Stimulation of the Peripheral Nervous System

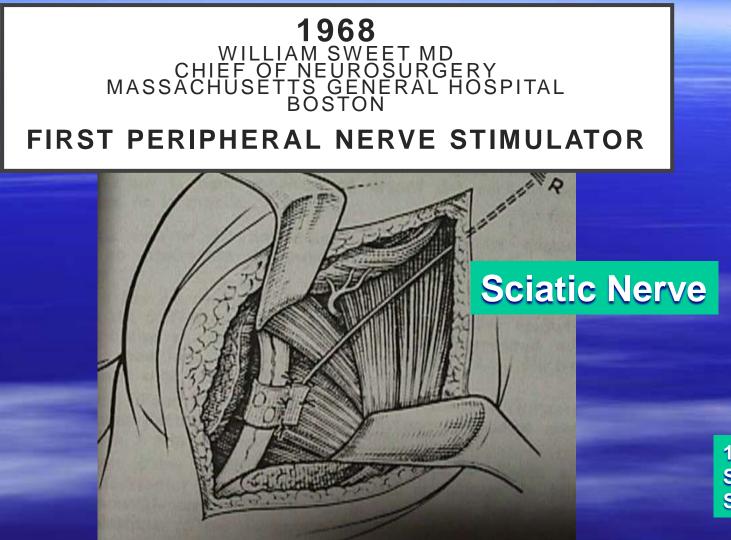
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Disclosures Equity Owner: • Ripple

- Microleads
- Mudjala



1967 : First Spinal Cord Stimulator

Cuff electrodes resulted in severe compression of the nerve





PNS Abandoned

PNS retried in the 80s with paddle leads over the nerves

- Results were good but short lasting.
- Undesirable stimulation of the motor fibers almost always prevented stimulation of the sensory fibers within a useful range
- At the time smallest voltage increments were in the 0.5 V, which did not allow enough "fine tuning" of the stimulation to prevent motor contractions.
 PW adjustments allowed some additional "tweaking", but not enough to be useful.

PNS retried in the 80s with paddle leads over the nerves

- Three indications for stimulation of the PNS circumvented these issues:
- Tibial nerve stimulation for foot drop. Stimulation of the motor fibers was the desirable outcome
- Vagus nerve stimulator for epilepsy
 - Expandable lead coil
 - Stimulation could be kept sub-threshold for paresthesiae so undesirable motor contractions could be kept to a minimum

 Interstim by Medtronic. Stimulation of the S3 nerve root. Some degree of motor contractions were acceptable and, in some instances, even desirable.

Today

 The current stimulation systems allow stimulation increments of at least 0.1 V with minute increments in the pulse width.

 Much easier to find the "Therapeutic Window" between sensory and motor stimulation.

Stimulation of the Peripheral Nervous System (PNS)

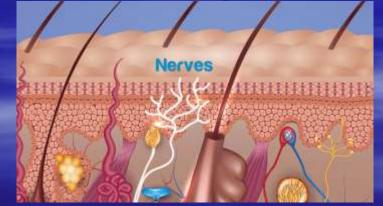
True PNS

Peripheral "Field" Stimulation

Large Named Peripheral



Network of Small Un-Named Branches of Peripheral Nerves



- Excellent alternative to Intra-Spinal Stimulation
- Many times a preferable alternative
 Sometimes as a supplement to Intra-Spinal Stimulation

Advantages of PNS over NTRASPINAL STIMULATION

	Advantage Over :	
	SCS	DRG
No need to enter the spinal canal	Yes	Yes
Less risk of extensive neurological damage	Yes	Yes
Much more precise distribution of the stimulation	Yes	
Much greater acceptance by patients	Yes	Yes
More effective in CRPS cases	Yes	

Ulnar nerve Median Nerve Musculocutaneous Nerve Superficial Radial Nerve Axillary Nerve Femoral Nerve Sciatic Nerve Saphenous Nerve Posterior Tibial Nerve

Mixed Mixed Mixed Sensory Mixed Mixed **Mixed** Sensory Mixed

Stimulation of the Peripheral Nervous System (PNS)

Equipment

Cylindrical leads

- Specifically designed for PNS and inserted through a needle

- Many with "Tines" to prevent migration

- Most often associated with an external power source

Surgical leads

- Paddle leads
- Cuff leads
- Utilized either with fully implantable IPG or RF system

Stimulation of the Peripheral Nervous System (PNS) Cylindrical leads

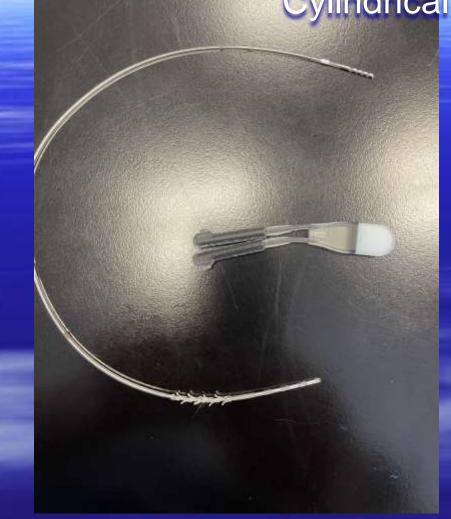




Cylindrical leads

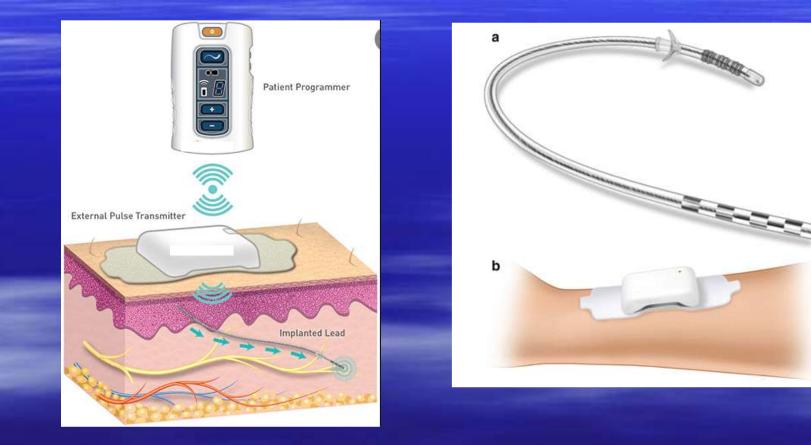


Cylindrical leads



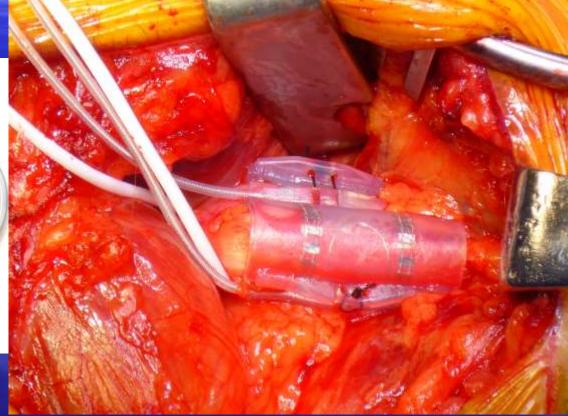


Cylindrical leads



Surgically placed leads: Cuff leads





Surgically placed leads: Paddle leads





	Cylindrical leads	Surgical leads
Invasiveness	Advantage	
Physical stability		Advantage
Better physical and electrical contact with the nerve		Advantage
More stable stimulation		Advantage
Implant Specialists	Pain Doctors Surgeons	Surgeons

A Systematic Literature Review of Peripheral Nerve Stimulation Therapies for the Treatment of Pain

Timothy R. Deer, MD,* Michael F. Esposito, MD,†W. Porter McRoberts, MD,‡ Jay S. Grider, DO, PhD, MBA, § Dawood Sayed, MD,¶ Paul Verrills, MD,k Tim J. Lamer, MD,kj Corey W. Hunter, MD,** Konstantin V. Slavin, MD,†† Jay M. Shah, MD,‡‡ Jonathan M. Hagedorn, MD, § § Tom Simopoulos, MD,¶¶ David Abejon Gonzalez, MD, PhD,kk Kasra Amirdelfan, MD,kkk Sameer Jain, MD,*** Ajax Yang, MD,††† Rohit Aiyer, MD,‡‡‡ Ajay Antony, MD, § § § Nomen Azeem, MD,¶¶¶ Robert M. Levy, MD, PhD,kkk and Nagy Mekhail, MD, PhD

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USPSTF: US Preventive Services Task Force

IPM-QRB: Interventional Pain Management Techniques–Quality Appraisal of Reliability and Risk of Bias Assessment. Scoring tool developed by the American Society of Interventional Pain Physicians (ASIPP) to assess RCTs

USPSTF: Level I evidence based upon 14 RCTs for PNS in the treatment of ➤ migraine headache Cluster headache shoulder pain Iow back pain ➢ pelvic pain \succ neuropathic pain of other origin.

USPSTF criteria suggest that all 14 studies evaluated meet Level I status as RCTs.

Using the mIPMQRB method 12 of the 14 were deemed high quality based on study design and clinically meaningful outcomes.

Two were deemed moderate quality

Of the 14 RCTs selected, two were deemed moderate risk of bias and 12 were scored as low risk of bias using the Cochrane scoring method

• mIMP-QRB: Level is based upon specific indications.

- Level I for occipital nerve stimulation (ONS) for the treatment of migraine headache based on four high-quality RCTs and one moderate-quality RCT.
- Level I for PNS for the treatment of chronic low back pain
- (targeting the cluneal nerve and its branches) based on three
- high-quality RCTs.
- Level II for sphenopalatine ganglion (SPG) stimulation for the treatment of cluster headache based on one high-quality RCT.
- Level II for PNS for the treatment of poststroke shoulder pain (targeting the axillary and suprascapular nerves) based on one high-quality RCT.
- Level II for PNS for the treatment of neuropathic pain of the extremities and trunk based on one high-quality RCT. Common nerves targeted for trunk pain include the ilioinguinal/iliohypogasrtic, intercostal, and cluneal nerves. Commonnerves targeted for the extremity include the median, ulnar, sural, and superficial peroneal nerves and the lateral femoral cutaneous nerves.
- Level III for peripheral tibial nerve stimulation (PTNS) for the treatment of chronic pelvic pain based on two low quality RCTs and one moderate-quality RCT.

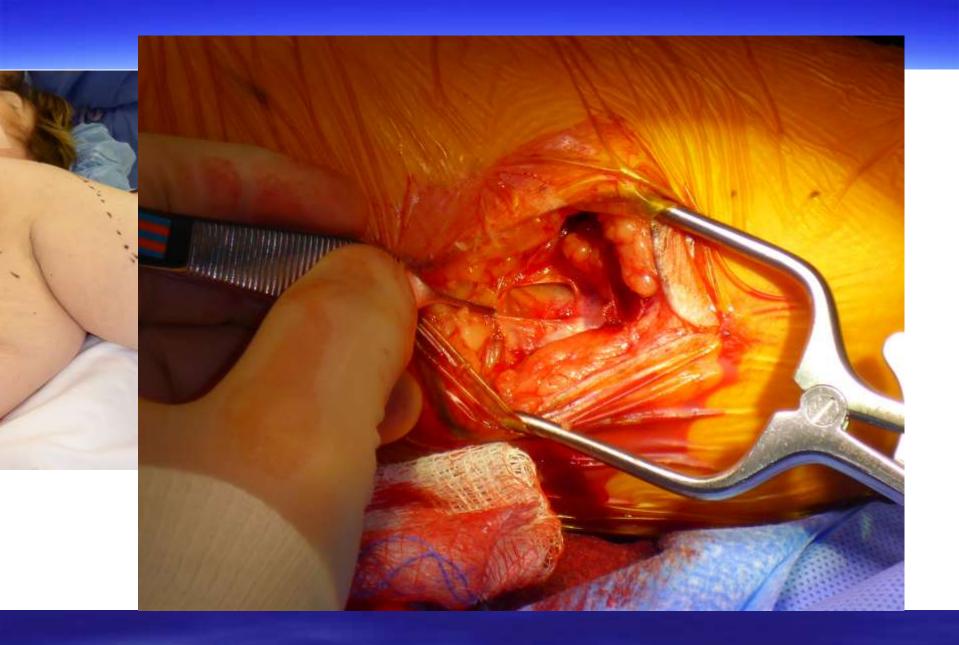
Taken together, these 14 RCTs suggest several key points:

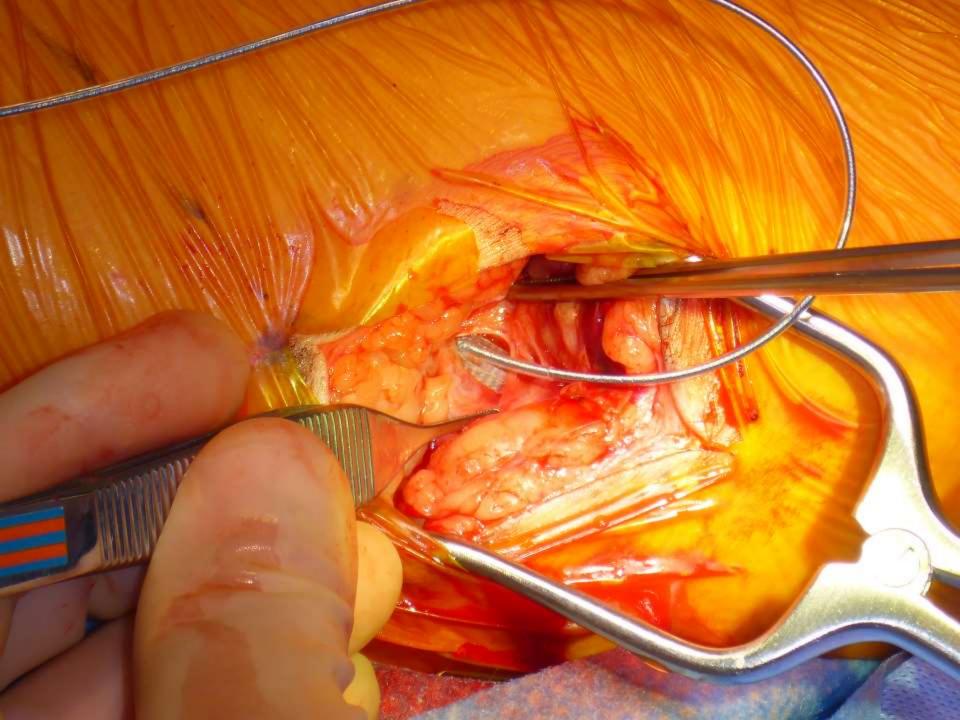
1. Multiple studies showing ONS can be beneficial for chronic migraine (CM), medication overuse headache (MOH), and intractable chronic migraine (ICM)

2. Moderate evidence (Level II) that implanted SPG stimulation is effective for cluster headaches

3. Strong evidence (Level I) that PNfS is beneficial for patients with continued low back pain following surgery medications, and/or interventional pain procedures4. moderate evidence (Level II) that implanted PNS can be expected to provide at least modest improvements in mononeuropathic pain and hemiplegic shoulder pain
5. PTNS may be helpful for overall pain, dyspareunia, andQoL in chronic pelvic pain (Level III)

Ulnar Nerve

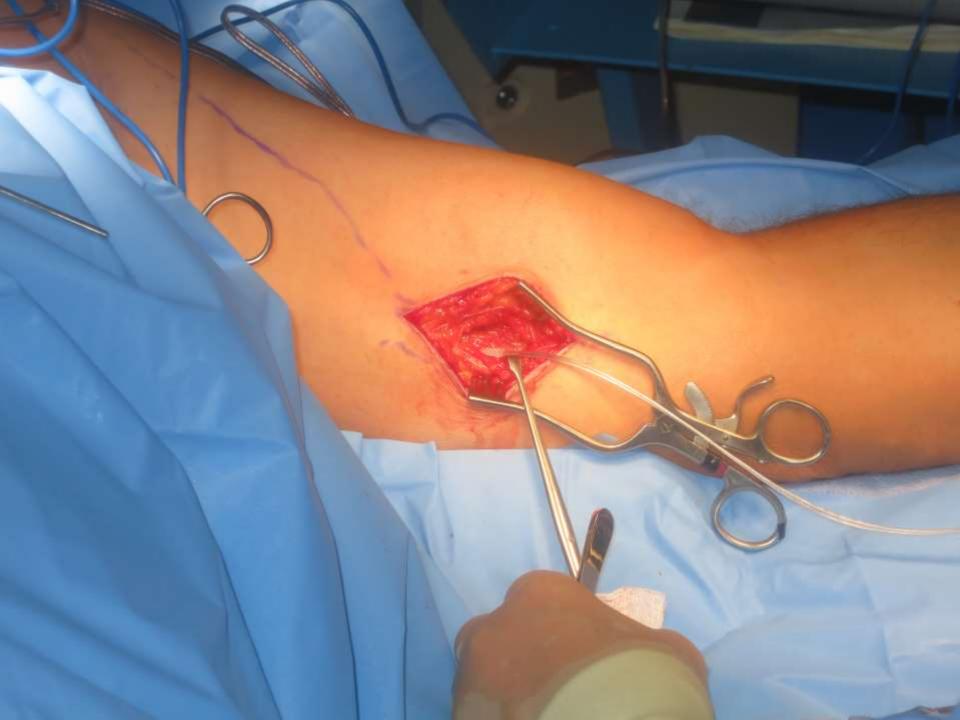




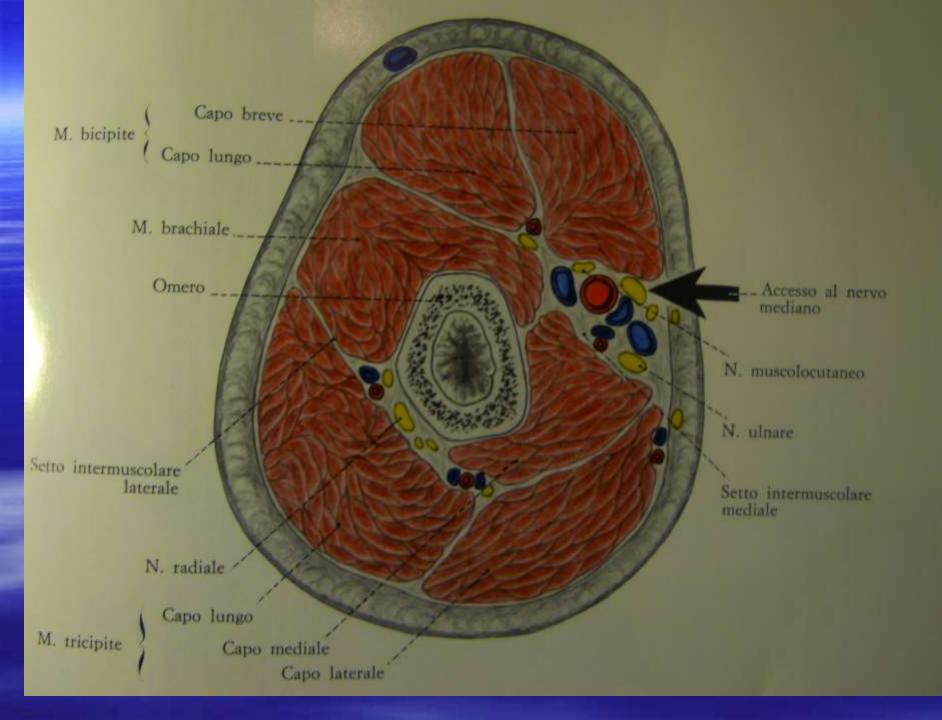


Median Nerve



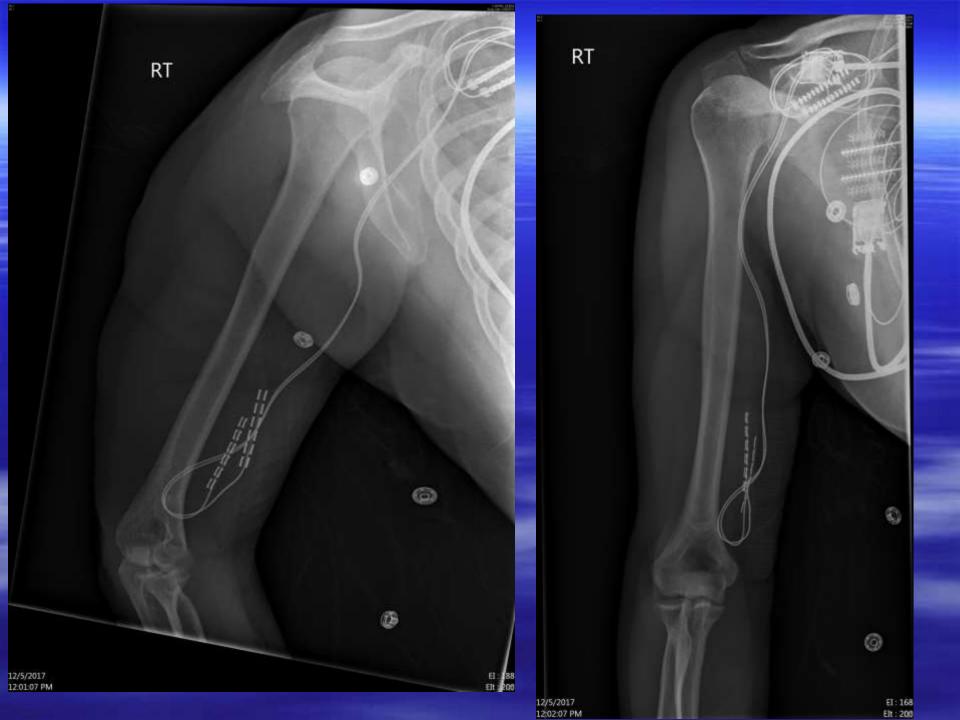


Combined Stimulation of Median and Ulnar nerve



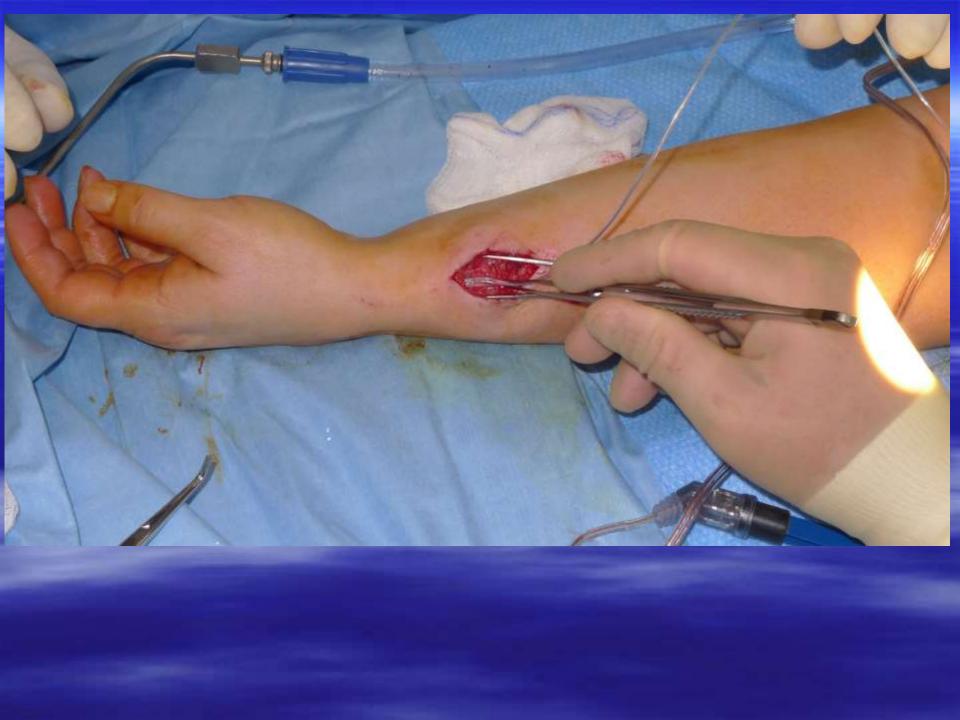
Electrode on Median Nerve

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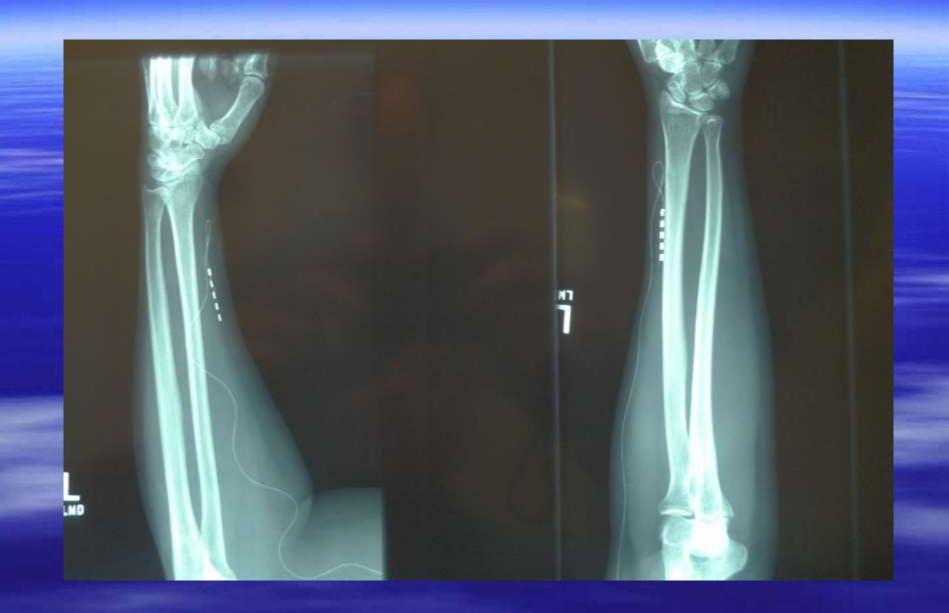


Superficial Radial Nerve



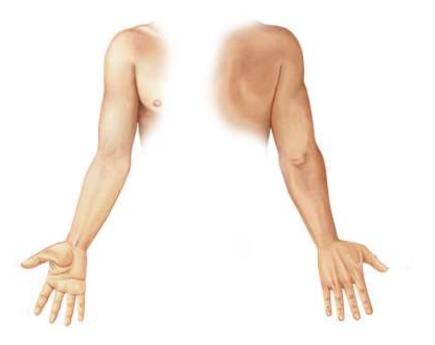


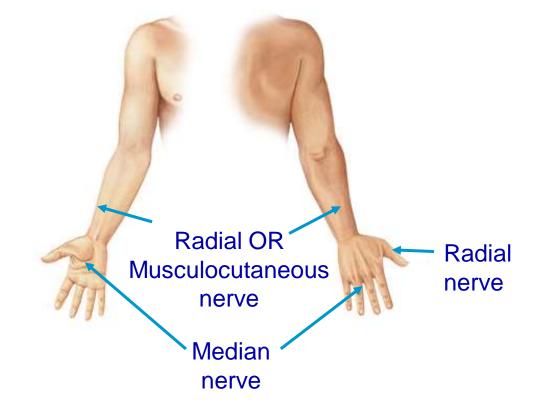




29 Y/O white female with severe CRPS 1 of the Right Upper Extremity Failed all treatments

- *****Excellent candidate for neurostimulation
- Does NOT want to have cervical epidural leads !!!!!!







Median Nerve

THE PAT

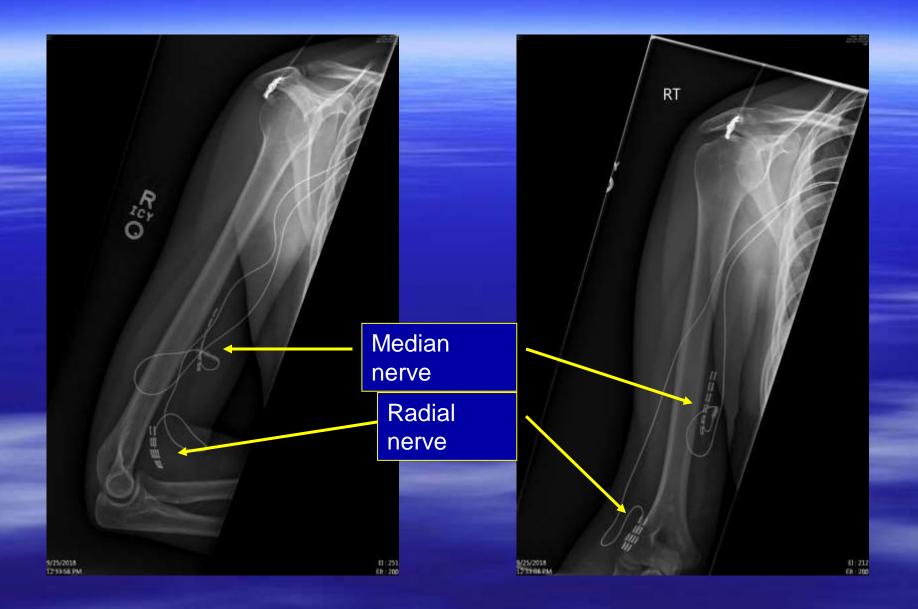


Median Nerve

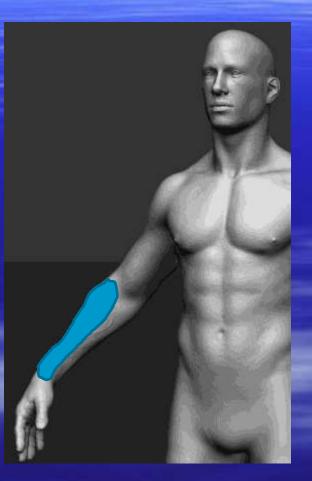


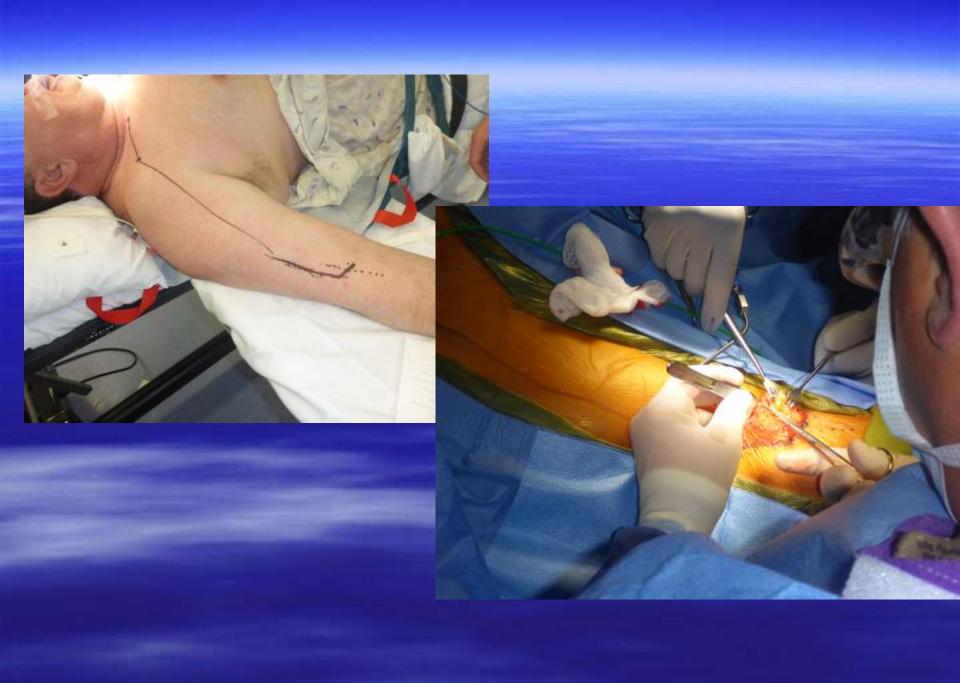






Pain in Musculo-Cutaneous Nerve Distribution





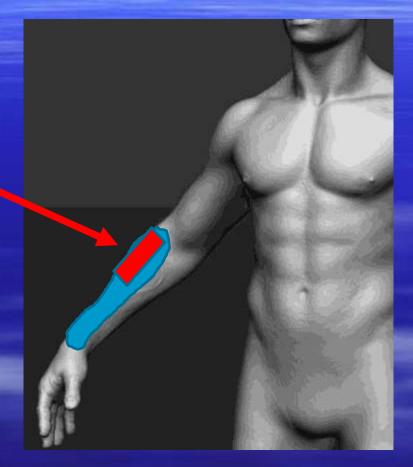


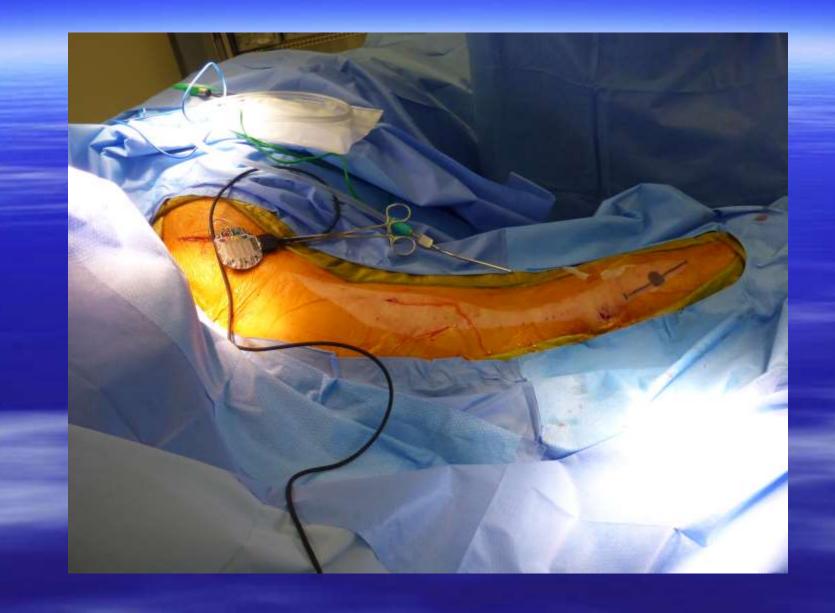




Pain in Musculo-Cutaneous Nerve Distribution

Nerve stimulation was missing this area

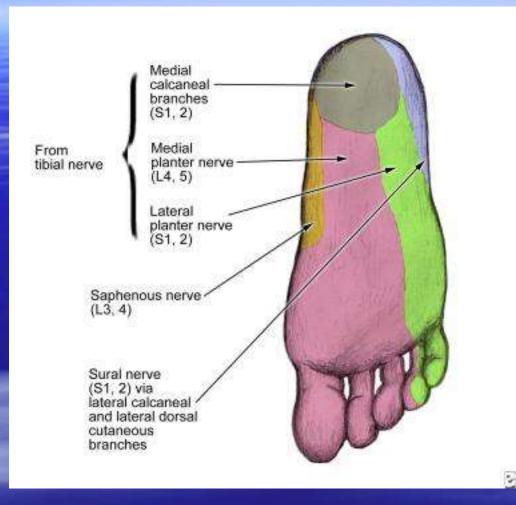








Posterior Tibial Nerve

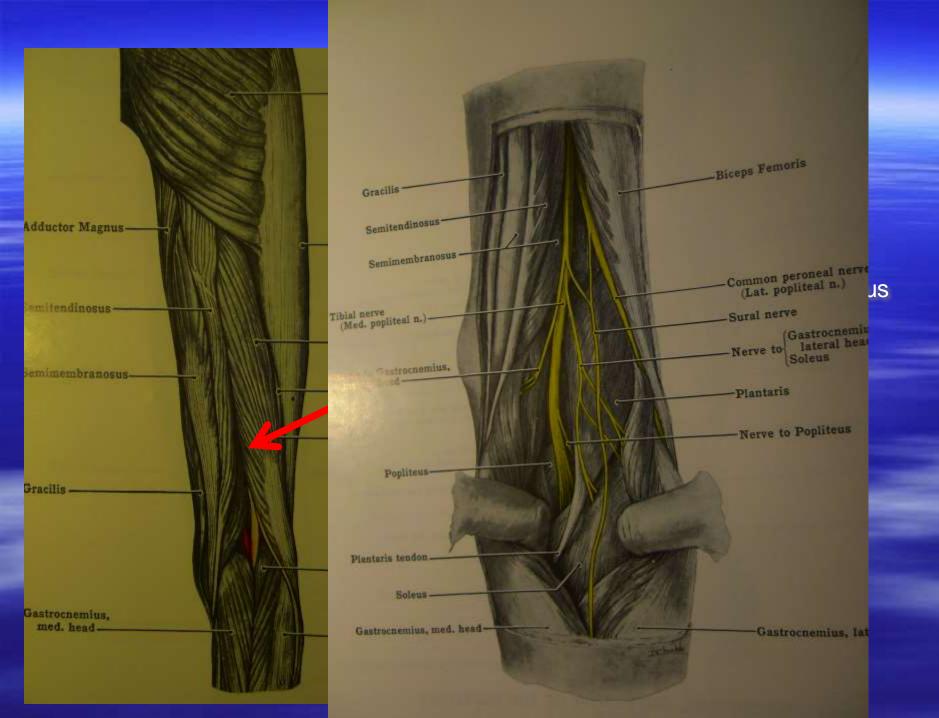




Sciatic Nerve



Pain in L5 S1 Distribution Below the Knee



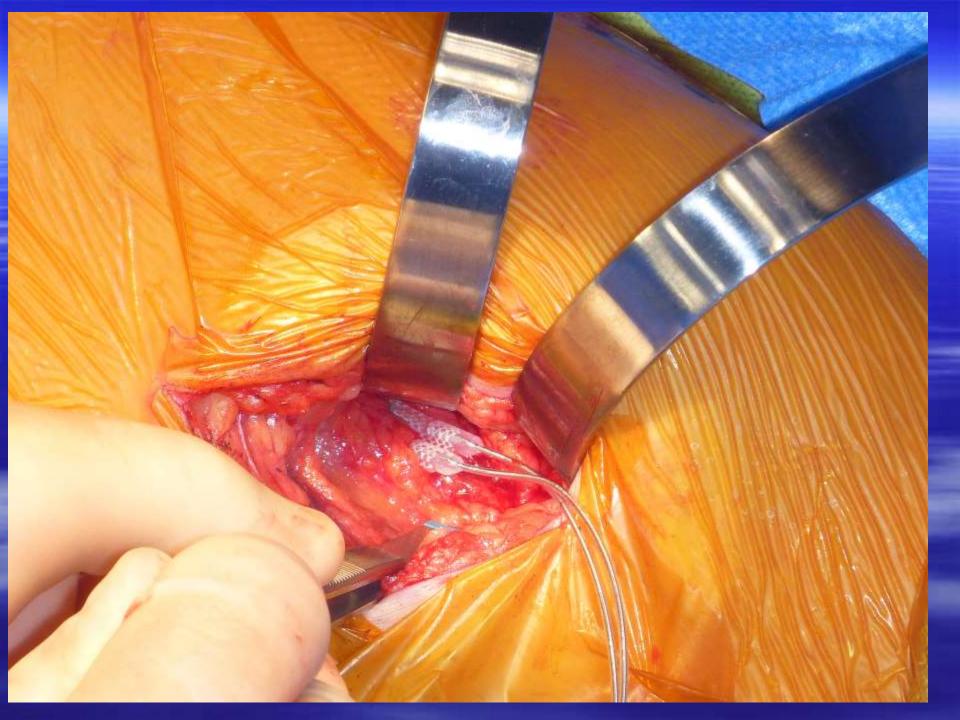


Biceps Femoris

- Sciatic Nerve

Semitendinosus

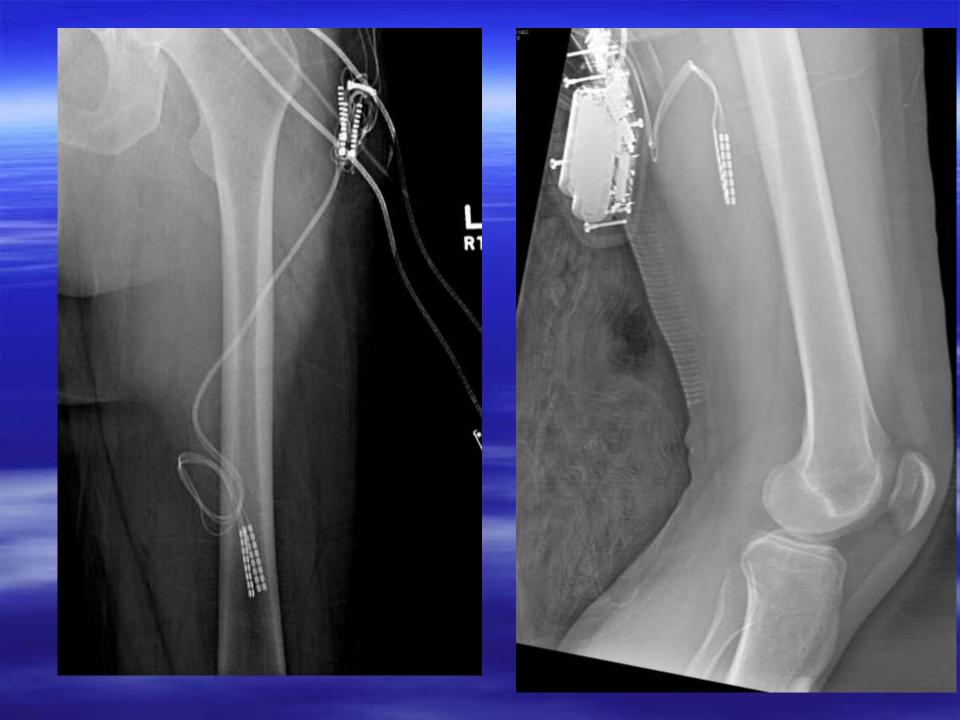
Sciatic Nerve

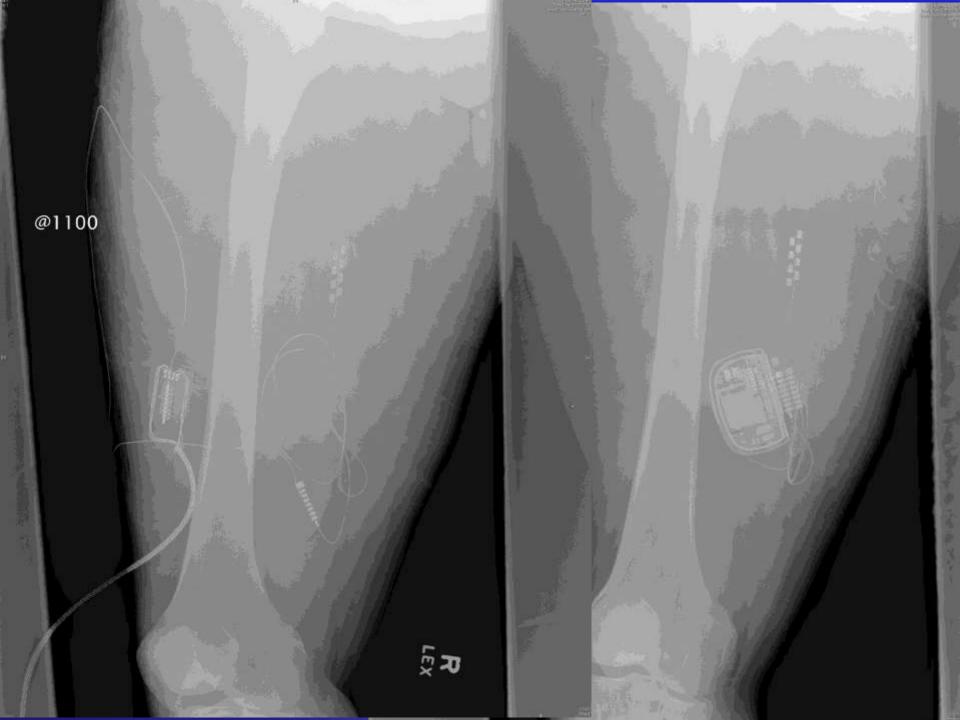






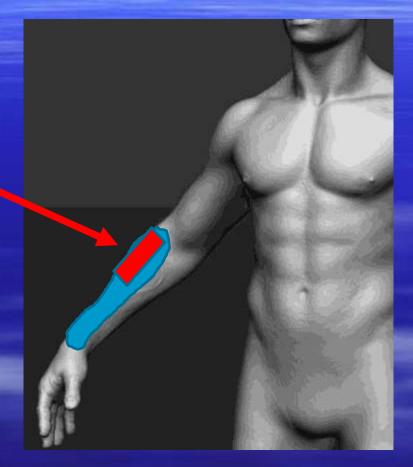






Pain in Musculo-Cutaneous Nerve Distribution

Nerve stimulation was missing this area



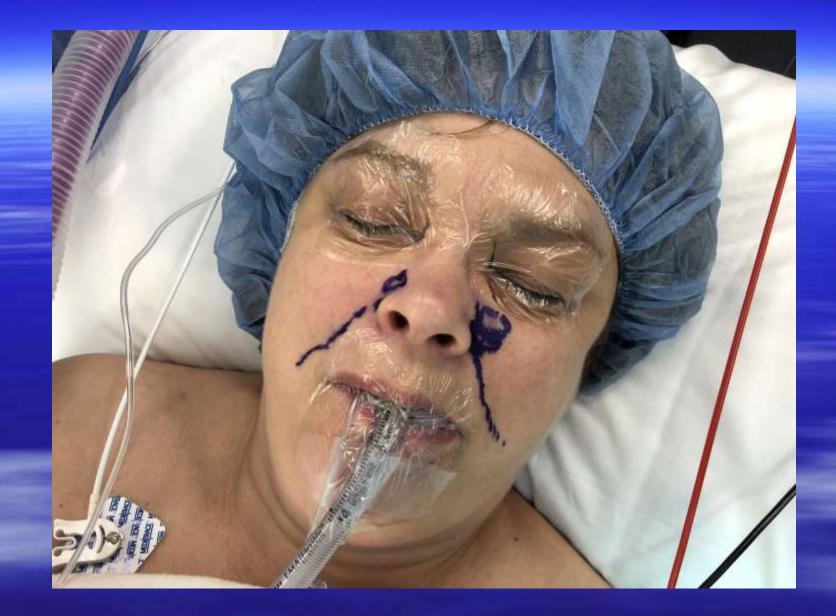
Combined SCS and PNfS

22 y/o
 Multi-level thoracic and lumbar spine degenerative disease
 Intractable pain in the lower/mid/upper lumbar area and both lower extremities

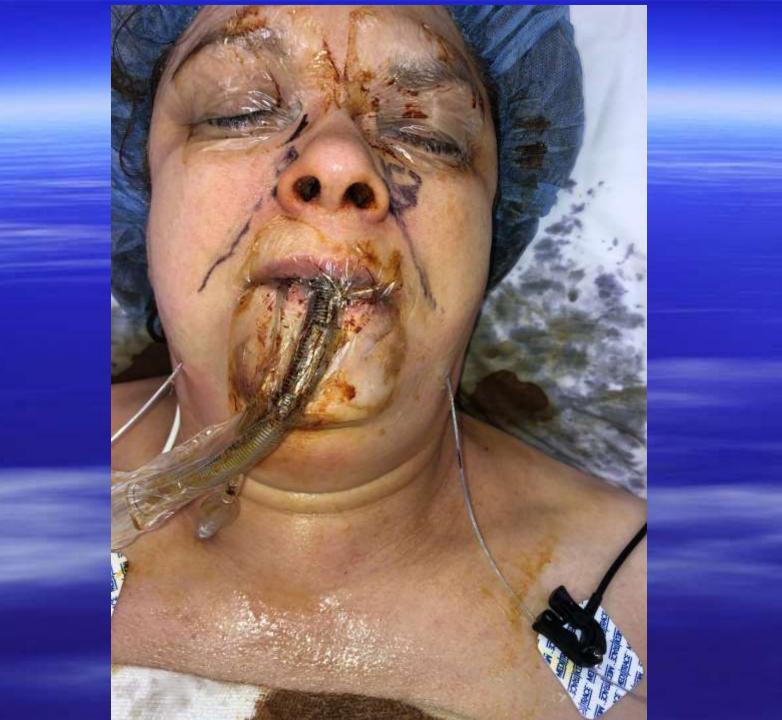












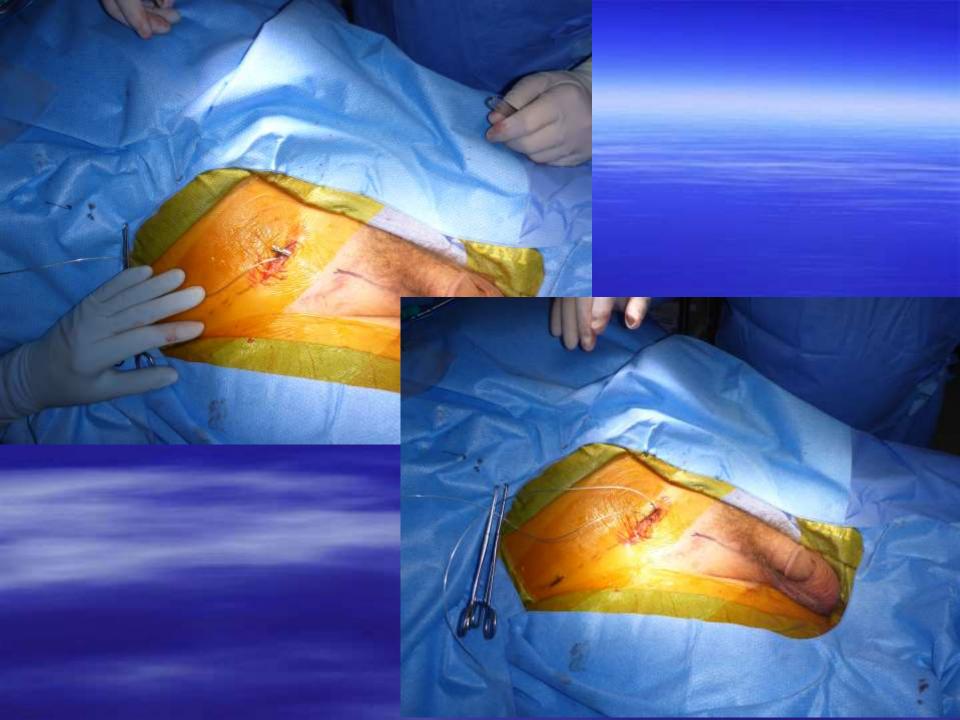


TESTICULAR PAIN





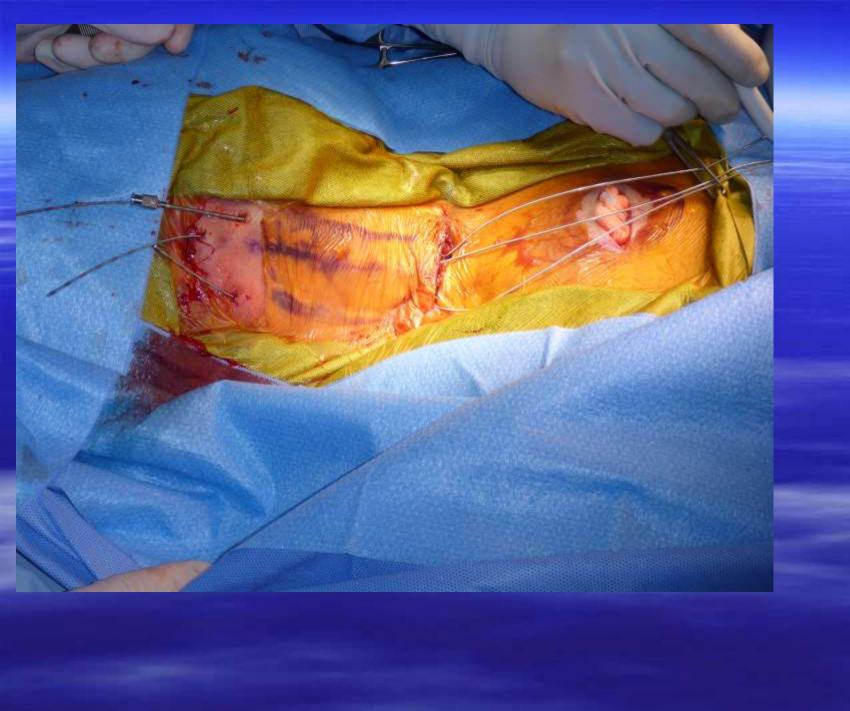






INTRACTABLE NECK PAIN FOLLOWING RADICAL NECK DISSECTION FOR THYROID CANCER



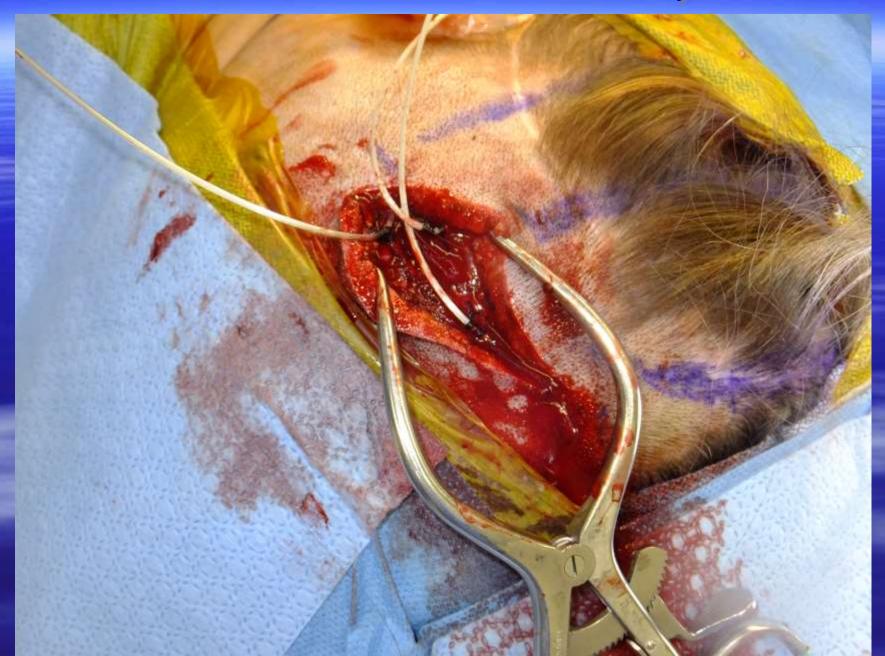




Severe Post- Frontal Craniotomy Pain



Severe Post- Frontal Craniotomy Pain



Severe Post- Frontal Craniotomy Pain





What is the Bggest Challenge with PNS?



THANK YOU

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