findings are in agreement with our previous report[27] of a sensitivity of 0.70 for detection of temporal lobe seizures on the Sensor Dot by a detection algorithm based on behind-the-ear EEG. In our study, the seizures from the temporal lobe that were not visible on EEG usually originated from the same patient, suggesting that stratification of who may be most suitable for wearable technologies may be helpful.

Statistical analyses revealed that seizure detection by the reviewer was significantly influenced by the seizure type (FIAS or FBTCS) and whether epileptic activity was clear on the wearable behind-the-ear EEG. This denotes the high dependency of the reviewer on the EEG signals, which is the only unequivocal indicator of epileptic activity. Although the analyses did not indicate a negative effect caused by a generalized set-up, the crosshead channel displayed focal seizures more clearly and played a significant role in confidently detecting them (Figure 2). Motor and non-motor seizures were detected with similar, albeit low, sensitivity. Surprisingly, the sensitivity was slightly higher for seizures in which patients were awake before the onset. This might be due to the higher percentage of frontal lobe seizures during sleep, which are more difficult to pick up on the behind-the-ear electrodes and often present with motor symptoms. Consequently, from the 73 frontal lobe seizures during sleep, only three were correctly annotated. During sleep in the hospital, patients might also move more due to the discomfort of the EEG cables, and other artifacts such as sweating may arise.

We previously reported the results of patient self-reporting of seizures in a subset of the SeizeIT2 focal patient cohort.[28] This showed a sensitivity of 0.47, in line with previous research.[2] Notably, we also showed a precision of 0.60. Patients occasionally misreported certain events as seizures in their diaries, a point also addressed by Hannon and colleagues.[29] The low precision can be explained by patients reporting more subtle feelings or

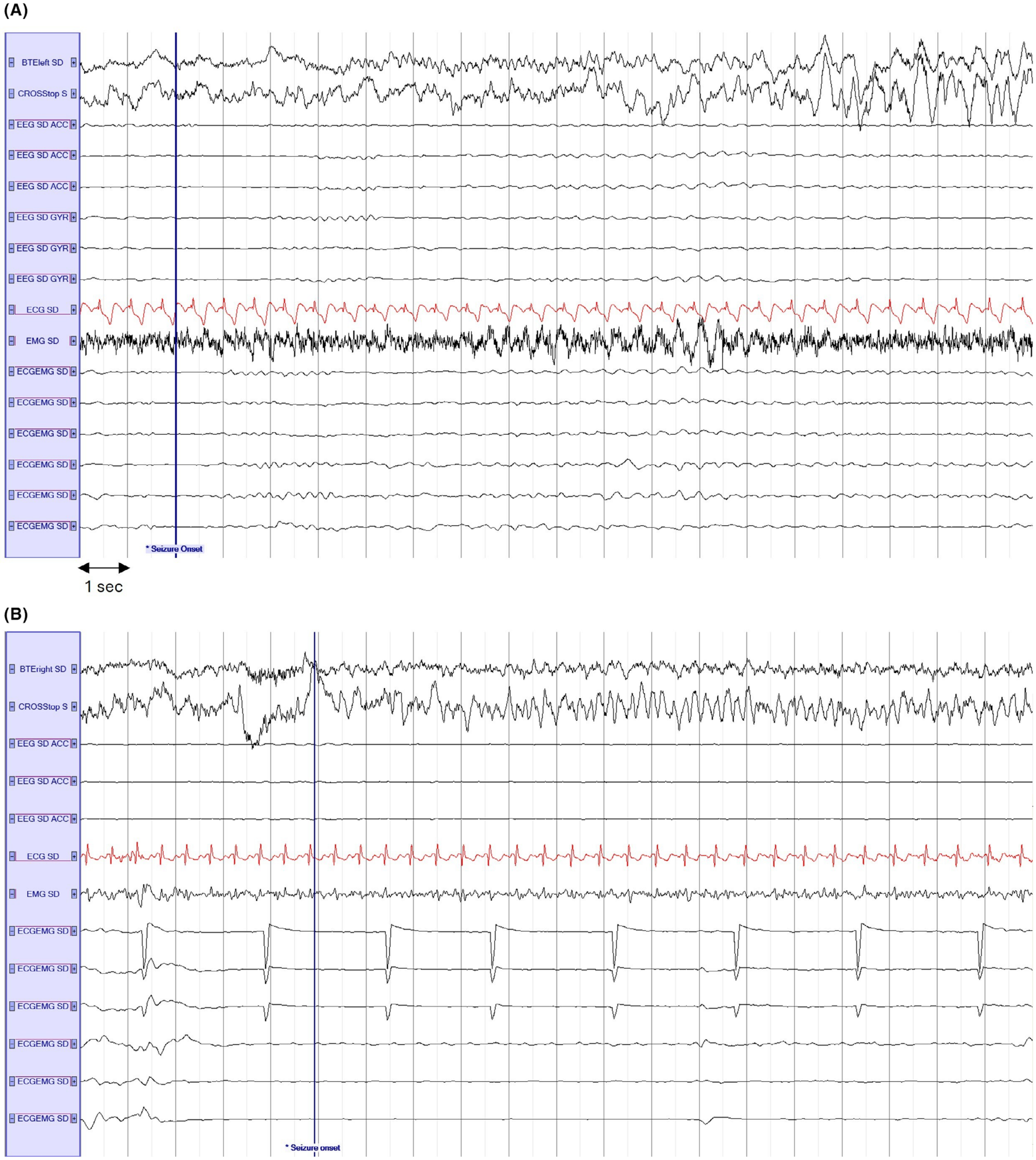
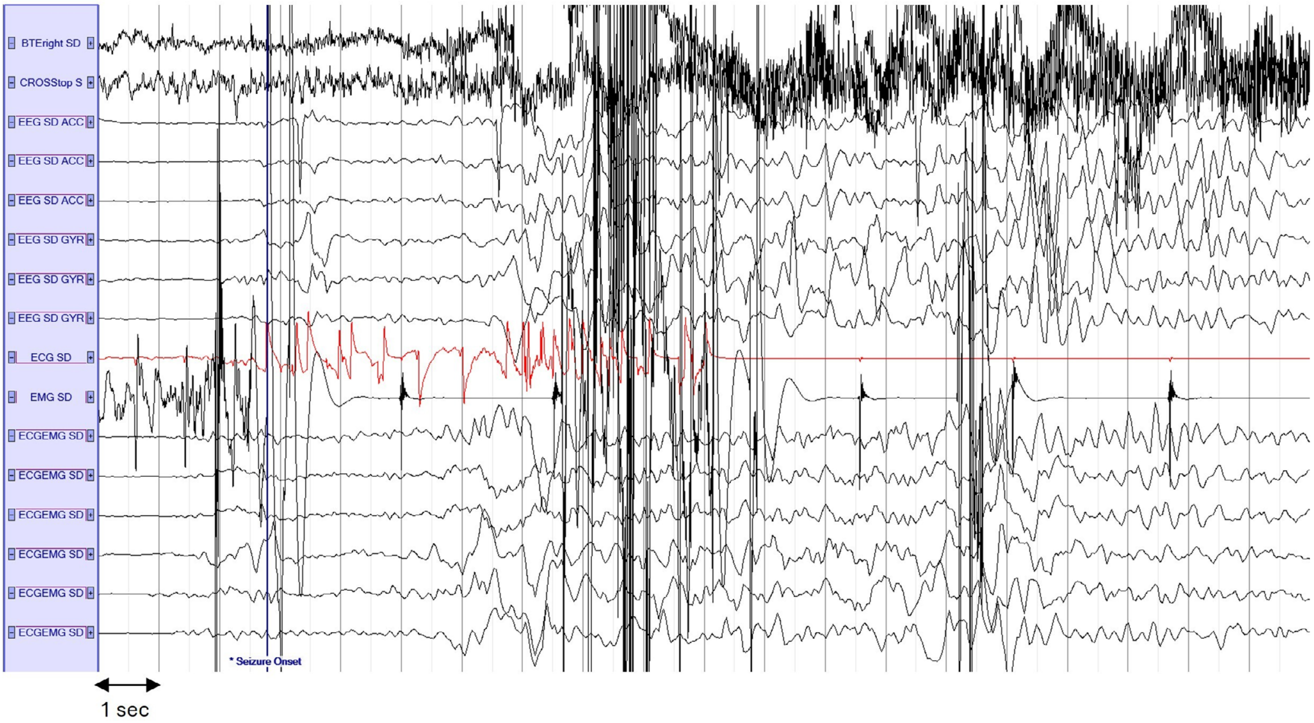


FIGURE 2 The figure shows two examples of focal seizures that were detected during visual review. (A) shows a focal impaired awareness seizure with bilateral onset in the temporal lobe, with manual automatisms, and (B) shows a focal impaired awareness seizure with right temporal lobe onset and motor arrest. Both examples show the seizure onset as marked by the EMU clinical team on the ground truth video-EEG. The channels in the recordings are labeled as: BTEleft = left behind-the-ear bilateral EEG channel; CROSStop = crosshead EEG channel; BTEright = right behind-the-ear bilateral EEG channel; ACC = accelerometer; GYR = gyroscope; ECG = electrocardiography; EMG = electromyography. For visualization during human review, a low frequency filter of 0.53 Hz, high frequency filter of 35 Hz, Notch filter of 50 Hz, sensitivity of 70 µV/cm, at a time base of 20 s, were applied.

(A)



(B)

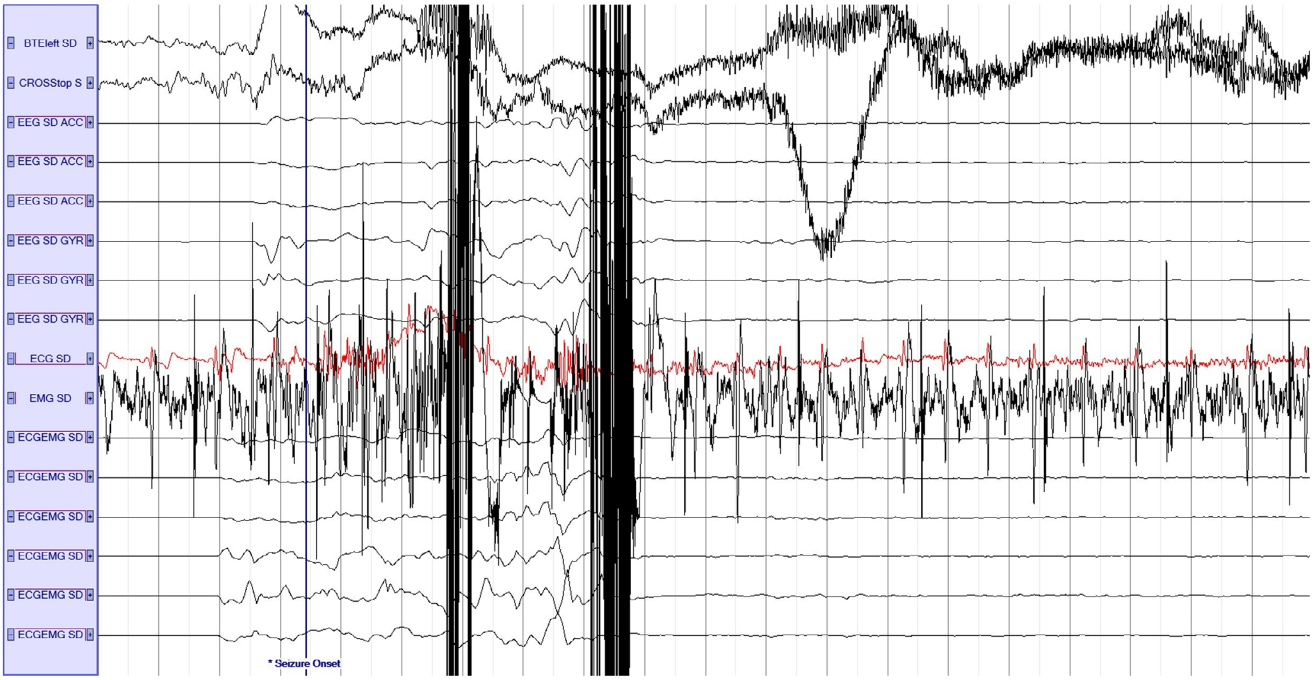


FIGURE 3 The figure shows two examples of focal seizures that were marked by the algorithm, but not withheld during visual review. (A) shows a focal impaired awareness seizure with right frontal lobe onset, with pedaling of the legs. (B) shows a focal impaired awareness seizure from the frontal lobe, with asymmetric tonic posturing. Marked movement and muscle artifacts are illustrated. The channels in the recordings are labeled as: BTEleft = left behind-the-ear bilateral EEG channel; CROSStop = crosshead EEG channel; BTEright = right behind-the-ear bilateral EEG channel; ACC = accelerometer; GYR = gyroscope; ECG = electrocardiography; EMG = electromyography. For visualization during human review, a low frequency filter of 0.53 Hz, high frequency filter of 35 Hz, Notch filter of 50 Hz, sensitivity of 70 μV/cm, at a time base of 20 s, were applied.

possible uncertainty regarding which symptoms may be ictal in origin.

The use of the Sensor Dot device in a real-life scenario, outside of the hospital, can become more challenging due to the decrease of the data quality. In an uncontrolled environment, the likelihood of corrupted data due to artifacts is higher, as reported in,[27] causing performance drops in the detection sensitivity, from 0.52 to 0.23. Practical limitations, such as signal interference and premature battery depletion or delayed replacement of a Dot, also reduced the amount of usable Sensor Dot data in this study.

Further enhancements to the device or detection algorithm may improve performance on real-world data. Algorithmic improvements could follow different paths; for instance, performance could be improved through better sampling and curation of the training data. Data segments could be characterized according to seizure type, seizure onset location, and different types of artifacts, and a more balanced representation of these segments could be included in the training set to ensure equal importance during training. Second, improvements to the wearable device itself, such as the use of additional recording channels, may help reduce the impact of artifacts. Finally, performance may be improved through personalization of the algorithm, for example, through transfer learning or the inclusion of more patient-specific data. Other approaches, such as data augmentation, may also help increase the diversity of seizure data and improve the robustness of the algorithm.

Also, combining information from a wearable device with a seizure diary could increase overall detection sensitivity for focal seizures, as different types of seizures may be detected and reported. Finally, in this group of patients, the involvement of a neurologist remains essential because of their expertise and knowledge of the patient's clinical history. They are able to determine in advance which patients show distinct seizure patterns on EEG and potentially tachycardia to help identify those for whom the Sensor Dot could be particularly beneficial.

In conclusion, while the Sensor Dot showed limited performance in detecting focal seizures overall, higher sensitivity was observed for FBTCS[21] and for focal seizures with distinct ictal EEG patterns and tachycardia, especially temporal lobe seizures. Involving the neurologist to identify the patients for whom this device could be of added value is essential. However, further research is warranted to mitigate artifacts, facilitate visual review, and increase detection sensitivity.

AUTHOR CONTRIBUTIONS

L.S., W.V.P., and M.D.V. contributed to the conception and design of the study. M.B. and C.C. developed the detection algorithm. L.S. and M.B. performed data analysis. Y.W., S.W., U.E., A.S.B., N.E., B.M., A.S., M.S., M.P.R., F.S., and A.S. I contributed to data annotation. All authors contributed to data collection and interpretation. L.S. drafted the original manuscript and prepared the figures. All authors critically revised the manuscript for important intellectual content.

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CONFLICT OF INTEREST STATEMENT

None of the authors have 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.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are openly available in OpenNeuro repository at https://doi.org/10.18112/openneuro.ds005873.v1.1.0.

ORCID

Lauren Swinnen https://orcid.org/0000-0003-0531-9101
Miguel Bhagubai https://orcid.org/0000-0002-2436-1738
Yvonne Weber https://orcid.org/0000-0002-0806-5592
Stefan Wolking https://orcid.org/0000-0002-1460-6623
Andreas Schulze-Bonhage https://orcid.org/0000-0003-2382-0506
Matthias Dümpelmann https://orcid.org/0000-0002-1476-7777
Nicolas Zabler https://orcid.org/0000-0002-4406-1863
Arjune Sen https://orcid.org/0000-0002-8948-4763
Andrea Biondi https://orcid.org/0000-0003-1072-665X

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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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