Stroke Recovery Models: Brain Computer Interface & More

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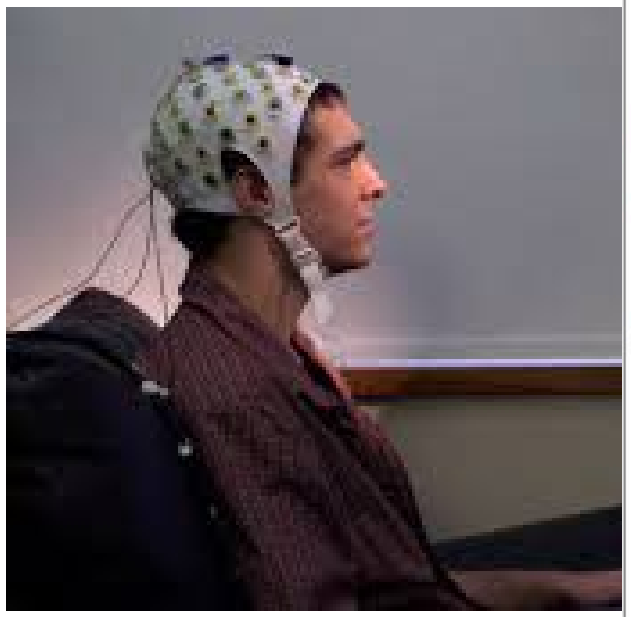
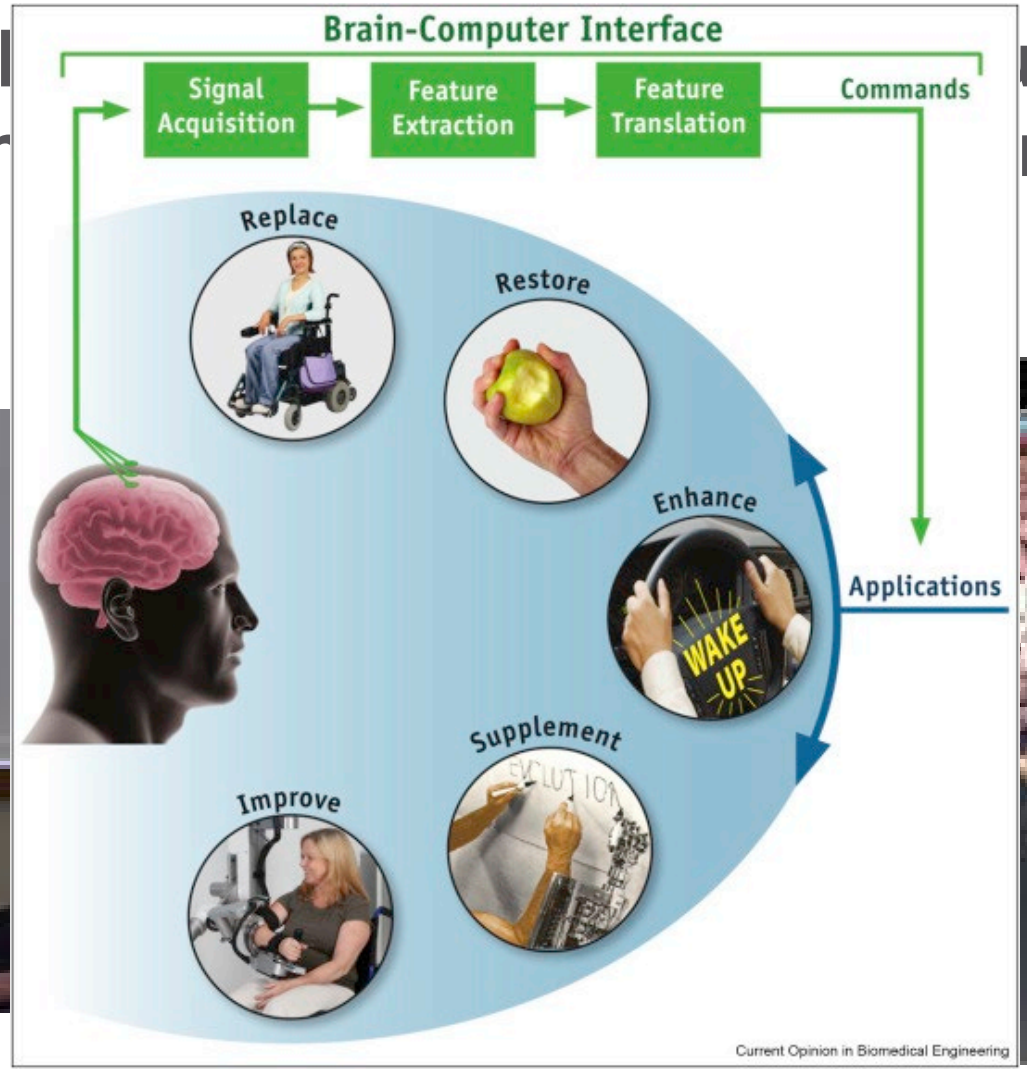
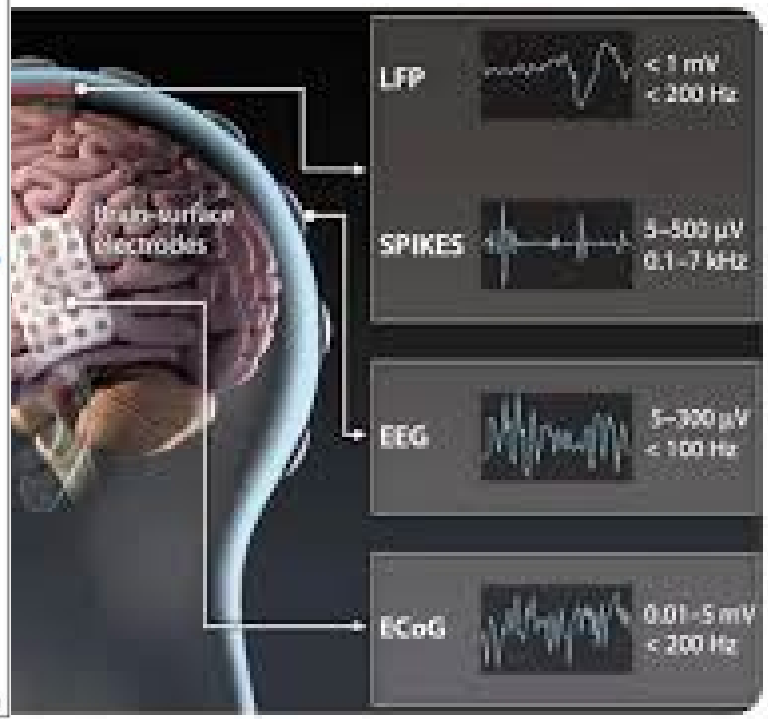
What is Brain Computer Interface?

(BCI) is a system th…nication between the brain…mputer or prosthetic limb)







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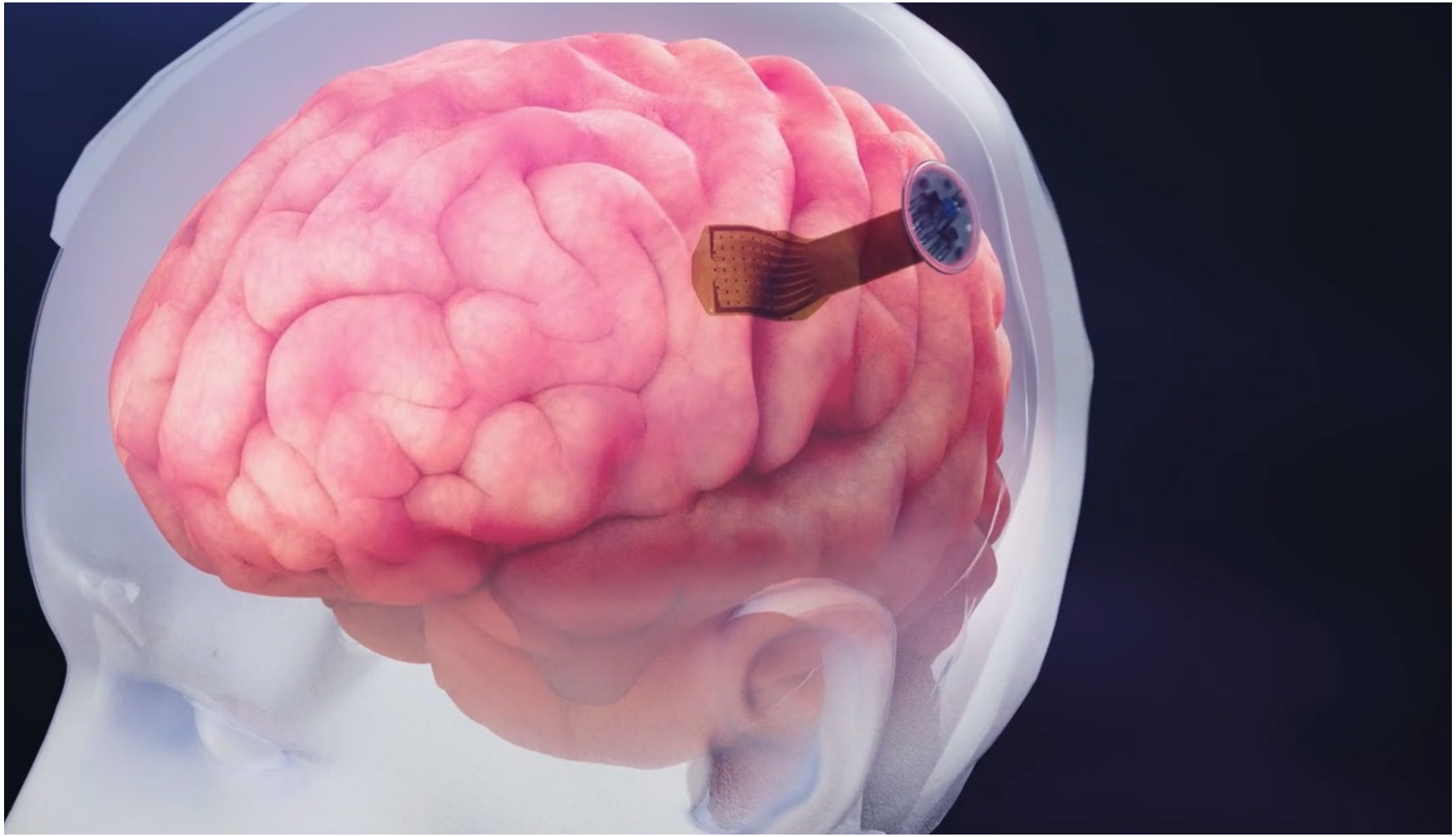
Cortical BCI: Thin film electrode



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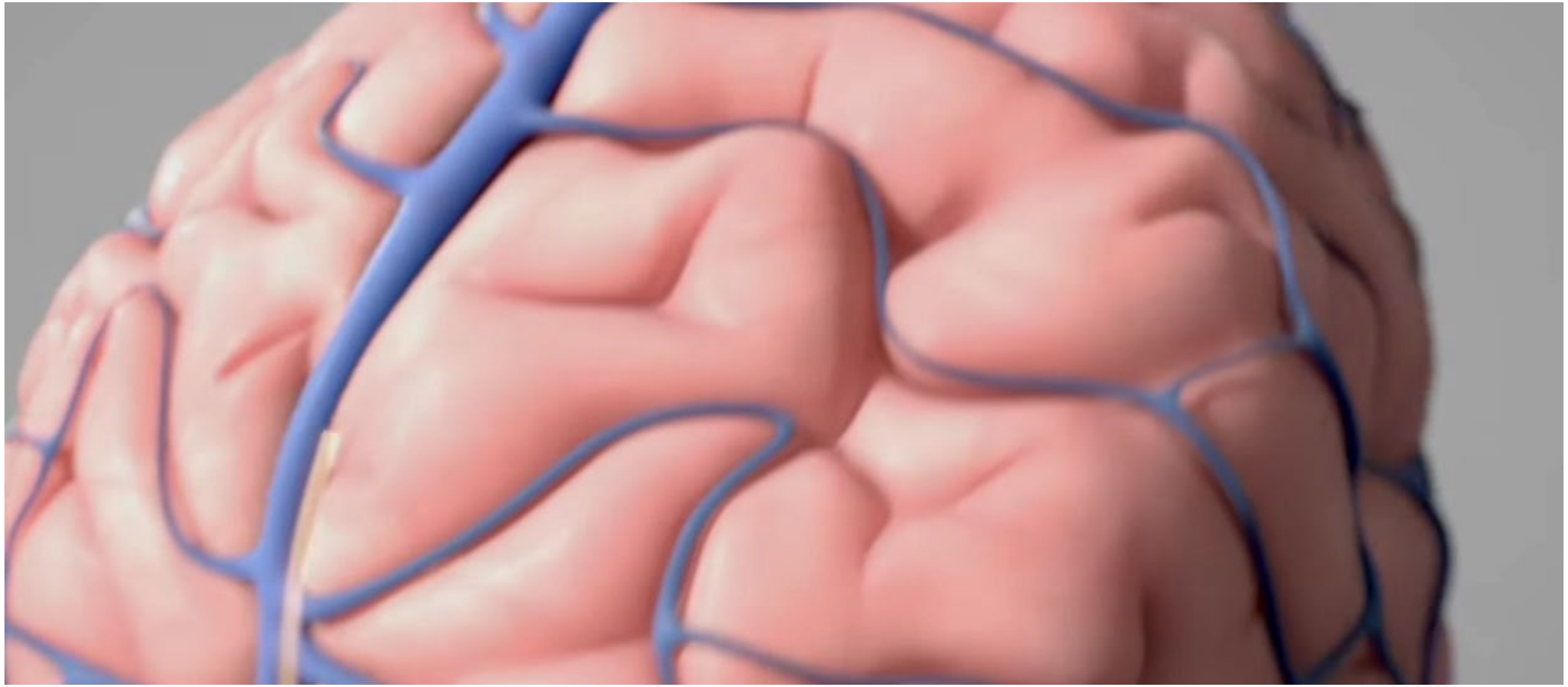
Endovascular BCI: The Stentrode



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Limitations to BCI in Stroke

- **Requires cortical activity**
- **Simulates lost function, does not restore it**
- **Primarily used to operate devices (phone, computer)**
  - Good for communication with caretaker
  - Could be used to drive motorized device

EEG-based Ipsilateral Cortex Stimulation

Theta-Gamma Coupling

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EEG-based Ipsilateral Cortex Stimulation

Headset

Identifies electrical signals from
parts of the brain.

Tablet

eal-time feedback visual motor imagery
guidance on a tablet.

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Neurorehabilitation & Neural Repair

Original Research Article

ASNR AMERICAN SOCIETY OF NEUROREHABILITATION

Neurorehabilitation and Neural Repair
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IpsiHand Brain–Computer Interface Therapy Induces Broad Upper Extremity Motor Rehabilitation in Chronic Stroke

Nabi Rustamov, MD, PhD[1,2], Lauren Souders, MOT[3], Lauren Sheehan, OTD[3], Alexandre Carter, MD, PhD[4,5], and Eric C. Leuthardt, MD, FNAI[1,2,3,6,7]

- **18 of 26 patients achieved clinically significant improvement in Fugl-Meyer UE exam**
  - >5.25 point improvement

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EEG stimulation

Advantages

- No surgical implant
- Less expensive than VNS
- Indicated for hemorrhagic AND ischemic stroke

Disadvantages

- Primarily focused on hand movement only
- CMS coverage

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Suite of Simulation Technologies

- **Computer-controlled VR and Robotic system**
  - Motor sensors, video game technologies, & adaptive robotics
  - Seamless immersive experience
- **Deep Immersion & Perception of Risk**
- **Multimodal Sensorimotor Engagement with Aerobic Exercise**
  - Sensory, Association & Motor Cortex Activation
  - Subcortical Engagement (BG, Thalamus, etc.)
  - Neurotransmitter Activation
  - Limbic System Involvement
  - Reward Pathways Activation
  - Asymmetric Compensation

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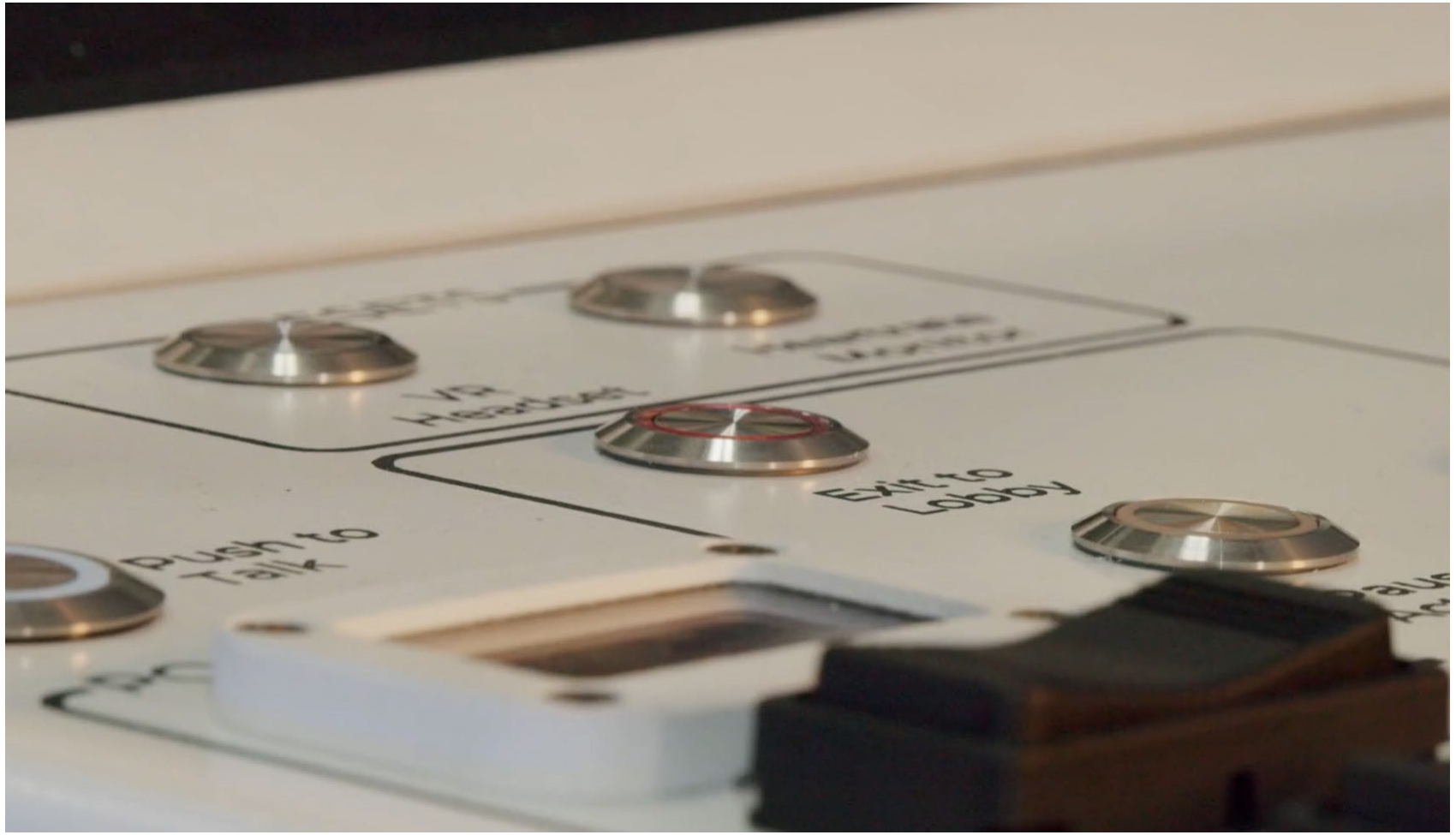
Immersive Virtual Reality and Robotics



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Initial Outcomes from Internal Testing

- **Interventions**
  - Six participants deemed “plateaued” by insurance companies
  - Age range 22-60 and included 3 men and 3 women
  - Protocol: Sessions - 5 times per week for 8 weeks; Avg session= 40–50 minutes
  - Physical Results:
    - Berg improvements 6-22%
    - TUG improvements 8-45%
  - Cognitive
    - Simple Reaction Time improvements = 4–36 ms
    - Choice Reaction Time improvements = 18–27%
  - Depression & anxiety rapidly decreased or eliminated
  - Hemispatial neglect: Markedly reduced in all participants (25-82%)
- **Safety & Tolerability:**
  - No side effects as measured by the Simulation Sickness Questionnaire and no physical adverse incidents occurred
  - No injuries or incidents occurred

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Immersive Virtual Reality and Robotics

Advantages

- **No surgical implant**
- **Indicated for mobility and balance**

Disadvantages

- **CMS and Insurance coverage**
- **Clinical data not robust**
- **Cost**
  - To the patient!

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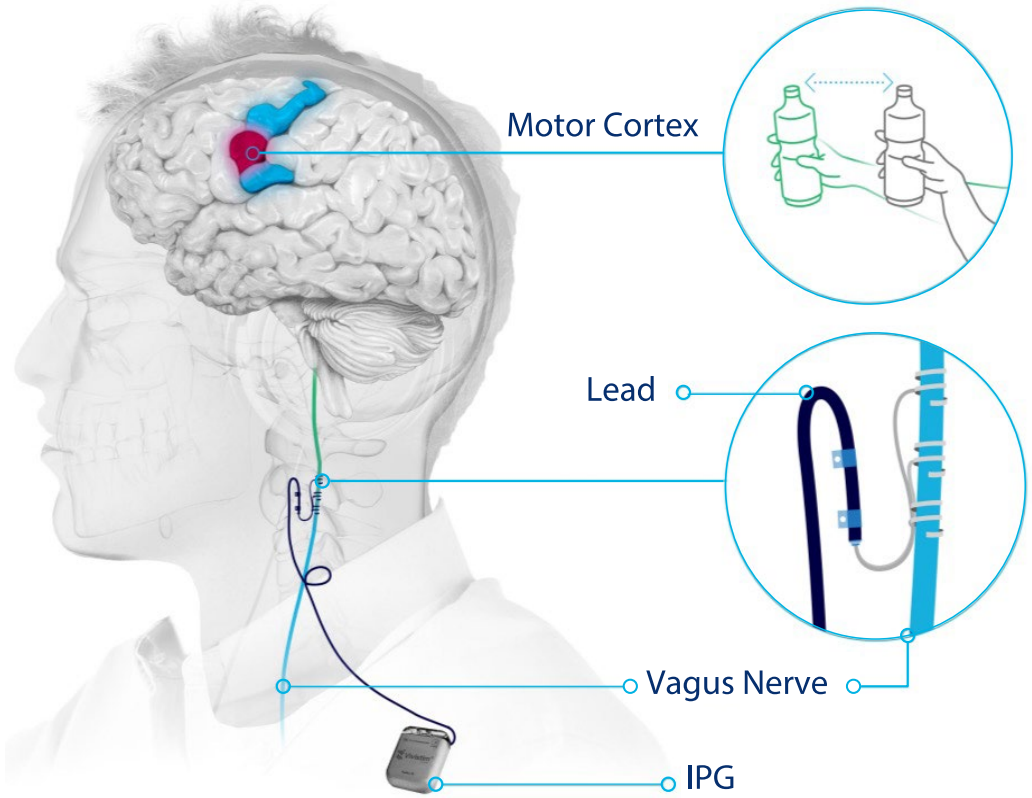
VNS Therapy for chronic stroke

Vivistim is the first FDA-approved neurostimulation device to pair vagus nerve stimulation (VNS) with upper extremity rehabilitation therapy and daily activities to help strengthen the brain connections needed to relearn motor tasks.



Pairing Vivistim with intensive rehab can result in significant and sustained improvements in arm and hand function.

1. Engineer, N D, et al. Targeted Vagus Nerve Stimulation for Rehabilitation After Stroke. Frontiers in neuroscience. 2019; 13, 280.
2. Dawson et al. Vagus nerve stimulation paired with rehabilitation for upper limb motor function after ischaemic stroke (VNS-REHAB): a randomised, blinded, pivotal, device trial. Lancet. 2021; 397 1545–1553.

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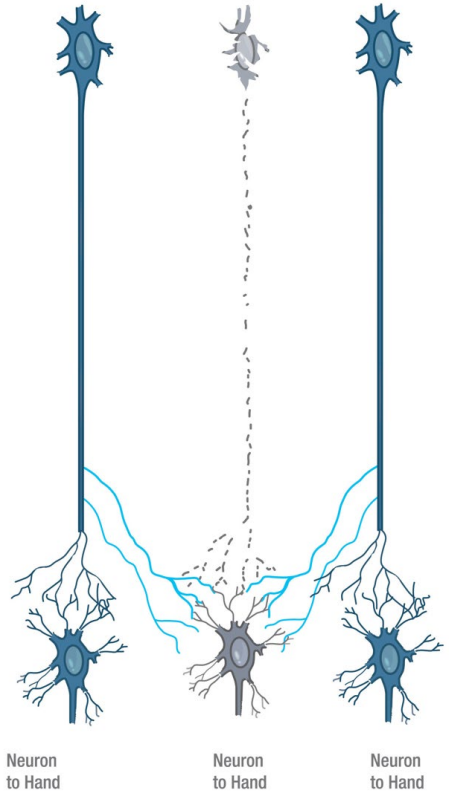
VNS Therapy works by boosting neuroplasticity

Paired VNS helps improve the brain's ability to efficiently relearn motor tasks



Paired VNS prompts release of specific neuromodulators **to activate the brain's attention system.**

High repetitions of salient, goal-driven, tasks helps **to induce motor learning.**

New neuronal connections are formed that bypass the areas damaged by the stroke.

1. Engineer, N D, et al. Targeted Vagus Nerve Stimulation for Rehabilitation After Stroke. Frontiers in neuroscience. 2019; 13, 280.

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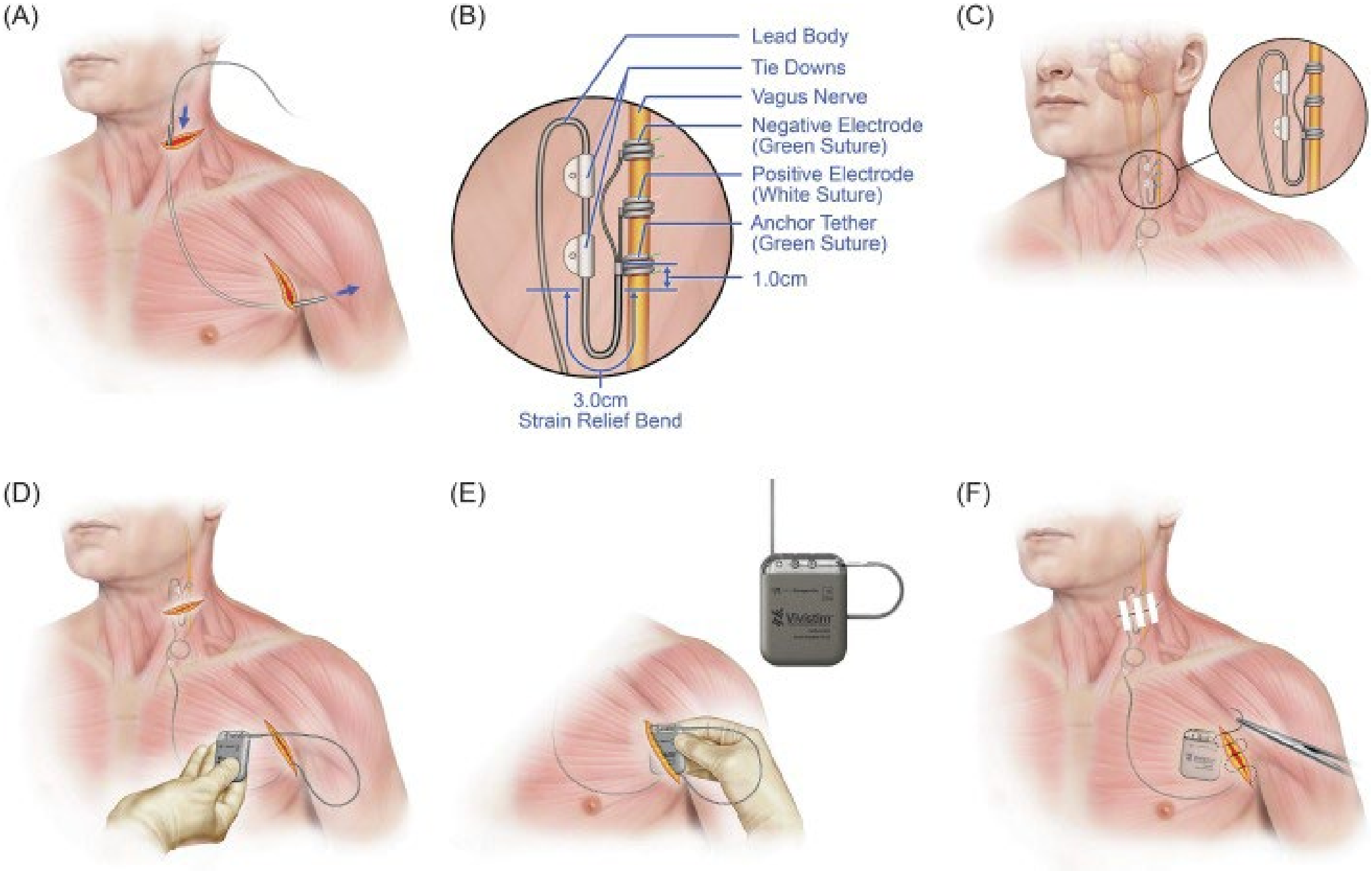

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THE LANCET

Published in final edited form as:
Lancet. 2021 April 24; 397(10284): 1545–1553. doi:10.1016/S0140-6736(21)00475-X.

Vagus Nerve Stimulation Paired with Rehabilitation for Upper Limb Motor Function After Ischaemic Stroke (VNS-REHAB): A Randomised, Blinded, Pivotal, Device Trial

Prof. Jesse Dawson, MD,

- **108 patients randomized**
  - –106 completed course of therapy
- **At 90 days, 47% exceeded minimum clinically significant improvement in Fugl-Meyer UE exam**
  - –>5.25 points

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Vagal Nerve Stimulation

Advantages

- **Strong clinical trial evidence**
- **Historically a safe procedure**

Disadvantages

- **Requires surgical implant**
- **Cost!**
  - To the facility
  - To the patient?
- **Primarily focused on hand movement only**
- **Indicated for ischemic stroke only**

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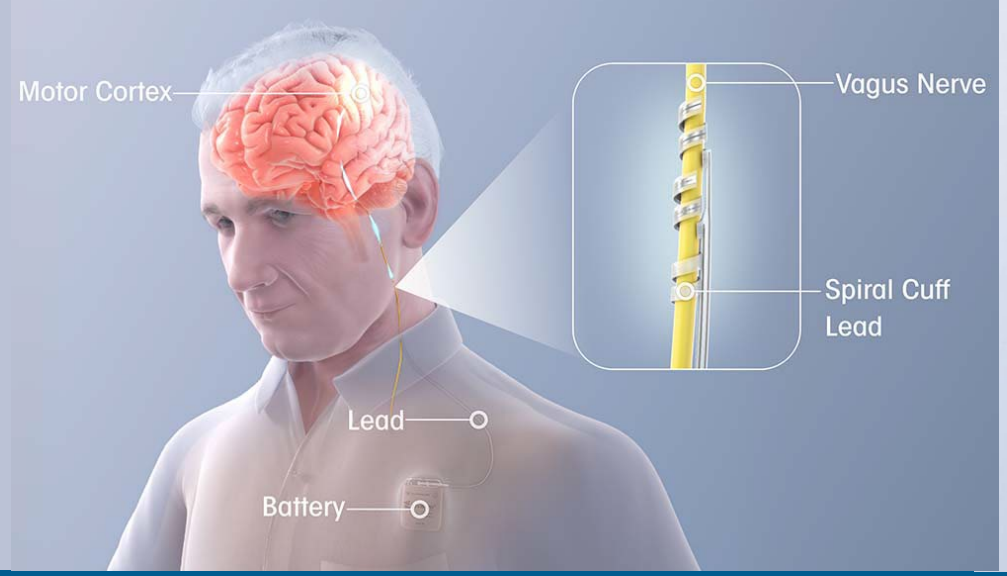

Vivistim and Stroke Rehabilitation

Rebecca Metz, PT, DPT
Physical Therapist

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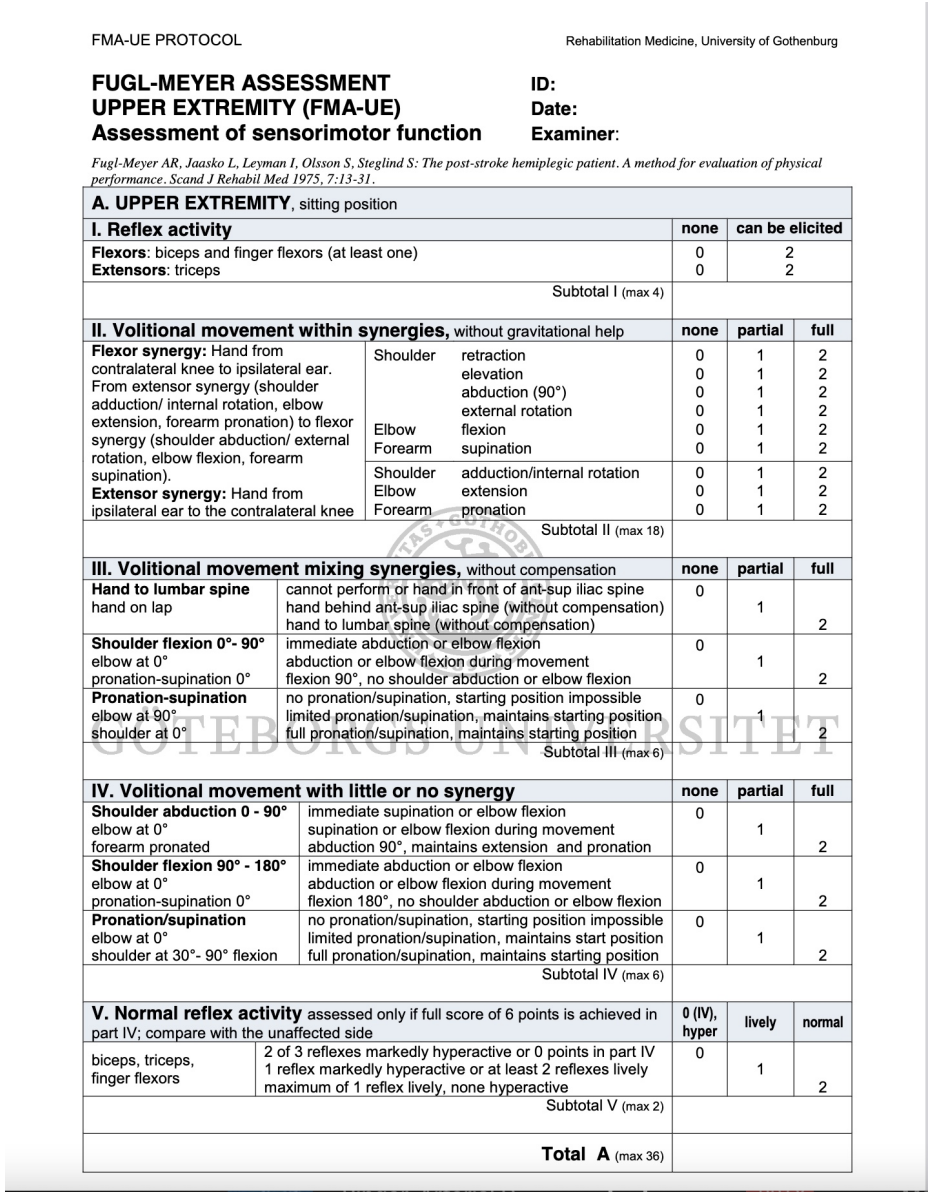
Fugl-Meyer Motor Assessment

- **FMA is used to determine appropriate candidates for Vivistim and as a functional outcome tool after placement**
- **Assessment takes 45 minutes and is done by the Physical Therapist**
- **Items scored on a 3-pointscale**
  - –0 = cannot perform
  - –1 = performs partially
  - –2 = performs fully
- **Must score at least 20 out of 66 on Motor Function UE**



FMA-UE PROTOCOL — Rehabilitation Medicine, University of Gothenburg

FUGL-MEYER ASSESSMENT
UPPER EXTREMITY (FMA-UE)
Assessment of sensorimotor function

ID: **Date:** **Examiner:**

Fugl-Meyer AR, Jaasko L, Leyman I, Olsson S, Steglind S: The post-stroke hemiplegic patient. A method for evaluation of physical performance. Scand J Rehabil Med 1975, 7:13-31.

A. UPPER EXTREMITY, sitting position

I. Reflex activity		**none**	**can be elicited**
Flexors: biceps and finger flexors (at least one)		0	2
Extensors: triceps		0	2
	Subtotal I (max 4)		

II. Volitional movement within synergies, without gravitational help			**none**	**partial**	**full**
Flexor synergy: Hand from contralateral knee to ipsilateral ear. From extensor synergy (shoulder adduction/ internal rotation, elbow extension, forearm pronation) to flexor synergy (shoulder abduction/ external rotation, elbow flexion, forearm supination).	Shoulder	retraction	0	1	2
		elevation	0	1	2
		abduction (90°)	0	1	2
		external rotation	0	1	2
	Elbow	flexion	0	1	2
	Forearm	supination	0	1	2
Extensor synergy: Hand from ipsilateral ear to the contralateral knee	Shoulder	adduction/internal rotation	0	1	2
	Elbow	extension	0	1	2
	Forearm	pronation	0	1	2
		Subtotal II (max 18)			

III. Volitional movement mixing synergies, without compensation		**none**	**partial**	**full**
Hand to lumbar spine hand on lap	cannot perform or hand in front of ant-sup iliac spine hand behind ant-sup iliac spine (without compensation) hand to lumbar spine (without compensation)	0	1	2
Shoulder flexion 0°- 90° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 90°, no shoulder abduction or elbow flexion	0	1	2
Pronation-supination elbow at 90° shoulder at 0°	no pronation/supination, starting position impossible limited pronation/supination, maintains starting position full pronation/supination, maintains starting position	0	1	2
	Subtotal III (max 6)			

IV. Volitional movement with little or no synergy		**none**	**partial**	**full**
Shoulder abduction 0 - 90° elbow at 0° forearm pronated	immediate supination or elbow flexion supination or elbow flexion during movement abduction 90°, maintains extension and pronation	0	1	2
Shoulder flexion 90° - 180° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 180°, no shoulder abduction or elbow flexion	0	1	2
Pronation/supination elbow at 0° shoulder at 30°- 90° flexion	no pronation/supination, starting position impossible limited pronation/supination, maintains start position full pronation/supination, maintains starting position	0	1	2
	Subtotal IV (max 6)			

V. Normal reflex activity assessed only if full score of 6 points is achieved in part IV; compare with the unaffected side		**0 (IV), hyper**	**lively**	**normal**
biceps, triceps, finger flexors	2 of 3 reflexes markedly hyperactive or 0 points in part IV 1 reflex markedly hyperactive or at least 2 reflexes lively maximum of 1 reflex lively, none hyperactive	0	1	2
	Subtotal V (max 2)			
	Total A (max 36)			

Principles of Paired VNS Rehabilitation

Active movement	• Active motion, without assistance from the therapist • Active-assisted movement and proximal arm support used sparingly • Passive motion should not be paired with VNS
Task specificity	• Goal-directed practice, focus on functional tasks that are meaningful to the individual
High repetitions	• High repetitions per session
Active engagement	• Training must be sufficiently salient to induce plasticity. Optimal learning occurs with high levels of motivation, attention, and engagement
Individualized practice	• Exercises are appropriately graded and progressed to adjust the difficulty level and maintain attention and engagement
Massed practice	• Practicing the same exercise (or similar) in one block of time as opposed to spreading practice over time
Variable practice	• Variability in task practice to maintain engagement and motivation • Exercise components remain the same, but the context is changed between repetitions or sessions

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Regimen Leverages In-Clinic and Out-of-Clinic Activities

In Clinic

Therapist activates VNS during functional, task-specific therapy

Tasks should be salient, driven by each patient's functional goals

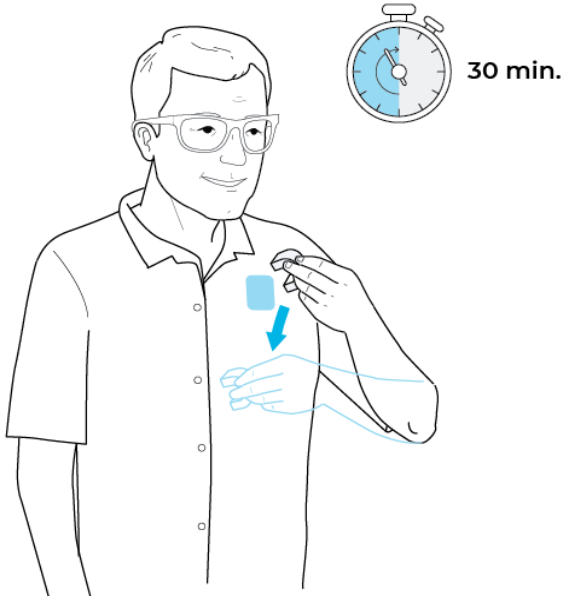
Sessions are 90 mins, 3x per week for a minimum of 6 weeks

Goal is to complete ≥300-500 movement repetitions per session

Out of Clinic

Patients also activate VNS with a magnet while doing daily activities with their affected arm

Self-activated sessions can be done up to 8x per day



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Paired VNS Protocol Resulting in Improved Patient Outcomes

In-Clinic Paired VNS			
Minimum Session Duration	**Weekly Frequency**	**Total Number Sessions**	**Repetitions per session***
90 min	3x	18	300-500

*Functional tasks should be meaningful to the individual with enough variability in task practice to maintain engagement and motivation.

At-Home Paired VNS		
Device Activation	**Daily Frequency**	**Duration per Swipe***
Patient swipes immediately before practicing desired motor activities	1 to 8 times	30 minutes

Therapists drive the outcomes with this therapy!

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Therapy Task Examples

Therapist will decide which tasks the patient should practice based on the goals set at the initial evaluation. The focus in on training functional tasks.

Examples of tasks included in the Vivistim clinic trials:

- Reach, grasp and release
- Gross motion
- Simulated feeding activities
- Release objects
- Open/close

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VNS Triggering Promotes Neuroplasticity

- Each movement repetition is associated with a **brief pulse of VNS** delivered by the therapist that releases the neurotransmitters responsible for inducing learning
- Therapist triggers VNS at a **key part of the task and while the patient is actively attempting the movement** (VNS is triggered even when the active attempt is not successful) to reinforce what the brain needs to learn and reinforcing new neuronal pathways
- For tasks involving a **sequence of movements**, the therapist may deliver more than one VNS pulse at specific points during a given movement

Home Therapy Examples






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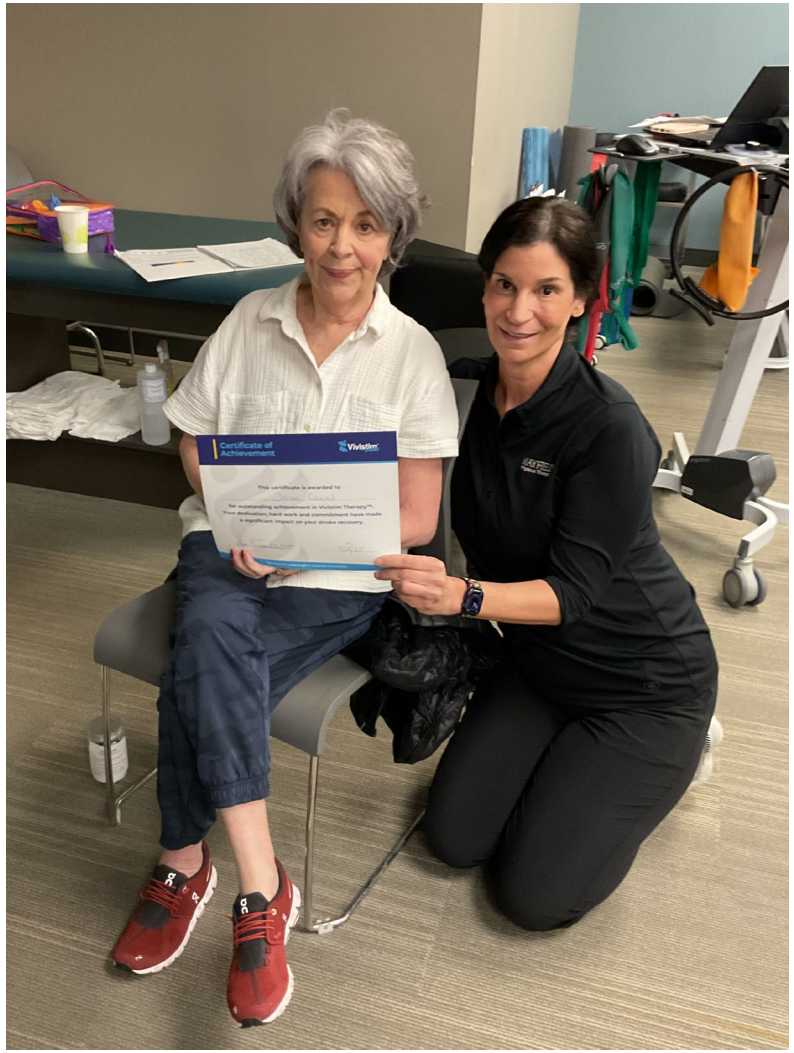
Mayfield Physical Therapy and Vivistim – Real Patient Stories



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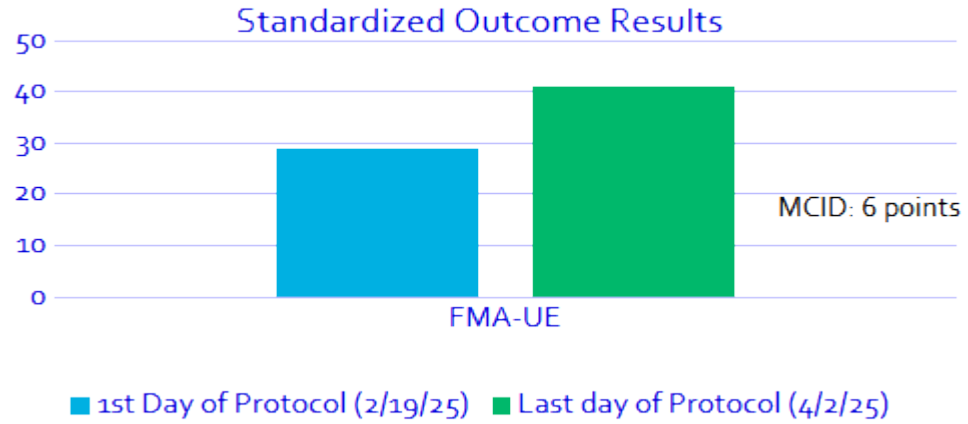
73 y/o Female, 3 years Post Ischemic Stroke Affecting Left Upper Extremity

Goals:	Functional gains:
- Use LUE to pull up pants - Be able to brush hair using hairbrush - Begin to practice typing	- Can pull up/take off pants using LUE - Able to open doors with different handles - Hung up coat with LUE for first time



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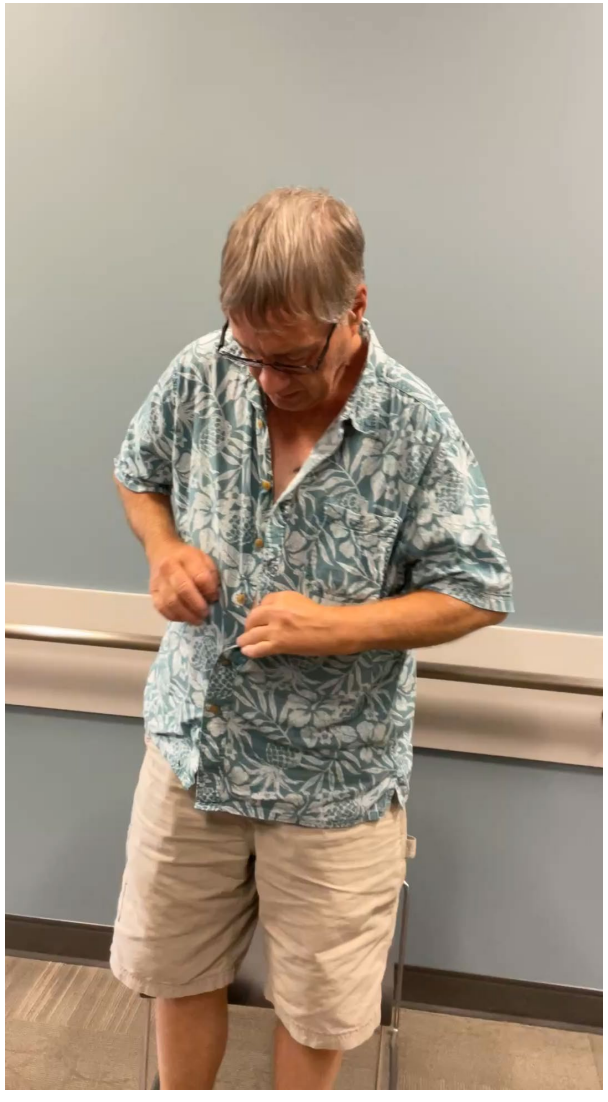
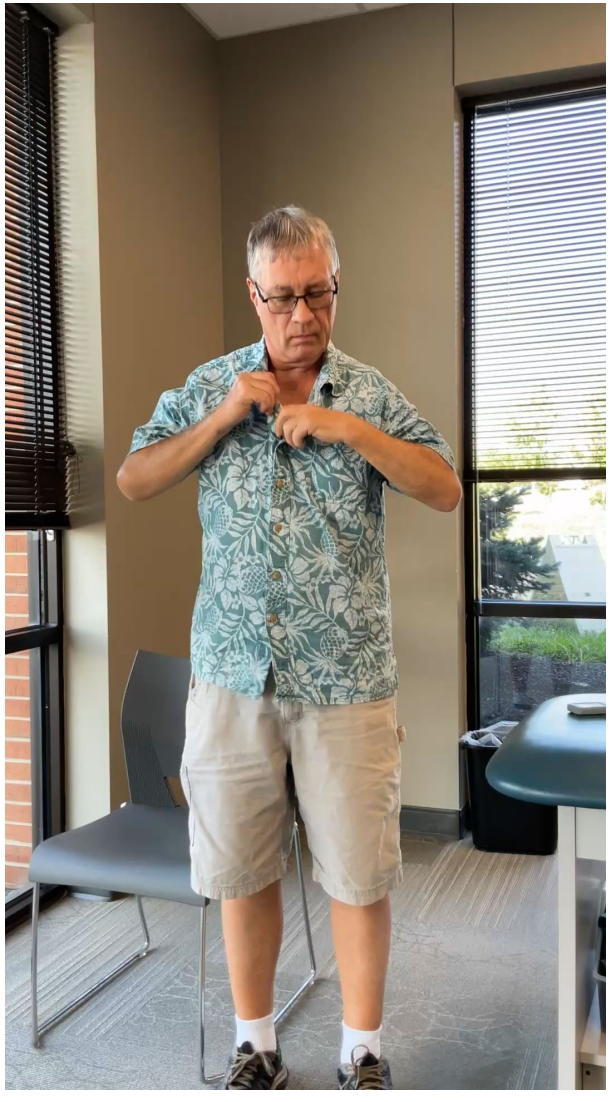
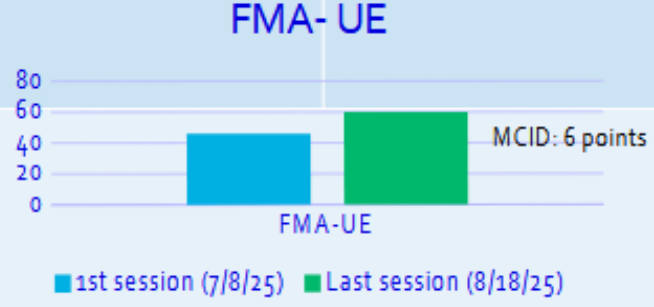
65 y/o Male, 2 Years Post Ischemic Stroke Affecting Left Upper Extremity





Goals:	Functional gains:
• To be able to button his shirt and tie shoes • Brush teeth with L hand • Hold objects in L hand without dropping while simultaneously using R hand	• Can hold onto the rake without L hand slipping while gardening • Eats cereal with L hand without spilling • Improved handwriting • Can button/unbutton shirt with improved efficiency



QUESTIONS

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