The New Witness Within

Neurotechnology and The Re-Diagnosis of Epilepsy

UCSF University of California San Francisco

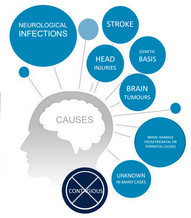
Tobias Haeusermann, Kristina Celeste Fong, Winston Chiong, Dan Dohan

WHAT IS epilepsy?[1]

A NEUROLOGICAL CONDITION characterized by *recurrent seizures*

Seizures are due to *brief disturbances* in the *electrical functions of the brain*

Epilepsy affects people of all ages



PROJECT OVERVIEW

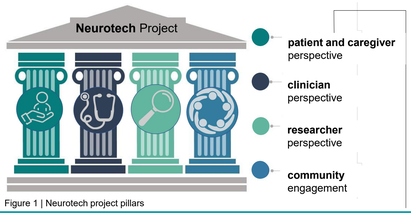


Figure 1 | Neurotech project pillars

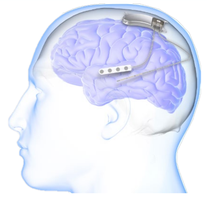
Design We are using an ethnographic study design, involving an **in-depth longitudinal case study**, mixed methods data collection including direct observation, and analysis of both pre-specified (**deductive**) and emergent (**inductive**) research questions.

Aim Explore the experiences of patients receiving clinical treatment with the NeuroPace Responsive Neurostimulation System (**RNS**) for refractory epilepsy.

Recruitment We are conducting this study at a level 4 epilepsy center and consulted treating epileptologists during case conference or via email to confirm study eligibility.

Data Collection We are carrying out ethnographic research at a single academic medical center with an active RNS treatment program and collected data via **direct observation of clinic visits** and **in-depth interviews** with **12 patients and their caregivers**. We are using deductive and inductive analyses to identify the relationship between these devices and the patients, caregivers and treating clinicians.

Timeframe Fieldwork began in June 2018 and has been ongoing.



QUOTES

Excerpts from observation notes and interview transcripts

Recordings themselves are meaningful, changing perceptions of illness

"It was pretty shocking but interesting at the same time because I'm like, 'Oh, that's my brain.' I never knew what the – it's just amazing to see the activity like how the spikes go from this to a lot more."

"a puzzle that's being slowly put together. That's just how I kind of see it because this has been a very slow, a slow and long process… like literally putting a puzzle together"

The clinician then pulls up the RNS recording data, and all the family huddles around the computer screen. This is the first time they are seeing device recordings…The patient's mother pulls out her phone to take photos, explaining that the patient's aunt is going to ask for pictures.

The clinician shows data from a Monday at 10am and points out the increase in wave height on the L hippocampal leads, explaining that this was a seizure. The mother is shocked by the time stamp, saying, "He was awake!"

The clinician says it looks like the patient's seizure activity is highest in the early morning hours i.e., 2am. The mother said the patient is asleep during that time, and she suspects this has been going on since childhood. The patient said, "I'll be damned! That's crazy!"

Confirmation or discordance with patient experience of illness

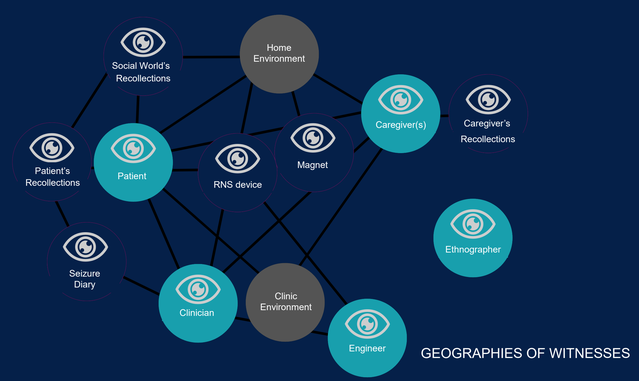
"Being able to look at that screen and figure out, you know, that there was legitimately something going on, which we had kind of seen before in the EEGs, but this one was so specific and he was able to explain what these different graphs and I felt very reassured in terms of, you know, not only what I had been doing but what he had been doing"

Patient: "I was surprised because I just wanted to see it because I wasn't sure if I did it right, or I was still very new to using the magnet, it was my first time using it, so I figured I was having an aura, so I figured I'd just swipe and see if they were able to catch it."

Caregiver: "Is she being overly sensitive in trying to… is she crying wolf is the wrong phrase, but it's more is she trying to be so diligent about capturing stuff that any little thing she feels, she captures it?"

"I used to think I could really tell the difference between an aura and a seizure. Especially if I didn't have a blank out or anything… I have auras a lot and I don't write them down, whereas I've written down every seizure that I've had, I think, for six years… I think maybe – and they call auras a seizure even though I feel like I can tell the difference. Now, I'm thinking that actually it can just be an aura…"

WITNESSING CONCEPT



GEOGRAPHIES OF WITNESSES

The conceptualization of epilepsy as a diagnostic category often relies on the seizure description by **the patient and other witnesses**. This dynamic might be changing, as technology development is gathering pace, with neurostimulation devices promising to **transform seizure detection and care** provision. The technology, in some sense, serves as **an additional witness**.

Every act of witnessing **implies some kind of mediation**: most fundamentally, putting an experience into language, or other forms of communication, for the benefit of those who were not there. At the same time, every act of mediation entails a kind of witnessing, particularly the **use of technology as a surrogate for an absent audience**.

CLINICAL BACKGROUND

"Open-loop" deep brain stimulation (DBS) devices have been used for decades to treat Parkinson's disease and other disorders by applying consistent **pre-programmed stimulation to targeted brain areas.**

"Closed-loop" neuromodulation systems (also called "adaptive," "bidirectional," "responsive," or "next-generation" brain stimulation) are now under development for several neurologic and psychiatric conditions. Closed-loop devices depart from established open-loop DBS by including the capacity **to continuously monitor** brain activity, to **decode** neural activity, and to **modulate** such activities based on internal software algorithms (see Figure 2).

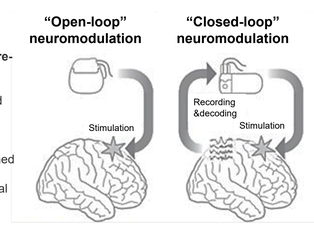


Figure 2 | Open- and closed-loop stimulation

They have been proposed and tested for a number of neurological conditions for which prevailing treatments are often unsatisfactory, including **drug-resistant epilepsy, refractory depression, anxiety, chronic pain, Alzheimer's disease** and **ischemic stroke**.

Following surgery, the device **records neural activity**, and patients regularly upload electrocorticography data to an internet cloud service maintained by device-manufacturer NeuroPace. This service includes a clinician interface allowing epileptologists to **access, download and review electrocorticographic data** (see Figure 3), and to program the RNS device when patients are present.

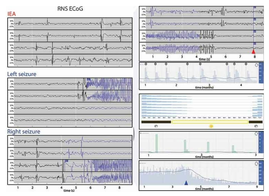
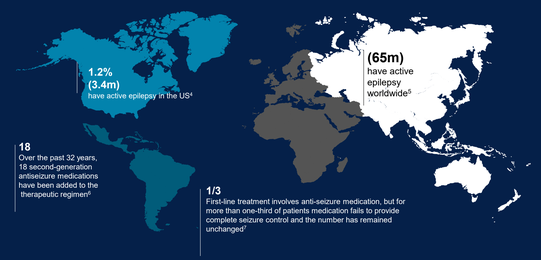


Figure 3 | RNS chronic intracranial electroencephalography (RNS cEEG)[2]

Once programmed and activated, the RNS device **delivers electrical counter-stimulation** when electrocorticography patterns suggest seizure activity to reduce seizure frequency and severity. In general, patients for whom stimulation has been activated are counseled not to expect immediate and permanent seizure freedom.

This device was **approved in 2013** by the U.S. Food and Drug Administration and is the only approved and commercially-available closed-loop brain stimulation device in clinical practice. To date, **over 3,000 patients have been implanted with RNS**, and long-term data indicate sustained tolerability and increasing efficacy over 9 years of follow-up.[3]



COMMON TREATMENT TRAJECTORY OF STUDIED COHORT

- **first seizures appear**
- **epilepsy diagnosis** — delay from first seizure to diagnosis of epilepsy can take several years
- **medication trials** — over 40 available
- **refractory diagnosis** — generally patients are either easy or difficult to control from the start and do not become treatment resistant over time
- **referral to epilepsy center** — under 1% of patients with drug-resistant epilepsy[8], average of 20 years since diagnosis[9]
- **medical tests** — including video monitoring, scalp EEG, and MRI, or, less frequently, with intracerebral electrodes
- **case conference** — interdisciplinary team of neurologists, neurosurgeons, neuropsychologists, nurses, and social workers
- **RNS option** — for patients with bilateral seizure foci or a seizure focus in close proximity to eloquent cortex
- **brain surgery** — neurosurgeon implants the device in the skull and places electrodes near the seizure focus
- **device records** — neural activity is captured and patients upload electrocorticographic data
- **data review** — clinician along with patient and caregivers define thresholds for abnormal (epileptiform) activity
- **stimulation activated** — in most cases, 2–6 months after device implantation, stimulation is turned on in clinic[10]
- **future collaboration** — In the coming years, clinicians, patients and caregivers work together to improve stimulation and care

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PIs: Chiong/Dohan

Tobias Haeusermann
PhD

tobias.haeuserman@ucsf.edu
decisionlab.ucsf.edu
cultureofmedicine.org