STIMUNERVE

amputation rate increasing

every 30 seconds a *leg* is amputated

85% amputations because diabetic foot ulcer

diabetics in the world

people with diabetes 4x from 1980 to 2014

2x increase in major amputations & degree of tissue loss for vascular surgery patients after COVID-19

~50-80% of amputees suffer from Phantom Limb Pain

phantom limb pain (PLP)

= pain that is felt in the area of amputation

- Very contemporary → Theories as to why phantom limb pain occurs are still being researched today
- stems from tangled sensory wires and mixed signals from the brain → mismatch between movement and the perception of that movement → pain
- can last from seconds, to minutes, to hours, to days

effects

- limits quality of life + functional capacity (work)
- related to psychological ill effects [suicidal ideation/self-harm]
- negatively affects interpersonal relationships
- difficult to comfortably wear prosthetic device

current treatment

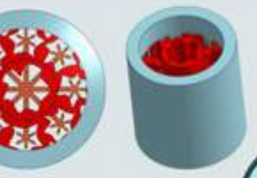
- Medication
- various forms of electrical stimulation
- acupuncture
- massage
- mirror box therapy
- virtual reality therapy

benefit

- Reduce reliance on opioids
- reducing/eliminating PLP
- Improve quality of life, rehabilitate and regain function faster

Overview

- nerve implantation that stimulates the peripheral nerve (sciatic nerve) by combining electrical leads with a scaffold
- electrical stimulation blocks the pain receptors, which stops the pain messages from being sent to the brain
- powered by an external battery placed near the knee
  - connected by a wire that goes through the leg
- remotely controlled with an app for when PLP is felt

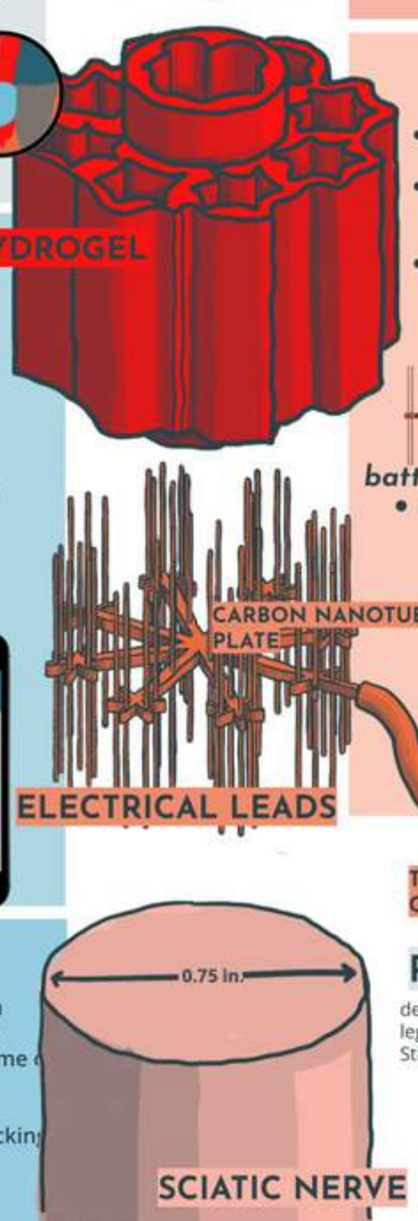


app (User Interface)

- controlled wirelessly via bluetooth
- different levels of stimulation can then be selected
- track electrical stimulation → does not exceed the threshold amount → avoid tissue damage
- threshold ≈ 2 hours of stimulation/day for 3 years
- notify of potential tissue damage that may occur based on their record of stimulation
- alert when the batteries are running low

value

- scaffold reduces foreign body reactions
- more direct control of nerve stimulation through implantation and nerve growth
- Electrode structure reaches higher volume of nerve → more likely to reach all/most fascicles
- User controls stimulation amount & tracking information
- Only tissue engineering device directed towards phantom limb pain specifically



scaffold

- using hydrogel-SIS scaffold to encase the threads
  - Biodegradable
  - will dissolve and be replaced by regrown axons
- wrapped in a small intestinal submucosa (SIS) to replace damaged tissues in the human body

→ enable restorative growth + reduce the foreign body reaction

- scaffold coated in nerve-growth factors (NGF) and glial cell line-derived neurotrophic factor (GDNF) to promote growth
- Scaffold optimized to have large surface area to volume ratio for largest uptake of growth factors

electrical

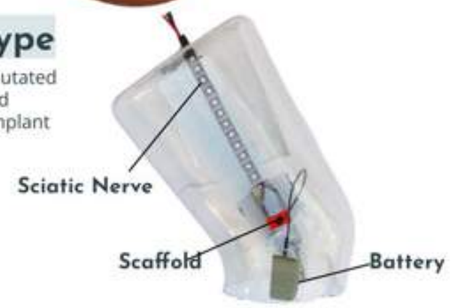
- guide nerve growth and embedded into the nerve
- structure allow for greater volume of the nerve to be covered & greater chance of hitting more nerve fascicles
- electrodes covered in silk → combat the mismatch between the mechanical components and the tissue → prevent foreign body reaction

battery

- powered by a 4.1 volt rechargeable lithium battery (made specifically for neuromodulation devices)
  - Superior reliability: almost no passive discharge → can be stored for decades and still operate to full capacity
  - small size and weight: 2.5 grams
  - can operate at 100% capacity for 1,000 cycles and then 80% capacity afterwards.

Prototype

depicting amputated leg portion and StimuNerve implant



Career Implications

patient

- Amputees with damaged tissue
- Those with peripheral nerve pain

practitioner

- Pain management specialist
  - Recommend this device
- Neurologist
  - Scans to detect nerve for surgery
- Neurological surgeon
  - Implant device in patient
- Physiatrist & Physical therapists
  - Help physically + emotionally after surgery

development

- Biomedical engineers
  - Tissue engineers
    - creating tissue/testing effectiveness in body
  - Peripheral nerve tissue engineering
- Biomaterial scientist
  - biomaterials [Carbon Nanotubes, silk, hydrogels]

FDA approval

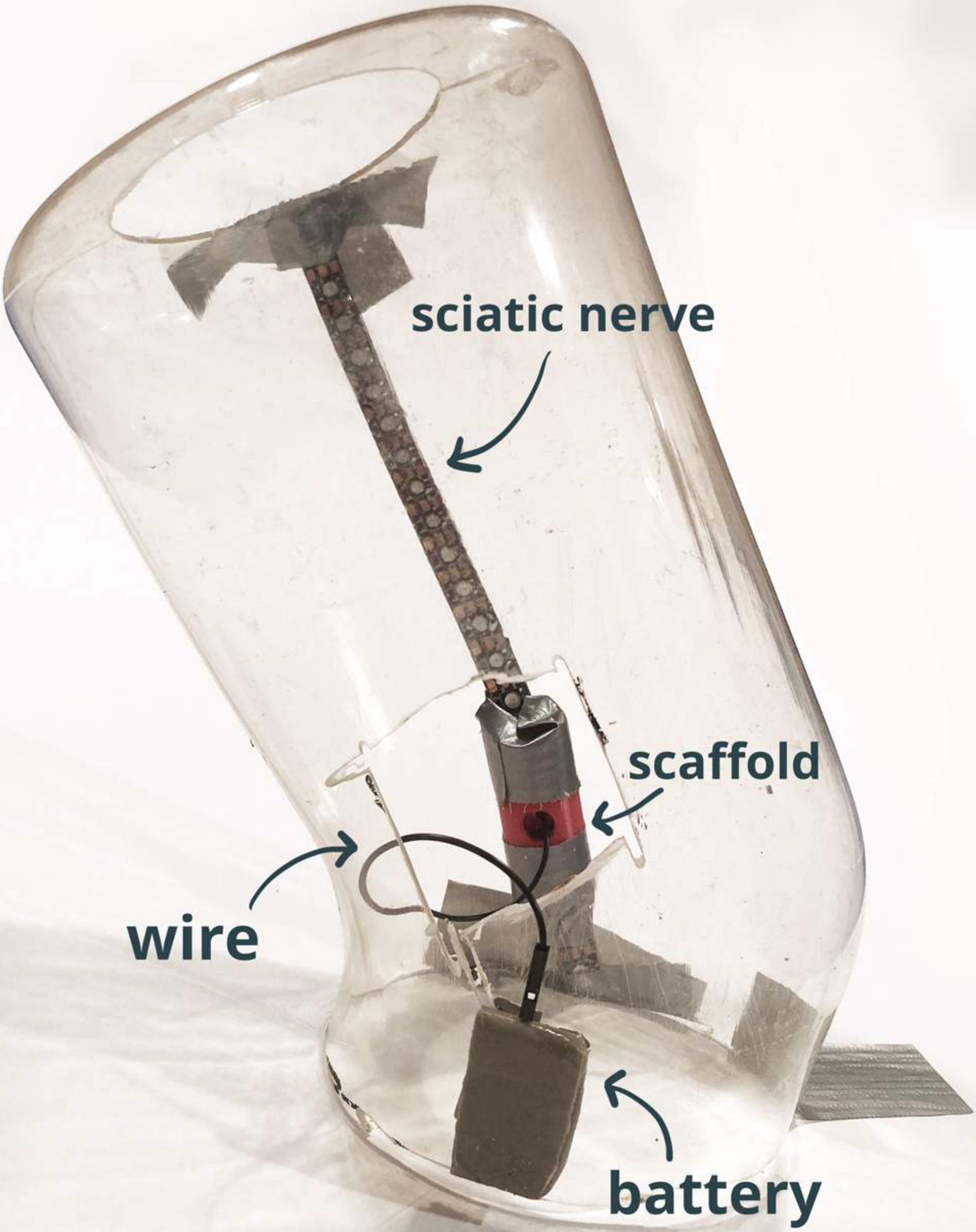
- Class 3 device
- Premarket approval (PMA) application
- Presenting adequate scientific evidence to demonstrate safety and efficacy
  - laboratory testing, clinical trials with human participants
  - Quality System Regulation: Facility inspections of manufacturer & all major suppliers

Training Requirements

- Neurologist with concentration in peripheral neuropathy
  - 4 years of medical school
  - 4-year residency program
    - one year of internal medicine & 3 yrs of neurology
    - training in medical & physical examination, electrodiagnostic tests, imaging tests
- Neurosurgeon with advanced training in Neuromodulation and peripheral nerve stimulation
  - 4 years of medical school
  - 5-7 yr neurosurgical residency program
  - neuromodulation fellowship: surgical techniques & circuit pathophysiological models
- Patient
  - Adjust to new life
    - Caution when around MRI & other large magnetic fields
    - Check in with doctor regularly
  - Train how to use & navigate app

Materials	Unit cost	Part cost
Nano carbon nanotube composite filament	$42/0.5kg	$0.03
Platinum electrode	$69.90/100mm	$69.90
Battery	$7.99	$7.99
Silk	$280 per 50mg/mL	$280
Microcontroller	$6.95	$6.95
Hydrogel	$5/gram	$150
SIS wrap:	$2,543.99/1x3	$850
Titanium case	$10/pound	$0.13
Glial cell line-derived neurotrophic factor Growth factors	$132/sheet	$132
	Total :	$1217
Surgery	$20,000-$90,000	

Gerald's Leg



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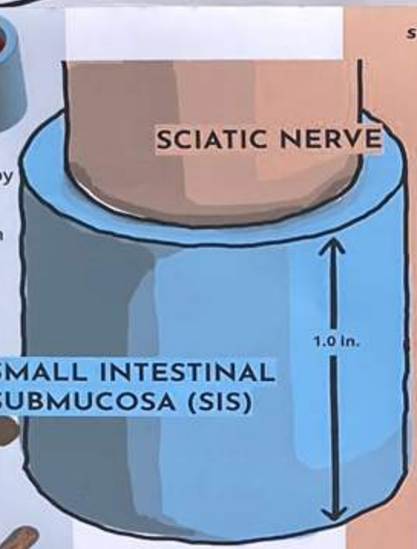

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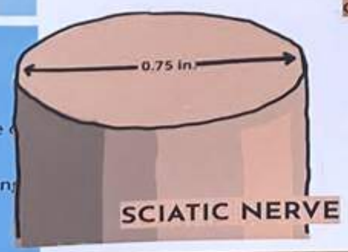

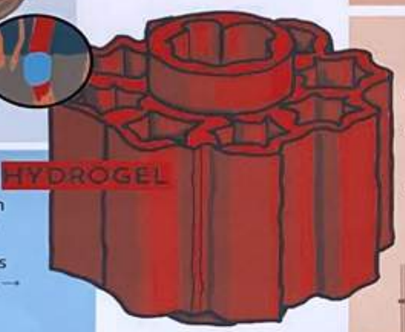

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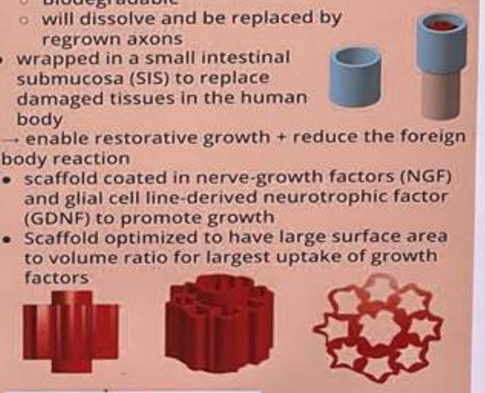

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Event Name:	Medical Innovation	Medical Innovations Team #15335	
Member Names:	Jessie Fan, Rachel Oh, Ananya Raghavan	School Name:	Morris Hills High School
HOSA Division:	Secondary Division	State/Assoc:	NJ
HOSA Chapter#:	12173	Innovation:	StimuNerve

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