A Presentation on Deep Brain Stimulators

BY

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Introduction

- The Brain being the largest and most complex organ in the human body works as the center of the central nervous system.
- The Brain is made up billions of nerves used for communicating with other part of the body through neurons and connections called synapses.
- It is responsible for controlling and managing the activities of the body (involuntarily and voluntarily).
- For proper functioning of the human body the Brain needs to function optimally.

Introduction…

- This optimal/efficient operation of the body can be altered by diseases and disorders.
- A damage to any part of the Brain can lead to memory loss, mental disorders and even death.
- To prevent and treat this disorders, Deep brain stimulation is administered with the aid of the Biomedical device – Deep Brain stimulator.
- Deep Brain stimulation is a surgical procedure that involves implanting electrodes in the brain. This electrodes send electrical pulses/signals that block abnormal activities.

Clinical Need

- According to Parkinson.org, more than 10 million people worldwide are living with Parkinson’s Disease (PD).
- Parkinson’s disease increases with age. Estimated 4 % of people with PD are diagnosed before 50.
- Men are 1.5 times more likely to have the disease than women
- Environmental factors and genetic makeup, race and ethnicity affect the risk of developing PD

Disorders associated with the Brain

- **Parkinson's Disease:** Tremor, rigidity, and slowness of movement caused by the death of dopamine-producing nerve cells responsible for relaying messages that control body movement.
- Essential tremor
- Dystonia
- Alzheimer's Disease
- Dementias
- Brain Cancer
- Mental Disorders
- Epilepsy and other seizure disorders etc.

Basal Ganglia

- Deep brain stimulation is administered below the cerebrum, in the basal ganglia.
- The basal ganglia is made up of subcortical nuclei. It functions as a feedback circuit. It receives information from many sources and sends the information back to the cortex through the thalamus.
- The Basal ganglia help in controlling motor and cognitive functions

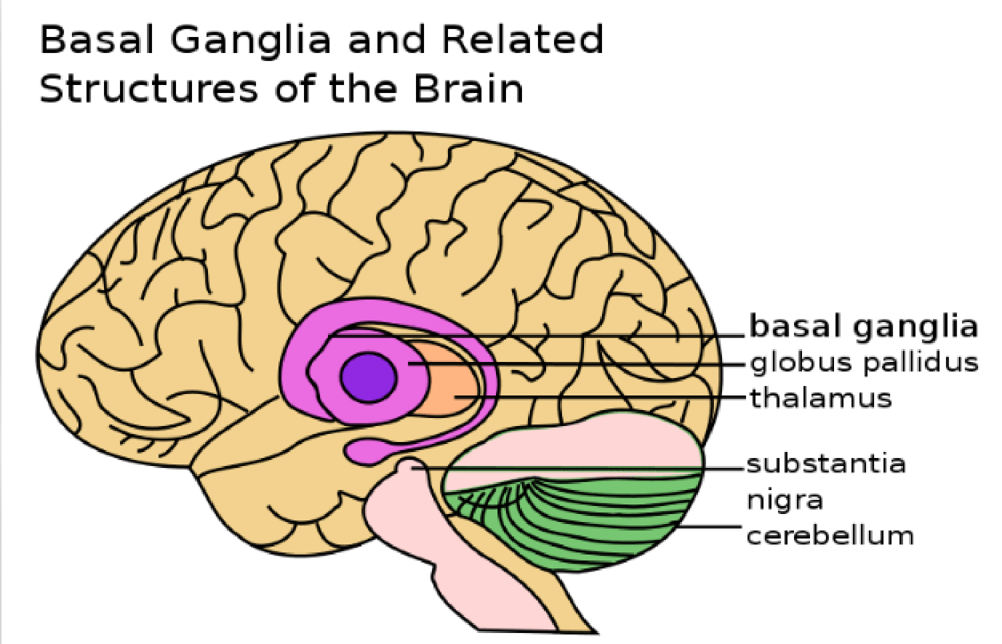

Fig 1: The Basal Ganglia. Taken from https://human-memory.net/basal-ganglia/

Target Localization

- There has to be localization of the subthalamic nucleus (STN) or global pallidus internus (GPI) before a DBS electrode can be implanted for therapy administration.
- Localization occurs in three steps.
- **Stereotactic frame fitting:** Rigid frame providing immobilization in three-dimensions. Magnetic resonance imaging (MRI) occurs after fitting.
- Microelectrode recording (MER) for real time localization in reference to stereotactic space
- Microelectrode fine-tuning with somatotopy or associated movement

Historic, Early Devices and Advancements

- Electrical Stimulation of the living brain can be traced back to 1874. American Physician Robert Bartholow experiments in an attempt to treat an aggressive basal cell carcinoma of the scalp.
- **Ablation:** American Neurosurgeon R. Meyers performed an ablation of the basal ganglia to control parkinsonian tremor in 1942.
- **Levodopa Therapy in 1948**
- Implanted stimulator to treat PD by French Neurosurgeon Alim-Louis Benabid. High frequency VIM stimulation.

Deep Brain Stimulator: The System

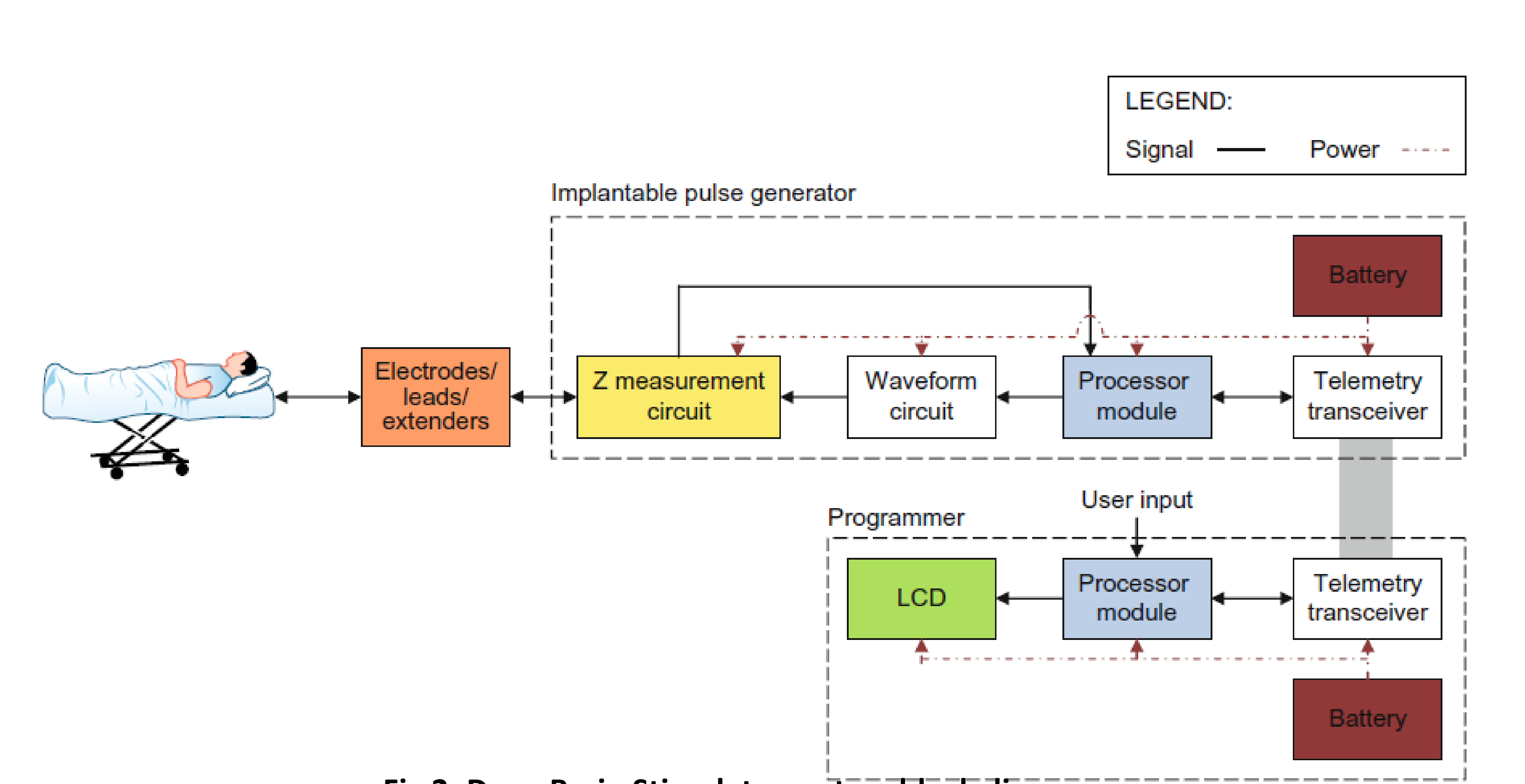

Fig 2: Deep Brain Stimulator system block diagram taken from medical device technology by Gail Dawn Baura

Deep Brain Stimulator: The System…

- There is an implantation of one or two of the electrodes. Each electrode will be at the local target.
- The electrodes are placed inside a 14nm drilled hole in the skull
- The leads are connected to percutaneous extension wires. The extension wires are inserted through the percutaneous tunnel in the head and neck for connection to the implantable pulse generation (IPG)
- The leads can be made up of platinum or iridium
- Stimulator programmers are used to control the DBS system and display data

Deep Brain Stimulator: The System…

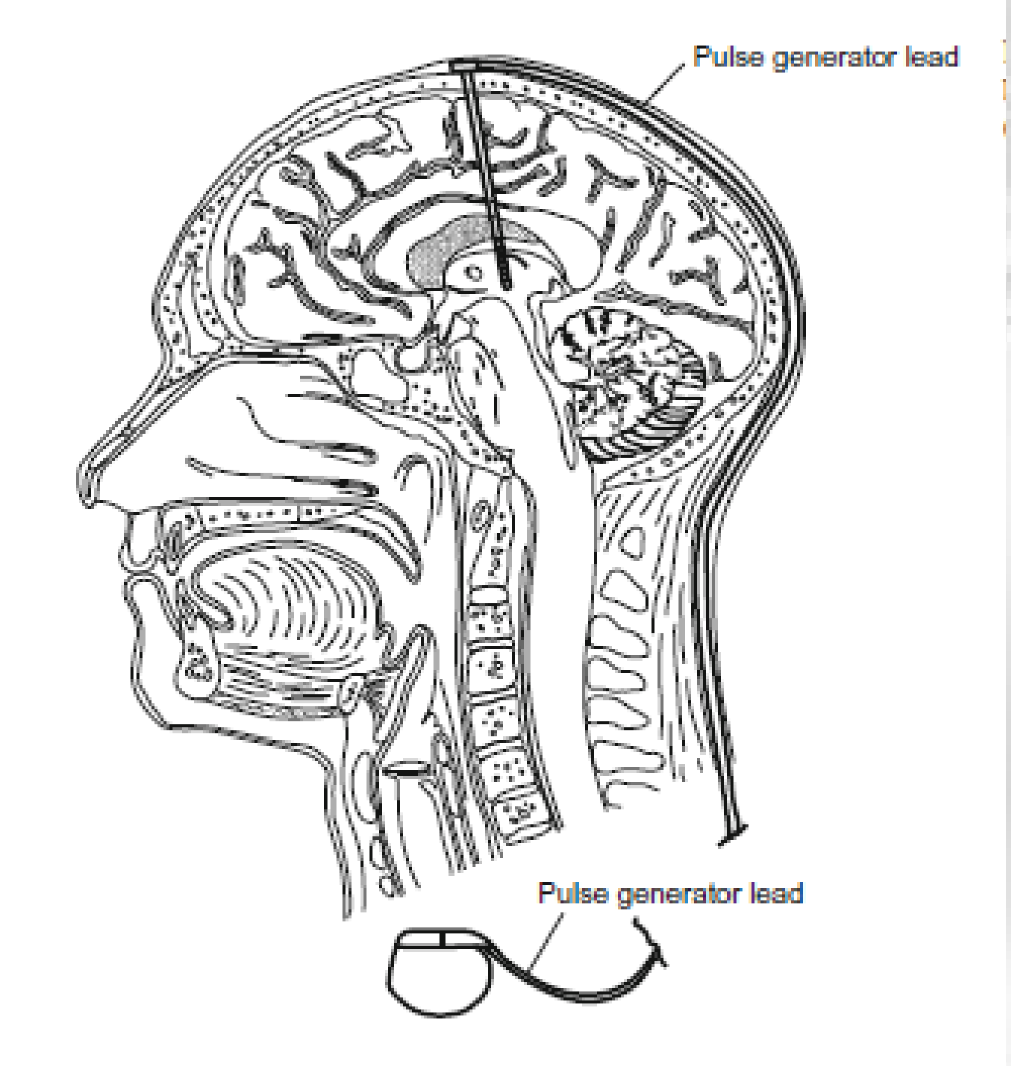

Fig 3: An illustration of Deep Brain Stimulation taken from medical device technology by Gail Dawn Baura

Deep Brain Stimulator: The System…

- In the case of stimulation, the Telemetry transceiver transmit data needed to the processor module for processing
- A waveform is generated by the waveform circuit based on the information received
- The signal waveform generated is passed to the z measurement circuit to check if the signal has an optimal impedance value before stimulation
- The brain is stimulated with the electrodes using the signal generated in the form of electric current.

Deep Brain Stimulator: The System…

- In the case of cell impedance recording, the impedance offered by the brain cells and neurons is passed through the electrodes in the form of electric current.
- A Z-measurement circuit is used to measure this impedance
- The impedance measured is fed back to the processor module for signal processing.
- The signal processed is received by a Telemetry transceiver for recording
- The processor can be programmed to give a specified input based on the user's input.

Deep Brain Stimulators: Types and features

- Three companies currently have FDA-approved devices: Medtronic manufactures Activa® Parkinson's Control Therapy; Abbott manufactures the St. Jude Medical Infinity DBS SystemTM; and Boston Scientific manufactures the VerciseTM DBS System.
- Activa SC by Medtronic manufactures: Controls one brain lead for unilateral stimulation. Digital patient programmer with up to 4 group settings.
- Activa PC by Medtronics manufactures: Controls two brain leads for bilateral stimulation. Digital patient programmer with up to 4 group settings.

Deep Brain Stimulators: Types and features

- Activa RC by Medtronic manufactures: Controls two brain leads for bilateral stimulation. Allows for some patient self-adjustment with certain parameters. Rechargeable and last up to six to nine years.
- Infinity by Abbott: Comes in two sizes. It has a non-rechargeable maintenance-free battery. It implements Bluetooth connectivity.
- Vercise by Boston Scientific: It contains a rechargeable battery with multiple independent current control technology. It is able to perform bilateral stimulation. 15 years battery life. Controlled wirelessly.

Deep Brain Stimulators: Types and features

Fig 4: Deep Brain Stimulator Device and patient programmer by Medtronic manufactures

Fig 5: Abbott's infinity Deep Brain Stimulation System

Key Features from Engineering Standards

- As of 2010, FDA recommends a specific consensus standard for neurostimulators: ANSI/AAMI/ISO 14708-3:2008 Implants for Surgery—Active Implantable Medical Devices—Part 3: Implantable Neurostimulators
- **Stimulation Pulse Characteristics:** The stimulation pulse generated must be stable to prevent any stimulation intensity change. Measurements should be made at an impedance of 499 Ω +/- 1 %.
- **Battery Indication:** A battery indicator must be put in place to give a warning about power depletion for implantable deep brain stimulators.

Key Features from Engineering Standards

- **Biologic Effects**: The implanted electrodes must not corrode or release any particulate matter in the body
- **Effect of Miscellaneous Medical Treatment:** The potential effects (positive or negative) from secondary diagnosis such as MRI, positron emission tomography scans should be considered and documented
- **Immunity from Electromagnetic Interference:** The implantable parts of the deep brain stimulator must not be affected by external electromagnetic fields (10 Hz – 30 MHz)

Ethics

- **Non-maleficence:** Do not harm. Risks, side effects involved, effects on developing brain, change in personal identity.
- **Beneficence:** Do well. Its effectiveness
- Proportionality and subsidiary: Risks and benefits in proportion.
- **Justice:** Rationing and prioritizing
- **Respect for autonomy:** Informed consent, competence to consent, use in minors.

Conclusion

- A deep brain stimulator is an electrical stimulator that discharges electrical current within the globus pallidus of the basal ganglia or subthalamic nucleus of the diencephalon, as a treatment for Parkinson’s disease
- Target localization before implantation is done in three steps: Stereotactic frame fitting, Microelectrode recording (MER) and Microelectrode fine-tuning with somatotopy.
- There is an implantation of one or two of the electrodes. Each electrode will be at the local target.
- Currently, only Three companies have FDA-approved Devices.

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