A prospective controlled study for EEG records comparison between Scalp-EEG and Ear-EEG wearable device, for subsequent analysis by an artificial intelligence-based system: SERAS-EEG study

G. Torres-Gaona[1], R. López[1], D. Blánquez[2], X. Raurich[2], J. Valls[2], L. Munsó[2], A. Trejo[3], A. Gómez-Ibáñez[4]

[1] Corachan Clinic, Neurosciences, Barcelona, Spain, [2] MJN neuroserveis, Blanes, Spain, [3] Synaptia Health Projects, Barcelona, Spain, [4] Clínica Universitaria de Navarra, Neurology, Pamplona, Spain

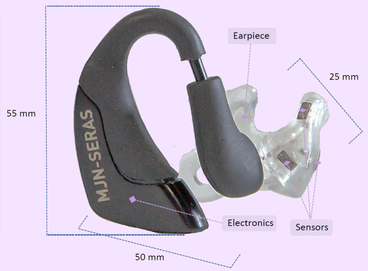
Purpose

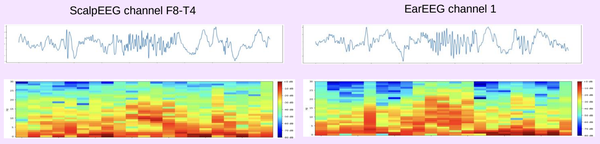
Ear-EEG is an earpiece shaped as a hearing-aid device, which continuously records the electrical brain activity. It uses an artificial intelligence algorithm, an (AI)-based system for early detection of preictal period of seizures. SERAS-EEG clinical study conducted the correlation between conventional EEG records and mjn-SERAS medical device, to identify preictal and interictal segments in drug-resistant epilepsy patients.

Materials and methods

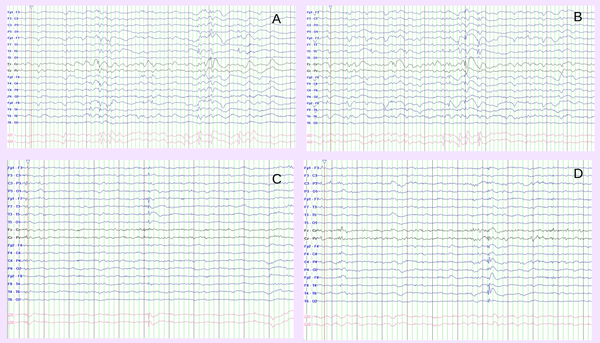
This is a prospective and controlled study for EEG records comparison, n=30, between Scalp-EEG and Ear-EEG device. Inclusion criteria were age between 12 and 65 years, of both sexes with a confirmed diagnosis of refractory drug-resistant epilepsy. We recorded and compared simultaneous ear-EEG and scalp-EEG, both groups used mjn-SERAS, which records two channels at the external auditory canal, simultaneously with scalp EEG 21-channel recordings using the 10-20 system. Subsequently, we extracted data from channels F8-T4 or F7-T3, according to the laterality of the epileptic focus in the epilepsy group. We analyzed the average correlation (AC) between the two types of recordings, with and without artifact removal, and filtered records (FR), comparing inter-subject and subjects recordings (SR), as well as between ictal and interictal periods in the epilepsy group. In this group, the registers were based on the recognition of ictal and interictal segments.

- **Size**: H 55 x W 50 x D 25 mm.
- **Weight**: 9.5 grams
- **Certificates**: CE mark, Bluetooth Smart (4.0)
- **Waterproof**: No
- **Sensor types**: 3 x dry sensors, 3-axis acceleration sensor
- **Vital parametres**: EEG
- **Runtime**: 18 hours
- **Charging time**: about 1 hour
- **Android Apps**: Android 10 or higher
- **iOs Apps**: iOS 14 or higher
- **Smart devices**: devices supporting Bluetooth Smart (4.0)





EEG signal and Spectrogram collected by both methods, in a 30-second section with 2-second intervals. spectrogram with blue background and red activity.



Comparison of the full montage of scalp EEG and ear EEG. (A and B) shows the EEG study of a patient with slow spike-wave complex discharges in the right frontotemporal region. (C and D) the study of another patient with independent interictal discharges in anterior temporal regions, the patient was wearing the device on the right side. The scalp channels are shown in the common bipolar montage synchronised at Natus Neuroworks. The two channels of the earEEG device are shown in pink.

Results

Thirty patients were studied, 16 people in control group and 14 with drug-resistant focal epilepsy, in whom 11 seizures were registered. We obtained a correlation of energies of 0.90 (CI95% 0.88 - 0.91) in filtered results (FR) and 0.88 (CI95% 0.86 - 0.90) in the whole sample. In the subset of epilepsy patients, an AC of 0.88 (CI95% 0.87 - 0.91) in FR and 0.87 (CI95% 0.83 - 0.89) in SR, while in controls AC 0.90 (CI95% 0.88 - 0.92) in FR and 0.89 (CI95% 0.87 - 0.92). No differences in the correlation of signals were found between controls and patients in the FR (-0.01 [-0.04;0.01], p=0.261).

Results distributed by ictal periods with AC of 0.88 (CI95% 0.83 – 0.92) and interictal periods of 0.89 (CI95% 0.87 – 0.91). In patients with epilepsy, no differences in correlation of signals were noted between interictal activity and seizures (mean difference in correlation between repose and seizures (-0.02 [-0.06; 0.02], p=0.352). However, correlation in controls was found to be smaller during sleep compared to repose (mean difference -0.04 [-0.08;-0.01], p=0.01).

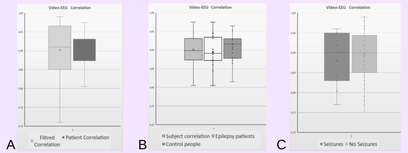
No adverse effects of the device have been reported. Most patients have tolerated the device well, with only a few cases mentioning a sensation of presence in the ear, which is well tolerated and disappears within a few hours.

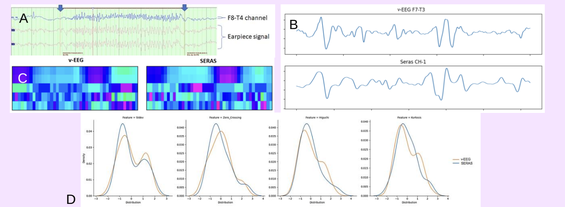
Patients characteristics

ID	AGE	Sex	Side	ASM(s)	Previous ASM(s)	Previous EEG	Seizure Frequency	Seizure Semiology	EEG records (h)	% with EarEEG	Seizure Records (Ear/total)
032200001	22	H	R	LEV, LCM		Right anterior temporal (T4 > F8) spike-wave complexes	3-4/weekly	Epigastric aura, unresponsiveness, automotor behaviors and later axial tonic posture	44	74%	0/0
032200002	26	H	R	LCM, PER	ESL, LTG, BRV	Right anterior temporal (T4 > F8) spike-wave complexes	5-6/monthly	Epigastric aura, unresponsiveness and automotor behaviors	46	78%	1/2
032200003		H	L	VPA, CNB	CBZ, LCM, PER	Bilateral frontal 2-3 Hz spike-wave complexes left predominant	1-2/daily	Tonic and hyperkinetic seizures	60	58%	0/0
032200004	62	H	R	PER, LTG	PHT, CBZ, LCM	Bilateral frontal 3-4 Hz spike-wave complexes left predominant	6/monthly	Axial tonic posture and upper limbs in flexion and late unresponsiveness	88	72%	1/1
032200005	47	H	L	LEV, LTG, VGB, VPA, PB	CBZ, PER	Bilateral frontal 3-4 Hz spike-wave complexes left predominant	4-5/daily	Atonic and tonic seizures with multiple falls, atypical absences	54	69%	2/2
032200006	30	M	L	CNB, BRV, LCM	CBZ, PER, LEV, LTG	Right anterior temporal (T4 > F8) spike-wave complexes	2/monthly	Perceptual disturbance, depersonalisation, jamais-vu, unresponsiveness and prolonged post-critical	48	45%	1/1
032200007	44	M	L	CBZ, BRV, CLB	LTG, LEV, PER	Bilateral frontal 2-3 Hz spike-wave complexes left predominant	3-4/monthly	Tonic-clonic bilateral	43	300%	0/0
032200008	22	H	L	CLB	LCM, ESL, CBZ, LTG	Right anterior temporal (F8>T6>T4) spike-wave complexes	4-6/weekly	Change in facial mimics, pallor, disconnection from the environment and bilateral upper limbs exploratory automatisms	41	61%	3/3
032200017	31	M	R	LTG, VPA, CNB	LCM, ESL, BRV, CBZ, PER, LEV	Right post-temporooccipital spike-wave complexes	5-7/monthly	Fear reaction, unresponsiveness and tonic posture axial and upper limbs	43	60%	0/0
032200021	20	M	L	ESL, PER, CNB	VPA, OXC, TPM, LCM	Left post-temporooccipital intermittent sharpes	2-3/monthly	Tonic and hyperkinetic seizures	12	100%	3/3
032200025	61	H	R	LEV, LCM, PER	ESL, BRV, TPM	Intercritical epileptiform abnormalities in both temporal regions	10/monthly	Unresponsiveness, tonic posture left upper limb, post-ictal aphasia.	10	110%	0/0
032200028	25	M	R	VPA, LEV, LCM	CBZ, CLB, ETS, RUF, VPA, LTG, TPM, LEV.	Bilateral frontal 2-3 Hz spike-wave complexes left predominant	5-6/weekly	Unresponsiveness, tonic posture and elevation both upper limbs	12	75%	1/1
032200029	23	H	L	VPA, LCM, LTG	CBZ, CLB, LEV, PER	Bilateral frontal 2-3 Hz spike-wave complexes right predominant	2-3/daily	Unresponsiveness and head drop	20	80%	1/1
032200030	23	M	L	ESL, PER, LCM	VPA, CBZ, LTG	Bilateral frontal 2-3 Hz spike-wave complexes right predominant	1-2/daily	Unresponsiveness, tonic posture axial and upper limbs	24	86%	1/1

Abbreviations. ASM: Anti-seizure medication. CBZ: Carbamazepine. CLZ: Clonazepam. OXC: Oxcarbamazepine. PHT: Phenytoin. CLB: Clobazam. LEV: Levetiracetam. LTG: Lamotrigine. PER: Perampanel. VPA: Valproat Acid. TPM: Topiramate. ETS: Ethosuximide. RFN: Rufinamide. LCS: Lacosamide. ESL: Eslicarbazepine

(A) Correlation of energies of 0.90 in filtered results (FR) and 0.88 in subject results (SR). (B) In the epilepsy group, an AC of 0.88 in FR and 0.87 in SR, and the control group 0.90% in FR and 0.89 in SR. (C) Results distributed by ictal periods with AC of 0.88 and interictal periods of 0.89.





Visual comparison between temporal anterior scalp-EEG and ear-EEG in a conventional viewer (A), with the temporary viewer for ear-EEG (B), between spectrograms generated from the signal of both (C) and after analysis of some features (D).

Discussion

SERAS-EEG study provides technical support for use of the mjn-SERAS to record EEG signals compared to the gold standard. According to the study conducted by I.C. Zibrandtsen and P. Kidmose et al., the results indicate that ear-EEG is capable of accurately identifying electroencephalographic energy patterns linked to focal seizures. In contrast, our study analyses the differences in correlation for ictal and interictal recording in patients with epilepsy, so we can suggest that the mjn-SERAS device can detect electroencephalographic energy patterns associated with epilepsy. Our study has limitations, the limited number of participants in the study may restrict the generalizability of the findings and the recordings were obtained in a controlled environment, which may not fully reflect real-life conditions.

A prospective, multicenter, pilot clinical trial is currently in progress to evaluate the mjn-SERAS device during the day-to-day life of the patient to analyze its performance in generating alerts in the case of the possibility of a high risk of epileptic seizures and describe improvements in different areas of personal development of epilepsy patients.

Acknowledgment

International consortium funded by European Union.