Medtronic

BRAINSENSE™ TECHNOLOGY : REAL-WORLD INSIGHTS

LFP-informed programming optimization for tremor control

The Medtronic Percept™ PC neurostimulator with BrainSense™ technology† is a platform for brain sensing. BrainSense™ technology uses brain signals to provide a window into a patient's condition, in real time, over time.

The BrainSense™ suite of tools offers decision-making support to select and optimize programming configurations and to maximize therapeutic results over time.‡

The majority of LFP-informed contact selection evidence is from the STN. This case is an example of LPF-informed contact selection in the GPi.[1]

Key Points:

- Local field potentials (LFP) captured with BrainSense™ technology in the globus pallidus (GPi) aligned with therapeutic contact selection.
- LFP-informed stimulation parameters were used to optimize the patient's settings for tremor control.

Patient Background:

- A patient with Parkinson's disease receiving bilateral GPi deep brain stimulation with Percept™ PC and Sensight™ leads was programmed in the clinic with the goal of improving tremor control.

†The sensing feature of the Percept™ PC system is intended for use in patients receiving DBS therapy where chronically-recorded bioelectric data may be useful, objective information regarding clinical status.

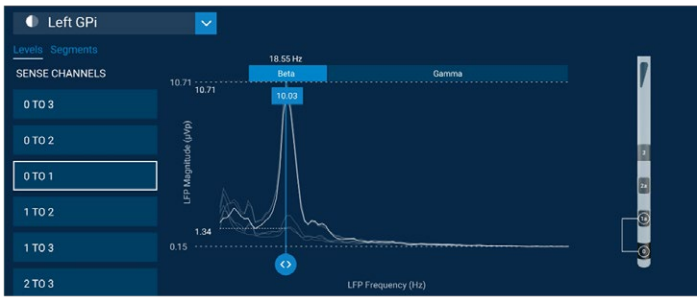
‡This case study is shared as an example of a single patient's experience with BrainSense™ technology. Individual patient experiences may vary. Physicians should use their own clinical judgment when deciding DBS programming.

1. Strelow JN, Dembek TA, Baldermann JC, et al. Low beta-band suppression as a tool for DBS contact selection for akinetic-rigid symptoms in Parkinson's disease. *Parkinsonism & Related Disorders*. 2023; 112.

BrainSense™ Survey – level analysis:

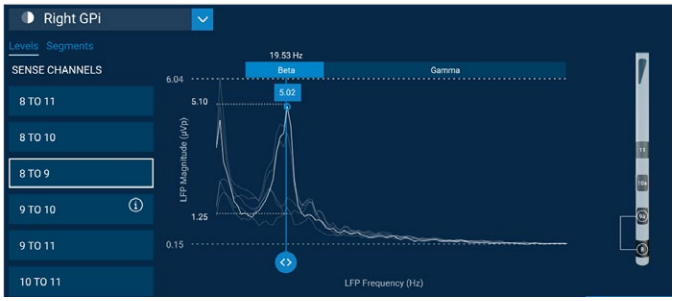
Bilateral beta (13 – 30 Hz) peaks identified.

Figure 1A Left GPi beta peaks



- Significant peak at 18.55 Hz with **more activity on the lowest contact pair**.
- Signal source was determined by analyzing adjacent level LFP signal amplitude with (**0 – 1)**>(1 – 2)>(2 – 3).

Figure 1B Right GPi beta peaks



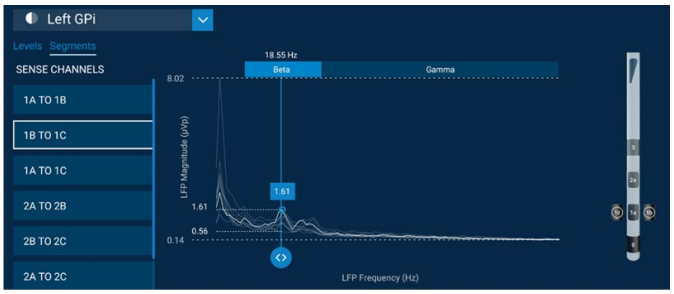
- Significant peak at 19.35 Hz with **more activity on the lowest contact pair**.
- Signal source was determined by analyzing adjacent level LFP signal amplitude with (**8 – 9)**>(9 – 10)>(10 – 11).

BrainSense™ Survey – segment analysis:

Directional bilateral beta (13 – 30 Hz) peaks identified.

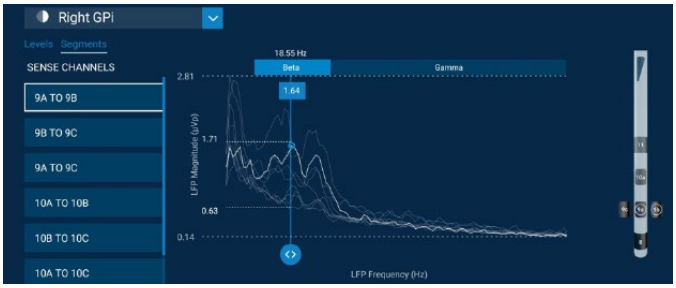
To further investigate the signal location, directional sensing data for both hemispheres was reviewed. Clinician used BrainSense™ Survey (segment analysis) to further identify the signal location of beta peaks (13 – 30 hz).

Figure 2A Left GPi



- Level 1 peak at 18.55 Hz was greater than level 2.

Figure 2B Right GPi



- Level 9 peaks at 18.55 Hz showed greater signal amplitude than level 10.

Segment analysis supported the presence of beta activity on levels 1 and 9.

Figure 3 Final adjustments using BrainSense™ data to inform programming optimization

- Initial programing on level 1 (left hemisphere) and 9 (right hemisphere) reduced the patient's tremor.
- **However, further optimized tremor suppression was seen with an addition of contact 0 and 8, aligning with areas demonstrating elevated beta power.**

LFP-informed stimulation parameters were used to optimize the patient's settings for tremor control.

Brief Statement: Medtronic DBS Therapy for Parkinson's Disease and Tremor

Product labeling must be reviewed prior to use for detailed disclosure of risks.

INDICATIONS:

Medtronic DBS Therapy for Parkinson's Disease: Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Parkinson's Disease is indicated for adjunctive therapy in reducing some of the symptoms in individuals with levodopa-responsive Parkinson's disease of at least 4 years' duration that are not adequately controlled with medication, including motor complications of recent onset (from 4 months to 3 years) or motor complications of longer-standing duration.

Medtronic DBS Therapy for Tremor: Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) using Medtronic DBS Therapy for Tremor is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

CONTRAINDICATIONS: Medtronic DBS Therapy is contraindicated for patients who are unable to properly operate the neurostimulator and patients for whom test stimulation is unsuccessful. The following procedures are contraindicated for patients with DBS systems: diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy), which can cause neurostimulation system or tissue damage and can result in severe injury or death; Transcranial Magnetic Stimulation (TMS); and certain MRI procedures using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area if the patient has an implanted Soletra™ Model 7426 Neurostimulator, Kinetra™ Model 7428 Neurostimulator, Activa™ SC Model 37602 Neurostimulator, or Model 64001 or 64002 pocket adaptor.

WARNINGS: There is a potential risk of brain tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths and a potential risk to drive tremor (cause tremor to occur at the same frequency as the programmed frequency) using low frequency settings. Extreme care should be used with lead implantation in patients with an increased risk of intracranial hemorrhage. Sources of electromagnetic interference (EMI) may cause device damage or patient injury. Theft detectors and security screening devices may cause stimulation to switch ON or OFF and may cause some patients to experience a momentary increase in perceived stimulation. The DBS System may be affected by or adversely affect medical equipment such as implanted cardiac devices (e.g., pacemaker, defibrillator), external defibrillation/cardioversion, ultrasonic equipment, electrocautery, or radiation therapy. MRI conditions that may cause excessive heating at the lead electrodes which can result in serious and permanent injury including coma, paralysis, or death, or that may cause device damage, include: neurostimulator implant location other than pectoral and abdominal regions; unapproved MRI parameters; partial system explants ("abandoned systems"); misidentification of neurostimulator model numbers; and broken conductor wires (in the lead, extension or pocket adaptor). The safety of electroconvulsive therapy (ECT) in patients receiving DBS Therapy has not been established. Abrupt cessation of stimulation should be avoided as it may cause a return of disease symptoms, in some cases with intensity greater than was experienced prior to system implant ("rebound" effect). New onset or worsening depression, suicidal ideations, suicide attempts, and suicide have been reported.

Patients should avoid activities that may put undue stress on the implanted components of the neurostimulation system. Activities that include sudden, excessive or repetitive bending, twisting, or stretching can cause component fracture or dislodgement that may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component. Patients should avoid manipulating the implanted system components or burr hole site as this can result in component damage, lead dislodgement, skin erosion, or stimulation at the implant site. Patients should not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA) as this could damage the neurostimulation system, before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their clinician. Patients using a rechargeable neurostimulator must not place the recharger over a medical device with which it is not compatible (eg, other neurostimulators, pacemaker, defibrillator, insulin pump). The recharger could accidentally change the operation of the medical device, which could result in a medical emergency. Patients should not use the recharger on an unhealed wound as the recharger system is not sterile and contact with the wound may cause an infection.

PRECAUTIONS: Loss of coordination in activities such as swimming may occur. Patients using a rechargeable neurostimulator for Parkinson's disease or essential tremor should check for skin irritation or redness near the neurostimulator during or after recharging, and contact their physician if symptoms persist.

ADVERSE EVENTS: Adverse events related to the therapy, device, or procedure can include intracranial hemorrhage, cerebral infarction, CSF leak, pneumocephalus, seizures, surgical site complications (including pain, infection, dehiscence, erosion, seroma, and hematoma), meningitis, encephalitis, brain abscess, cerebral edema, aseptic cyst formation, device complications (including lead fracture and device migration) that may require revision or explant, extension fibrosis (tightening or bowstringing), new or exacerbation of neurological symptoms (including vision disorders, speech and swallowing disorders, motor coordination and balance disorders, sensory disturbances, cognitive impairment, and sleep disorders), psychiatric and behavioral disorders (including psychosis and abnormal thinking), cough, shocking or jolting sensation, ineffective therapy and weight gain or loss.

Safety and effectiveness has not been established for patients with neurological disease other than idiopathic Parkinson's disease or Essential Tremor, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression, patients who are pregnant, or patients under 18 years. Safety and effectiveness of Medtronic DBS Therapy for Tremor has not been established for bilateral stimulation or for patients over 80 years of age.

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