Vagus Nerve Stimulation for Improving Upper Motor Function After Brain Injury

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Disclosures

- Maggie Meixell, OTR/L, CSRS: none
- Beth Sher OTR/L: none
- Jenna Price, OTR/L, CBIS:
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Objectives

- Provide an introduction to stroke including incidence, prevalence, signs and symptoms, and functional impacts
- Present therapeutic approaches to improving motor function after stroke including the current gold standard and experimental approaches
- Share information regarding vagus nerve stimulation in general and an FDA approved, surgically-implanted, vagus nerve stimulation device used to help improve upper limb motor deficits after stroke and the therapeutic approaches to surgical follow-up
- Discuss a research registry designed to collect acute and long-term follow-up data on implanted patients treated with paired vagus nerve stimulation

Introduction to and Overview of Stroke

Maggie Meixell, OTR/L, CSRS

Stroke: An Overview

- Each year, over 795,000 people in the United States experience a stroke
- Stroke-related costs come to over $55 billion each year
- Stroke is the third most common cause of death and the main cause of adult disability in the US and EU
- The largest effect on stroke survivors and their families is the long term impairments that limit functioning and participation in valued activities

Types of Strokes

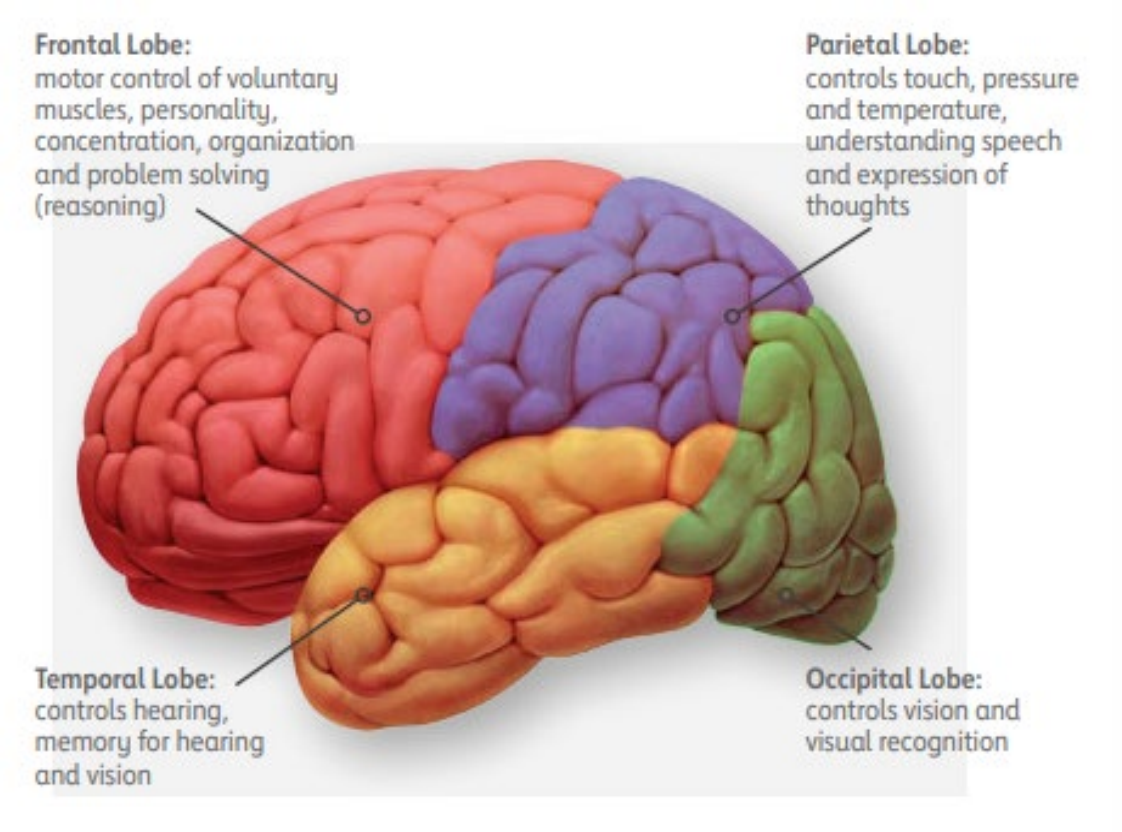
Ischemic stroke

- More common (87% of strokes)
- Caused by a blockage of blood flow to the brain
- Treated with thrombolytic drugs in the first hours after an acute stroke

Hemorrhagic stroke

- Less common (13% of strokes)
- Brain bleed caused by weakened blood vessels
- Surgical treatment may be used to stop the bleeding

Signs and Symptoms



Weakness on one side of the body	Difficulty speaking
Trouble swallowing	Fatigue
Changes in mood	Cognitive changes
Behavior changes	Decreased vision

"Let's Talk About Stroke" 2022 American Stroke Association

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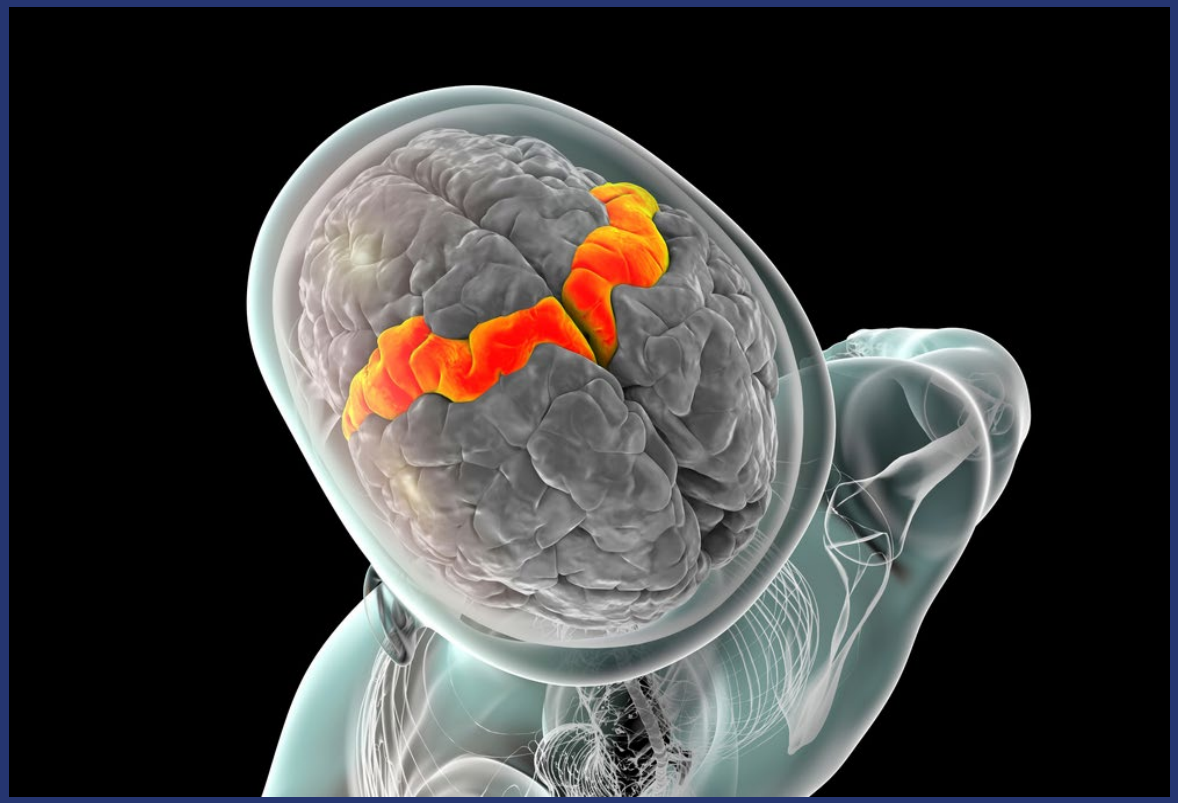
Motor Impairments following Stroke

- Motor impairment affects about 50%-80% of stroke survivors
- Often caused by strokes in the motor cortex in the frontal lobe or associated pathways in the cerebrum or cerebellum



Kateryna Kon, Shutterstock

Common Motor Impairments

- Hemiparesis: Partial weakness of one side of the body
- Hemiplegia: Complete loss of movement on one side
- Fine motor dysfunction: Difficulty with coordination and dexterity
- Spasticity and contractures: Increased muscle tone leading to stiffness and reduced range of motion

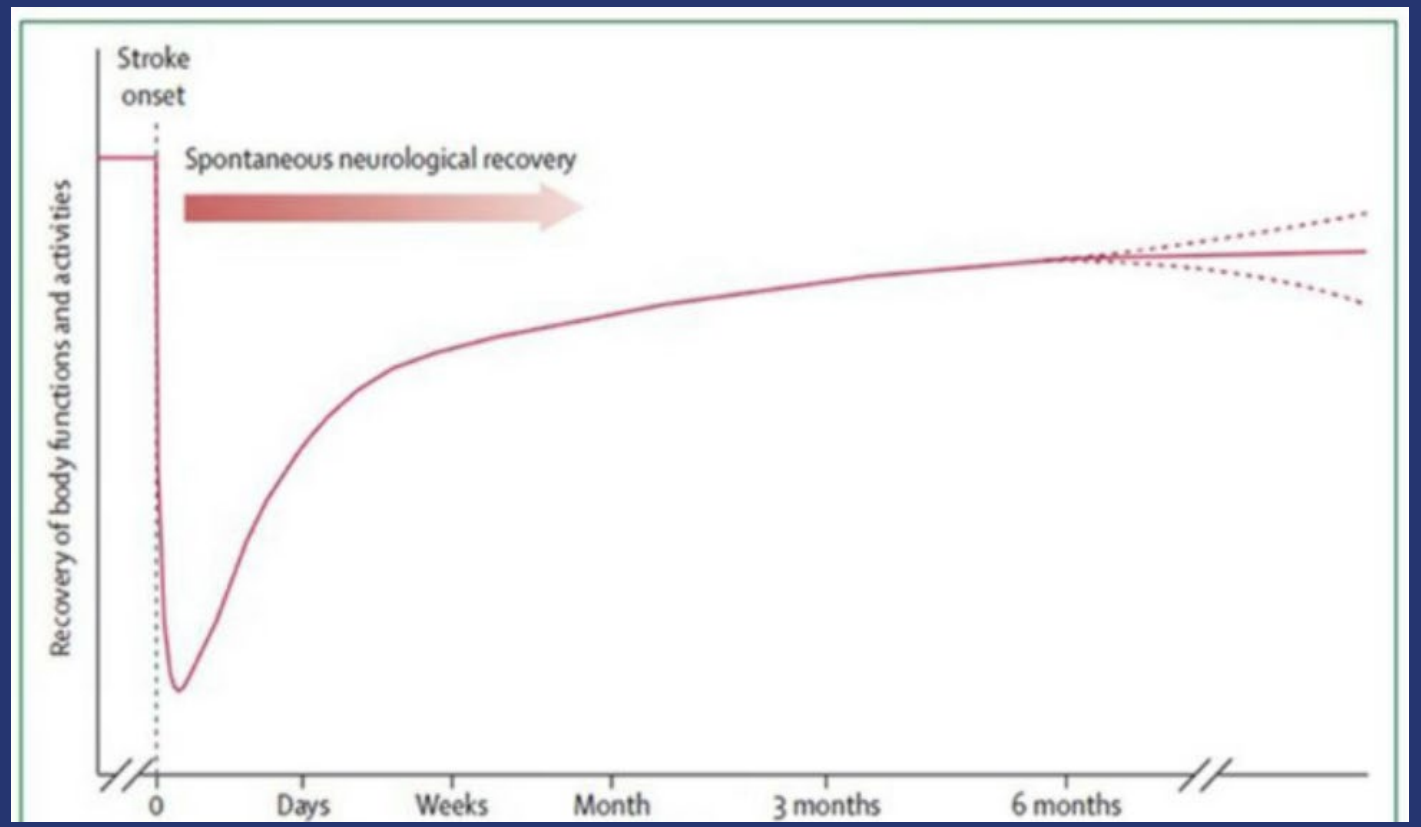
Upper Extremity Functioning

- Activities of daily living (ADLs) rely heavily on upper extremity functioning
- Loss of upper extremity functioning tends to reduce participation in meaningful activities and engagement in society
- Stroke survivors with upper extremity impairments consistently score worse on subjective measures of anxiety, quality of life, and overall well-being.

Chronic stroke: an unsolved case

- Long term stroke recovery is dependent on several factors
  - Age, sex, location of the stroke, comorbidities, and severity of initial impairments
- Initial severity of motor impairment is the biggest predictor of recovery
- Recovery is often slower and less complete for the arm compared to the leg

Chronic stroke: an unsolved case



Biggest improvements tend to occur in the first 3 months post-stroke.
After 6 months, functioning can plateau or even worsen over time

Hatem SM et al. Rehabilitation of Motor Function after Stroke: A Multiple Systematic Review Focused on Techniques to Stimulate Upper Extremity Recovery. Front Hum Neurosci. 2016;10:442.

Chronic Stroke: an unsolved case

Improving acute stroke survival rates

An aging population

Increased number of stroke survivors living with a disability

Therapeutic Approaches to Improving Motor Function After Stroke

Beth Sher OTR/L

Conventional Rehabilitation Therapy

Physical: Strength, Lower Limb Movement, Gait, Balance, Bed mobility

Occupational: ADL's, UE Function, Vision, Driving, IADL's

Speech: Communication, Language Impairments, Swallowing

Therapy uses Neurodevelopmental treatment (NDT), Proprioceptive Neuromuscular Facilitation/Inhibition, Functional training, and Motor learning

Constraint Induced Therapy (CIMT)

- Focus is on constraining the non-affected side, Forcing the use of affected side completing repetitive tasks
- Original Protocol: 6 hours of therapy a day for 2 weeks
- Modified CIMT: Practiced for 30mts.- 3 hours of therapy over 10 sessions

Mental Practice

Mental Practice; visualizing movements to help brain form neural connections.

Paired with conventional therapy

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Brain –Computer Interface (BCI)

Systems that establish a direct communication pathway between brain electrical activity and external devices- often using electrodes- to detect brain signals during visualization and links them to electrical stimulation of the affected limb.

Robotic Therapy for the Upper Limb

Armeo Spring

A-6-m2 Upper Limb Intelligent Isokinetic trainer

Virtual Reality (VR)

Other devices for the UE:

Smart Gloves, BIONESS (using NMES) , ARMin, ReHabticKnob, SEM glove, REAplan, Bilateral robot-assisted mirror therapy

Robotic Therapy for the Lower Limb

- Loko Mat PRO provide weight supported gait
- ExoSkeltons

Advantages & Disadvantages

- High intensity Repetitions: Robots allow for hundreds of repetitions which is hard to achieve with traditional manual therapy.

- Objective Metrics: Technologies provide real-time data on quality and improvements

- **High acquisition Cost**
- **Maintenance cost**
- **Technical complexity & Set up Time**
- **Lack of human interaction**
- **Limited Space and Infrastructure**
- **Need for more clear evidence that it is superior to Conventional therapy**

This involves practicing activities specific to one's goals.
Practicing every day activities
like cutting food or folding clothes.

Task Specific Exercise Therapy (TST)

Vagus Nerve Stimulation (VNS)

Jenna Price, OTR/L, CBIS

Disclaimer

Jenna Price, OTR/L, CBIS does not have any financial ties to Vivistim or Mobia Medical for this presentation.

What is a Vagus Nerve Stimulator?

- An implanted device that stimulates the Vagus Nerve which in turn activates the brain
- Has been approved for uses in epilepsy, depression, and now in stroke rehabilitation
- Helps to increase and facilitate neuroplasticity in the chronic CVA population

Paired VNS in Stroke Rehabilitation

- FDA approved for Chronic Ischemic Stroke with Upper Limb Impairment

- Pairs intense, high repetition, saliant, traditional therapy methods with the benefits of VNS stimulation

The Research

Research Suggests

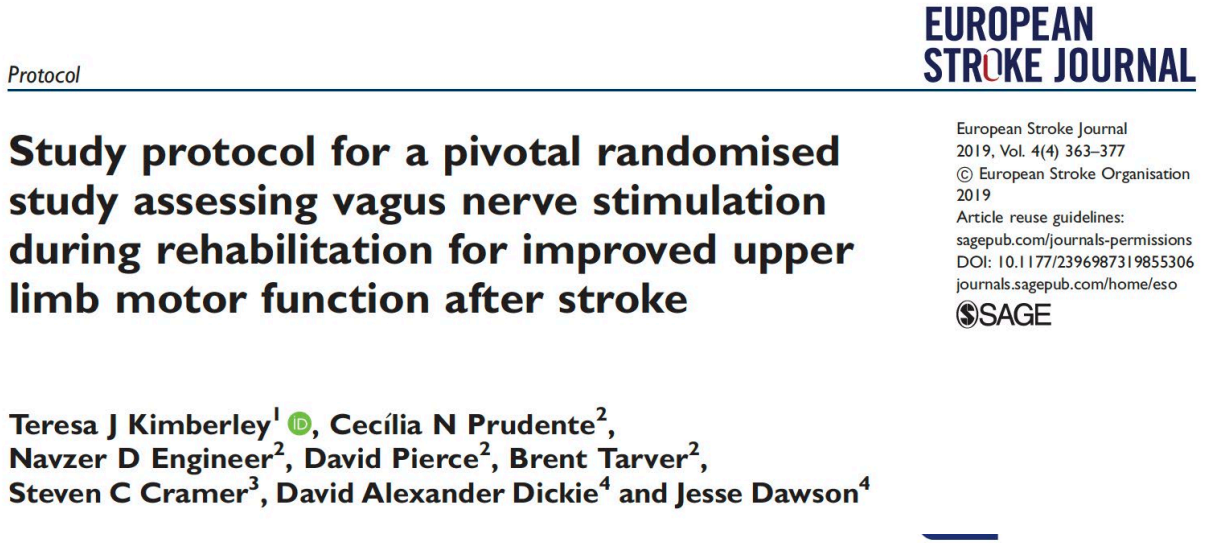
High numbers of upper extremity repetitions are required for neuroplastic changes

Repetitions should require “active engagement” and be functionally relevant

Therapy Protocol from Pivotal Trial as a Guide

- Approx 30-50 repetitions in each category
- Graded and progressed to require challenge/success
- Requires preparation and planning
- Total **reps** 300-500
- Total **stimulations** will be more than that (because some tasks get more than 1 stim)

- Reach and grasp objects
- Gross Movement
- Flip objects
- Eating tasks
- Insert objects
- Open and close containers
- Patient-specific goal



Protocol

EUROPEAN STROKE JOURNAL

Study protocol for a pivotal randomised study assessing vagus nerve stimulation during rehabilitation for improved upper limb motor function after stroke

European Stroke Journal
2019, Vol. 4(4) 363–377

DOI: 10.1177/2396987319855306
journals.sagepub.com/home/eso
SAGE

Teresa J Kimberley[1], Cecília N Prudente[2], Navzer D Engineer[2], David Pierce[2], Brent Tarver[2], Steven C Cramer[3], David Alexander Dickie[4] and Jesse Dawson[4]

The Pivotal Study

- Triple Blind Random Control Trial
  - All participants were given the VNS
    - Group 1 – VNS implanted and turned on
    - Group 2 – VNS implanted but not turned on
  - Both were provided with same therapy protocol for 6 weeks
    - Group 1 showed significant improvements in FMA scores compared to Group 2
  - After initial treatment, Group 2 VNS was then turned on and followed the protocol
    - Scores after 6 weeks met with Group 1

Long Term Results

RESEARCH ARTICLE | Originally Published 7 May 2025 |

Check for updates

Long-Term Outcomes of Vagus Nerve Stimulation Paired With Upper Extremity Rehabilitation After Stroke

Teresa J. Kimberley, PhD, Steven C. Cramer, MD, Steven L. Wolf, PhD, Charles Liu, MD, Perman Gochyyev, PhD, and Jesse Dawson, MD VNS-REHAB Trial Group | AUTHOR INFO & AFFILIATIONS

Stroke • Volume 56, Number 8 • https://doi.org/10.1161/STROKEAHA.124.050479

- 74 participants from the pivital study
- 1-year follow up after completion of 6-week protocol
- Those treated with paired VNS maintained Long Term improvements both in function and in quality of life

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Referral Process and Determining Candidacy

Referral from Physician

- Ischemic Stroke in the Chronic Phase (> 6 months post)
- Able to demonstrate active movement in affected limb (such as using limb as a functional assist, able to demonstrate some digit movement, fair proximal control and strength)

Therapy Assessment

- Do they meet evaluation criteria?
- Is tone/spasticity well managed?
- Are they able to consistently come to therapy 3x/week for 6 weeks?
- Can they tolerate 90 minutes of therapy?
- Do they have specific goals you want to accomplish?
- Are they motivated? Will do home programs? Have a good support system?

Surgical Consult/Insurance Verification

- Make sure the patient is healthy enough for surgery
- Ensure patient's insurance will cover device along with therapy protocol

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Types of Clients

‘Not Yet’ Client

- Minimal to no UE movement
- Poor follow through with home programs in the past
- Poor awareness
- Minimal to no family support
- Benefit restrictions
- Not in Chronic Phase/Not ischemic stroke
- High, uncontrolled tone

- Home Programs!
- Refer to community settings
- Educate on the FDA approval
- Educate on tone management, implement splinting/casting as needed
- Work on improving awareness and attention to affected limb
- Work on improving function of limb through "traditional therapy" techniques

‘Almost’ Client

- Good proximal movement
- Minimal-no hand function
- Fair-good follow through with home programs
- Fair-good family support
- Fair-good insurance benefits
- Fair-good motivation
- Fair-good endurance
- Mod-High tone, somewhat controlled

- See patient for "traditional therapy"
- Review home programs
- Complete family and patient training and education
- Educate on device and benefits
- Focus on areas that they are lacking in therapy while they continue to work on proximal movement at home
- Education on tone management

‘Lower Level’ Client

- Good proximal movement
- Minimal-fair hand function
  - Able to complete grasp and release of a poker chip
- Fair-good follow through with home programs
- Fair-good family support
- Fair-good benefits
- Fair-good motivation
- Fair-good endurance
- FMA 15-25
- Reliable transportation
- Min-mod tone, fairly managed

- See patient for traditional therapy, if possible
- Review home programs
- Complete family and patient training and education
- Educate on device and benefits
- Complete referral to surgeon and VNS
- Work on improving endurance
- Further assess for tone needs or adaptive device needs

Ideal

- Fair-Good endurance
- FMA of 25 or more
- High Motivation
- Specific Goals
- Good family/social support
- Reliable transportation

- Complete referral to surgeon
- Discuss with client process and protocol
- Complete education on VNS
- Decide on POC
  - See pt in clinic until surgery
  - Continue with HEP
- Review and re-educate on HEP

After Surgical Implant

- Seen for OT evaluation approximately 2 weeks after implant
- Education and training is completed by VNS representative along with the Occupational Therapist
- Evaluations are completed that include, but not limited to
  - Self-Assessment
  - FMA-UE
  - Box and Blocks
  - 9-Hole Peg Test
- Goals are established

Therapy Protocol

- 3x/week for 6 weeks (18 total therapy sessions)
- 90 min sessions (can be OT only or OT/PT combined)
  - Saliant
  - High Repetitions
  - Task-specific
- Looks very similar to traditional OT sessions
  - The VNS is triggered at strategic points during the movements and tasks

Home Program Sessions

- Up to 8 magnet swipes per day
  - Each swipe turns the VNS on for 30 minutes
- With each magnet swipe, the client is completing
  - Traditional home programs (fine motor, GE/GR exercises, strengthening, bimanual tasks, etc.)
  - Daily ADLs (dressing, grooming, bathing, feeding) with emphasis of using affected limb
  - Daily IADLs (cleaning, laundry, yard work, dishes) with emphasis on using affected limb
- Assign daily and/or weekly tasks for patients to complete at home and when not in structured treatment sessions

After Protocol and Beyond

- Encourage continuing to swipe the magnet up to 8x/day
- Have a structured home program “Improvement Playbook”
  - Organized
  - Variety of activities
  - Daily log
  - Write patient specific goals in areas that are easily visible
- Schedule Follow Ups
  - Formal – reassessment in clinic at 3-6 months post protocol
  - Informal – phone calls and email check in

VNS Results in the "Real World"

Atlantic Health System

- Assessed their first 25 patients that received Vivistim
  - 40-80 years old, 1-11 years post stroke
  - FMA scores improved from an average 33/66 to 43/66
  - 1 patient that required explanation of device at 410 days post implant maintained a 25 point FMA improvement, indicating sustained benefits

Mt. Sinai

- Assessed their first 6 patients that received Vivistim
  - Used Gamification Rehabilitation during their in-clinic training
  - FMA scores improved from by an average of 9.3 +/-3.6 points after initial 6 weeks and improved on average 14+/-6.3 points at 4 month follow up (compared to baseline)

Case Study 1

- JB is a 62 year old, right-handed male with diagnosis of R paramedian pons infarct in January 2021 resulting in left hemiparesis.
- In the Spring of 2024, JB was educated on the VNS system, initial assessment was completed, and referral was sent for surgical consult.
- Received the implant in February 2025 and started his protocol in March 2025.
- Goals: improve LUE function, return to fly fishing and hiking, and play with grandchildren

Results

Assessment	Eval	18th visit	6 Month Follow Up
FMA-UE	37/66	43/66	46/66
Grip	25.4#	24.9#	25.2#
Box and Blocks	14	23	25
Self-Assessment	47/100	69/100	n/a

Case Study 2

- CJ is a 59 year old female with a history of Moyamoya disease and ischemic CVAs in 2020 and 2021, pt reports second stroke caused L hemiparesis impacting coordination, fine motor control and overall decreased hand function
- VNS device was implanted in December 2025 and started therapy protocol in February 2026
- Goals: improve LUE function, improve handwriting, decrease reliance on family and caregivers for ADLs and IADLs.

Results

Assessment	Eval	18th visit
FMA-UE	44/66	54/66
Grip	10.4#	17#
Box and Blocks	2	7

Ability KC Results (5 clients)

Assessment	Before	18th Visit
FMA	23/ 66	41/66
Grip	11.23#	15.75#
Self-Assessment	21/100	39/100

The GRASP Research Registry

Stephanie A. Kolakowsky-Hayner, PhD, CBIST, FACRM

Introduction to GRASP: The Vivistim Registry for Post-Stroke Care

Grasp REGISTRY

THE GRASP REGISTRY collects real-world data on stroke survivors considering to or have received the Vivistim System.

THE PURPOSE is to understand long-term outcomes, support clinical decision-making, and demonstrate sustained therapy benefit for people with arm and hand deficits post-stroke.

SITES gain access to real-world outcomes data and future publication opportunities.

PATIENTS contribute to future stroke care improvements and receive continued monitoring.

MICROTRANSPONDER uses the data to understand long term benefits, improve therapy adoption, and evolve care standards.

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Patient Profiles: Who Belongs in GRASP

☑ PROSPECTIVE ☑ RETROSPECTIVE ☑ CONTROL

CANDIDATES IN-SCOPE

- Stroke survivors with upper limb motor deficits
- Patients actively considering Vivistim *(prospective)*
- Past Vivistim patients *(retrospective)*
- Patients who are not implanted with Vivistim *(control cohort)*

WHY IT MATTERS

- Advances understanding of post-stroke recovery patterns
- Generates evidence for broader access and health equity
- Empowers patients to shape the future of neuro-rehab

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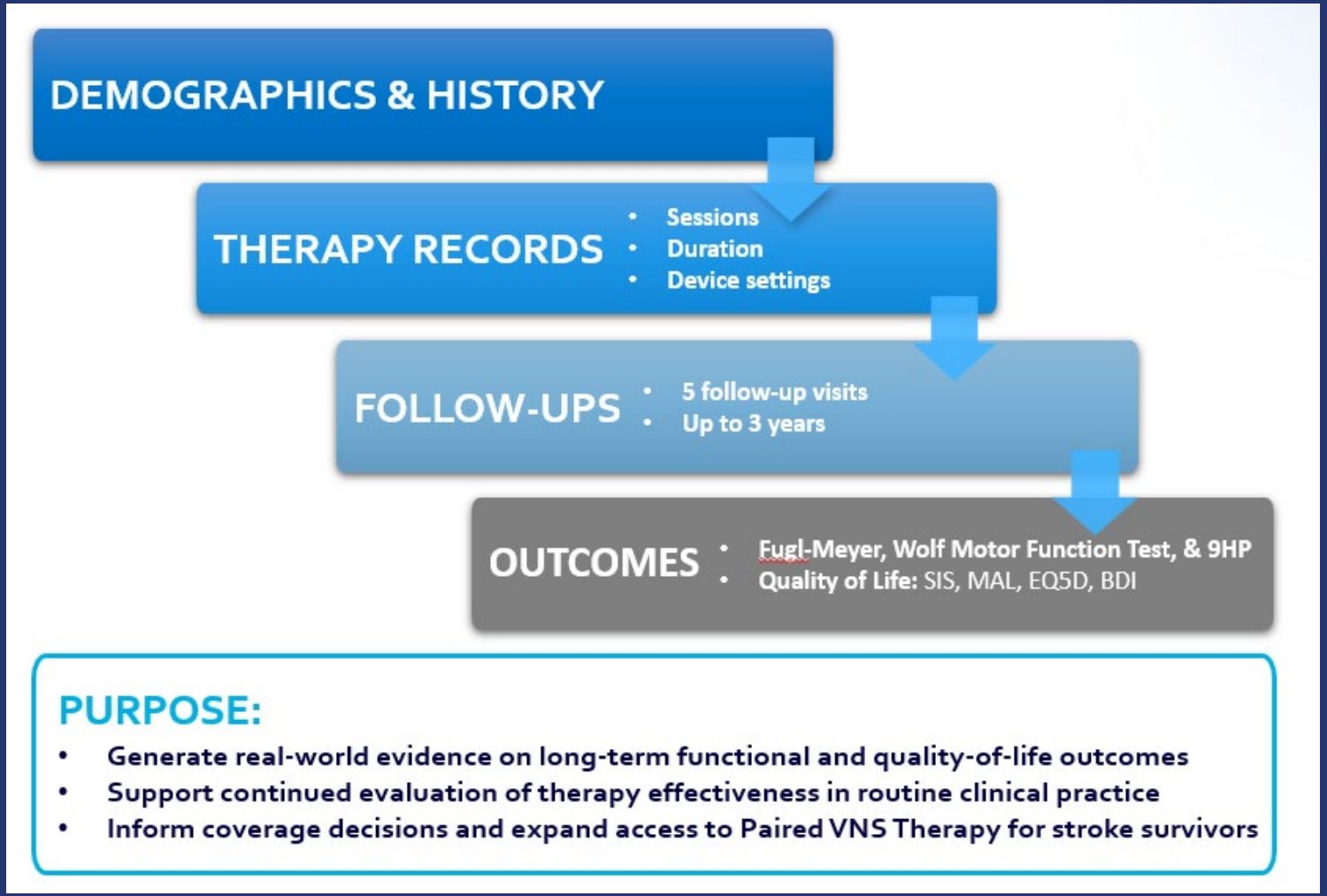
Data Collection & Follow-up: Submission Guidelines and Benchmarks



Follow-up Timeline: Simple, Sustainable Data Collection

VISIT SCHEDULE

- Baseline (pre-therapy or decision not to implant)
- 3 months, 6 months, 1 year, 2 years, 3 years

EFFORT-LIGHT MODEL

- Only 5 follow-up visits
- Registry operates independently from commercial
- Sites reimbursed for each time and properly completed form

FLEXIBLE ENROLLMENT

- Prospective patients
- Retrospective allowed
- Non-implant patients are eligible

	ENROLL	BASELINE	POST IMPLANT	END OF THERAPY	3 MONTH	6 MONTH	12 MONTH	2 YEAR	3 YEAR
GENERAL DOCUMENTATION									
Consent	X								
Demographics		X							
Surgery Details			X						
ASSESSMENT FORMS									
FMA		X			X	X	X	X	X
WMFT (Optional)		X			X	X	X	X	X
9 HP		X			X	X	X	X	X
QUALITY OF LIFE FORMS									
EQ5D		X			X	X	X	X	X
SIS		X			X	X	X	X	X
MAL		X			X	X	X	X	X
BDI		X			X	X	X	X	X
RECOVERY INSIGHTS									
Therapy Forms/ Rehab Summary				X	X	X	X	X	X
Satisfaction Surveys/ Global Impressions					X	X	X	X	X
Healthcare Utilization		X					X	X	X

IMPLANTED PATIENTS: All follow-up time frames are based on the implant date.

NON-IMPLANTED PATIENTS: All follow-up time frames are based on the date of registry entry.

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Frequently Asked Questions

Q:	**Are the timepoints the same as the pivotal study?**	**A:**	No. For the Vivistim Grasp Registry, data will be collected at baseline, 3, 6, and 12 months after implantation, as well as yearly thereafter for up to three (3) years post-implant.
Q:	**When is the Baseline visit?**	**A:**	Baseline is after enrollment but typically before implant; it must be performed prior to the start of therapy to receive payment.
Q:	**How does someone who is considering the implant sign-up to participate in the Vivistim Grasp Registry?**	**A:**	Once a site has IRB approval, the site investigator discusses the Vivistim Grasp Registry with the patient and reviews the informed consent with the patient. Once the patient signs the consent, they are enrolled into the Registry.
Q:	**Who is eligible for the Vivistim GRASP Registry?**	**A:**	People who meet the requirements for Vivistim implant are eligible for the Registry.
Q:	**What activities do participants complete for this Registry?**	**A:**	Vivistim patients receive therapy as part of their ongoing (non-Registry) treatment. Registry participants should complete questionnaires and have assessments performed by registry personnel.
Q:	**Is the Registry information secure?**	**A:**	Yes. All information is stored in a HIPAA compliant electronic database system.
Q:	**Why should a patient who has been implanted participate? What will the data be used for?**	**A:**	The information collected will provide aggregated real-world usage and outcomes data on the Vivistim System. The Registry will collect acute and long-term follow-up data on Vivistim implanted patients treated with Paired VNS™. Participation in the Vivistim Registry does not impact Vivistim treatment or therapy.

Frequently Asked Questions (continued)

Q:	**Where can I learn more information about the registry?**	**A:**	https://clinicaltrials.gov/ct2/show/NCT05301140
Q:	**What if a potential participant reads something on the consent form that they don't agree with?**	**A:**	There is no obligation to join the Registry. The site's registry coordinator or registry investigator can discuss questions with the patient. If the patient does not agree with the consent form, then they should not consent.
Q:	**Can a participant leave the Registry after it has begun?**	**A:**	Yes, they can withdraw their consent at any time.
Q:	**Will your company be providing sponsor conducted audits/monitor visits?**	**A:**	It has not yet been determined if monitoring visits will be performed; if performed, they may be done remotely or in-person.
Q:	**Will this study be using an external payment Management Portal, such as Greenphire?**	**A:**	No, an external payment portal will not be utilized.
Q:	**Are there plans for publication?**	**A:**	It is intended that aggregated data will be published.
Q:	**Does a CDA need to be developed?**	**A:**	A draft CTA template is provided within the start-up materials and includes a confidentiality section.
Q:	**How will payments be made to the sites?**	**A:**	Payments are made via wire transfer using payment information included within the CTA.

Thank you for your attention!

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