Preclinical evaluation of a new stereoelectroencephalography - guided radiofrequency ablation system with real time temperature monitoring

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INTRODUCTION

sEEG-guided RF ablation is a procedure that uses sEEG electrodes implanted for seizure evaluation to create tissue lesions. The procedure has been performed primarily in Europe for >20 years and has shown to result in seizure free or reduction of seizure frequency with minimal risks[1].

OBJECTIVES

Previous studies have been performed without monitoring the temperature at which ablations were performed. **Here we present preclinical in vivo data for the characterization of a new system capable of monitoring and controlling the ablation temperature during the procedure.**

METHODS

Six neurosurgeons implanted 18 sEEG electrodes into the brain of three pigs (6/animal). Monopolar and bipolar RF ablations (n=34) were performed using minimum (50°C, 5s) default (80°C, 120s) and maximum (85-90°C, 600s) temperature and time settings (Table 1) . MRI and histology were used for lesion characterization. Impedance measurements were performed pre- and post-ablation. User feedback was obtained using a questionnaire.

Fig 1. Swine sEEG implantation

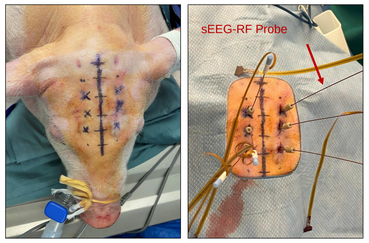


Table 1. Ablation parameters

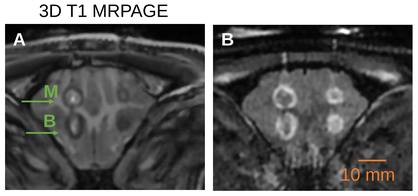
TC=temperature control; m=manual;
T=temperature; t=time; M=monopolar; B= bipolar

Settings: T (°C), t (s)	Config	N
85°C, 600s (Max)	M, TC	4
85°C, 600s (Max)	B, TC	3
~88-90°C, 600s (Max)	M, m	4
~88-90°C, 600s (Max)	B, m	5
80°C, 120s (Default)	M, TC	6
80°C, 120s (Default)	B, TC	4
50°C, 5s (Minimum)	M, TC	5
50°C, 5s (Minimum)	B, TC	3

RESULTS

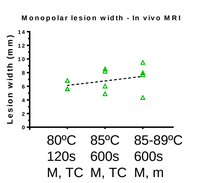
In vivo: lesion size is proportional to ablation parameters

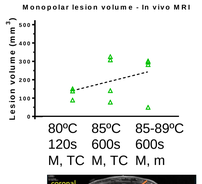
3D T1 MRPAGE



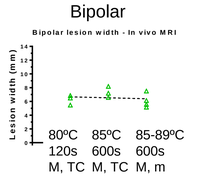
- Monopolar – spherical; Bipolar – ellipsoid
- Inner core and outer ring
- Minimum settings: no visible lesion
- Default and maximum settings: lesion size correlates with ablation parameters
- Maximal lesion size:
  - width up to 9 mm
  - height up to 10 mm (bipolar)
  - volume up to ~350 mm^3

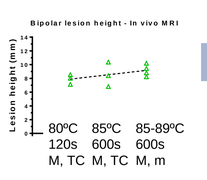
Monopolar

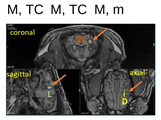




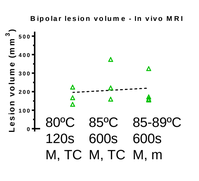
Bipolar







Width (W), height (L) and depth (D)



Monopolar Ablation Parameters	Average Width (mm) ± SD	Average Volume (mm^3) ± SD	n
80°C, 120 s, M-TC	6.04 ± 0.70	126.14 ± 32.49	3
85°C, 600 s M-TC	6.92 ± 1.74	213.04 ± 122.85	4
88°C-90°C, 600 s, M-m	7.38 ± 2.17	232.56 ± 122.18	4

Bipolar Ablation Parameters	Average Width (mm) ± SD	Average Height (mm) ± SD	Average Volume (mm^3) ± SD	n
80°C, 120 s, B-TC	6.27 ± 0.72	7.89 ± 0.71	174.27 ± 46.76	3
85°C, 600 s B-TC	7.32 ± 0.81	8.53 ± 1.78	251.19 ± 110.51	3
88°C-90°C, 600 s, B-m	6.09 ± 1.03	9.17 ± 0.85	202.71 ± 81.38	4

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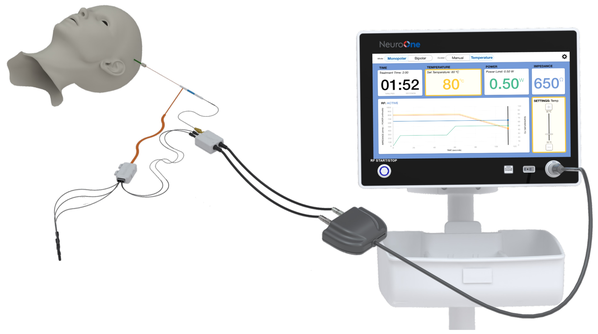
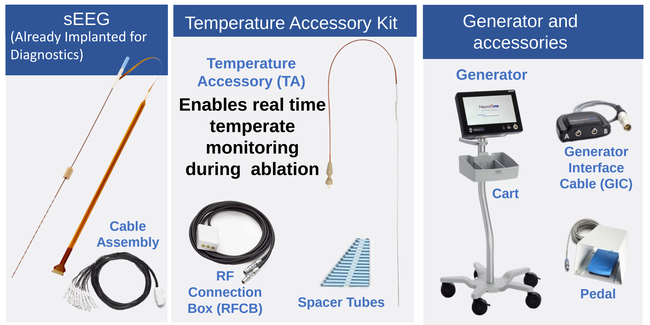
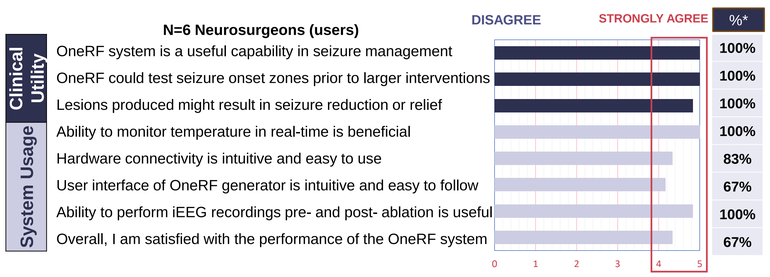
RESULTS

sEEG guided RF ablation system (FDA cleared K231675)





Overall customer feedback is very strong



*** Percentage of users scoring >4**

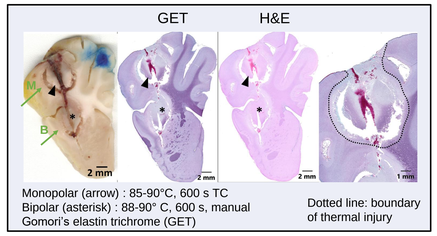
Recordings pre and post-ablation are feasible

Impedance pre- and post-ablation

Monopolar Ablation Parameters	Begin Average ± SD (Ohm)	End Average ± SD (Ohm)	N*
50°C, 5 s, TC	577.04 ± 116.67	515.06 ± 86.25	5
80°C, 120 s, TC	573.82 ± 116.44	509.25 ± 167.68	4
85°C, 600 s TC	552.02 ± 90.88	501.05 ± 83.09	4
88°C-90°C, 600 s, m	421.15 ± 138.40	334.70 ± 113.03	4

Bipolar Ablation Parameters	Begin Average ± SD (Ohm)	End Average ± SD (Ohm)	N*
50°C, 5 s, TC	768.2 0± 102.73	703.23 ± 97.19	3
80°C, 120 s, TC	505.27 ± 126.62	483.42 ± 186.12	4
85°C, 600 s TC	669.50 ± 209.17	586.30 ± 142.18	3
88°C-90°C, 600 s, m	891.16 ± 126.06	711.94 ± 117.54	5

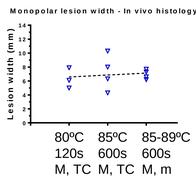
Histology: lesions are well delineated

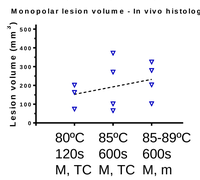


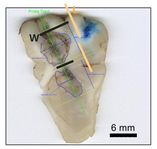
- Monopolar – spherical; Bipolar – ellipsoid
- Necrotic core: coagulative necrosis
- Transition zone: a band of variably vacuolated and degenerated but intact tissue
- Viable tissue: intact neuroparenchyma, no evidence of cellular degeneration

- Minimum settings: no visible lesion
- Default and maximum settings: lesion size correlates with ablation parameters
- Maximal lesion size:
  - width up to 10 mm;
  - height up to 12 mm (bipolar)
  - volume up to ~400 mm^3

Monopolar

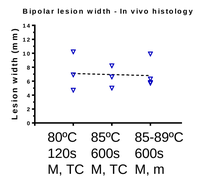


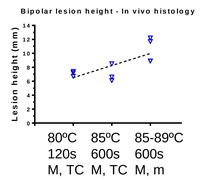


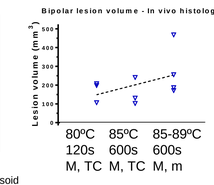


- Lesion width (W) and length (L)
- Volume was calculated as an ellipsoid

Bipolar







SUMMARY AND CONCLUSIONS

- **The sEEG guided new ablation system is able to create lesions in the swine brain in vivo**
- **Lesion sizes are proportional to the ablation parameters: temperature and time**
- **Lesion characterization in MRI and histology:**
  - **Similar appearance and shape (spherical ad ellipsoid)**
  - **Well demarcated lesions for ablations at default and worst-case scenario parameters**
  - **No detectable lesion for ablations performed at minimum parameters**
  - **Histologically distinct zones: necrotic core, transition zone, surrounded by intact parenchyma**
- **Intracranial EEG recordings are feasible pre- and post-ablation**
- **The system is intuitive and easy to use**
- **The only FDA cleared sEEG guided RF ablation system able to monitor and regulate temperature during ablation**
- **Potential to reduce the number of surgical procedures by providing treatment using the same sEEG electrodes for ablation and diagnostic purposes**

"Caution: Federal law restricts this device to sale by or on the order of a physician"