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Evaluation of WISE Cortical Strip electrodes for Intraoperative Neurophysiological monitoring during perirolandic brain surgery (WIN study)

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Introduction

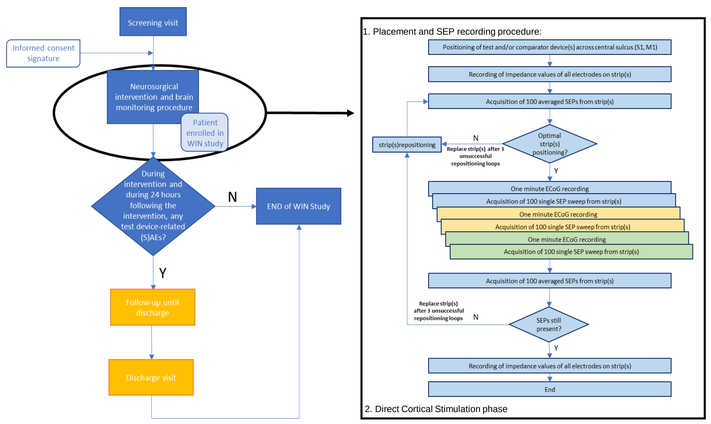
Strip electrodes with embedded metal contacts are routinely used for intraoperative neurophysiological monitoring during brain surgery. For reliable application, the electrodes should have low impedance and sufficient adherence to record and stimulate directly on the brain surface. We aimed to evaluate safety, performance and usability of a novel strip electrode made by a thin polymer base with embedded metal nanoparticles (WCS, WISE Srl., Italy) for intraoperative use in perirolandic brain surgery.

Methods

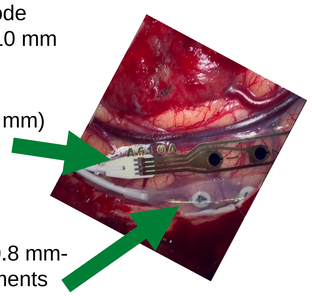
- Study type
  - Multicenter**,** prospective, interventional, open-label medical device study, sponsored by WISE Srl., Cologno Monzese, Italy
  - Clinical study registration: ClinicalTrials.gov (ID: NCT03731455)
- Inclusion & exclusion criteria

Inclusion Criteria	Exclusion Criteria
• Brain tumor or epilepsy that require neurosurgical intervention and exposure of the central region of the cerebral cortex including at least the hand-forearm areas in the primary motor cortex and the primary somatosensory cortex (i.e. excision of tumor, open approach); • Age: 18 – 75 years at the time of enrollment; • Required intraoperative neurophysiological monitoring with subdural electrodes; • Willingness to provide informed consent for participating in the study.	• Significant psychiatric impairments which, in the opinion of the investigator, will interfere with the proper administration or completion of the protocol; • Acute or untreated infections (viral, bacterial or fungal) • Current treatment with antibiotics • anticoagulant medication that cannot be discontinued during the perioperative period • patients with factor XIII deficiency or any other hematological disease • previous craniotomy within the vicinity of the central region • breastfeeding, positive urine pregnancy test or not using adequate contraception • A co-morbid disease or condition that could confound the neurological and functional evaluations or compromise survival • Current use or a recent history of illicit drug(s) use or alcohol abuse • Active participation in another investigational device study

- Safety and adverse events (AEs) assessment
  - Rating by an external clinical event committee
- Usability assessment
  - Neurosurgeon and neurophysiologist rated per questionnaire
- Study workflow



- **Recording and stimulation electrodes**
  - 4-contact subdural strip platinum electrodes, contact diameter 2.3 mm, interelectrode distance between electrode centers 10 mm
  - **Test device (TD)**
    Silicon polymer base (thickness 0.25 mm) with embedded metal nanoparticles, WISE S.r.l., Cologno Monzese, Italy
  - **Comparator device (CD)**
    Platinum metal plates embedded in 0.8 mm-silicon trays, Ad-Tech Medical Instruments Corporation, Racine, Wisconsin, USA



- **Time points of impedance measurement**
  - At placement (P)
  - After recording of the following pattern (SEP recording) repeated for a total of 3 times: 1 minute of EEG + average over 100 SEP stimuli
  - After direct cortical stimulation to elicit motor evoked potentials (DCStim)

Results

1 Patient characteristics and outcome

Patients

- 32 patients
- Age: 51.6 ± 14.94 years of age; 19 – 74 years
- Gender distribution: 15 males and 17 females
- Surgeries:
  - intrinsic brain tumors (22 patients)
  - Extraaxial brain tumors (7 patients),
  - Metastasis (7 patients)
  - Epilepsy surgery (1 patient)
- Outcome
  - Day 1: new neurological sequela in 14 patients
  - Three months: persistent slight neurological sequelae in 7 patients

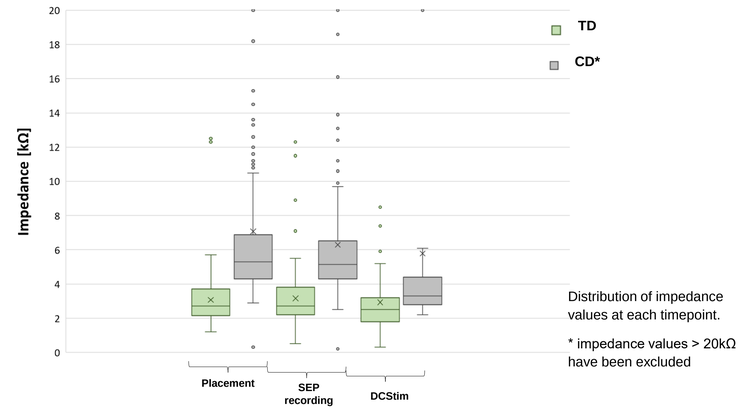
2 Adverse events and side effects

- No side effects (e.g., bleeding).
- AE: in two patients seizures related to the direct cortical stimulation for motor evoked potentials (DCStim) performed with the TD.
  (Data of DCStim is not presented here)

3 Impedance values of TD and CD

	TD[1]		CD	
	P + SEP recording	DCStim	P + SEP recording	DCStim
Total number of patients	32	27[3]	32	27
any impedance measurements, n patients (%)	32 (100.0)	27 (100.0)	32 (100.0)	12 (44.4)
max impedance across all recording times ≥10 kΩ [2] , n patients (%)	2 (6.3)	1 (3.7)	13 (40.6)	2 (7.4)
Number of recording times per patient – Mean (Min, Max)	2.0 (1, 3)	2.1 (1, 9)	1.9 (1, 3)	1.7 (1, 6)
Median Number of electrodes used (Min, Max)	4.0 (2, 4)	4.0 (1, 4)	4.0 (1, 4)	4.0 (1, 4)
Impedance – Mean (SD)	3.11 (1.577)	2.81 (2.232)	6.83 (6.567)	5.30 (9.887)
Impedance – Median (IQR)	2.70 (2.30,3.70)	2.50 (1.80, 3.10)	5.30 (4.30,6.60)	3.30 (2.80, 4.10)

[1] Stable performance of the TD is confirmed by the preservation of impedance values below 10 kΩ.
[2] Percentage of patients with any impedance measurement.
[3] This excludes patients with the TD that were excluded from the resection phase due to recommendations from the Swiss authorities.
SEP = somatosensory evoked potentials recorded by the device; DCStim = direct cortical stimulation by the device to elicit motor evoked potentials.



Distribution of impedance values at each timepoint.

* impedance values > 20kΩ have been excluded

4 Usability rating

- TD was rated better for adhesion on the brain surface.
- The stability of TD against displacement was rated as satisfactory.
- A limitation with respect to positioning was noted, due to its thinness, when partial exposure of the motor cortex required sliding the TD under the dura.

Conclusions

- The TD had significant lower impedance than the CD. This might be related to better adhesion and conformability to the brain surface.
- No limitations with respect to safety were noted.
- The TD is suitable for direct recording and DCStim of the brain surface. In small keyhole craniotomies its use might be limited.

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