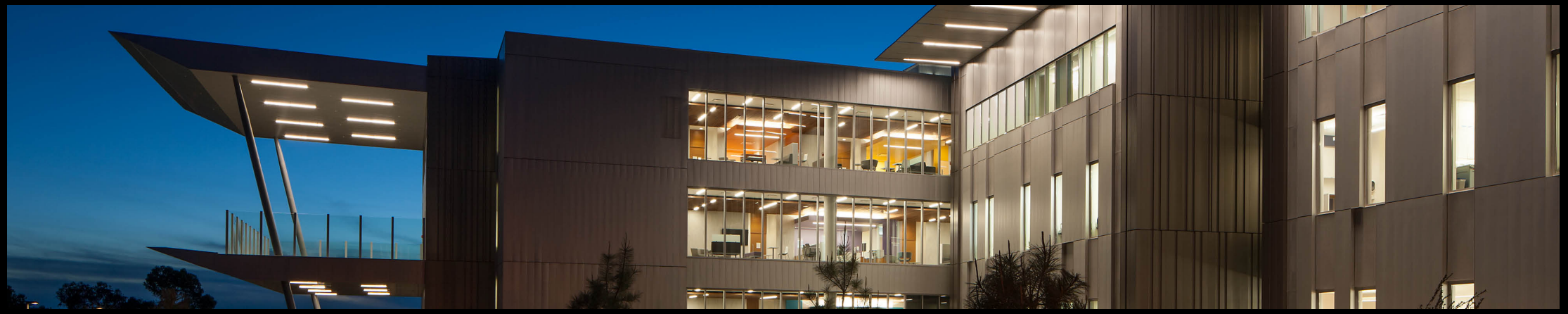

Is it all about the Waveform?

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Professor of Anesthesiology
University of California, San Diego

AAPM 2022 38TH ANNUAL MEETING

OBJECTIVES

1 Understand SCS waveforms available for treatment of pain

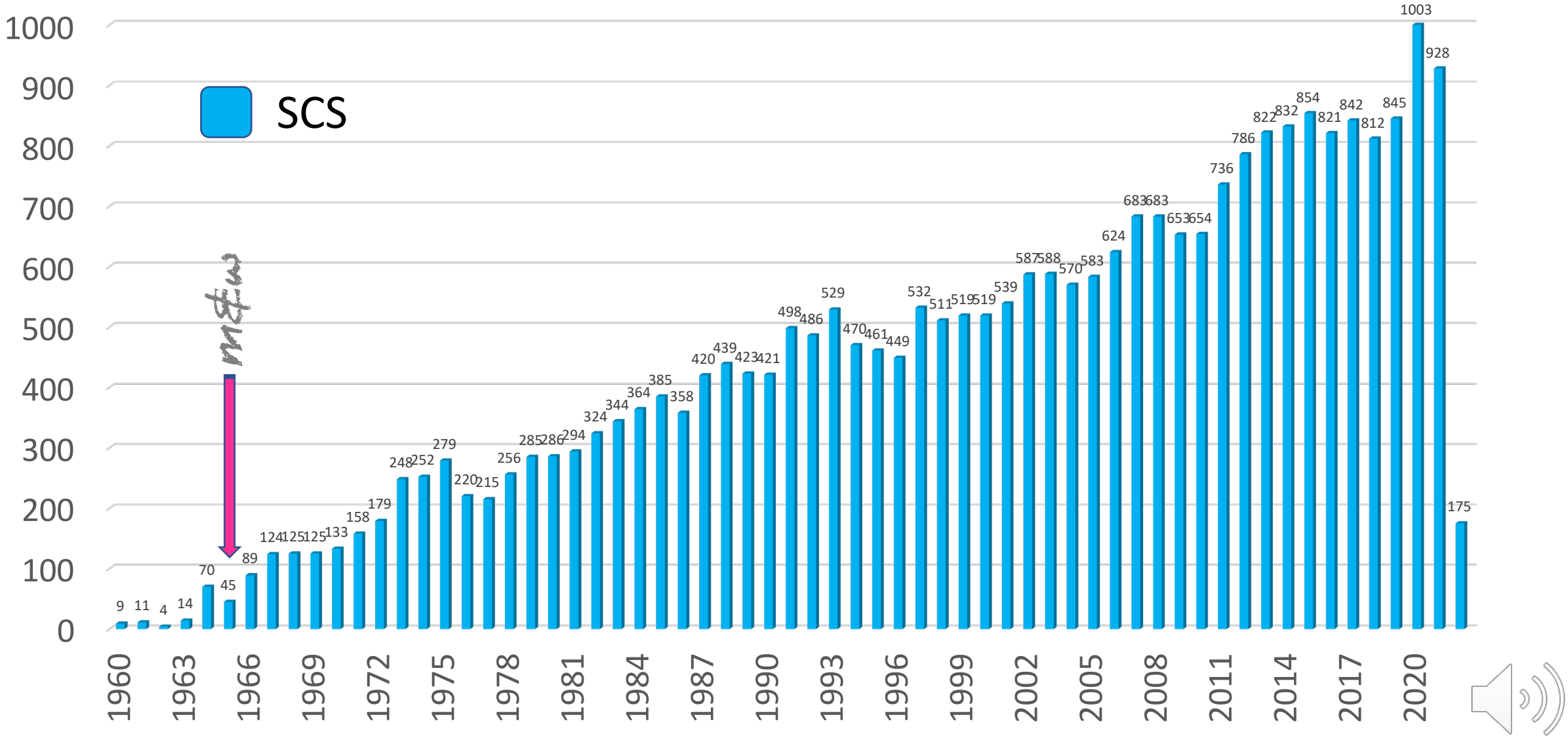
2 Review RCT efficacy and safety data for waveforms / devices

3 Consider implications for clinical decision making

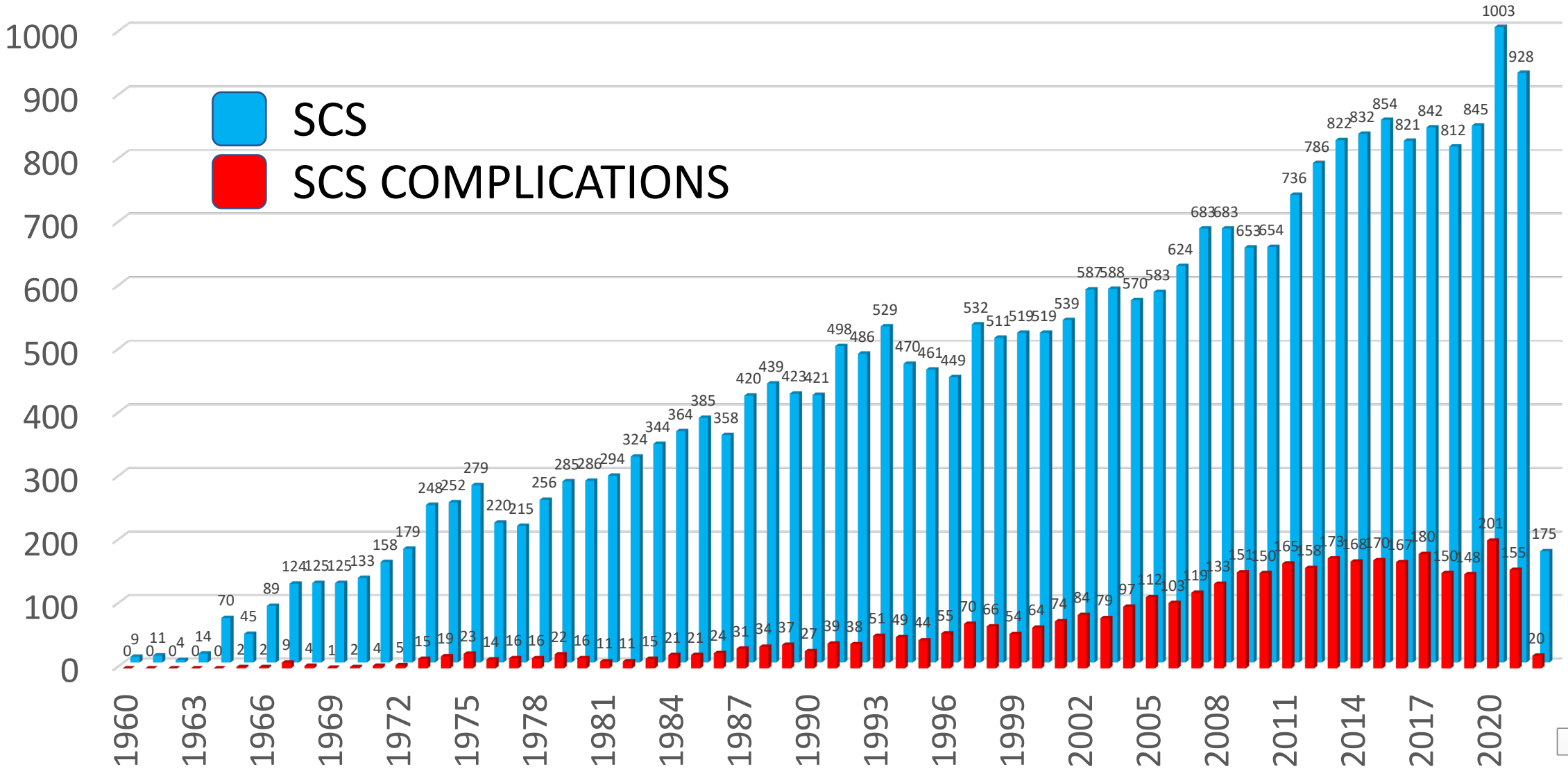
FINANCIAL DISCLOSURES

▪ Semnur/ Scilex	PI; Research Support
▪ Boston Scientific	PI; Research Support
▪ Mainstay Medical	PI; Research Support
▪ SKK	PI; Research Support
▪ Medtronic	CO-I, Research Support
▪ SI-Bone	CO-I; Research Support
▪ PainScan	Consultant

PubMed.Gov: SPINAL CORD STIMULATOR PUBLICATIONS; 1960-2022



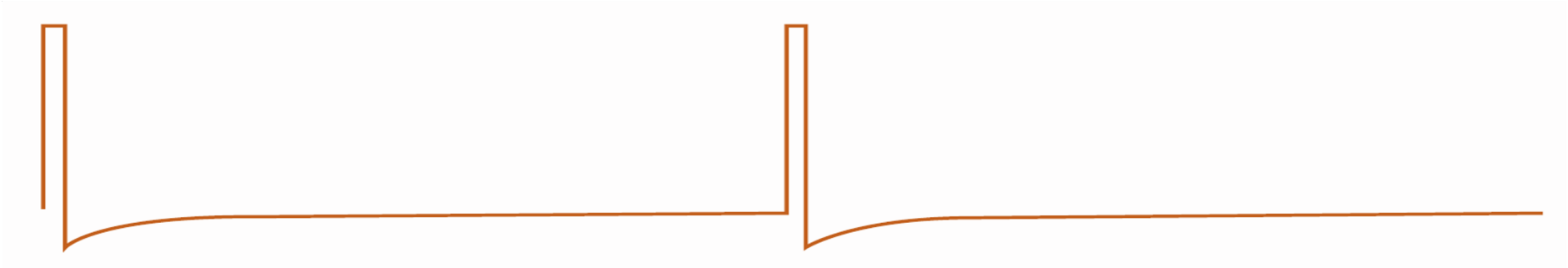
PubMed.Gov: SPINAL CORD STIMULATOR PUBLICATIONS; 1960-2022



SPINAL CORD STIMULATION: Advances

LEADS	IPG	WAVEFORMS
▪ # Contacts (1-32) ▪ Percutaneous ▪ Paddle ▪ DRG	▪ Voltage ⇢ Current ▪ Single ⇢ Multi Source ▪ Updatable Platform ▪ MRI Compatibility ▪ Size/ Invasiveness	▪ P-SCS ▪ PF-SCS ▪ DRG-S ▪ Closed Loop- ECAP

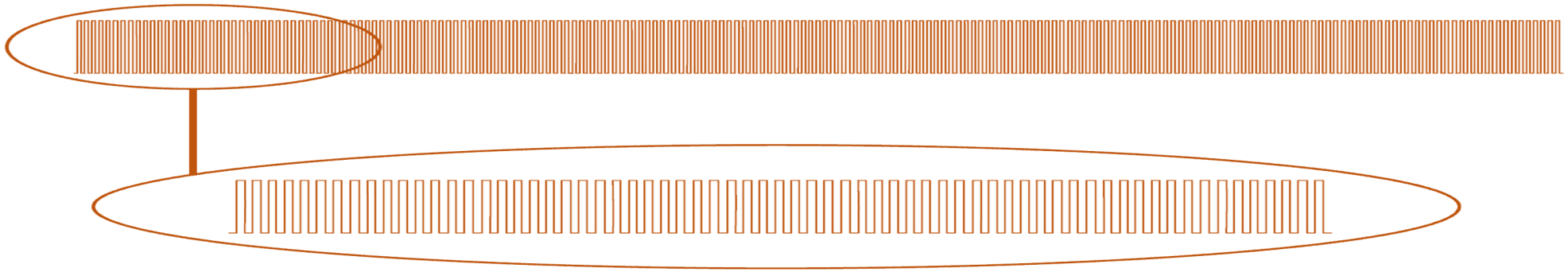
Stimulation Waveform Patterns: P-SCS (Tonic)



CHARACTERISTICS	MECHANISM
▪ Tonic/ Repetitive/ Single ▪ Low Freq: 40-60 Hz ▪ Pulse Width: 200-500 µs ▪ Amplitude 3.5-8.5 mA	**Most Published Evidence** 1. Segmental Spinal Mechanism DH Inhibitory Neurons (GABA) 2. ↓ Microglia/ Astrocyte Activation 3. Descending Anti-Nociceptive Sys.

Caylor J, et al. Spinal cord stimulation in chronic pain: evidence and theory for mechanisms of action. Bioelectron Med. 2019 Jun 28;5:12.

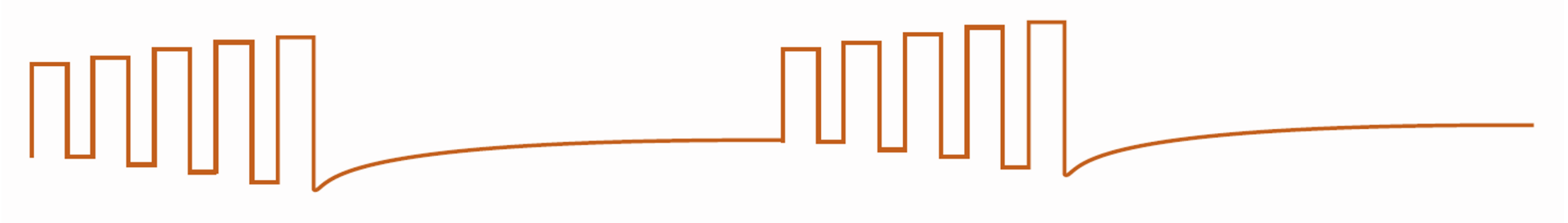
Stimulation Waveform Patterns: PF-SCS (HF-SCS)



CHARACTERISTICS	MECHANISM
• Continuous Mode • High Freq: 10 KHz • Pulse With: 30 µs • Amplitude 50-70% PT	**Mechanism not clear** 1. Segmental Modulation of DH Circuits 2. Modulation of Neuro-Inflammation 3. Thermal Homeostatic Changes • What about 100 Hz – 10K Hz? • 1-5 KHz PF-SCS (HD-SCS)

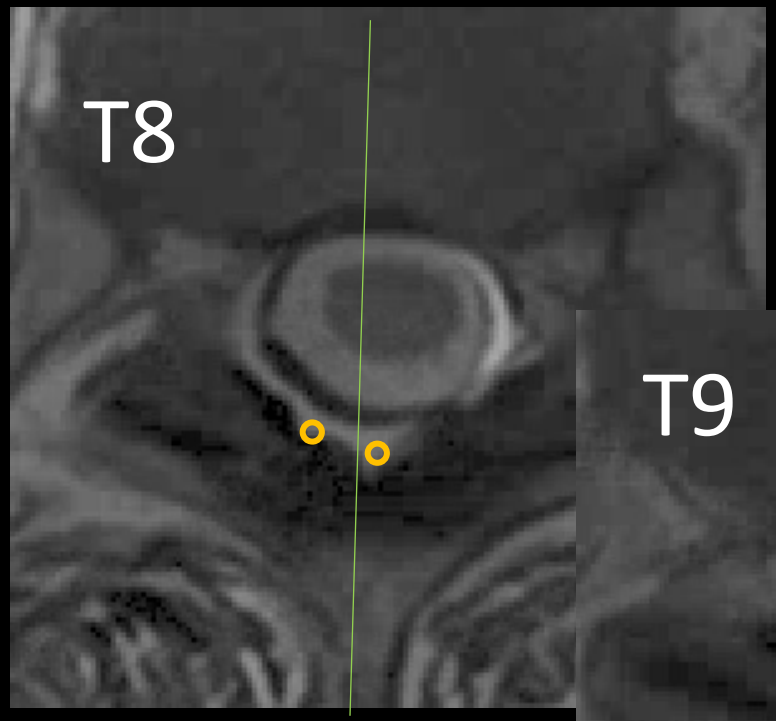
Caylor J, et al. Spinal cord stimulation in chronic pain: evidence and theory for mechanisms of action. Bioelectron Med. 2019 Jun 28;5:12.

Stimulation Waveform Patterns: PF-SCS (B-SCS)



CHARACTERISTICS	MECHANISM
▪ 5 Pulse - Burst ▪ Inter-Burst Freq: 40 Hz ▪ Intra-Burst Freq : 500 Hz ▪ Pulse Width: 1000 µs ▪ Amplitude 50-70% PT	**Mechanism not clear** ***Emulates Endogenous Patterns*** 1. Segmental Spinal Mechanism (non-GABA) ○ [Cortical Attentional Mechanisms]

Caylor J, et al. Spinal cord stimulation in chronic pain: evidence and theory for mechanisms of action. Bioelectron Med. 2019 Jun 28;5:12.
De Ridder D, Bet al. World Neurosurgery. 2013;80(5):642–649.e641.
De Ridder D, et al. Neurosurgery. 2010;66(5):986–90.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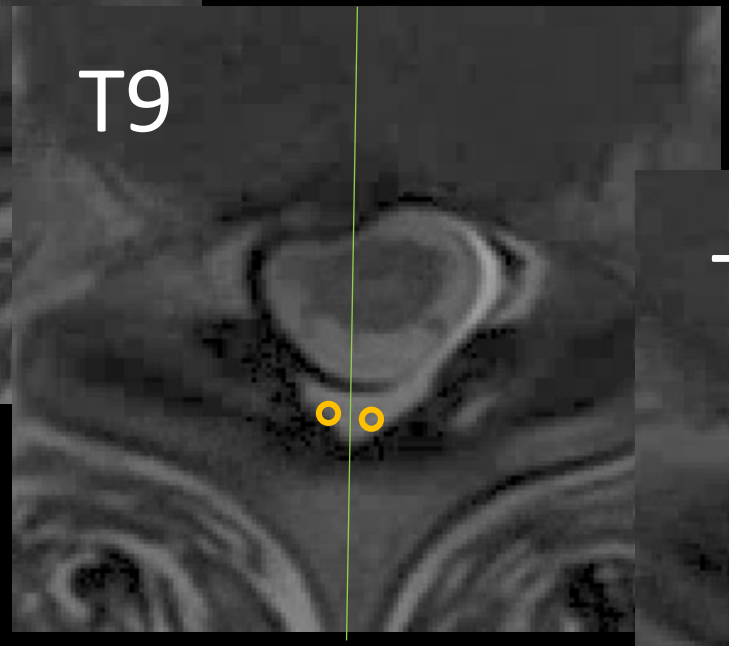
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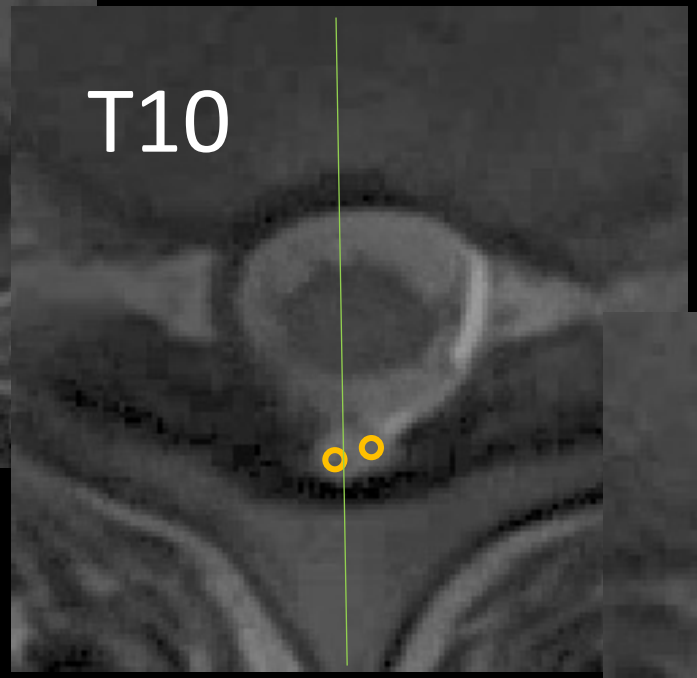
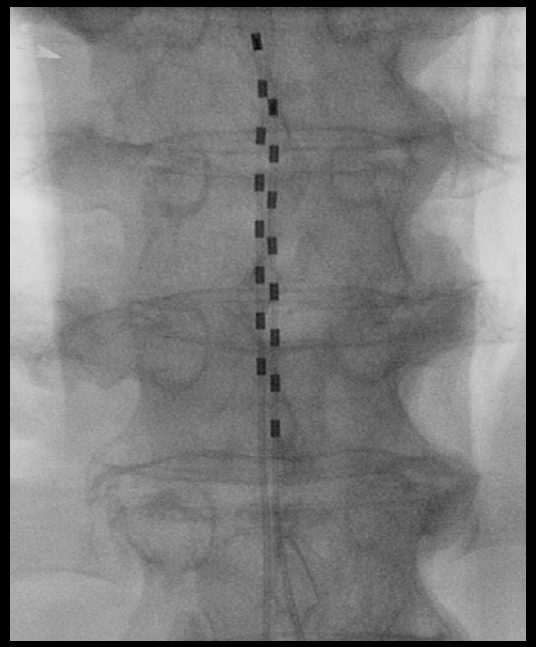
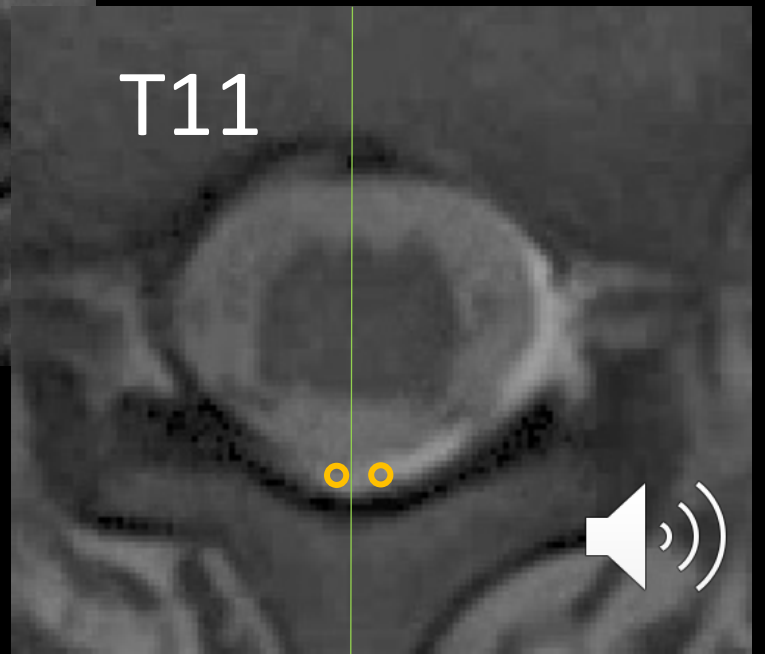

T10


T5
T6
T7
T8
T9
T10
T11
T12
L1




T11

Closed Loop ECAP-SCS (P-SCS)

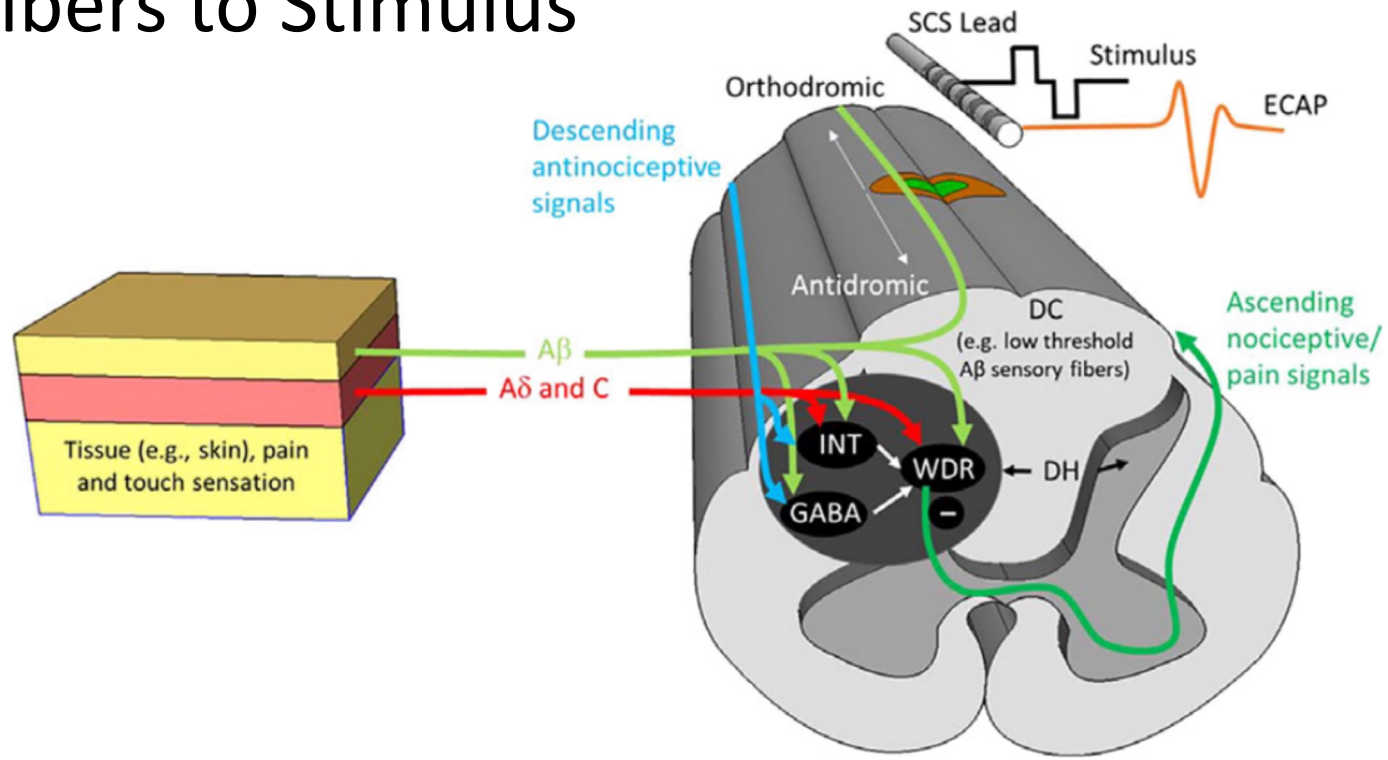
What is ECAP?

Evoked Compound Action Potential

EP-Response of Nerve Fibers to Stimulus

- Conduction velocity
- Amplitude
- Fiber diameter
- # Fibers Recruited
- AP Frequency

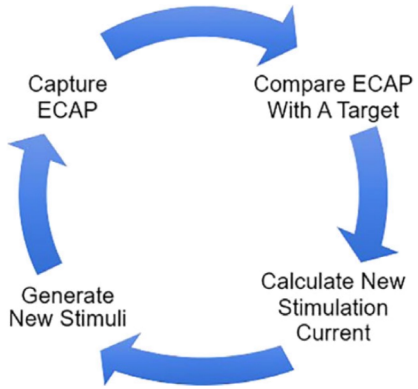
- Neuronal Excitability
- Neuropathic vs Somatic



Caylor J, et al. Bioelectron Med. 2019 Jun 28;5:12.
Russo R, et al. J Physiol. 1996;493(1):55–66.
Devor M. Exp Brain Res. 2009;196(1):115–28.
Levy R, et al. Neuromodulation. 2019 Apr;22(3):317-326. (EVOKE)
Russo M, et al. Neuromodulation. 2018 Jan;21(1):38-47. (AVALON)

Closed Loop ECAP-SCS (P-SCS)

- ECAP – Feed Back Control
- Adjust DC Fiber Recruitment
- Maintain Therapeutic Window

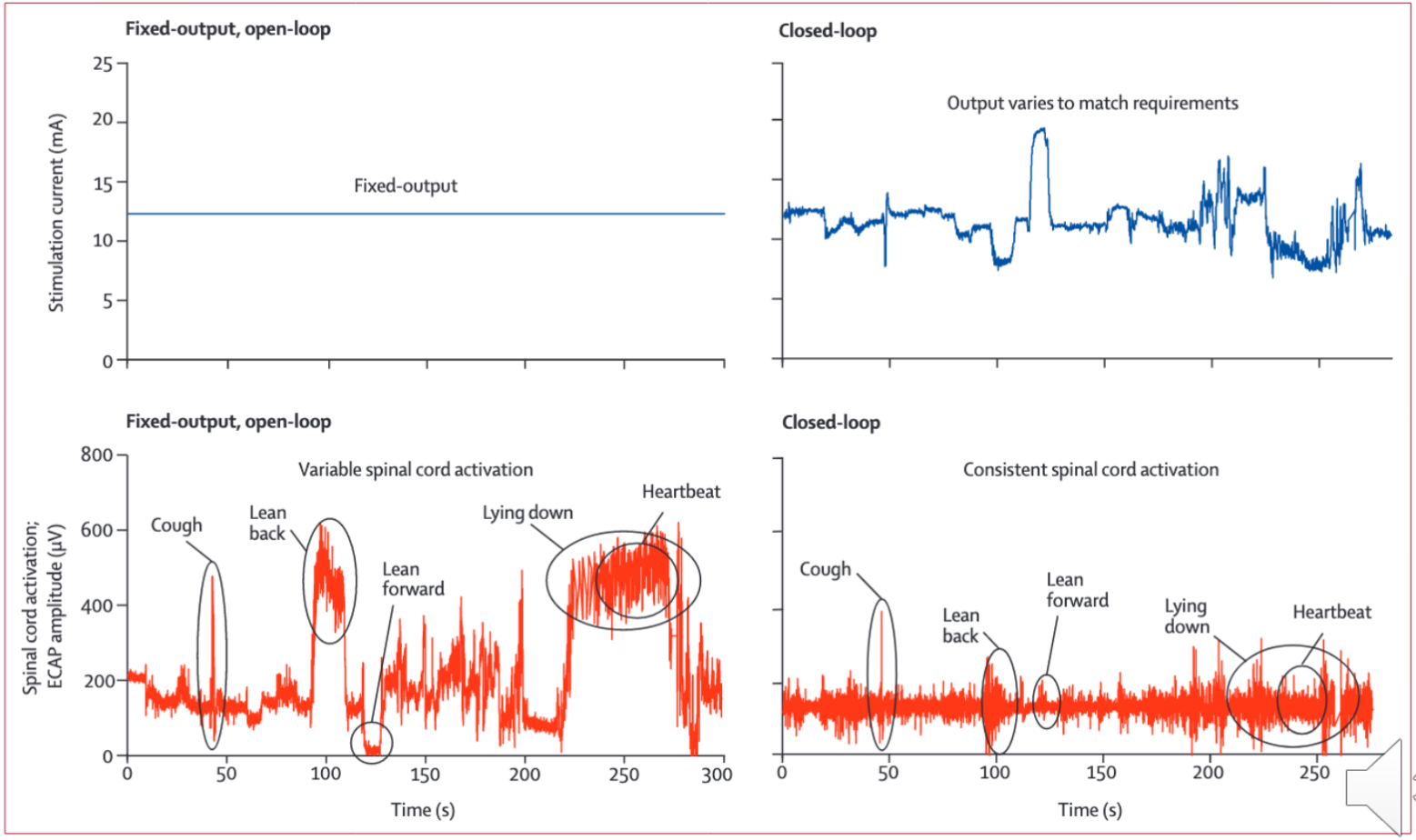


OPEN - LOOP

- Fixed Output Stimulation
- Variable SC Activation

CLOSED - LOOP

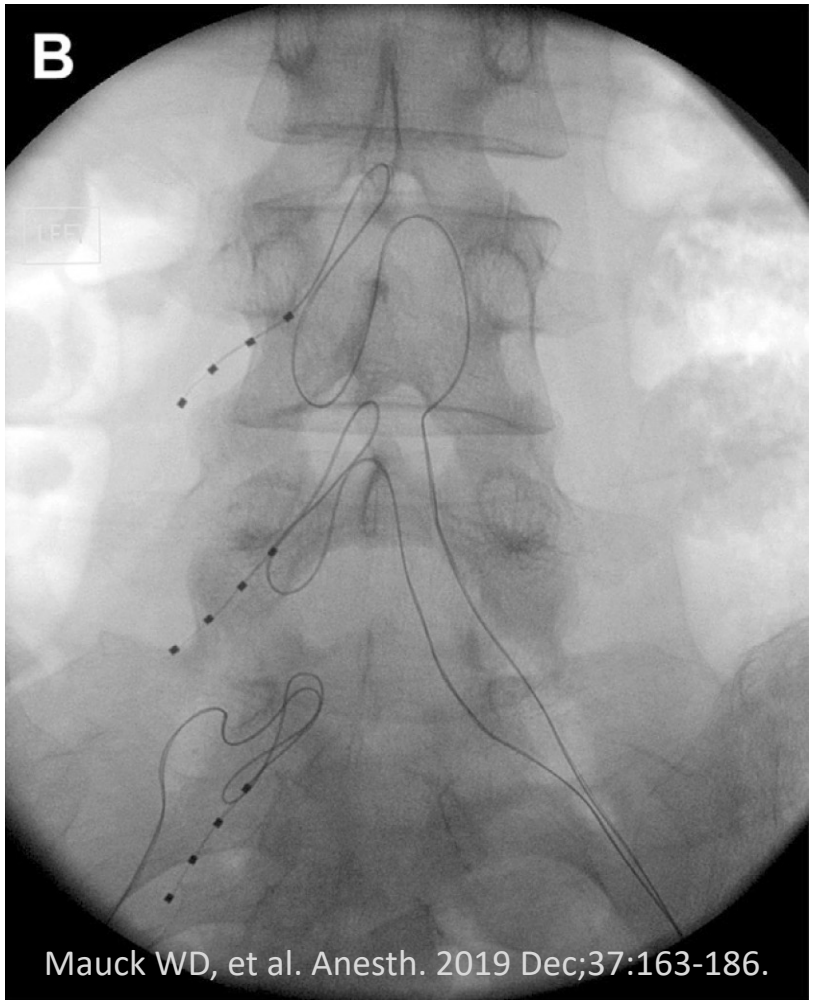
- Dynamic Output Stimulation
- Consistent SC Activation



Mekhail N, et al. Lancet Neurol. 2020 Feb;19(2):123-134. (EVOKE)
Levy R, et al. Neuromodulation. 2019 Apr;22(3):317-326. (EVOKE)

DRG-S

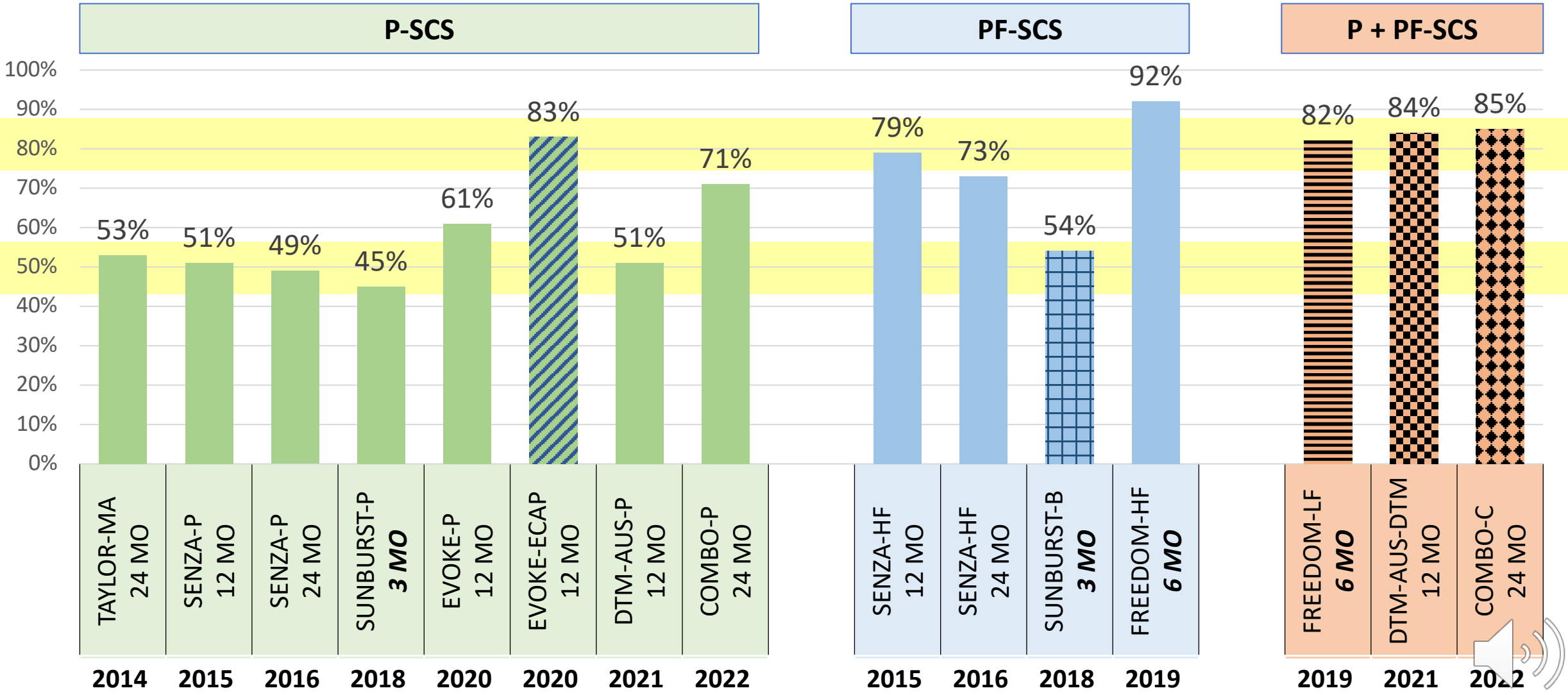
- Tonic - PF
- Low Freq: 20 Hz
- Pulse Width: 300 – 400 µs
- Amplitude 0.6 – 1 mA



Mauck WD, et al. Anesth. 2019 Dec;37:163-186.

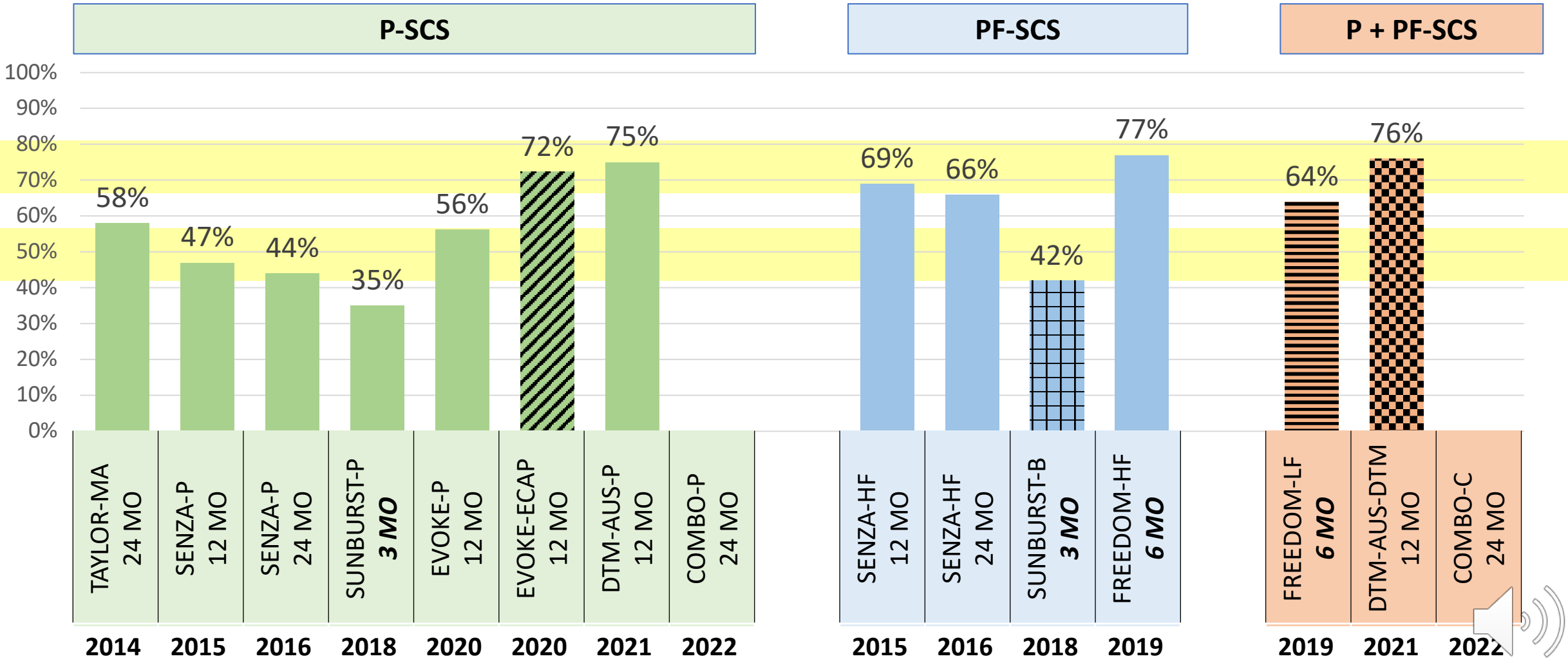
Comparative Efficacy of SCS by Waveform for Low Back and Leg Pain

% Subjects Reporting ≥ 50% Pain Relief From Baseline



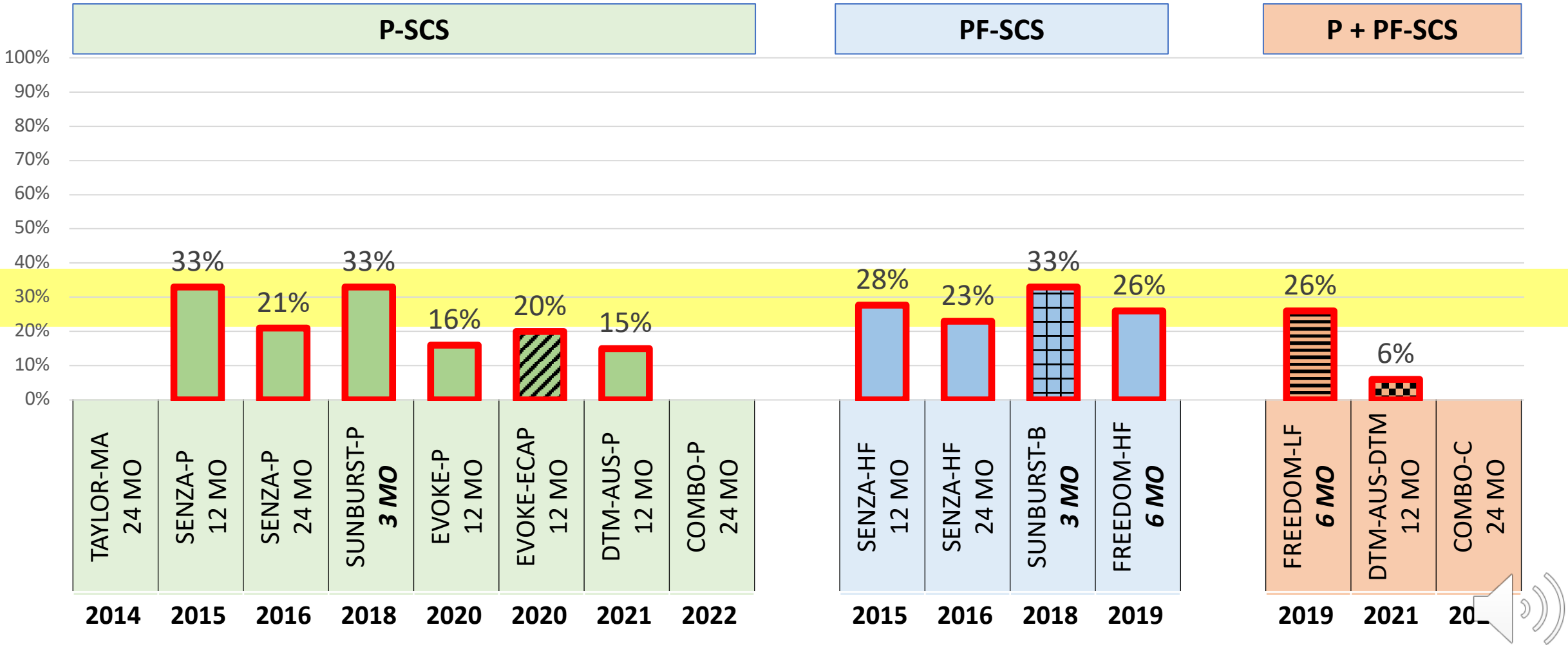
Comparative Efficacy of SCS by Waveform for Low Back and Leg Pain

% Pain Reduction From Baseline

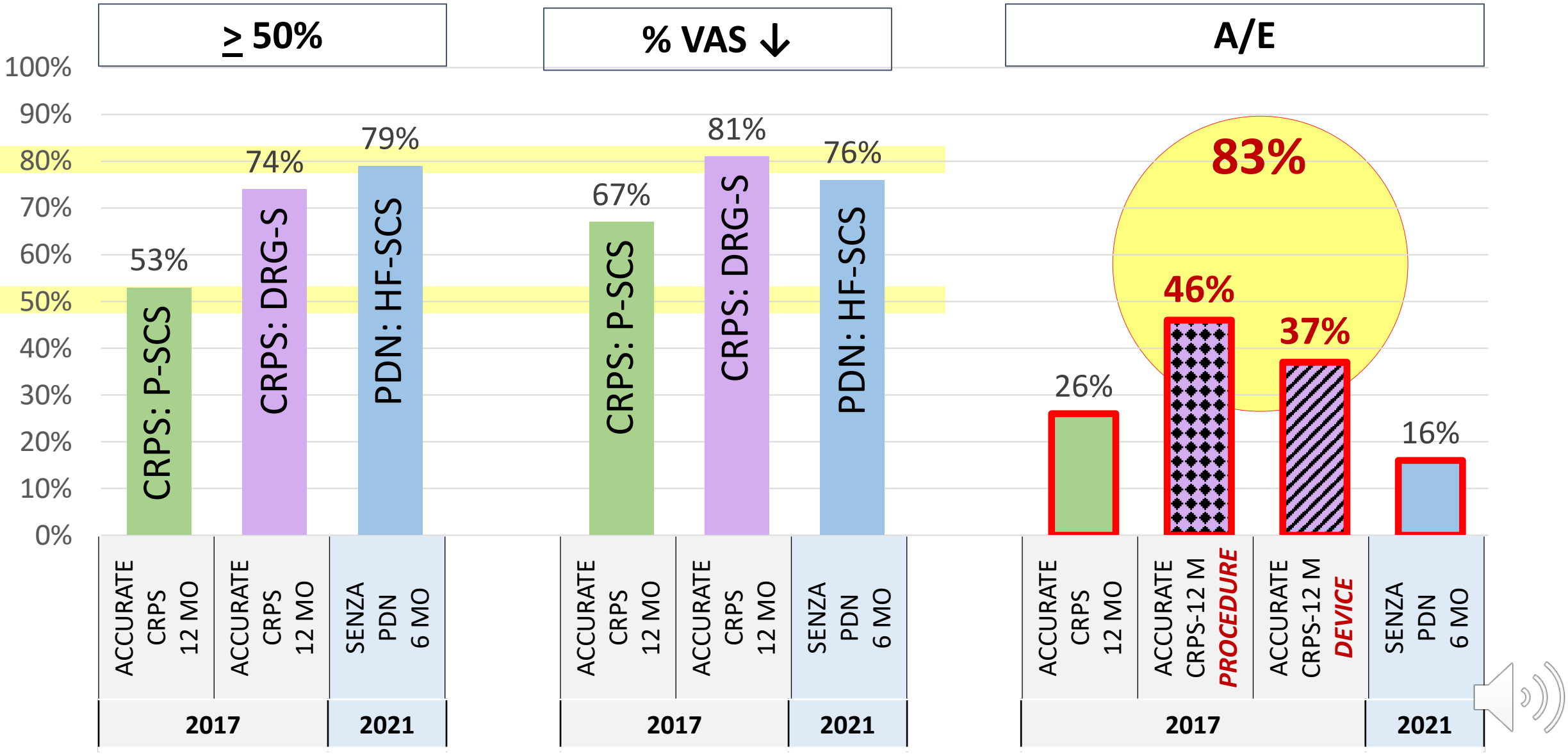


Comparative Efficacy of SCS by Waveform for Low Back and Leg Pain

% Subjects with Device Related AE+SAE



Comparative Efficacy & Safety of SCS by Waveform for Limb Pain



Is it All About the Waveform?

- New Waveforms – High levels of efficacy (80/80)
- Clinically Meaningful and Life-Changing (Right Pt)
- Patient selection is key for success

Is it All About the Waveform?

- Efficiency – Battery preservation?
- Which waveform for which condition?
- Patient preference & Waveform Likeability?
- Durability of effect over the long-run?

Is it All About the Waveform?

- Efficiency – Battery preservation?
- Which waveform for which condition?
- Patient preference & Waveform Likeability?
- Durability of effect over the long-run?

Treat the PATIENT,
Not the IMAGE !

Treat the PATIENT,
Not the WAVEFORM !

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