Neuromodulation for Chronic Pain

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- Stratus Medical – Consultant, Research Funding

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Objectives
Neuromodulation Techniques

- Spinal Cord Stimulation
- Dorsal Root Stimulation
- Intrathecal Therapy
- Peripheral Nerve Stimulation

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Central Neuromodulation

I. Spinal Cord Stimulation

II. Dorsal Root Ganglion Stimulation

III. Intrathecal Therapy

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DISCOVER THE RIGHT FIT

Neurostimulation for Chronic Pain Relief

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Agenda

01 Understanding pain & common pain conditions

02 Therapeutic options for pain relief

03 How patients obtain a neurostimulation implant

Understanding Chronic Pain & Common Pain Conditions

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Chronic pain is one of the most common reasons Americans seek medical care

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CYCLE OF PAIN:
The Effects of Pain Go Beyond Pain Scores

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Understanding the different types of pain is critical to evaluating pain relief solutions for patients

NEUROPATHIC vs MECHANICAL	CHRONIC vs ACUTE	BROAD vs FOCAL

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Common Pain Conditions

01 Back & Leg Pain
- Persistent pain following spine surgery
- Nonsurgical back pain
- Sciatica/Radiculopathy

02 Complex Regional Pain Syndrome (CRPS)
- CRPS I
- CRPS II also including Phantom Limb Pain or Residual Limb (Stump) Pain

03 Pain caused by Diabetic Peripheral Neuropathy (DPN)

Back and Leg Pain

BACK PAIN: PAIN THAT CAN RANGE IN INTENSITY FROM A DULL, CONSTANT ACHE TO A SUDDEN, SHARP OR SHOOTING PAIN

PERSISTENT PAIN FOLLOWING SPINE SURGERY

- Referred to as "Failed Back Surgery Syndrome" (FBSS) or post-laminectomy syndrome
- Factors that may affect outcome of spine surgery:
  - Spinal anatomy may not have been the only cause of pain
  - Scar tissue build up (epidural fibrosis) or damage from the surgical procedure

NONSURGICAL BACK PAIN

- Patients with chronic back pain that is refractory to conventional medical management (CMM), have no prior back surgery, or are not candidates for corrective surgery.
- Patients may present with multiple back pain diagnosis and lack a surgically corrective pathology

SCIATICA/RADICULOPATHY

- Pain, numbness and/or weakness that radiates along the sciatic nerve from the lower back to the buttocks and leg
- Vast majority of symptoms result from lower back disorders between L4 and S1
- Commonly caused by disc problems

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Complex Regional Pain Syndrome (CRPS) and Causalgia

CRPS IS PROLONGED PAIN AND INFLAMMATION WITHOUT AN IDENTIFIABLE PERIPHERAL NERVE LESION, INJURY OR IRRITATION; CAUSALGIA IS DUE TO AN INJURY OR TRAUMA TO A PERIPHERAL NERVE

CHRONIC REGIONAL PAIN SYNDROME (CRPS)

- Occurs after an illness or injury that didn't directly damage the nerves in the affected limb
- May occur after a heart attack, stroke, or infection

CAUSALGIA

- May occur after surgery or a sprain/injury
  - Common surgeries include hernia surgery, pelvic floor surgery, and foot, ankle, hip, or knee surgery
- May occur after amputation (phantom limb and stump pain)
  - pain that feels like its coming from a body part that is no longer there
- Pain is typically localized to the area around the injured nerve, and does not radiate through body

CRPS AND CAUSALGIA SYMPTOMS MAY INCLUDE:

- Burning or throbbing pain
- Sensitivity to touch
- Swelling
- Changes to skin temperature, color, and/or texture

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Budapest Clinical Criteria for CRPS

1. Continuing pain disproportionate to any inciting event
2. Patient-Reported Symptoms (at least 1 symptom in ≥ 3 of 4 categories)
   - Sensory (Hyperesthesia, Allodynia)
   - Vasomotor (Temperature and skin color asymmetry or changes)
   - Sudomotor/Edema (Edema, sweating changes/asymmetry)
   - Motor/Trophic (Decreased ROM, weakness, tremor, dystonia, hair/skin/nail changes)
3. Clinician Observed Signs (at least 1 sign in ≥ 2 of 4 categories)
   - Sensory (**Hyperalgesia** to pinprick, **Allodynia** to light touch, vibration, pressure, or joint movement)
   - Vasomotor (Temperature asymmetry, color changes, color asymmetry)
   - Sudomotor/Edema (Edema, sweating changes/asymmetry)
   - Motor/Trophic (Decreased ROM, weakness, tremor, dystonia, trophic skin/hair/nail changes
4. Exclusion – No other Dx better explain the signs and symptoms

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Diabetic Peripheral Neuropathy (DPN)

DIABETES IS ONE OF THE MOST PREVALENT CHRONIC CONDITIONS IN THE U.S., WITH ROUGHLY ONE IN FIVE DIAGNOSED EXPECTED TO DEVELOP PAIN ASSOCIATED WITH DPN

DIABETIC PERIPHERAL NEUROPATHY (DPN) IS ONE OF THE LONG-TERM COMPLICATIONS OF DIABETES.

- Over time, high blood glucose (sugar) levels can lead to nerve damage in the body
- Nerve damage can result in potentially debilitating symptoms, including:
  - Numbness
  - Tingling
  - Burning
  - Shooting Pain
- Neuropathy typically affects the feet and legs

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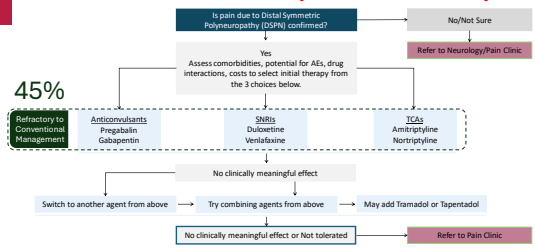
ADA Position Statement | Diabetic Neuropathy



*DSPN is most common among chronic diabetic neuropathies.
Bansal R, et al. Diabetic Neuropathy: A Position Statement by the American Diabetes Association. *Diabetes Care*, Jan 2017.

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Therapeutic Options for Chronic Pain Relief

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Neurostimulation: When the pain doesn't go away

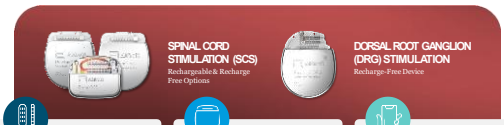
More then **30%** of Americans **suffer from chronic pain.**

Worldwide, approximately **50,000** **Patients undergo SCS therapy each year.** Studies show that SCS can **stabilize or decrease opioid** usage.

Neurostimulation has been around for **over 50 years.**

"NEUROSTIMULATION TREATMENTS STIMULATE THE SPINAL CORD, A NERVE, OR A SET OF NERVES USING CONTROLLED ELECTRICAL IMPULSES TO ALLEVIATE PAIN." - NORTH AMERICAN NEUROSTIMULATION SOCIETY (NANS)

Understanding the neurostimulation therapy components



SPINAL CORD STIMULATION (SCS)
Rechargeable & Recharge Free Options

DORSAL ROOT GANGLION (DRG) STIMULATION
Recharge-Free Device

LEADS
Thin wires that deliver electrical pulses from the battery to nerves along the spinal cord or to the DRG

BATTERY
A small device that is connected to the leads to supply power

PATIENT CONTROLLER
An iOS[‡] software compatible app that enables you to adjust your therapy

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Neuromodulation: When the pain doesn't go away

SCS STIMULATION FOR BROAD PAIN†

Back & Leg Pain
- Persistent pain following spine surgery (including FBSS)[1,2,3]
- Nonsurgical back pain also including Sciatica/Radiculopathy

Pain caused by Diabetic Peripheral Neuropathy (DPN)

18X PATIENTS WITH DPN ARE **18 TIMES MORE LIKELY TO EXPERIENCE SIGNIFICANT PAIN RELIEF** IF TREATED WITH SCS THERAPY COMPARED TO CONVENTIONAL MEDICAL MANAGEMENT.

DRG STIMULATION FOR FOCAL PAIN†

Complex Regional Pain Syndrome (CRPS)
- CRPS I
- CRPS II also including Phantom Limb Pain or Residual Limb (Stump) Pain

81.4% PATIENTS WHO RECEIVED DRG STIMULATION THERAPY HAD AN **81.4% REDUCTION IN THEIR PAIN** AT 12 MONTHS

*The ilantR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.
**Combined data from comparative studies in the Abbott Clinical Summaries PJ. Analysis of all randomized subjects in an intent-to-treat approach.
† Chronic, intractable pain
†† Pain that is broadly felt in large area of the body

How patients obtain a neurostimulation therapy?

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Determining if patients are neurostimulation candidates

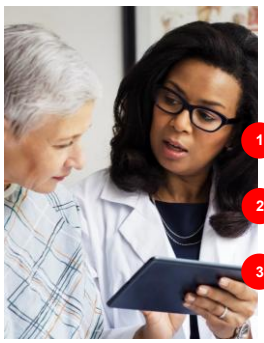
PATIENT SELECTION IS CRITICAL FOR THE SUCCESS OF SCS THERAPY

GOOD CANDIDATES FOR NEUROSTIMULATION

- Pain is 24/7 and neuropathic
- Pain is not primarily mechanical
- Conservative therapies have failed
- Would not benefit from additional surgery or the risks outweigh the potential benefits
- Able to pass psychological evaluation
- Do not have untreated depression or drug addiction
- They have no medical conditions that would keep them from undergoing implantation

BAD CANDIDATES FOR NEUROSTIMULATION

- Pain is primarily mechanical and not neuropathic.
- Pain is not 24/7- It goes away when they walk, sit, lay down, etc.
- Patient says, "It's in the center of my lower back and feels like a vice grip when I walk."
- Fibromyalgia
- Pain is due to arthritis in the back, knee or other areas
- Anyone who appears like they don't want to get better
- Have some type of dementia or cognitive issues
- Presence of secondary gain or litigation
- Pain due to implantable hardware



Steps to getting pain management therapies

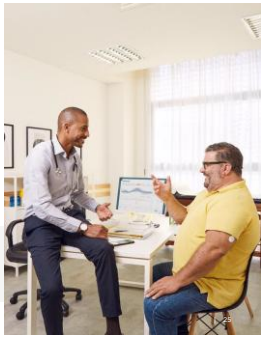
1. Referral to Pain Management Specialist
2. Patient's Temporary Evaluation of Therapy
3. Moving Forward With the Implanted System

#1: Pain specialist referral

HELP YOUR PATIENTS TAKE THE FIRST STEP TOWARD NEUROSTIMULATION

- Determine whether the patient is a candidate for each neurostimulation pain management therapy
- Vendor representative can help answer any additional questions

A TRIAL SYSTEM CAN HELP YOUR PATIENTS DETERMINE HOW WELL THE THERAPY WILL WORK FOR THEM



Describing neurostimulation to patients

"A **pacemaker** for your pain"

"**Noise-cancelling** headphones for pain signals"

"Similar to a TENS unit that sits **under your skin**"

"Helps to **block pain signals** travelling to the brain"

"A treatment option for your chronic pain that you can **test drive** before committing to permanently"

#2: Temporary evaluation

- A short procedure will be performed at a hospital or a same-day surgery center
- The pain management physician will place temporary leads and connect them to a small external battery
- The representative will program the patient's system under the physician's guidance

AFTER THE TRIAL, THE PATIENT AND MYSELF WILL DECIDE WHETHER THE THERAPY IS RIGHT FOR THEM

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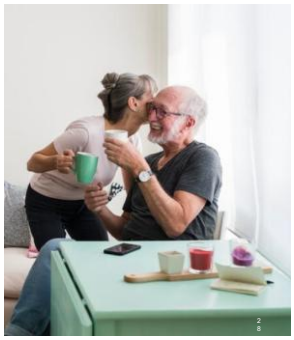
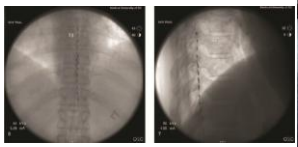
#2: Temporary evaluation

- The typical evaluation period is 5–7 days
- During the trial, the patient can assess whether the therapy:
  - Provides meaningful pain relief (>50-75 % pain relief)
  - Improves their ability to perform daily activities (walking, standing, sitting)
  - Improves their sleeping habits



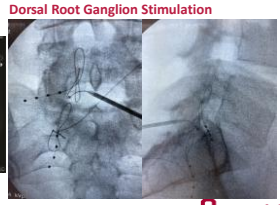
Neuromodulation Lead Placement Trials

Spinal Cord Stimulation



AP Lat

Dorsal Root Ganglion Stimulation



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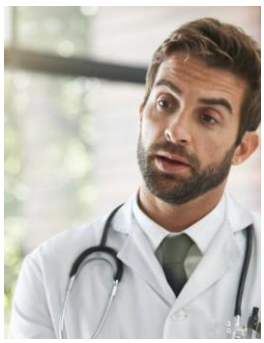
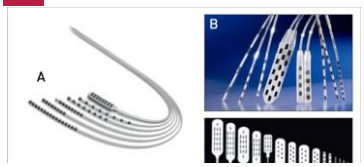
#3: Implanted system

- Upon the completion of a successful trial, the pain management specialist may schedule the patient for a long-term implant.
- The chosen neurostimulation system will be implanted in a minimally invasive surgical procedure, usually on an outpatient basis.
- The three basic components of the implanted system are similar to those of the temporary system but with the battery fully implanted.
- The patient will have access to a vendor specialist throughout their journey to adjust therapy settings as needed.



Leads and Batteries



Percutaneous vs paddle leads.

Intrathecal Therapy (ITT)

52 year old male with history to cervical fusion and degenerative lumbar disc disease presents with chronic neck and low back pain.

Exhausted medications, PT, injections, RFAs. Had SCS Trial/implantation of Cervical Spine lost of efficacy subsequently. Lumbar Pain without radiculopathy are denying further treatments such as RFAs. Oral opioids are increasing and becoming ineffective.

Imaging

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Treatment Options?

- Continuing current protocols with oral opioids
- Revised Cervical SCS
- Lumbar SCS
- Intrathecal Therapy
- None of above

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Treatment Options?

- Continuing current protocols with oral opioids
- Revised Cervical SCS
- Lumbar SCS
- Intrathecal Therapy
- None of above

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Intrathecal Therapy Comprised of 2 processes

I. Trialing
   I. Injection of pain medication intrathecally

II. Permanent Implantation
   I. Catheter/anchors and Pump

PACC Guidelines

The Polyanalgesic Consensus Conference (PACC)*: Intrathecal Drug Delivery Guidance on Safety and Therapy Optimization When Treating Chronic Noncancer Pain

The Polyanalgesic Consensus Conference (PACC)*: Updates on Clinical Pharmacology and Comorbidity Management in Intrathecal Drug Delivery for Cancer Pain

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Indications for ITT

- Axial neck or back pain
  - Multiple VCFs
  - Discogenic pain
  - Spinal Stenosis
  - Diffuse multiple-level spondylosis
- Failed back surgery syndrome
- Abdominal/pelvic pain
  - Visceral or Somatic
- Extremity pain
  - Radicular pain
  - Joint pain
- Complex regional pain syndrome (CRPS)
- Trunk pain
  - Postherpetic neuralgia
  - Post-thoracotomy syndrome
- Cancer pain, direct invasion and chemotherapy related with >3 mos survival
- Analgesic efficacy with systemic opioid delivery complicated by intolerable side effects

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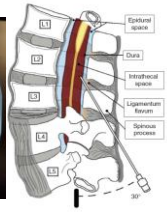
Intrathecal Therapy Trial

Drug	Intrathecal Bolus Trialing Starting Dose Ranges[1]	Intrathecal Infusion Trialing Starting Dose Ranges[1]
Bupivacaine	0.5–2.5 mg	0.01–4 mg/day
Clonidine	5–20 μg	20–100 μg/day
Fentanyl	15–75 μg	25–75 μg/day
Hydromorphone	0.025–0.1 mg	0.01–0.15 mg/day
Morphine	0.1–0.5 mg	0.1–0.5 mg/day
Sufentanil	5–20 μg	10–20 μg/day
Ziconotide	1–5 μg	0.5–2.4 μg/day
Baclofen[2]	50 μg, 75 μg, 100 μg	



Abd-Elsayed, A. Neuromodulation of the Spine. P. 189.

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Intrathecal Catheter Placement

General Pain

Pain Location	Catheter Tip
Feet	T12–L1
Lower legs	T11–T12
Knees	T11
Lumbar back pain	T10
Lumbar back + bilateral legs	T9–T10
SI joint/pelvis	T10–T11
Abdomen	T6–T8
Chest wall	T4–T6
Upper extremity	C5–T1
Neck	C1–C4 (rare)
Diffuse cancer pain	T7–T9 (most common)

Cancer Pain

Cancer Type	Catheter Tip Position
Pelvic Cancer	T10-T12
Pancreatic Cancer	T5-T7
Upper Abdominal	T4-T6
Diffuse Mets	Higher on dominant pain distribution

Deer TR et al. Polyanalgesic Consensus Conference (PACC) Guideline Update. Neuromodulation 2024.

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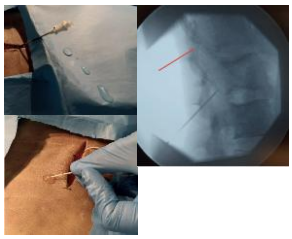
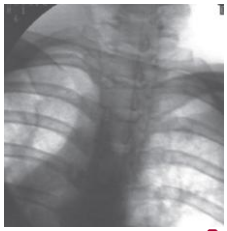
Catheter Access/Placement





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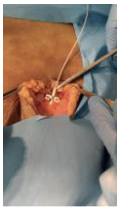
Anchoring



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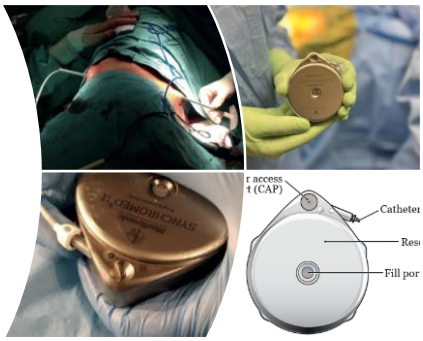
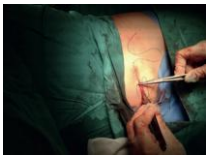
Tunneling the Catheter to Pump Pocket



Closure of Anchoring and Pump Pocket

- 3 layers closure
  - Inner/outer deep layers with absorbable sutures (eg. Vicryl)
  - Skin with non-absorbable suture (e.g Prolene, Silk) or staples



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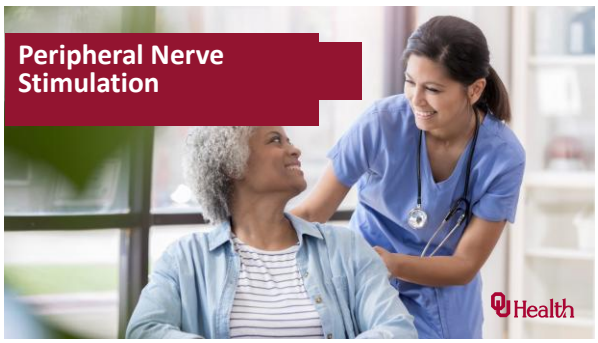
Peripheral Nerve Stimulation



PNS Indications & Contraindications

Indications – Pain Management

- Adults
- Severe intractable chronic pain – peripheral nerve origin
- As the sole mitigating agent
- As an adjunct to other modes of therapy used in a multidisciplinary approach

Contraindications – Patient

- Poor surgical risks
- Pregnancy
- Inability to operate the system
- Exposure to shortwave, microwave, or ultrasound diathermy
- Occupational exposure to high levels of non-ionizing radiation
- Implanted cardiac systems

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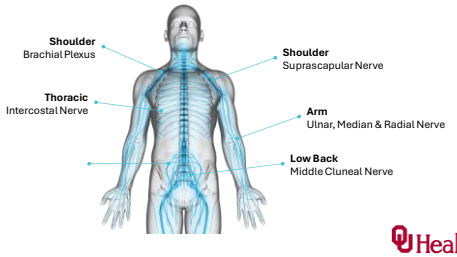
Treatment Areas – Upper Extremity, Thoracic and Low Back



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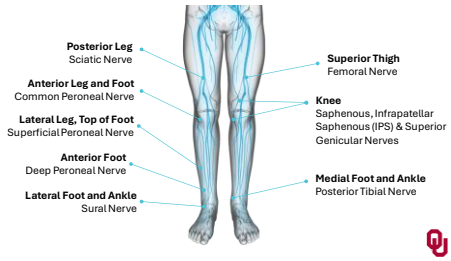
Treatment Areas – Lower Extremity



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Patients Present with Chronic Head & Neck Pain

Pain Radiating Down the Neck or Up to the Head	Occipital Pain Radiating to Eyes or Temples	Temporary Response to Occipital Injections or Upper Cervical Injections

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Patients with Chronic Knee Pain

Painful Total Joint	Post-Traumatic Patients	Painful Total Knee After Appropriate Workup
Primary TKA	Poor Surgical Candidates	
Revised or Multiply Revised TKA	Non-Surgical Candidates	

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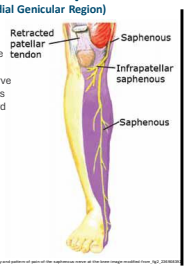
Infrapatellar Saphenous Nerve "IPS"

(Inferior Medial Genicular Region)

Anatomy

- General Route: The IPS branches from the saphenous nerve at a variety of levels and extends toward the patella
- The IPS Nerve is a sensory nerve



Patient Identification

- Total Knee Arthroplasty
- Tibial Nail
- Arthroscopy
- ACL Repair
- Tendon Harvest

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Infrapatellar Saphenous Nerve "IPS"

Placement

Patient Position:
Supine

Fluoro Views:
AP and Lateral

Wearable

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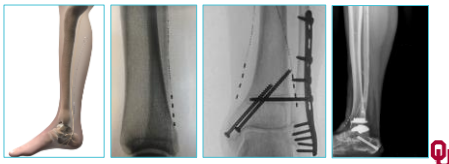
Patients Present with Chronic Foot & Ankle Pain

Total Ankle	Post-Traumatic Patients	Non-Surgical Candidates
Ankle Fusion	Post-Tarsal Tunnel Repair	Neuropathic Pain – Lower Extremity
CRPS	Poor Surgical Candidates	Specific Mononeuropathy



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Posterior Tibial Nerve "Post Tib"

Anatomy

- Branches from the sciatic nerve in the popliteal region
- Innervates the posterior, medial portion of lower leg and down under the medial arch
- Motor and Sensory nerve

Patient Identification

- Neuropathic Pain – Lower Extremity
- Specific Mononeuropathy
- CRPS – Type 2
- Post Tarsal Tunnel Repair
- Post Surgical Pain
- Foot & Ankle Trauma

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Posterior Tibial Nerve "Post Tib"

Placement

Patient Position:
Supine

Fluoro Views:
AP and Lateral

Wearable

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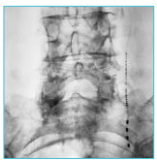
Patients Present with Chronic Low Back, Leg or SI Joint Pain

Persistent SI Joint Pain	Non-Surgical SCS Patients	Post-SI Fusion Failure of All Types
SCS Patients with Inadequate Sacral Coverage	Persistent Spinal Pain Syndrome due to SI Pathology	Low Back Pain Radiating to Buttocks & Leg (Mimicking Radiculopathy)



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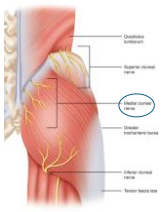
Middle/Medial Cluneal Nerves

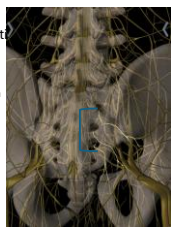
Anatomy

- A branch of the posterior ramus of the sacral nerve roots, arising from the dorsal rami of the S1 to S4 at the corresponding foramina
- The MCN is a sensory nerve



Patient Identificat

- SI Joint Fusion
- SI Joint Stabilization
- Lumbar Fusions



OU Health

Middle/Medial Cluneal Nerves

Placement

Patient Position:
Prone

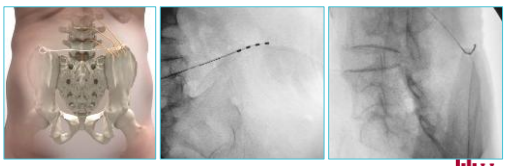
Fluoro Views:
AP and Lateral

Wearable

OU Health

Patients Present with Chronic Low Back and Leg Pain

Persistent Pain after Lumbar Surgery	Pocket Pain from Previous or Current IPG Implants	Nerve Trauma from Iliac Crest Grafts after Lumbar Fusion
SCS Patients with Inadequate Iliac Crest Coverage	Post-Traumatic Patients	Nerve Entrapment by Quadratus Lumborum Spasm



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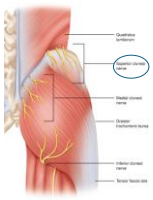
Superior Cluneal Nerves

Anatomy

- The superior cluneal nerves are formed from branches of the T11 – L5 spinal nerves
- The nerves cross in 3 branches over the top of the iliac crest and can become entrapped in the fibro-osseous tunnel formed by the iliolumbar ligament and quadratus lumborum muscle
- The Superior Cluneal Nerves are sensory nerves



Presentation

- Low Back Pain – Surgical or Non-Surgical
- SCS Patients with Inadequate Back Pain Coverage
- Patients with Hardware

OU Health

Superior Cluneal Nerves

Placement

Patient Position:
Prone

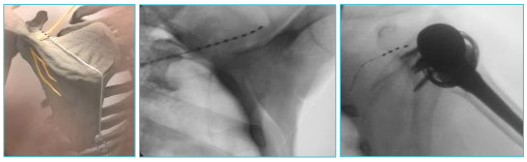
Fluoro Views:
AP and
Contralateral Oblique

Wearable

OU Health

Patients Present with Chronic Shoulder Pain

Infraspinatus Weakness and/or Atrophy	Post-Surgical Pain	Non-Surgical Candidate
"Frozen Shoulder"	Post-Traumatic Patients	Poor Surgical Candidate

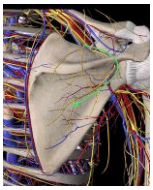


OU Health

Suprascapular Nerves

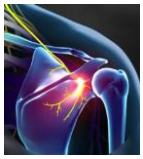
Anatomy

- Origin: Direct branch of the upper trunk of the Brachial Plexus (C4-C6)
- General Route: Crosses the posterior neck, under the trapezius, toward the suprascapular foramen/notch, and then through the spinoglenoid notch
- The Suprascapular Nerve is a sensory and motor nerve



Patient Identification

- Posterolateral Shoulder Pain
- Infraspinatus Weakness and/or Atrophy
- "Frozen shoulder"
- Post-Surgical Pain



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Suprascapular Nerves

Placement

Patient Position: Prone

Fluoro Views: AP and 35-45 degrees of cephalad tilt

Wearable

Health

Clinical Evidence

Health

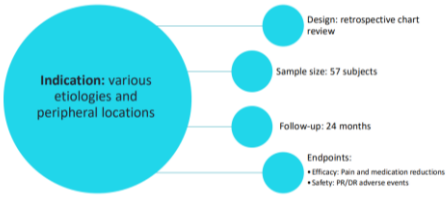
Efficacy of Peripheral Nerve Stimulation with a High Frequency Electromagnetic Coupled (HF-EMC) Powered Implanted Receiver in Treating Different Pain Targets/Neuralgias

Robert Moghim, MD
Alaa Abd-Elsayed, MD

Journal of Pain Research

Health

Study Design



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Procedure Locations

Device Placement	#19 Genicular (knee)
	#15 Superior Cluneal (low back)
	#14 Posterior Tibial/Sural (ankle)
	#7 Middle Cluneal (SI joint)
	#1 Radial/Ulnar (hand)
	#1 Peroneal (foot)

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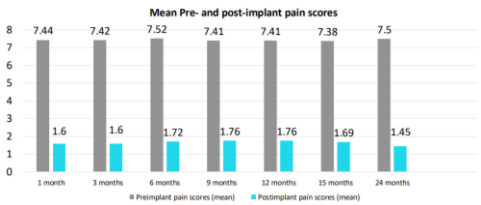
Pain Score Reductions

A Verbal Rating Scale (VRS) of more than 70% at all follow-up visits



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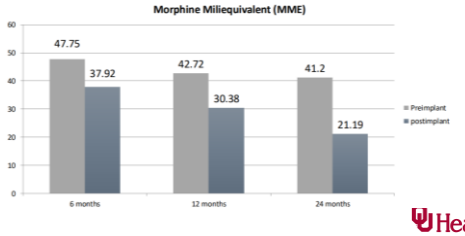
Medication Reductions (MME)

Mean Morphine Milliequivalent reduced with 47% at 24 months post-implant



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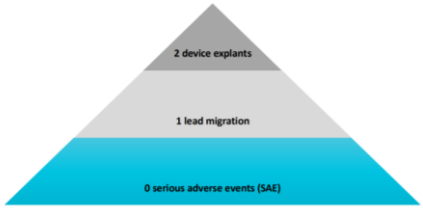
Safety



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PNS

PNS has been shown to be safe and effective in treating chronic pain at different sites with sustained pain relief for up to 24 months. This study is unique in providing long-term follow-up data.

Peripheral nerve stimulation at the posterior tibial nerve was successful for this series of patients suffering from chronic, debilitating pain in the foot due to peripheral neuropathy.

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Conclusion

- Chronic pain syndrome is a socially ubiquitous condition
- Interventional strategies are available to augment medical therapies
- Direct relationship with your preferred Pain physician provider(s) is imperative

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Thank you for your attention

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Q & A

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