DBS in Epilepsy

Last updated: January 13, 2021

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DBS is indicated for poorly localized or multiple regions of seizure origin.
Comparison of Neuromodulations (RNS, DBS, VNS) – see p. E11 >>

ANTERIOR NUCLEI OF THALAMUS (ANT)
Cakir, Lehtimäki et al. Deep brain stimulation targeting for refractory epilepsy. Epilepsia 2017

Image of Anterior Nucleus of Thalamus Using 1.5T MRI for Deep Brain Stimulation Targeting in Refractory Epilepsy
Elena Jiltsova, MD; Timo Möttönen, MD; Markus Hahlström, MSc; Joonaas Haapulaho, MD, PhD; Timo Tahtinen, MD; Jukka Peltola, MD, PhD; Juha Ohman, MD, PhD; Elina-Marie Larsson, MD, PhD; Tommi Kiekara, MD, PhD; Kai Lehtimäki, MD, PhD

ANATOMY

Central node of Papez circuit
Fronto-temporal epilepsies may respond best (as opposed to parieto-occipital epilepsies). Irving Cooper reasoned that due to its location in Papez circuit, ANT could serve as a key location to disrupt limbic seizures.

- dimensions 4 x 10 x 5.5 mm
- located at the floor of the lateral ventricle
- surrounded by plexus choroideus, the thalamostriatal vein, and the internal cerebral vein:
  - located at the anterior-superior-medial aspect of the thalamus and constitutes its anterodorsal border.
  - partially enveloped (isolated from the rest of thalamus) by a myelin-rich sheath belonging to the mammillothalamic tract (MTT) and the internal medullary lamina
  - subnuclei (all have distinct patterns of connectivity): anterodorsal, anteroventral, and anteromedial.
  - projects to superior frontal and temporal lobe structures commonly involved in seizures.
  - inputs from the subiculum, the mammillary bodies via the mammillothalamic tract, and the retrosplenial cortex.
  - MTT joins ANT at its inferior border slightly anterior to the midpoint of ANT in the anterior–posterior axis (this junction is close to the border between anterior principal and anteromedial subnucleus according to the Schaltenbrand–Wahren atlas).
INDICATIONS

- most useful in partial epilepsy (with/without secondary generalization).
- there is no seizure type that would predict response to DBS.
  o according to study by Piacentino et al. (6 patients) ANT DBS was most effective in patients with epileptic origins strictly in the limbic system who had no discrete anatomical lesions.
  o DBS is least effective for FAS (focal aware seizures); however, maybe DBS converts FUAS (focal unaware seizures) to FAS and gives such false impression?
- Available in Europe since 2011.

FDA APPROVAL

May 1, 2018 FDA has granted premarket approval for Medtronic’s DBS therapy:

- adjunctive therapy for reducing the frequency of seizures
- bilateral anterior thalamic nucleus stimulation
- 18 years of age or older
- partial-onset seizures, with or without secondary generalization
- refractory to ≥ 3 antiepileptic medications.
- ≥ 6 seizures per month over the 3 most recent months (with no more than 30 days between seizures).

Medtronic has preauthorization request guides and also letter samples for appeals in denial cases.

TARGET

Nucleus (antero)principalis
  - superior, anterior part of ANT
  - best stim contacts – 2–3 mm above where mammillothalamic tract terminates.

High anatomical variability (more variable coordinates than any other stereotactic target) – direct targeting is preferable!

INDIRECT TARGETING

AC-PC coordinates (golden coordinates in parentheses): 12-5-2

10-16 (12) mm superior
4-7 (5) mm lateral
0-3 (2) mm anterior to MCP or 8 mm anterior to PC

N.B. individual variations up to 5 mm (even between sides) – need direct targeting!

- indirect targeting is particularly challenging in epilepsy as the thalamus is known to atrophy in the setting of chronic epilepsy.
- no characteristic MER signatures.
- no side effect profile to guide targeting.
- Dr. Lehtimäki targets slightly lateral to prevent lead slipping medially into 3rd ventricle.

Lehtimäki et al. analyzed the placement of 62 contacts in 15 patients, 10 of whom were responders. Using an ANT-normalized coordinate system, they found that contacts in responders were placed significantly more anteriorly and superiorly than those in nonresponders. They hypothesized that the white matter structures at the inferior and posterior aspects of the ANT prevented the spread of stimulation current into the ANT, which limited the utility of electrodes placed in that region.

Krishna et al. found similar results, noting that patients with the most long-term stimulation benefit had electrodes placed in the anterointernal ANT in close proximity to the mammillothalamic tract.

Schaltenbrand-Warren atlas:

ANT: 12 mm superior, 5-6 lateral, 0-2 anterior to MCP

Plate 5.5mm lateral
**Anterior medial temporal cortex (AMTC)**

ANT (anterior CSF border or mtt junction) is 4-5mm more anterior in axial plates compared to sagittal plates.

Coronal plates correlate with sagittal plates in Y axis.

ANT is more medial in coronal plates compared to sagittal plates.

Mai atlas (2008):

Correlates relatively well with schaltenbrandt atlas sagittal plates (anterior border = 5mm anterior to MCP, mamillothalamic tract at midcommisural plane)

**Measured 5mm below the superior border**

Axial plates of SWA seems to be the most realistic approximation of ANT location compared to patient data.

Lehtimäki K, unpublished
DIRECT TARGETING:

ANT is commonly located more anterior and superior in 3T MRI compared to the target based on SW atlas sagittal data.

Target - within the anteroventral subdivision of the ANT, superior and slightly posterior to the entry of the MTT into the ANT.

- MTT/ANT junction is slightly anterior to the midpoint of ANT in the anterior–posterior axis;
- MTT/ANT junction is close to the border between anterior principal and anteromedial subnucleus according to the Schaltenbrand–Wahren atlas.

3T MRI with transmit-receive coil:

a) STIR
b) FGATIR (better and faster than STIR)
c) DTI – some experts say it does not add extra value to FGATIR

Comparison of three imaging protocols in delineating the mammillothalamic tract (arrowheads) and ANT (arrow):

A. MP-RAGE acquired at 0.8 mm – poor delineation of the mammillothalamic tract and ANT.
B. MP-RAGE acquired at 1.2 mm – better illustrates the mammillothalamic tract and ANT.
C. FGATIR acquired at 0.8 mm – superior delineation of the mammillothalamic tract allowing more precise definition of the ANT.

FGATIR (3T):
MPRAGE (3T):


STIR (3T, mt = mammillothalamic tract, Apr + AM = ANT):


STIR (1.5T, mt = mammillothalamic tract, ANT = Anterior nucleus of the thalamus, eml = external medullary lamina):


DTI (coregistered to FGATIR) of the mammillothalamic tract:

Source of picture: Cukiert, Lehtimäki (2017)

FGATIR MR images in the axial (A), coronal (B), and sagittal (C) planes. The mammillothalamic tract (arrow) is clearly visualized as a linear hypointensity extending dorsally from the mammillary body (arrowhead) to the anterior thalamus.

Cadaveric dissection in the sagittal plane (D) illustrates the course of the mammillothalamic tract (arrow) originating in the mammillary body (arrowhead) and projecting to the anterior thalamus.

ANT DBS electrode (Medtronic 3389) localization coregistered to the preoperative FGATIR MR image. Final electrode localization is shown relative to the mammillothalamic tract (arrow) in the coronal (A) and axial (B) planes. Coronal (C), axial (B), left parasagittal (E), and right parasagittal (F) images show VTAs for the right (blue) and left (red) ANT electrodes relative to the mammillothalamic tract (arrow) and ANT (arrowhead). The VTAs are closely localized to the junction of the mammillothalamic tract and ANT on both sides.

Source of picture: Cukiert, Lehtimäki (2017)

DBS in Epilepsy E27 (6)
Surgical target 3.5mm from CSF surface

The centre of 3389 (interspace 1&2) to target point

Two uppermost contacts (3&2) in ANT

74% of the contacts (blue color) responders

83% of the contacts (red color) non-responders.

Transventricular trajectory:

Extraventricular trajectory (missed ANT):

Clinical effect was achieved only with these settings

Source of picture: Lehtimäki et al. (2018)
**Electrode Verification – hippocampal electrodes**

- hippocampal electrodes are placed, and the Medtronic Activa PC+S system used to record ANT stimulation-induced hippocampal evoked potentials as electrophysiological confirmation of appropriate placement of the ANT leads.

**Electrode Verification – impedances**

- impedances in CSF are lower than in parenchyma (“CSF wicking” effect – CSF tracks along DBS lead into brain parenchyma and impedances drop).
- impedance in CSF is 200-300 Ohm.

**Electrode Verification – MER**

Unnecessary and dangerous (narrow vascular window) in transventricular trajectory.

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Trajectory angle should be adapted to align with the target region of the ANT. In the MORE trial, 73% of DBS implants (146 leads) placed by transventricular trajectory through the ANT was successful. The correct depth of the lead is the most important factor associated with a successful lead placement in the ANT, especially if the TV route is used. The rate of ANT miss using transventricular trajectory with 3389 lead is 17.2%.

**Trajectories**

**SANTE trial** – transventricular frontal (recommended for highest accuracy without safety issues)
- **MORI registry** – lateral extraventricular (fails to enter ANT most often of all approaches)
- Mayo Clinic – posterior extraventricular.

Trajectory angle should be adjusted to align with the individual shape of the ANT! However, the trajectory of the lead is not the only factor in successful lead placement. The correct depth of the lead is the most important factor associated with a successful lead placement in the ANT, especially if the TV route is used. The rate of ANT miss using transventricular trajectory with 3389 lead is 17.2%.

**Transventricular frontal (precoronal)**
- ~60° posterior from an axial plane parallel to AC-PC plane, i.e. ~30° anterior from a coronal plane perpendicular to AC-PC plane.
- Trajectory typically runs through the narrow vascular window between the superior choroidal vein and thalamostriate vein (between caudate and ANT), blunt stylet advanced slowly pushes veins away.
- Sometimes choroid plexus is on top of ANT (but it is a mobile structure so hemorrhage is rare – Dr. Lehtimäki goes through it).
- MORE study - two distinct types of displacements were observed:
  a) too deep position of the lead in a trajectory through the ANT (placing of most superior contacts at MD or internal medullary lamina)
  b) medial deviation of the lead – 1 lead situated in structures bordering the thalamostriate and 2 leads were positioned in CSF spaces related to the penetration of the lateral ventricle.

TV trajectory traverses ANT with at least 95% probability, the main surgical challenge being the correct depth of the lead!

![](image)

**Lateral extraventricular (transcoronal)**
- passes through eloquent cortex, such as the operculum.
- provides improved mediolateral coverage.
- thalamostriate vein runs at the anterior and lateral aspect of ANT - in order to reach ANT from frontal EV approach, a very lateral and posterior entry point is needed to pass the thalamostriate vein, which is in contrast limited by frontal eloquent cortex; compromise between these anatomical limits is most likely achieved by adjusting the target inferiorly, laterally, and posteriorly, probably aiming to stimulate the MTT-ANT junction rather than ANT nucleus per se.

**Posterior interior parasagittal**
- greatest anteroposterior coverage
- anterior to ANT = no neuronal activity (lateral ventricle) - Cells representative of ANT if within the nucleus but anterior to target region
- inferior (along electrode trajectory) = No neuronal activity (ML) - Spiking activity with lower spike amplitude and more regular firing patterns than ANT (DM nucleus)
HARDWARE (MEDTRONIC)

PATIENT REMOTE

- same as for movement disorders but has blue button “Seizure” – it is programmable (e.g. logging the event, restarting stim cycle).

BATTERY

ACTIVA PC

- same as for movement disorders. [see p. Op360 >>]

List price – 17,000 USD (2019 October)

PERCEPT PC (MODEL B35200)

Medtronic.com/Percept >>

- BrainSense™ technology - captures local field potentials (LFP) using the implanted DBS lead simultaneously while delivering therapeutic stimulation. [see below >>]
- full-body 3T MRI eligibility (1.5T with Activa PC)
- > 15% longer battery life than Activa PC (smart battery technology provides real-time prediction of remaining battery life based on usage history).
- 20% smaller than Activa PC.

LEADS

FDA approved:

3387 (used in SANTE trial)

3389 - preferred

- use “at target” cannula; “10 mm above” cannula may cause DBS lead to deviate (some experts set target 8 mm deeper so that “10 mm above” cannula enters the parenchyma).

N.B. with lead 3389, the distance between the centers of first and last contact is 6 mm - when planning trajectory and target, plan that 6 mm segment to incorporate into ANT.

List price – 17,000 USD (2019 October)

Medtronic.com/Percept >>
DBS IN EPILEPSY

1. 4.5% of the patients had asymptomatic intracranial hemorrhage (ICH) in SANTE ← more frequent than in DBS surgery for movement disorders specifically (2.16% of ICH)

2. Exacerbating seizures / inducing new seizures (0.5-13% with 74-86% of those occurring around the time of electrode placement or initiation of stimulation)
   - review of 2101 electrode placements across 16 reports revealed an incidence of new onset seizures in up to 13% of patients. At least 74% of seizures occurred around the time of electrode placement, with many patients experiencing intracranial hemorrhage.
   - others estimated that DBS is associated with a < 2.4% (95% CI 1.7% - 3.3%) risk of seizures and that the procedural risk of seizures from chronic DBS was approximately 0.5% (95% CI 0.02% – 1.0%).
   - separate report examined 161 patients (288 leads) - 4.3% experienced seizures - the vast majority (86%) of seizures occurred within 48 hours after lead implantation.

3. Psychiatric side effects
   - SANTE: depression 37.3% (vs 1.8% in controls) – patients need to be watched closely!
   - changing stim contacts almost always helps.

4. Cognitive side effects
   - SANTE: subjective memory impairment 27.3% (vs 1.8% in controls); all resolved with no group differences on objective neuropsychological testing.
   - At 7 years: no significant cognitive declines or worsening of depression scores were observed through the blinded phase or at year 7.
   - Improved scores were observed at 7-years on measures of executive functions and attention.
Neuropsychological monitoring of memory and mood + slow titration are recommended in ANT DBS!

**PROGRAMMING**

3 sensing configurations possible:

- epilepsy signature LFP peaks are typically located in 8-12 Hz range (Percept PC can record only in 5 Hz wide band) – look for those recorded (upon patient triggered events) and also during programming session.
- turn LFP detection right after battery implantation (POD 0) – will obtain baseline LFP peaks while still off stim.

**STIMULATION**

Differences from DBS for movement disorders

1) intermittent (vs. continuous) stimulation – “cycling”
2) contact is programmed to be a cathode (negatively charged electrode) and case as anode* – to cause depolarization block.

*patients may feel tingling at battery site

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Typical Starting Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amplitude</td>
<td>5 V</td>
</tr>
<tr>
<td>*in clinical practice clinicians may start at a lower amplitude and titrate up lower as they access patient response and tolerability.</td>
<td></td>
</tr>
<tr>
<td>Pulse Width</td>
<td>90 μs</td>
</tr>
<tr>
<td>Electrode Configuration</td>
<td>Unipolar Mode: Single electrode or two adjacent electrodes negative, case positive. (all patients in the SANTE clinical trial were in unipolar mode)</td>
</tr>
<tr>
<td>Cycle of Therapy</td>
<td>Cycling mode ON: 1 minute on, 5 minutes off.</td>
</tr>
<tr>
<td>SoftStart/Stop</td>
<td>programmed to 8 seconds</td>
</tr>
</tbody>
</table>

**Phase I** (start 2-3 weeks postop) – increasing output

- **Amplitude** – start at 0.5 mA (old way - 1.5-2.0 V) and increase q2-4 weeks by 0.5 mA (0.5 V) or even longer intervals - analogy with adjusting AEDs up to 5 mA (4-5.5-0.0 V, up to 9.0 V); most patients need 2-3 mA.
- gradual amplitude increase helps to minimize occurrence of psychiatric side effects
- keep symmetrical between sides.
- corresponds to 4-7 mA (some experts recommend current-based programming to mitigate impedance effects that maybe very asymmetric)

**Pulse width 90 msec (this is invariable*)**

**Frequency 145 Hz (this is invariable*)**

*hardware allows to change it but in studies it did not make any difference

Duty cycle: 1 min on, 5 mins off.

**Monopolar**

- typically not the deepest contact
- usually most centrally located contact
- do not use contacts with low impedances – electrical current will shunt into CSF (not into parenchyma).
- contacts in thalamus but outside ANT cannot stimulate ANT as white matter capsule creates barrier.
- alternative – wide bipolar stim (anode most distal).

N.B. bipolar stimulation is used to limit current spread into surrounding structures.

**Phase II** – changing cycling

Decreasing off time from 5 to 3 min.

**OUTCOMES**

- best effects are on disabling, multifocal epilepsy as well as temporal lobe epilepsy (involvement of Papez circuit).
- it takes time for efficacy to build up (vs. DBS in movement disorders).

5. **Sleep disturbances with vivid dreams.**
seizures may intensify upon initiation of stimulation.

There is a putative association between VNS and DBS responses. In 10/11 patients, the response to VNS seemed to be similar to the response to DBS; progressive response to VNS was likely to correlate with a progressive response to DBS in 3/3 patients; partial response to VNS was associated with a fluctuating response pattern to DBS in 2 patients; 5/6 nonresponders to VNS were also nonresponders to DBS (one of the VNS nonresponders obtained progressive response to DBS).


STIMULATION OF THE ANTERIOR NUCLEUS OF THALAMUS FOR EPILEPSY (SANTE) TRIAL

Comprehensive set of trial data:


1-year outcome:


7-year outcome:


- level I evidence for medically refractory partial seizures with or without secondary generalization - positive effects of bilateral stimulation appear to be long-lasting - patients had improved quality of life.
- multicenter, prospective, randomized, double-blind, parallel groups pivotal study – high quality data.
- 110 patients who were implanted with a Medtronic DBS system at 17 centers located in the U.S.
- blinded phase – 3 months.

- patients with ≥ 50% reduction in seizures (median seizure reduction numbers are very close):
  - 3 months: 40.4% vs. 14.5% in placebo
  - 25 months: 54% (n=81)
  - 37 months: 67% (n=42)
  - 5 years: 68%
  - 7 years: 78% (18% experienced at least one 6-month seizure-free period, 7% were seizure-free for the preceding 2 years)
- in real life may expect better results than in SANTE, as SANTE investigators did not know the exact target location.
- statistically significant reduction in seizure frequency only in temporal epilepsies - 44.2% (vs. controls - 21.8%).
- complex partial seizures were significantly reduced compared to simple partial and partial to generalized seizures.
- patients previously implanted with a VNS device* or who underwent resective surgery prior to DBS had outcomes that were not different from previously nonoperated patients.

*for SANTE trial, patients had VNS explanted because VNS was ineffective

- side effects – see above
- analysis revealed placement outside the ANT in 8.2% of electrodes (vs. 3.6% in DBS for movement disorders).
- of note, one outlier subject in the trial whose seizures dramatically worsened (210 seizures in 3 days compared to their baseline seizure rate of 19 seizures per month) necessitated outlier analysis to satisfy primary endpoints and played a role in delaying FDA approval for years, until long-term data demonstrated clearer benefit.

**Please note the following:**

- Multicenter international registry conducted since October 2011 in 13 countries and using an open label observational study design to evaluate the long-term effectiveness, safety, and performance of ANT-DBS.
- EPAS - FDA-mandated postapproval DBS trial
• CMT, together with the parafascicular nuclei, form the posterior group of the intralaminar nuclei of the thalamus. The motor cortex provides input to the CMT, as do the globus pallidus internus (GP). CMT projects back to the motor cortex as well as the striatum with particular preference for the putamen and the head of the caudate nucleus proximal to the internal capsule.

• N.B. CMT has much more widespread connections than ANT (only putamen).

• majority of available data support the use of CMT DBS for the treatment of generalized epilepsies, including patients suffering from Lennox-Gastaut syndrome.

• current data is only from IV and IIb IV studies.

• imaging – CMT cannot be seen even on 7T MRI (vs. ANT).

• placed under general anesthesia with recruiting response.

• if electrode is too lateral – sensory side effects.

Outcomes

• the largest series, published by Son et al. in 2016 reported a 79% response rate (11 of 14 patients), with a mean seizure frequency reduction of 69%; they did not find any correlation between lead positioning and the magnitude of seizure reduction on regression analysis.

• best responders more anterior and lateral in CM, concentrated in paraventricular portion.

• less effective in focal epilepsies although it did help with secondary generalization.

• causes no change in neuropsychological tests; benefit - improved attention.

### HIPPOCAMPUS

- patients selected from population undergoing invasive electrodes: diagnostic electrodes replaced with stimulation electrodes at site of seizure focus.

- 60-100% response rates (some become seizure free).

- causes no change in neuropsychological tests.

#### Study

<table>
<thead>
<tr>
<th>Author</th>
<th>n</th>
<th>Randomization</th>
<th>Stim Param</th>
<th>Seizure Outcome</th>
<th>Neuro-Psych Outcome</th>
<th>Comment</th>
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<tbody>
<tr>
<td>Velasco et al Epileps 97</td>
<td>9</td>
<td>Immediate on vs 1 mo delay</td>
<td>130 Hz 450 us cycle</td>
<td>100% RR 4v/sz free</td>
<td>No decline</td>
<td>Absence of MS on MRI predicts success</td>
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<tr>
<td>Boon et al Epileps 97</td>
<td>10</td>
<td>no</td>
<td>130 Hz 450 us cycle</td>
<td>70% RR 1/0 vs sz free (+MS)</td>
<td>No decline</td>
<td>Partial selection based on dec in spikes with sim</td>
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<tr>
<td>Telz-Zellenbo et al Neurol 96</td>
<td>4</td>
<td>Alternating 1 mo blocks over 6 mo</td>
<td>100 Hz 90 us cont</td>
<td>25% RR 1/2 vs sz free</td>
<td>No decline</td>
<td>Design of randomizer not optimal</td>
</tr>
</tbody>
</table>

Cukiert et al. (2017) - the results of a prospective, double-blind, randomized controlled trial evaluating the efficacy of unilateral and bilateral HCP DBS in 16 patients with refractory TLE: o 2 months after surgery, all patients were randomized to stimulation on or off for a 6-month blinded period.

- o of the 8 patients randomized to the on-stimulation group, 4 became seizure free and 7 were defined as responders, whereas 1 patient did not respond to DBS therapy.

- o the experimental group experienced significantly fewer simple partial and complex partial seizures than the control group throughout the blinded period.

Vonck et al. reported on 11 patients who underwent bilateral HCP DBS electrode implantation, with stimulation latereality applied based on seizure localization. After 2.5 months of follow up, and after switching to bilateral stimulation as necessary, 6 patients achieved ≥ 90% seizure reduction, 3 patients achieved seizure reduction rates ranging from 40% to 70%, and 2 patients achieved ≤ 30% seizure reduction. Importantly, the authors found that switching from unilateral to bilateral stimulation further improved seizure outcomes in 3 of 5 patients with unilateral ictal onset. Implementing day-night cycling after attaining treatment stability did not affect seizure control, and no changes in neuropsychological testing were noted after DBS therapy.

**STN**

<table>
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<th>Author</th>
<th>N</th>
<th>Localization of epilepsy</th>
<th>Outcome</th>
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<tr>
<td>Benbadh/Chabardes 2002</td>
<td>3</td>
<td>sensory motor cortex</td>
<td>67-87%</td>
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<tr>
<td></td>
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<td>&lt; 50%</td>
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<tr>
<td>Shon (Seoul) Stereoeact Funct Neurosurg 2005;83:84-90</td>
<td>2</td>
<td>FLE s/p failure</td>
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<td></td>
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<td>87-89%</td>
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<td>Handforth (UCLA) Epilepsia 47(7):1239–1241, 2006</td>
<td>1</td>
<td>Frontal ictal epilepsy</td>
<td>50%</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>33%</td>
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<tr>
<td>Neme (Santiago)</td>
<td>1</td>
<td>&gt; 50%</td>
<td></td>
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<tr>
<td></td>
<td>3</td>
<td>&lt; 50%</td>
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**CEREBELLUM**

- While the cerebellum (hemispheres) has the longest history in DBS for the treatment of epilepsy, results have been mixed. Therefore, stimulation of the cerebellum has fallen out of favor.

**NUCL. ACCUMBENS**

**POSTERIOR HYPOTHALAMUS**

**BIBLIOGRAPHY** for ch. “Epilepsy and Seizures” → follow this [LINK](#)