

Dorsal Column Spinal Cord Stimulation

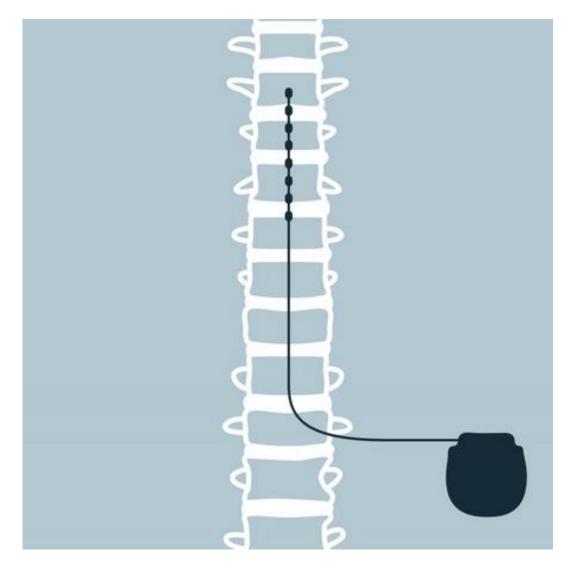
Ryan S. D'Souza MD Tuesday, January 4, 2022 7-8:30 pm ET



- To discuss proposed biochemical mechanisms of action
- To review commonly approved pain conditions
- To discuss how to choose the appropriate candidate
- To review the actual surgical steps involved in trial + implant
- To review landmark RCTs that led to emergence of dorsal column SCS
- To review various waveforms (tonic, burst, 10-kHz, DTM, closed-loop)
- To review common complications



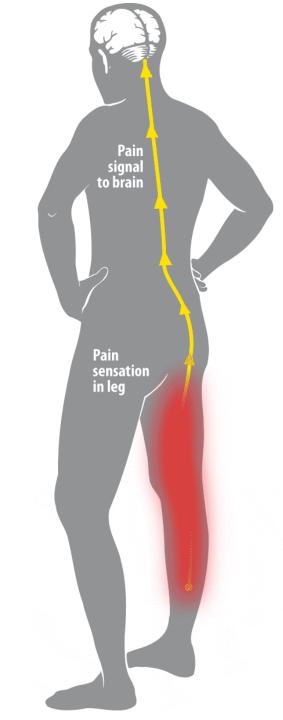
What is Dorsal Column SCS?



PROPOSED MECHANISMS OF ACTION

- Gate Control Theory
- Activate specific receptor subtypes (5-HT, GABA, NE, Dopamine, Ach)
- Glial activation

WE DON'T REALLY KNOW...



APPROVED INDICATIONS FOR SCS

- Failed Back Surgery Syndrome
- Refractory Angina Pectoris
- Complex Regional Pain Syndrome (CRPS)
- Painful Diabetic Neuropathy
- Limb Ischemia

LANDMARK STUDIES

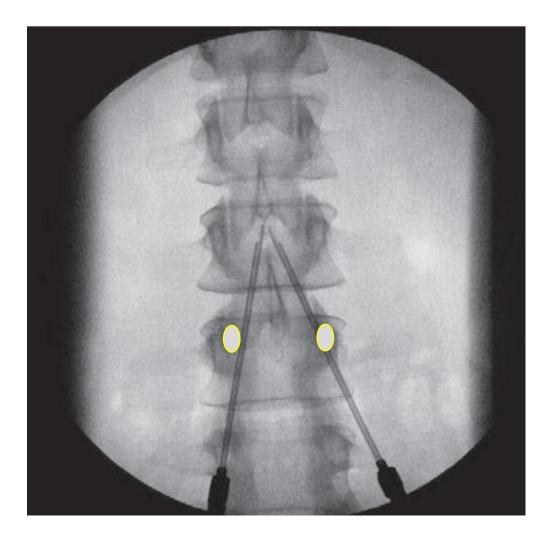
- <u>Kemler et al (NEJM)</u>: First RCT, SCS+PT vs PT alone in reflex sympathetic dystrophy; intention-to-treat analysis showed that SCS+PT group had a 2.4 cm reduction in intensity of pain at 6 months compared to an increase of 0.2 cm in PT only group
- North et al (Neurosurgery): SCS versus spine surgery, pts w/ prior back surgery; SCS > repeat surgery (pain relief, satisfaction); SCS cohort less likely to cross over to the repeat surgery cohort, reoperation cohort required increased opioids
- <u>PROCESS trial (Kumar et al)</u>: Multicenter RCT, SCS for FBSS, more SCS patients (48% vs 9%) versus controls undergoing conventional medical management achieved 50% of more pain relief in the legs

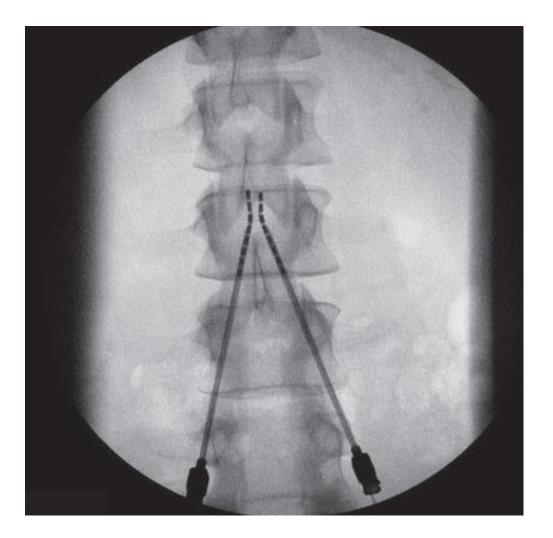
LANDMARK STUDIES

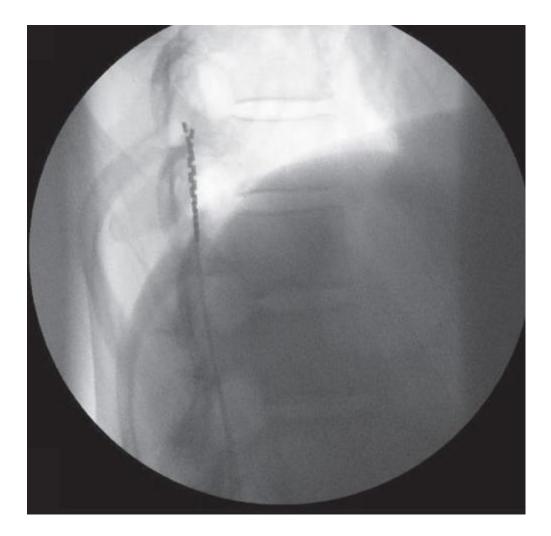
- **SENZA trial:** 10-kHz SCS vs traditional paresthesia-based SCS
- **SENZA-PDN trial (JAMA Neuro):** 10-kHz vs BMT for PDN
- **ACCURATE trial:** DRG vs tonic SCS for lower extremity CRPS
- **<u>DTM trial</u>**: DTM SCS vs traditional SCS
- **EVOKE trial:** ECAP-controlled closed loop SCS vs fixed open-loop SCS
- Ubbink et al (1999, ESES): SCS vs BMT for critical limb ischemia

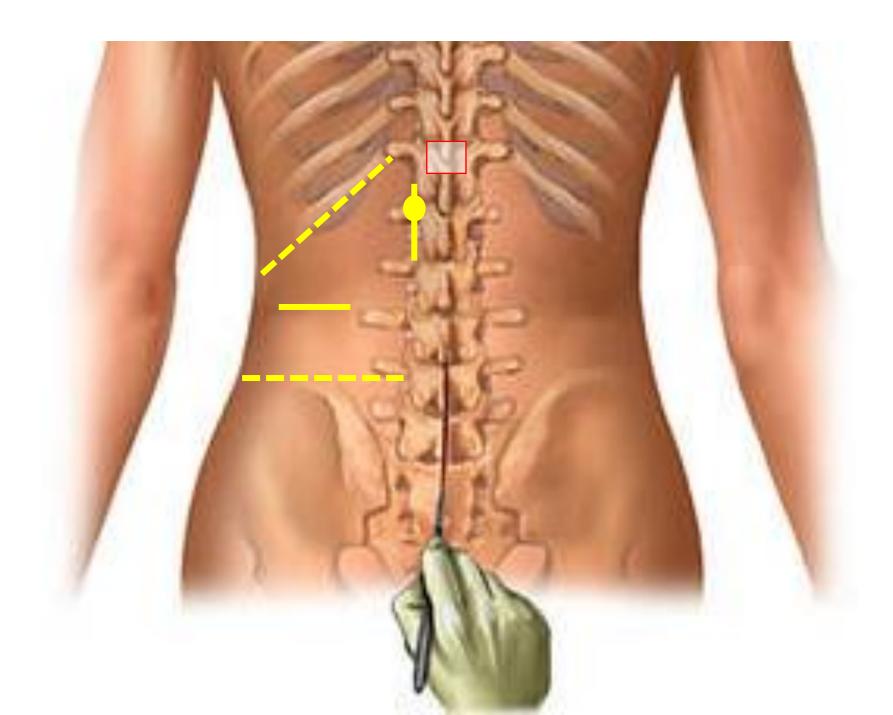
• Positioning is key











STEPS IN PERFORMING AN SCS IMPLANT



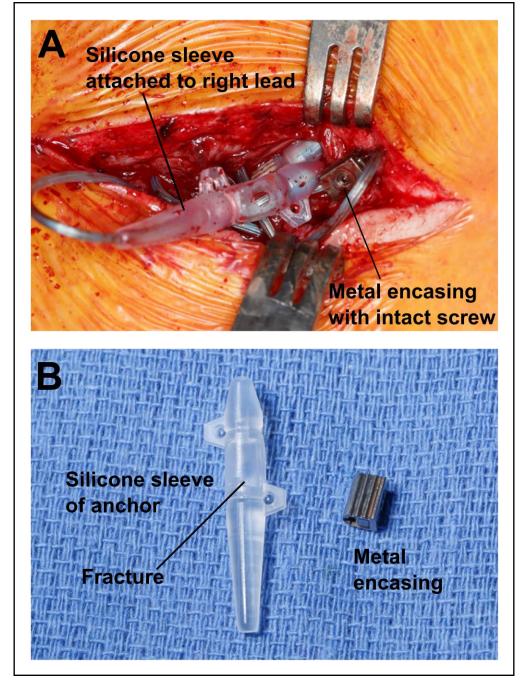
STEPS IN PERFORMING AN SCS IMPLANT









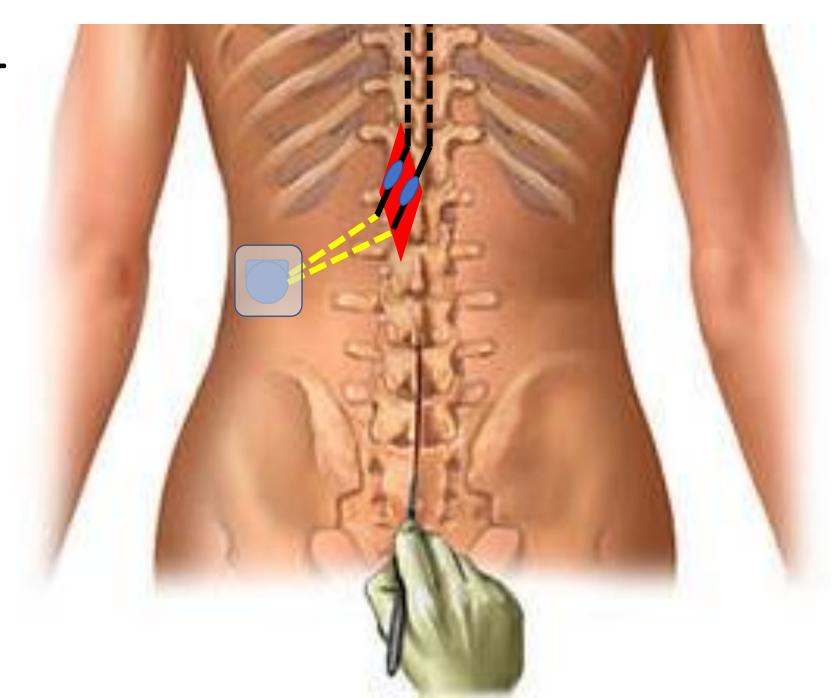


D'Souza RS, Hunt CL. Neuromodulation. 2021 Sep 6.

STEPS IN PERFORMING A STAGED SCS IMPLANT

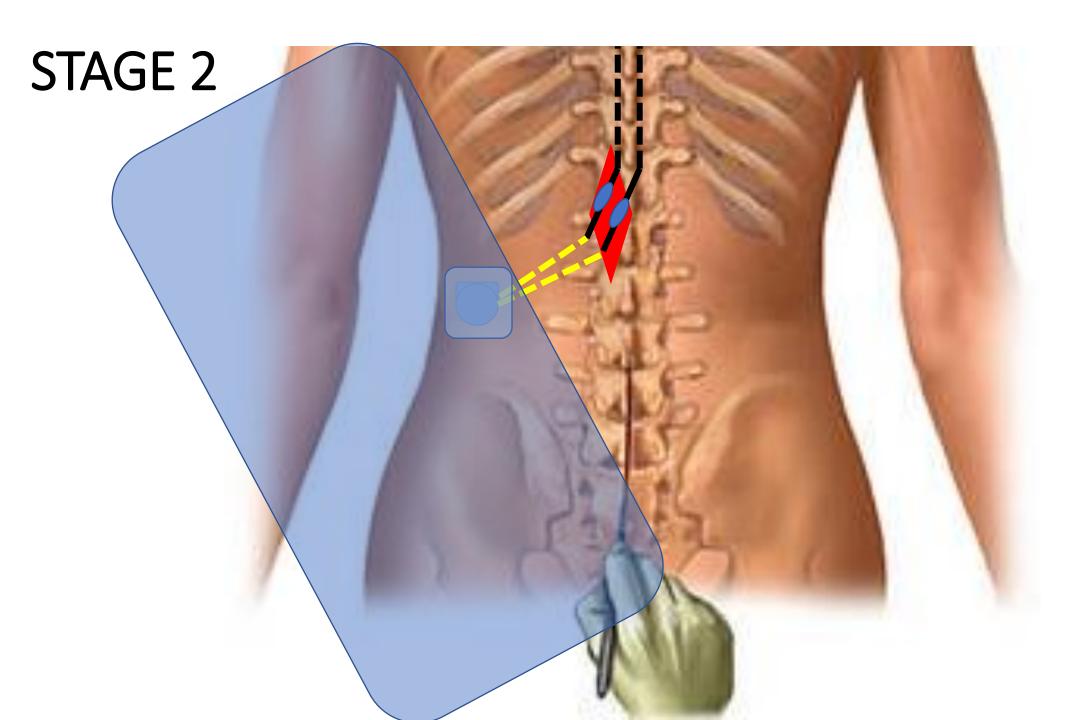
- Strategy for patients with high risk of bleeding
- Stage 1: surgically place and anchor percutaneous leads with cutdown, tunnel to external battery
- Stage 2: open midline incision, disconnect connector, remove external battery, and tunnel to opposite side for internal IPG
- Strategy allows for least manipulation of neuraxial space

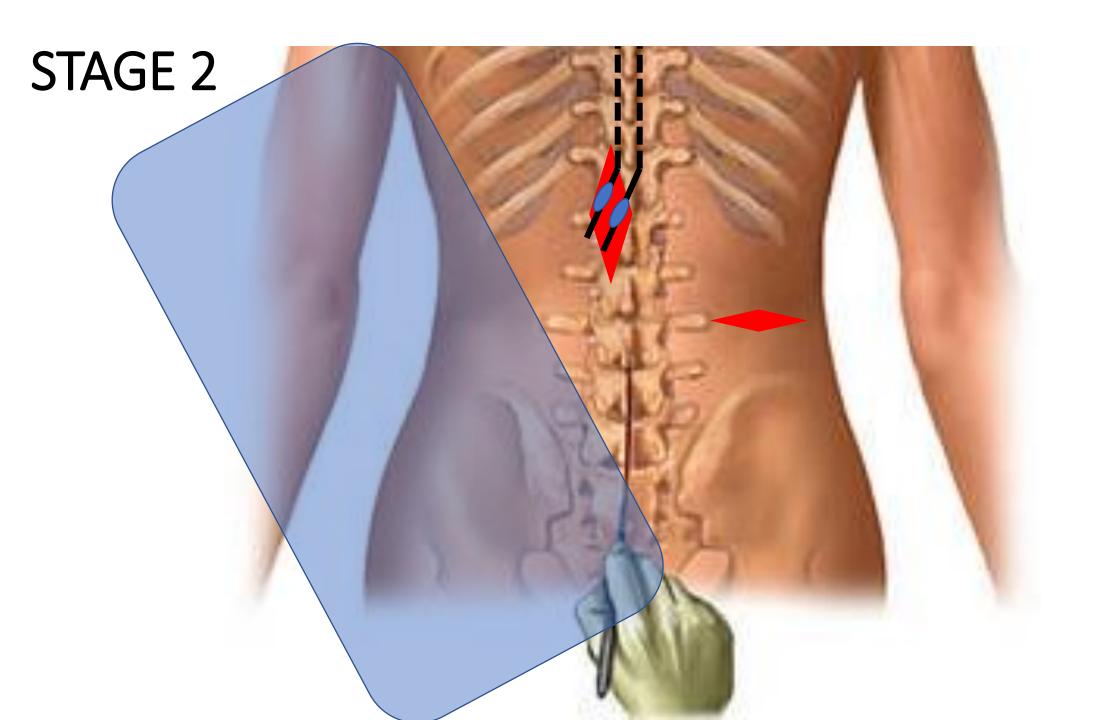
STAGE 1

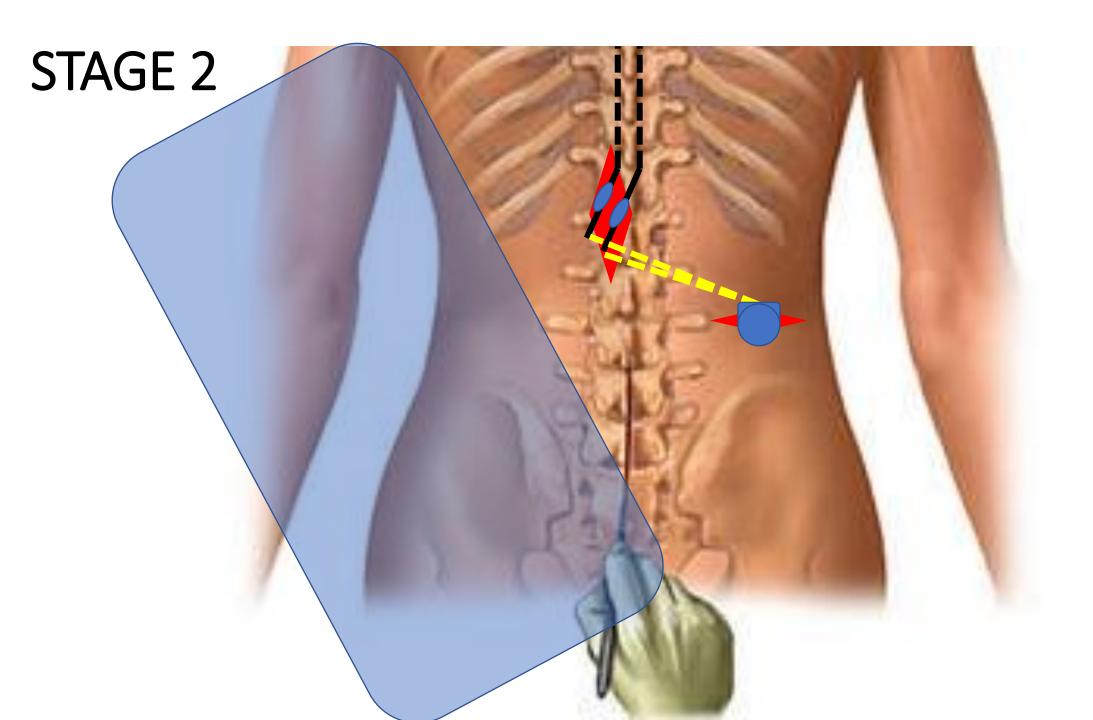


STAGE 1 END (Trial for 5-7 days)



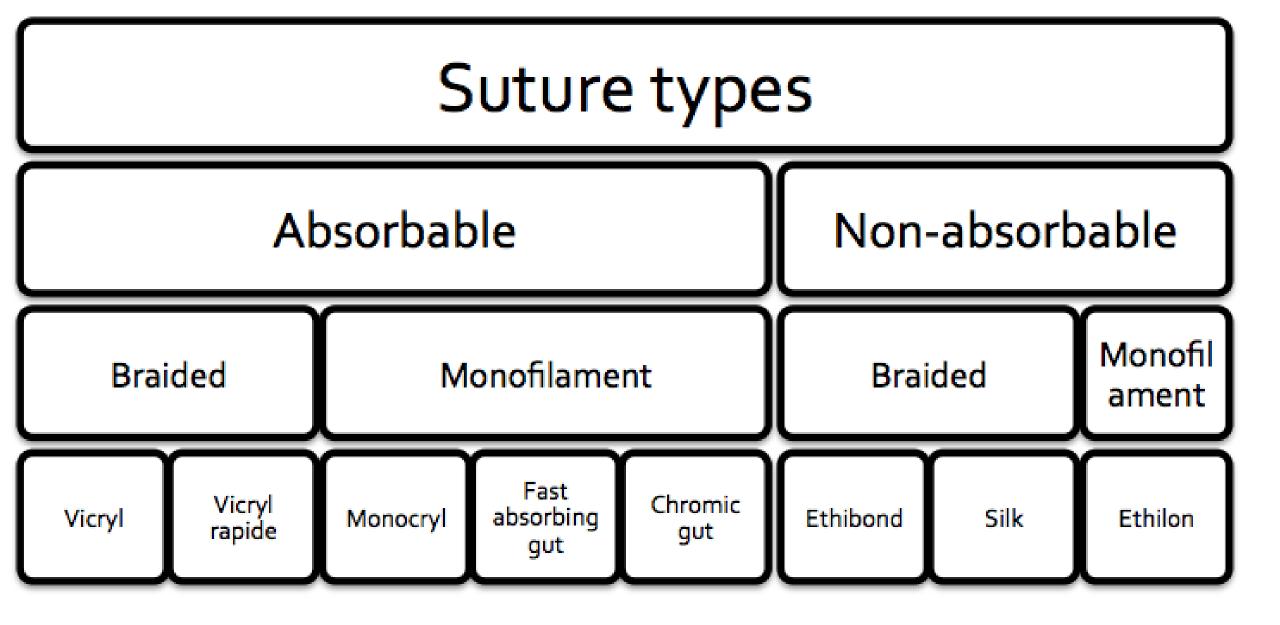






STAGE 2





ASRA Best Practices Regarding Closure

- Synthetic, nonabsorbable suture for anchoring: polyester (Ethibond), polypropylene (Prolene[®]), or nylon (Ethilon[®])
- Nonabsorbable sutures retain most of their tensile strength after 60 days
- Although silk is nonabsorbable suture, it does degrade with a variable rate and therefore loses its tensile strength quicker
- Nylon sutures: high tensile strength, low tissue reactivity, inexpensive; more cumbersome in deeper fascia
- Polypropylene: high tensile strength, low tissue reactivity, good infection resistance; low elasticity
- Polyester suture (Ethibond): good strength and durability; braided
- Five throws required to maintain knot security

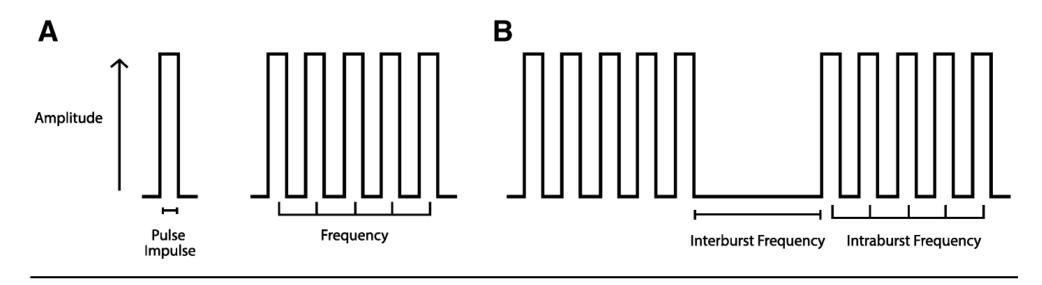
ASRA Best Practices Regarding Closure

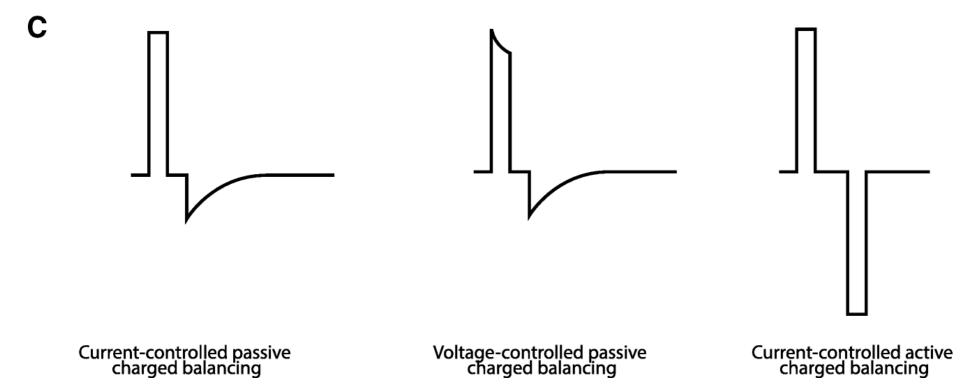
- Absorbable sutures: decrease dead space and encourage subcutaneous wound approximation in deep layers prior to superficial skin closure
- Polyglactin (Vicryl[®]): braided suture (increased bacterial adherence up to 10 times > monofilament suture)
- Monocryl: good for superficial closure; retains 60-70% of its original strength at 7 days post-implant and 30-40% strength at 14 days postimplant
- Staples: increased risk of infection in some surgical settings vs subcuticular closures (low quality evidence)

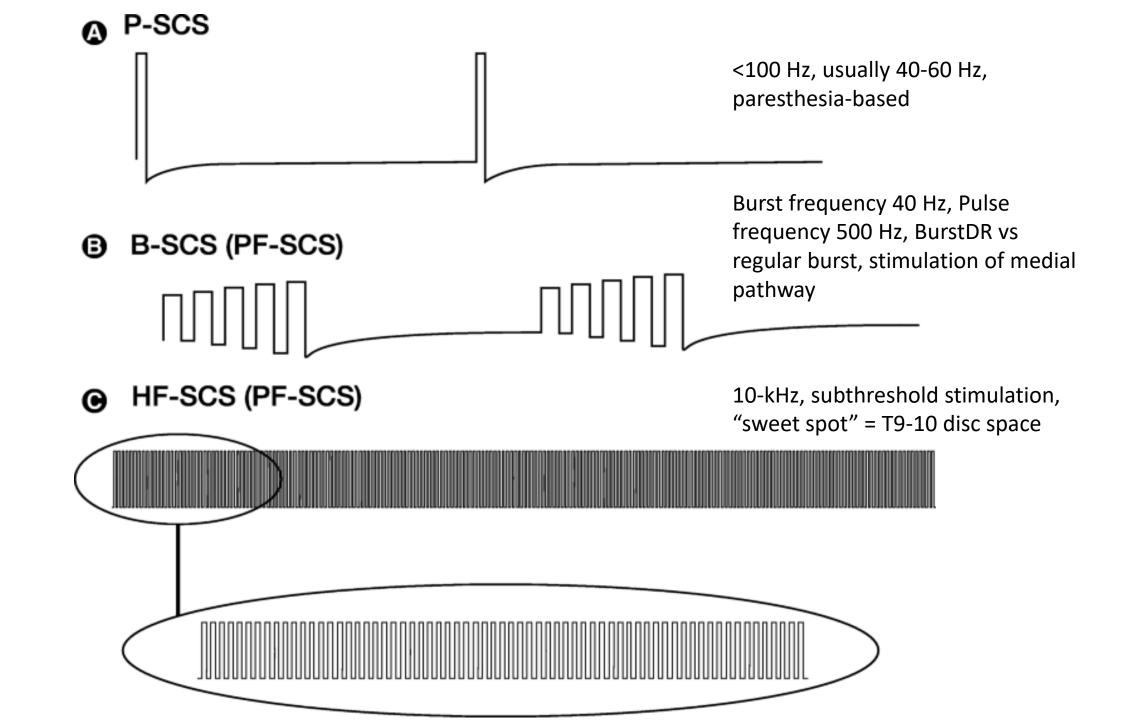
CHOOSING THE APPROPRIATE PATIENT

- Approved indication
- Failed 1st line/2nd line treatment
- Benefits > risks (example: factor XI deficiency)
- Mental health and behavioral issues
- Optimization (smoking, immunosuppression, pre-op opioid use)
- Appropriate expectations (define what success entails)
- Balance of patient selection (sensitivity vs specificity)

Parameters for the Spinal Cord Stimulation

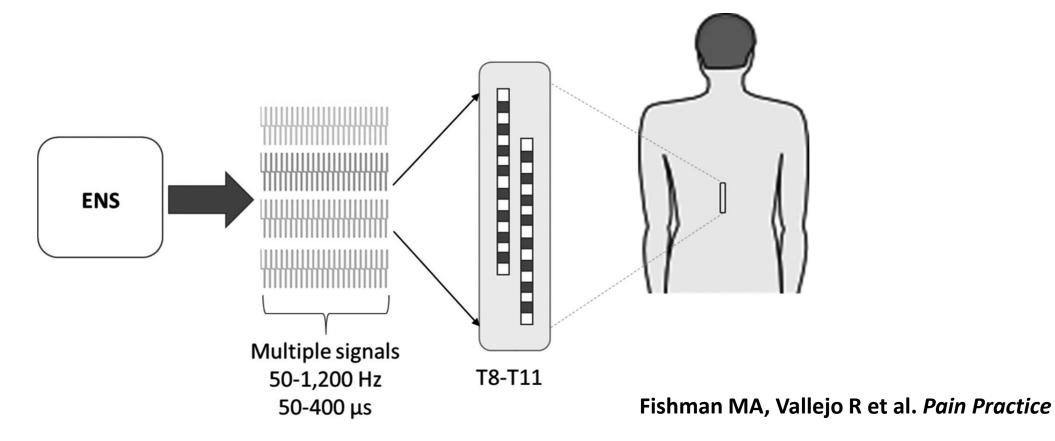




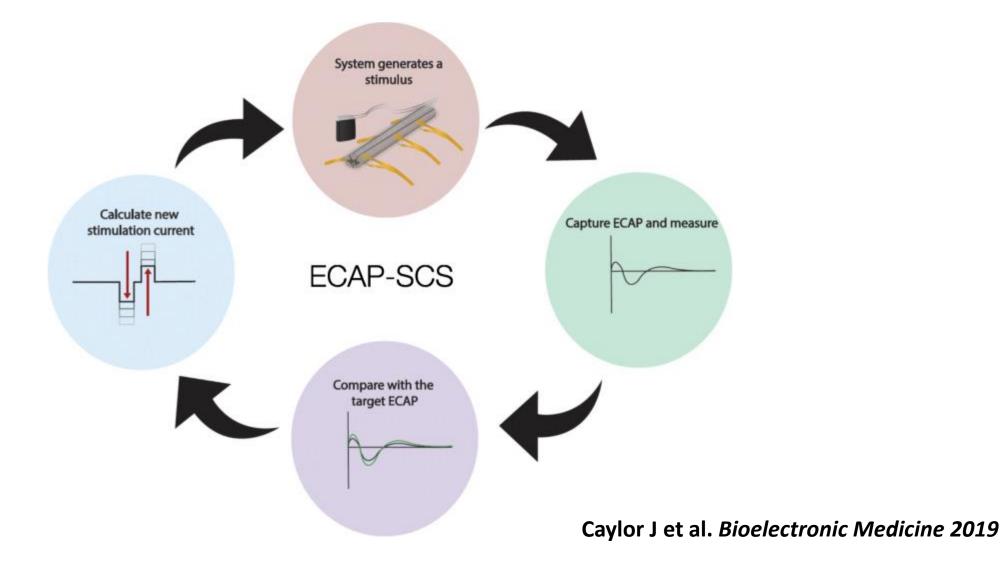


DIFFERENTIAL-TARGET MULTIPLEXED SCS WAVEFORM

• Multiple electrical signals for modulating glial cells and neurons and rebalance their interactions



CLOSED-LOOP SCS WAVEFORM



COMBINATION SCS WAVEFORMS



Journal of *Clinical Medicine*



Article

Real-World Outcomes Using a Spinal Cord Stimulation Device Capable of Combination Therapy for Chronic Pain: A European, Multicenter Experience

Jan Willem Kallewaard ^{1,*}^(D), Jose Francisco Paz-Solis ², Pasquale De Negri ³, Maria Angeles Canós-Verdecho ⁴^(D), Hayat Belaid ⁵, Simon J. Thomson ⁶^(D), David Abejón ⁷, Jan Vesper ⁸, Vivek Mehta ⁹, Philippe Rigoard ¹⁰, Paolo Maino ¹¹, Sarah Love-Jones ¹², Isaac F. Peña ¹³^(D), Simon Bayerl ¹⁴, Christophe Perruchoud ¹⁵, Renaud Bougeard ¹⁶, Cleo Mertz ¹⁷, Yu Pei ¹⁸ and Roshini Jain ¹⁸

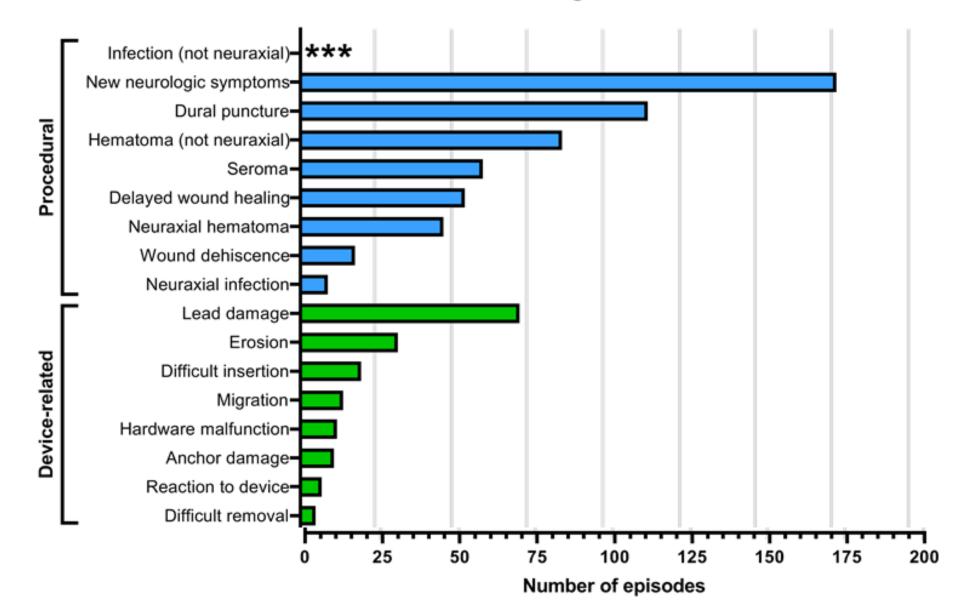
COMPLICATIONS WITH DORSAL COLUMN SCS



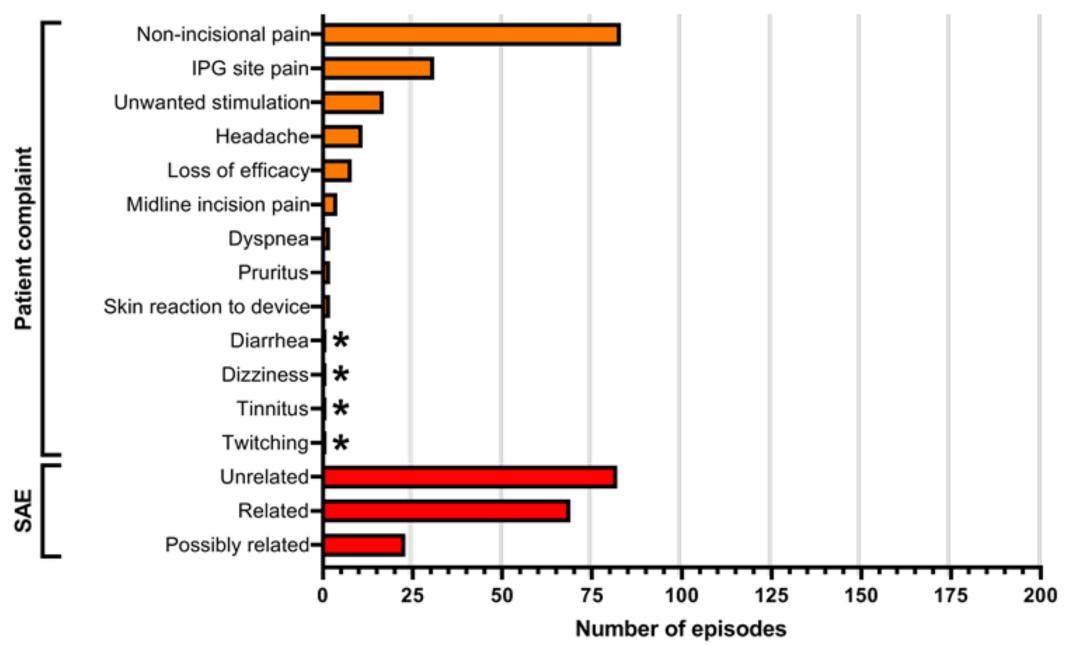
- MOST CONCERNING: epidural hematoma, abscess, meningitis, nerve injury
- OTHER CONCERNS: lead migration, loss of efficacy, hardware complications

D'Souza RS et al. Clin J Pain 2021, in press

Subcategorization of procedural, device-related, patient complaint, and serious adverse event categories



D'Souza RS et al. Clin J Pain 2021, in press



NACC GUIDELINES: PRE-OPERATIVE RISK RECOMMENDATIONS

RECOMMENDATION	USPSTF GRADE
Obtain preoperative MRI prior to SCS implant	III
Perform pre-operative optimization of diabetes	II-1
Optimize risk factors that increase infection risk such as immunosuppression	III
Address platelet counts of 100k or less	II-3
Obtain preoperative CBC and BMP	III
Preoperative screening + decolonization of MSSA/MRSA with mupirocin BID and daily chlorhexidine washings for five days	l
Address systemic or local skin infection at site of planned implant	111

NACC GUIDELINES: INTRAOPERATIVE AND POSTOPERATIVE RISK RECOMMENDATIONS

RECOMMENDATION	USPSTF GRADE
Laminar flow OR to reduce outdoor airborne pathogens	II-2
Chlorhexidine-alcohol or povidone-iodine prep	I
Removal hair by clipping (if required)	I
Minimize OR traffic and surgical time	III
Non-pressured irrigation of wounds by saline solution	II-1
Sterile occlusive dressing for 24-48 hours postoperatively	I
Inspect wound within 7-10 days postoperatively	III
Successful trial = at least 50% pain relief	III

NACC GUIDELINES: INFECTION PREVENTION LEVEL I

RECOMMENDATION

Decolonize MSSA/MRSA carriers through application of mupirocin ointment and chlorhexidine baths

Use preoperative abx within 1 hour prior to surgical incision

Remove hair immediately prior to surgery with electrical clippers

Use iodophor-impregnated drapes.

Use laminar flow and high-efficiency particulate air (HEPA) filters in the OR for implants

Limit procedure room traffic

Do not continue postoperative antibiotics beyond 24 hours.

NACC GUIDELINES: INFECTION PREVENTION LEVEL II

RECOMMENDATION
Identify and treat all remote infections prior to trials/implants
Optimize glucose control
Discontinue tobacco use
Perform preoperative surgical scrub for a minimum of 2-5 minutes
Keep nails short (no artificial nails)
Wear a surgical mask and cap or hood to fully cover hair
Use sterile gown and gloves; double glove
Limit operative time
Apply an occlusive dressing for 24-48 hours

NACC GUIDELINES: INFECTION PREVENTION LEVEL III

RECOMMENDATION

Do not wear arm or hand jewelry

Limit tissue trauma, maintain hemostasis, eradicate dead space, and avoid electrocautery at tissue surface

Maximum time of 1 year for defining a deep SSI of an implantable device Educate patient on proper incision care, symptoms of SSI, and importance of reporting symptoms

Wash hands before and after dressing changes, and use sterile technique

When SSI is suspected, prescribe an appropriate antibiotic that covers the likely causative organisms (consider local resistance patterns and culture results)



- Contact e-mail: <u>dsouza.ryan@mayo.edu</u>
- Mentoring opportunities





QUESTIONS?