

# NEUROMODULATION

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# DISCLOSURE

No financial ties to device companies

Salaried employment for neuromodulation device procedures.

# OUTLINE

Definitions and demographics

Evidence base

Procedures:

- Trials and IPG insertions.

- Joondalup experience

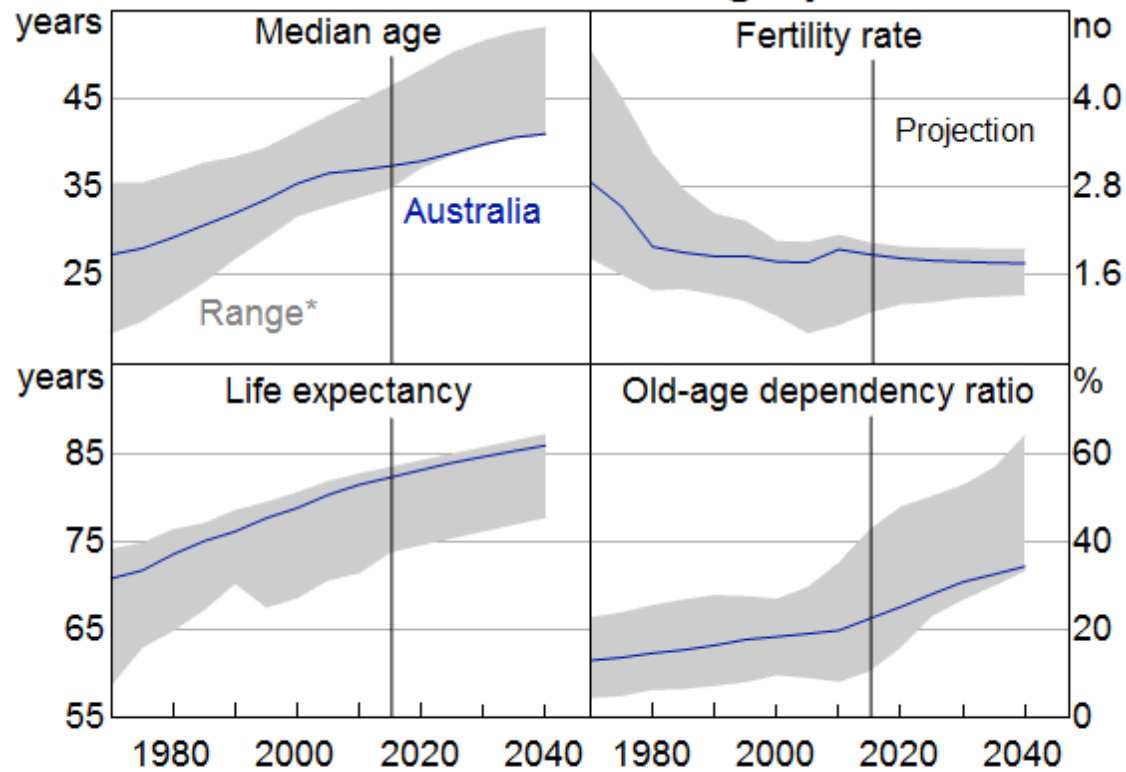
The Future

# DEMOGRAPHICS OF PAIN



# THE LUCKY COUNTRY

## Advanced Economies – Demographic Indicators



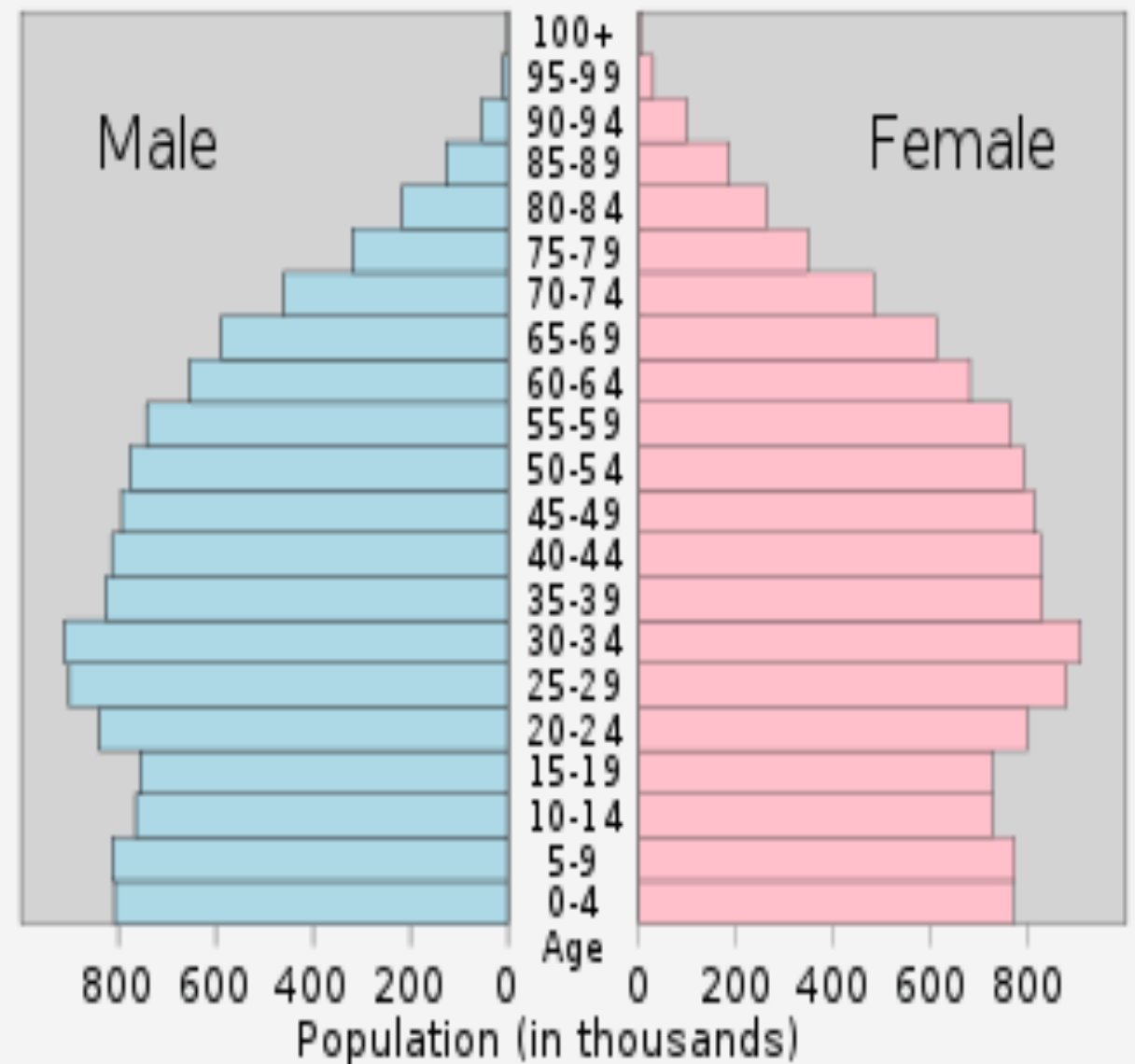
\* Range over 37 advanced economies

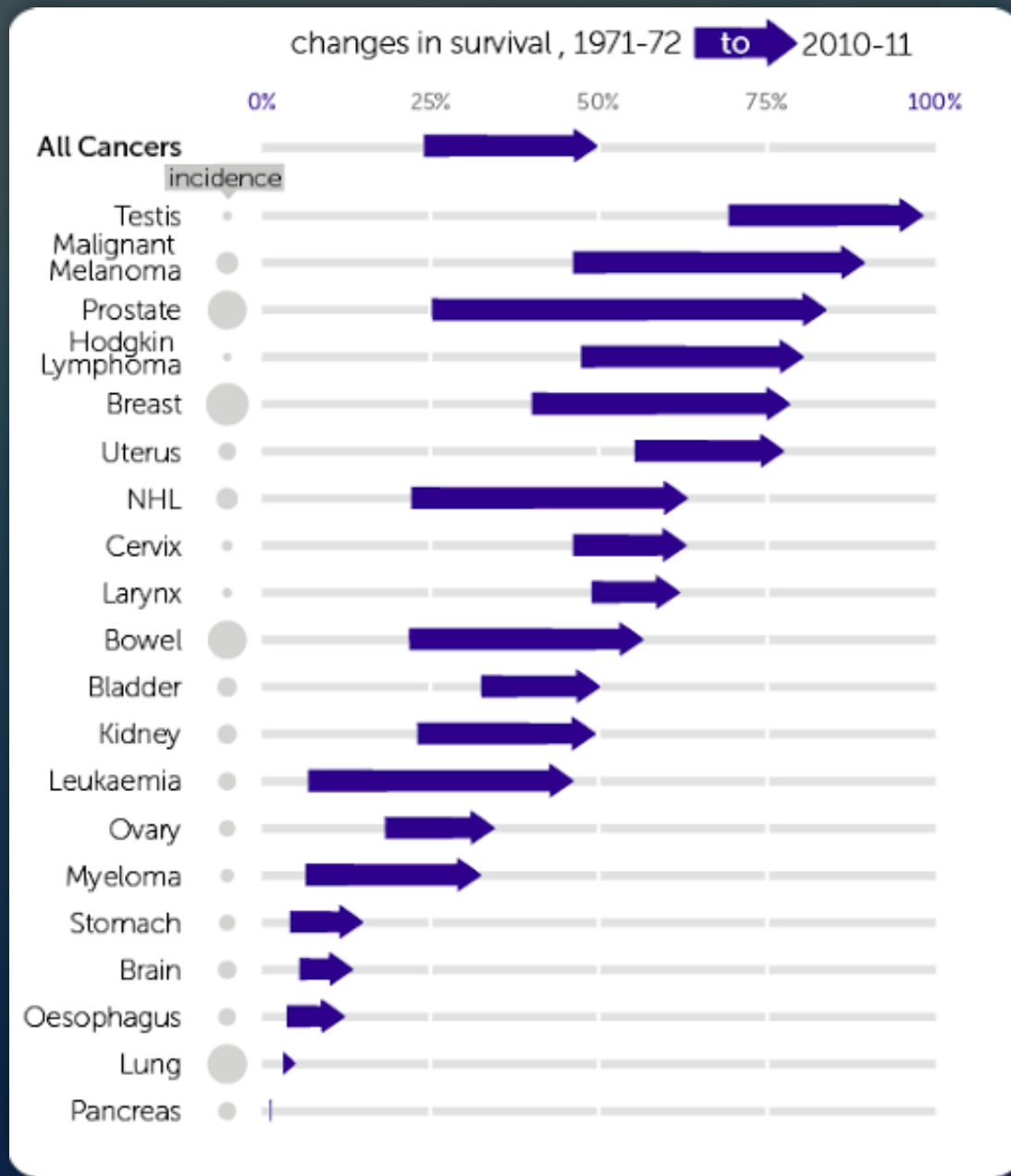
Source: United Nations

Source: United Nations

\* Range over 37 advanced economies

## Population of Australia (2017)





# CANCER MANAGEMENT IS EVOLVING RAPIDLY

TREATMENTS HAVE CHANGED  
SURVIVAL HAS IMPROVED

# NOW WE HAVE SURVIVORS



WHICH IS FANTASTIC



BUT OFTEN PAINFUL DUE TO



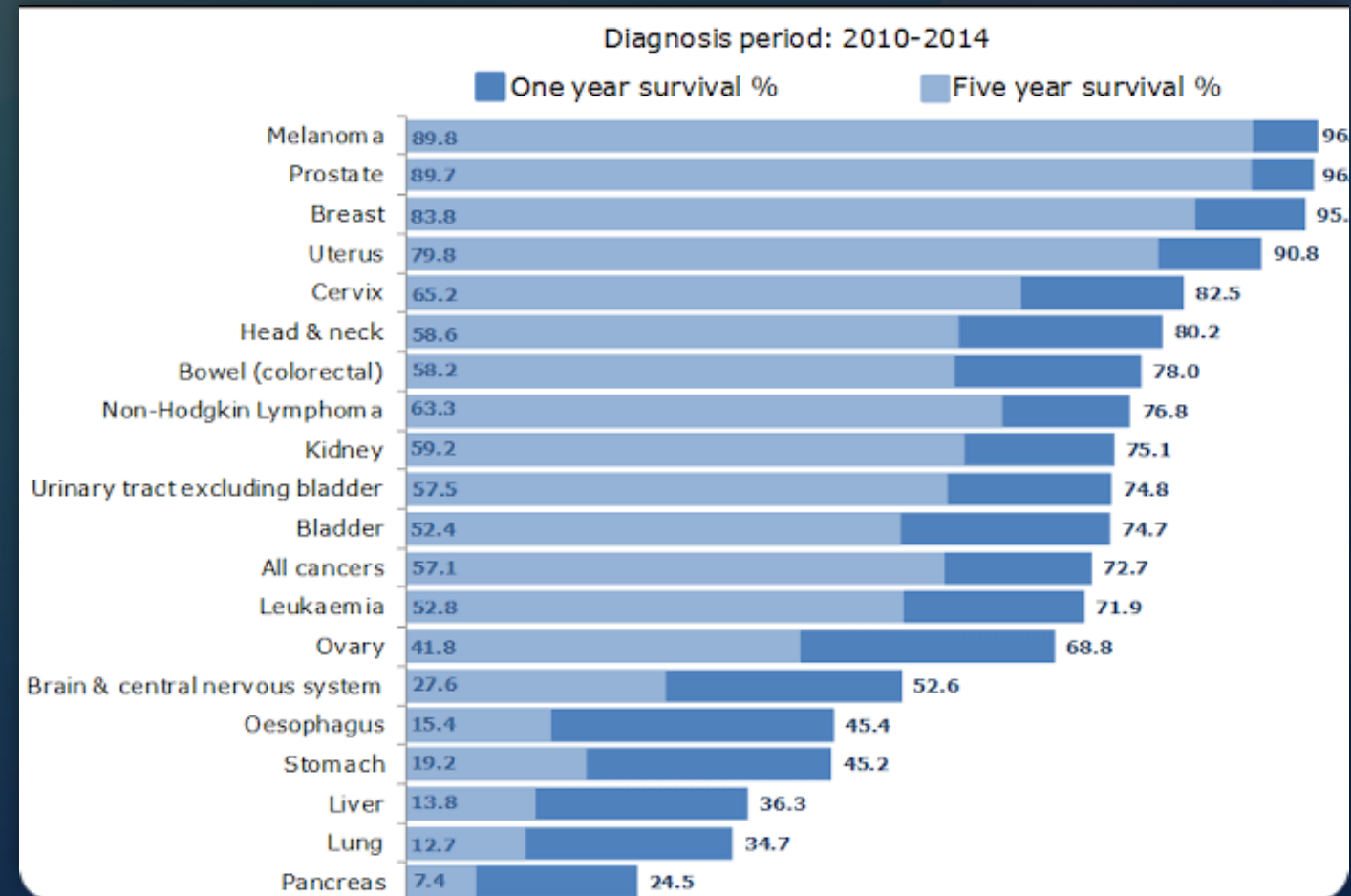
CANCER



SURGERY



CHEMO & RADIO





# DEMOGRAPHICS OF PAIN

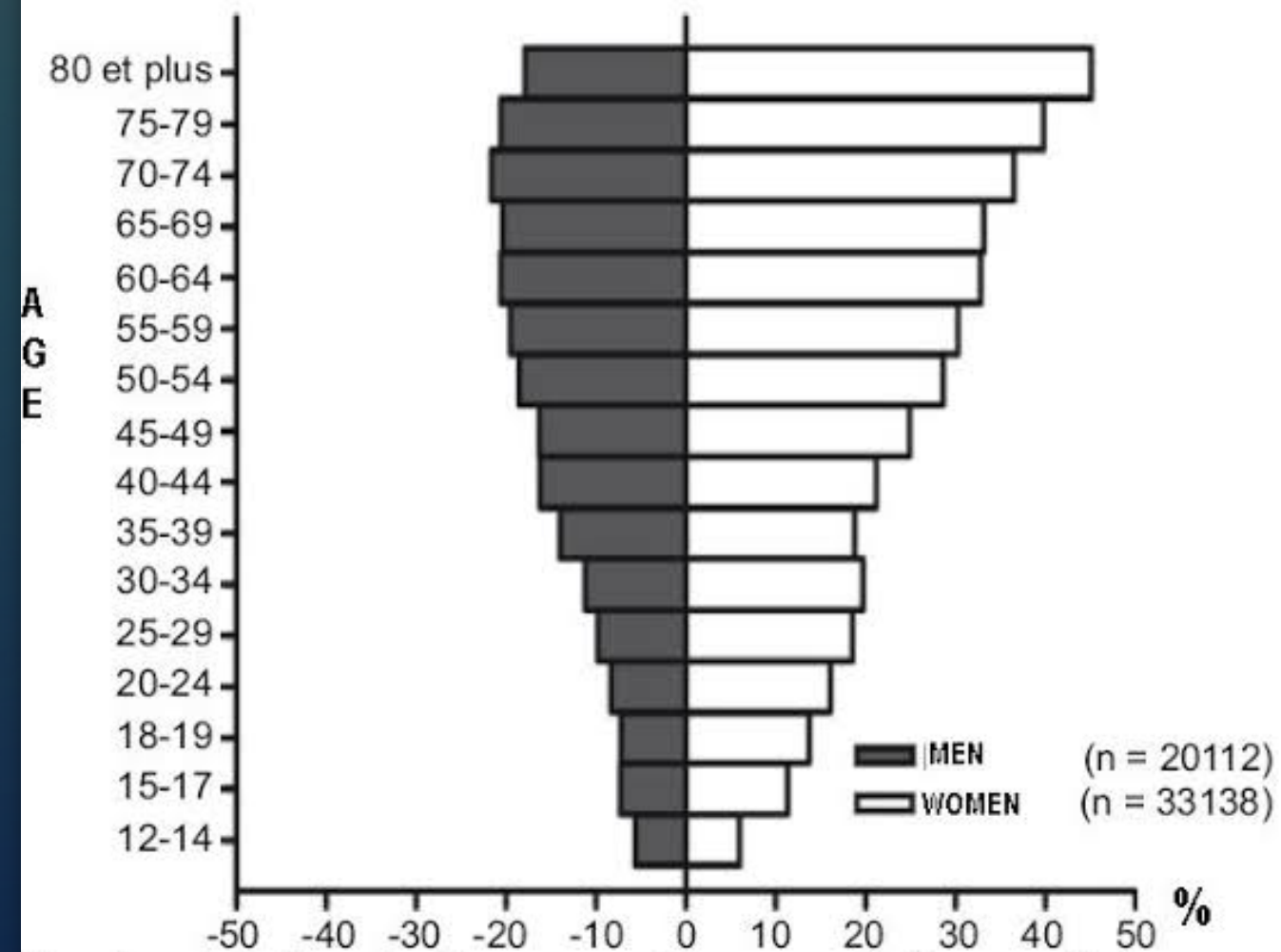
◆ PAIN AS A PROBLEM IS RELATED TO

◆ AGE

◆ SEX

◆ AND OTHER THINGS

### Proportion of Respondents Suffering From Chronic Pain



Chronic pain in Canada: do women suffer more pain than man? J. Barcellos de Souza et al. Douleur analg. (2009) 22:134-139

Barcellos de Souza et al. Douleur analg. (2009) 22:134-139

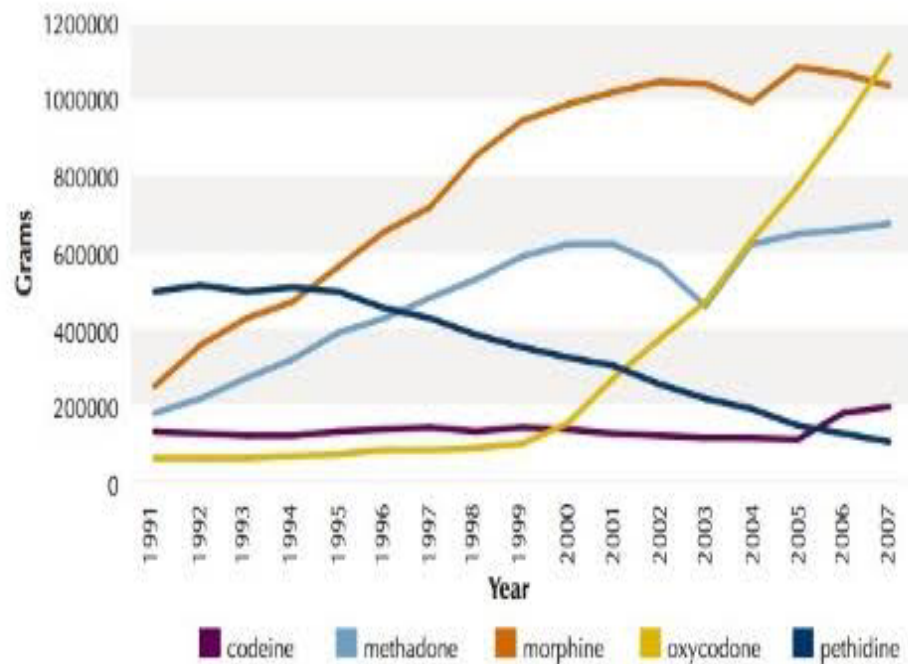
Chronic pain in Canada: do women suffer more pain than man? J.

-20 -40 -30 -50 -10 0 10 20 30 40 20 %

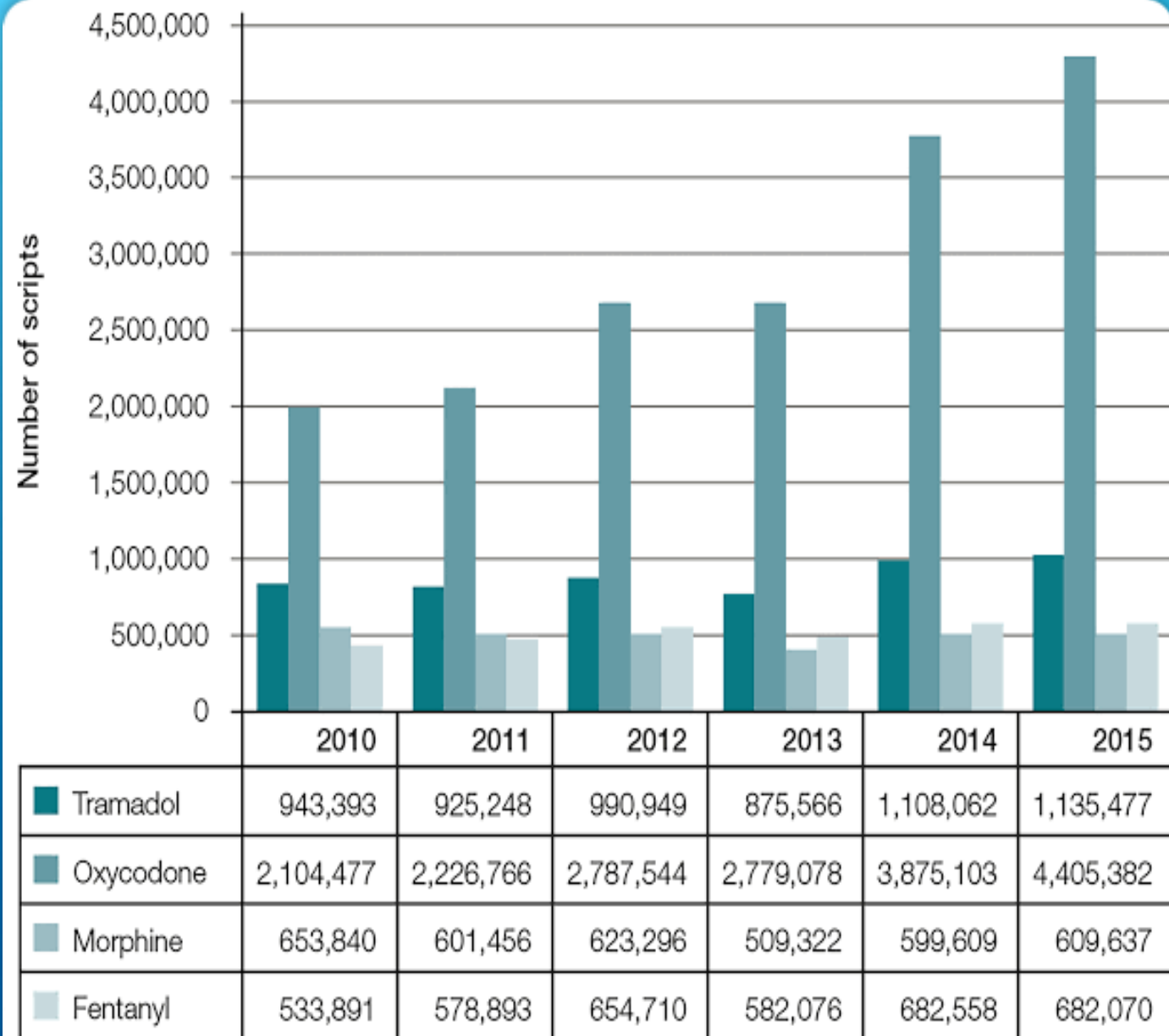


# BUT WE HAVE TREATMENTS FOR PAIN

Figure 4: Pharmaceutical opioid base supply (grams) Australia from 1991-2007



Source: Dobbin 2008, Morphine, Unpublished paper provided to the Drugs and Crime Prevention Committee. Data extracted from the National Drug-control System (NDS) domestic transaction data by the Commonwealth Department of Health and Ageing.

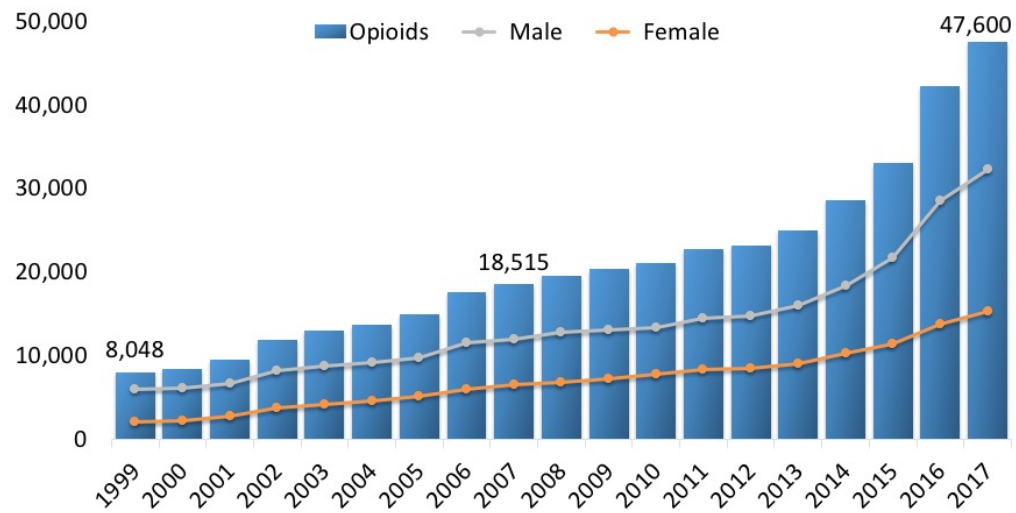


Source: Dobbin 2008, Morphine, Unpublished paper provided to the Drugs and Crime Prevention Committee. Data extracted from the National Drug-control System (NDS) domestic transaction data by the Commonwealth Department of Health and Ageing.

codeine methadone morphine oxycodone pethidine

# BUT THE CURE COMES AT A COST

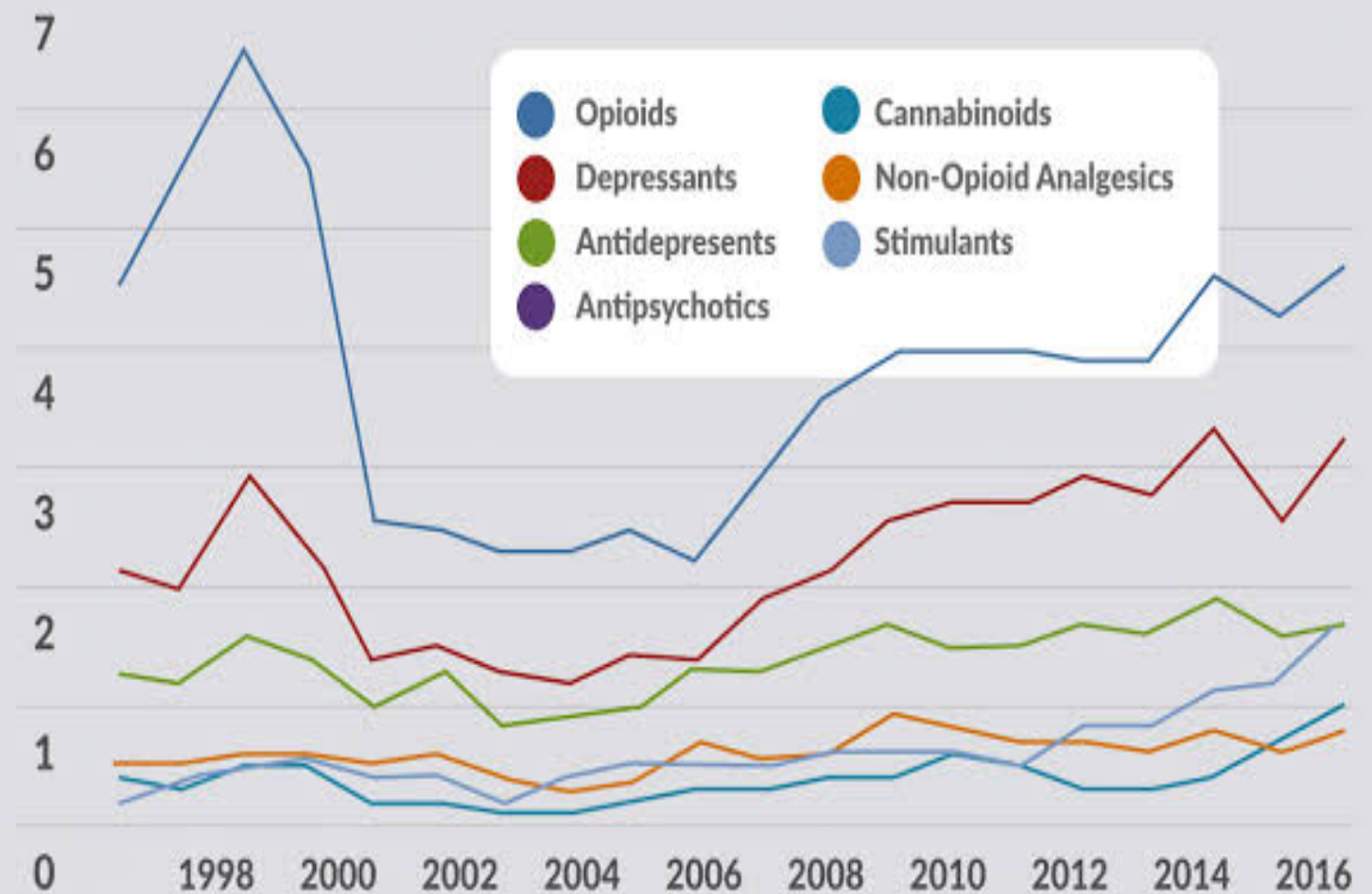
Figure 3. National Drug Overdose Deaths Involving Any Opioid, Number Among All Ages, by Gender, 1999-2017



Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018

## Causes of death by common drug types, 1997-2016

Death Rates (Per 100,000)



Note: Data refers to age-specific death rates. Source: ABS

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# SUMMARY OF DEMOGRAPHICS

- WE ARE GETTING OLDER
  - WE HAVE MORE AGE RELATED DISEASES, INCLUDING CANCER
- WE HAVE MORE CANCER SURVIVORS
- PAIN IS A GROWING PROBLEM
  - OPIOID TREATMENTS HAVE BEEN RISING
  - DEATHS ARE RISING WITH AND FROM THIS

The background features a blue gradient with a pattern of semi-transparent hexagons. The top half is a lighter cyan, and the bottom half is a darker navy blue. The hexagons are scattered across the top and bottom sections.

# POLITICS & LEGALITIES



# THE CHANGING FACE OF THE

NEW YORK TIMES

2ND MAY, 2019

[HTTPS://WWW.NYTIMES.COM/  
2019/05/02/HEALTH/INSYS-  
TRIAL-VERDICT-KAPOOR.HTML](https://www.nytimes.com/2019/05/02/health/insys-trial-verdict-kaipoor.html)

nytimes.com

The New York Times

## *Top Executives of Insys, an Opioid Company, Are Found Guilty of Racketeering*



John Kapoor, the founder of Insys Therapeutics, at federal court in Boston.

Steven Senne/Associated Press

Steven Senne/Associated Press

John Kapoor, the founder of Insys Therapeutics, at federal court in Boston.

# THIS ISN'T A ONE OFF

NEW YORK TIMES

23 APRIL 2019

[HTTPS://WWW.NYTIMES.COM/  
2019/04/23/NYREGION/OPIOID-  
CRISIS-DRUG-TRAFFICKING-  
ROCHESTER.HTML](https://www.nytimes.com/2019/04/23/nyregion/opioid-crisis-drug-trafficking-rochester.html)

nytimes.com

The New York Times

## *Distributor Faces Federal Criminal Charges Over Opioid Crisis*

The charges against the wholesaler, Rochester Drug Cooperative, and two of its former executives marked a new tactic for prosecutors in tackling the epidemic of addiction to prescription painkillers.



Laurence F. Doud III, who had served as chief executive of Rochester Drug Cooperative, surrendered to Drug Enforcement Administration agents on Tuesday.

Cooperative' surrendered to Drug Enforcement Administration agents on Tuesday.  
Laurence F. Doud III, who had served as chief executive of Rochester Drug



# MEDICAL SOCIETY BANKRUPTCY

25TH MAY 2019

[HTTPS://WWW.THEGUARDIAN.COM/  
US-NEWS/2019/MAY/25/AMERICAN-  
PAIN-SOCIETY-DOCTORS-  
PAINKILLERS](https://www.theguardian.com/us-news/2019/may/25/american-pain-society-doctors-painkillers)

“THE FIFTH VITAL SIGN”

Medical group that pushed doctors to prescribe painkillers forced to close

American Pain Society accused of being pawn of big pharma  
Booked nearly \$1m from leading opioid manufacturers



More than 250m opioid prescriptions a year were dispensed in the US, enough to provide 30 days of pills. Photograph: Jessica Hill/AP

# FACULTY OF PAIN MEDICINE

## - RECOGNITION OF CHANGE

- ◆ GENERATIONAL CHANGE IN FPM AGAINST OPIOIDS
  - ◆ LACK OF EVIDENCE OF BENEFIT/ EVIDENCE OF HARM
- ◆ DRIVE TO LOOK AT ALTERNATIVES
  - ◆ NON-OPIOIDS AND NON-TRADITIONAL OPIOIDS.
  - ◆ PROCEDURAL INTERVENTIONS



# NEUROMODULATION

# WHAT IS NEUROMODULATION

“The alteration of nerve activity through targeted delivery of a stimulus to specific neurological sites in the body.”

Stimulus can be of any nature:

- Commonly taken to mean electrical (“Spinal cord stimulation”)
- Also includes chemical (eg intrathecal drug delivery)
- Can include other mechanisms (eg magnetic)

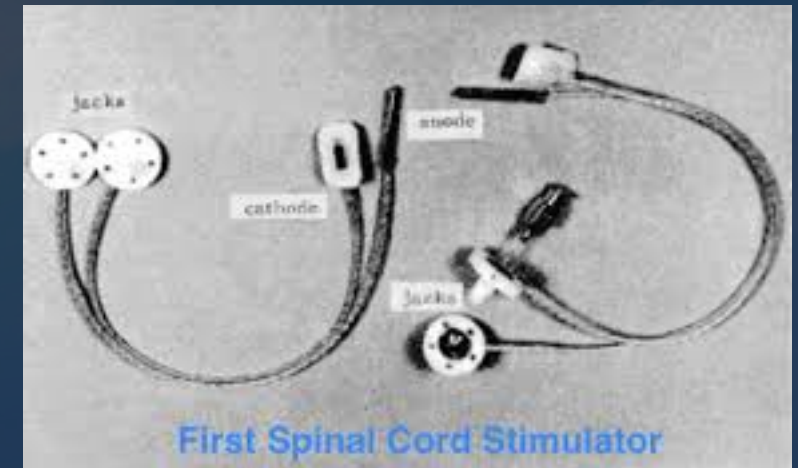
# FEATURES OF NEUROMODULATION

General features of all neuromodulation approaches:

- Targeted anatomically
- Reversible in nature
- Provide continuous treatment.



# HISTORY



Has been going for a long time.

- Followed on from gate theory of pain in 1965

Spinal cord stimulation first done in 1967.

Originally came from pacemaker companies and technologies.





# EVIDENCE BASE

# CARDIAC ISCHAEMIA

Early evidence in ischaemic cardiac pain -  
ESBY study

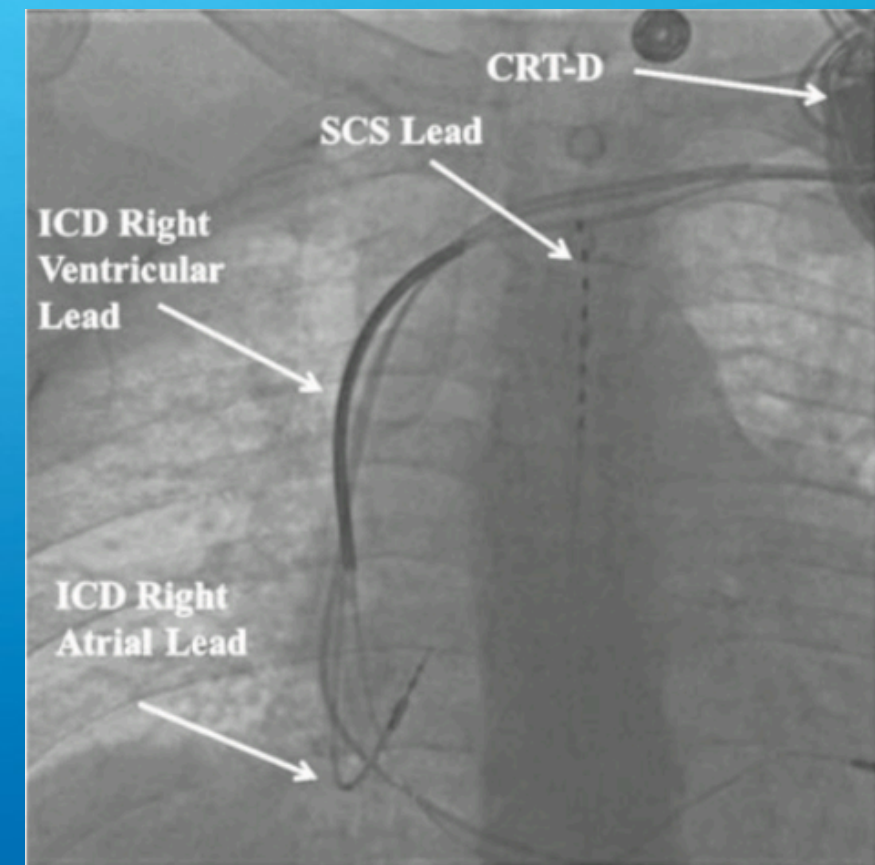
Mannheimer et. al. *Circulation* 1998; 97:1157-1163

104 patients, randomised to CABG vs SCS.

Treatment benefit: CABG 79.5%, SCS 83.7%

Much lower mortality (7 vs 1  $p=0.02$ ) and  
cerebrovascular events (8 vs 2  $p=0.03$ ).

Overall morbidity not different.



# LONGER TERM CARDIAC ISCHAEMIA

ong-term effects of spinal cord stimulation and coronary artery bypass grafting on quality of life and survival in the ESBY study

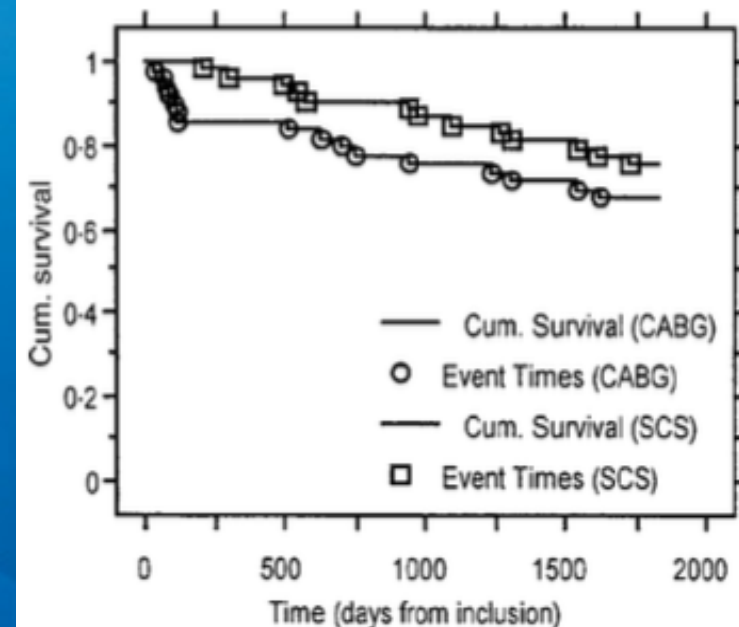
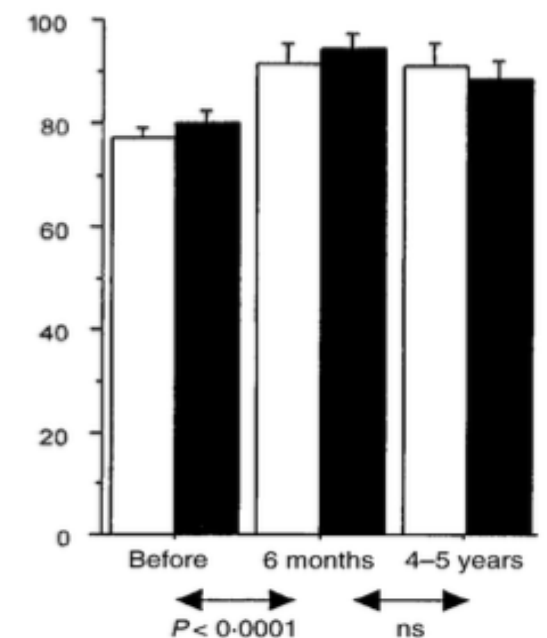
Ekre et al.

Eur Heart J, 2002; 23: 1938–1945, doi:10.1053/euhj.2002. 3286)

5 year followup of ESBY study:

Both groups showed sustained improvement in their quality of life

No mortality difference in either group (28%)





# CARDIAC ISCHAEMIA

Efficacy of spinal cord stimulation as an adjunct therapy for chronic refractory angina pectoris  
Imran et al  
International Journal of Cardiology. 2017. Vol 227: 535-542

Meta analysis, n=518 from 14 studies

SCS for refractory angina was associated with

- Higher exercise duration
- Lower angina severity and frequency
- Lower use of nitrates



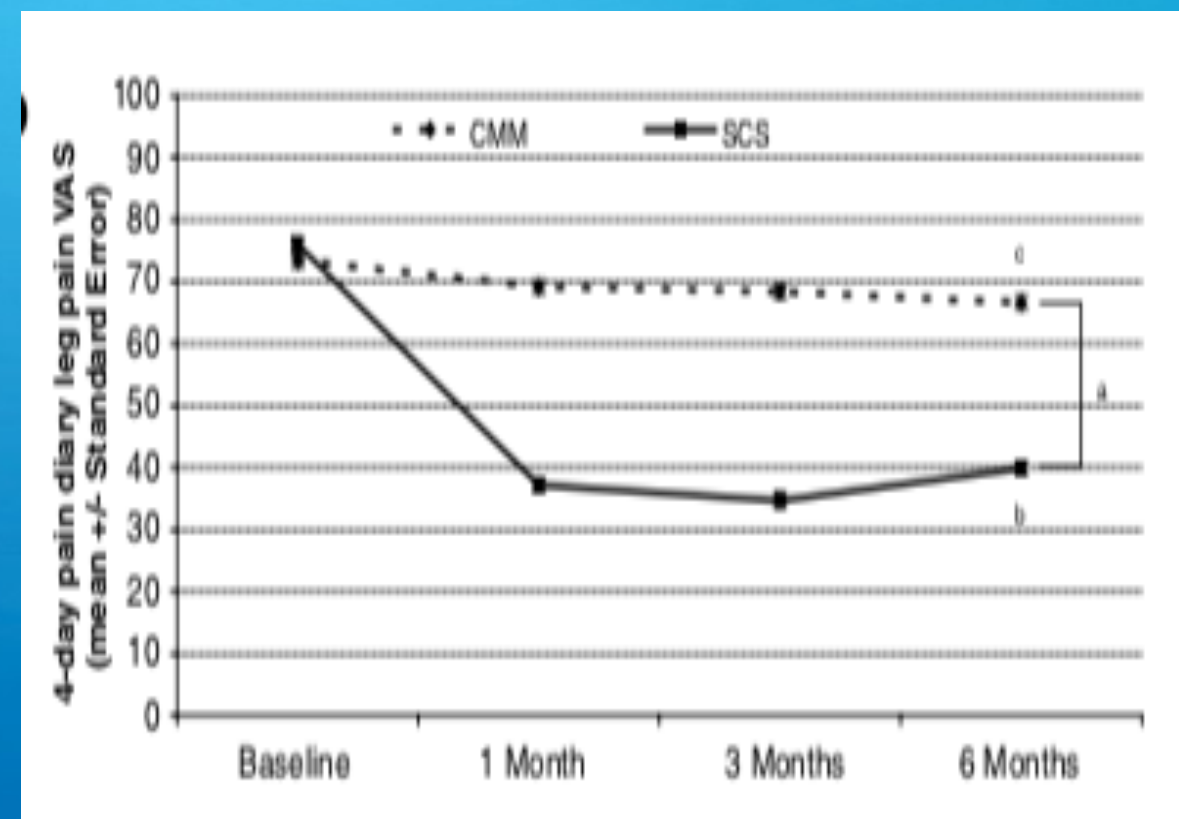
# BACK PAIN

Long standing indication for SCS.

Strong evidence base.

North et al 2005 RCT FBSS -  
52% success @ 3 yr (19% surg)

Kumar et al 2008 RCT FBSS -  
Improvement in leg pain



# BACK PAIN - NEWER MODES

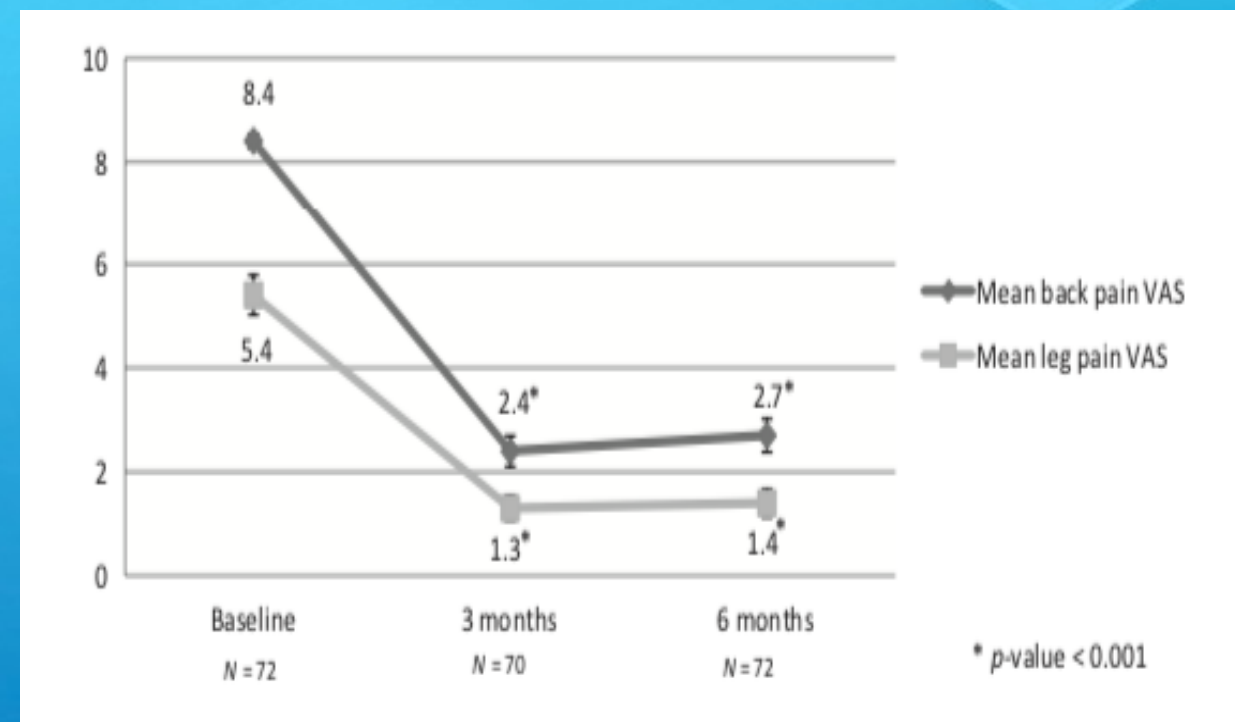
High-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back Pain Patients: Results of a Prospective Multicenter European Clinical Study  
Van Buyten et al Neuromodulation 2013; 16: 59–66

Used 10 KHz stimulus (sub perception)

n=83, significant improvements

Backpain 8.4 -> 2.7

Leg pain 5.4 -> 1.4



# BACK PAIN – NEWER MODES

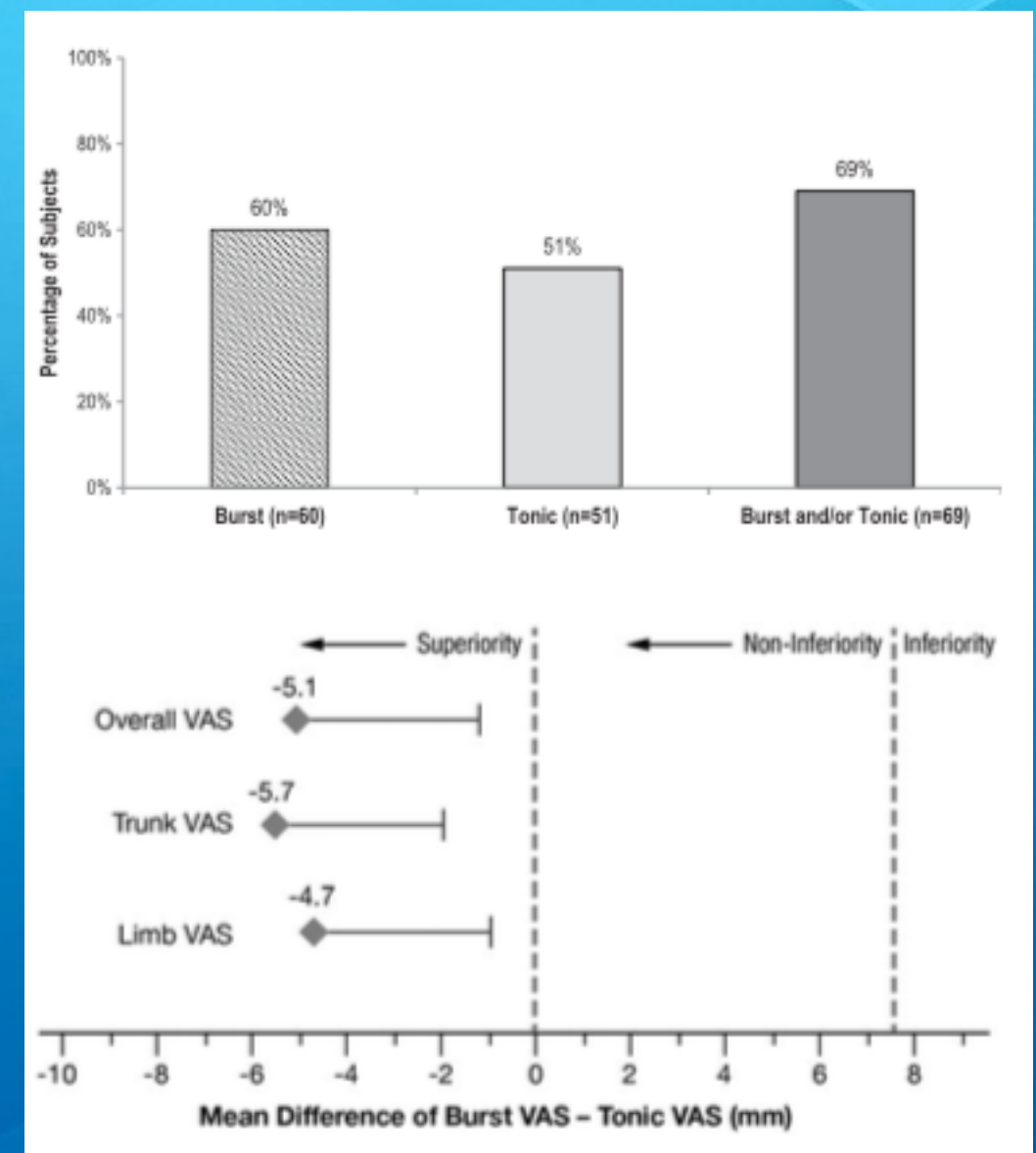
Success Using Neuromodulation With BURST (SUNBURST) Study: Results From a Prospective, Randomized Controlled Trial Using a Novel Burst Waveform

Deer et al. Neuromodulation 2018; 21: 56–66

Randomized crossover study,  
n=100

12 weeks Tonic, 12 weeks Burst.

Improved responder rate to 69%





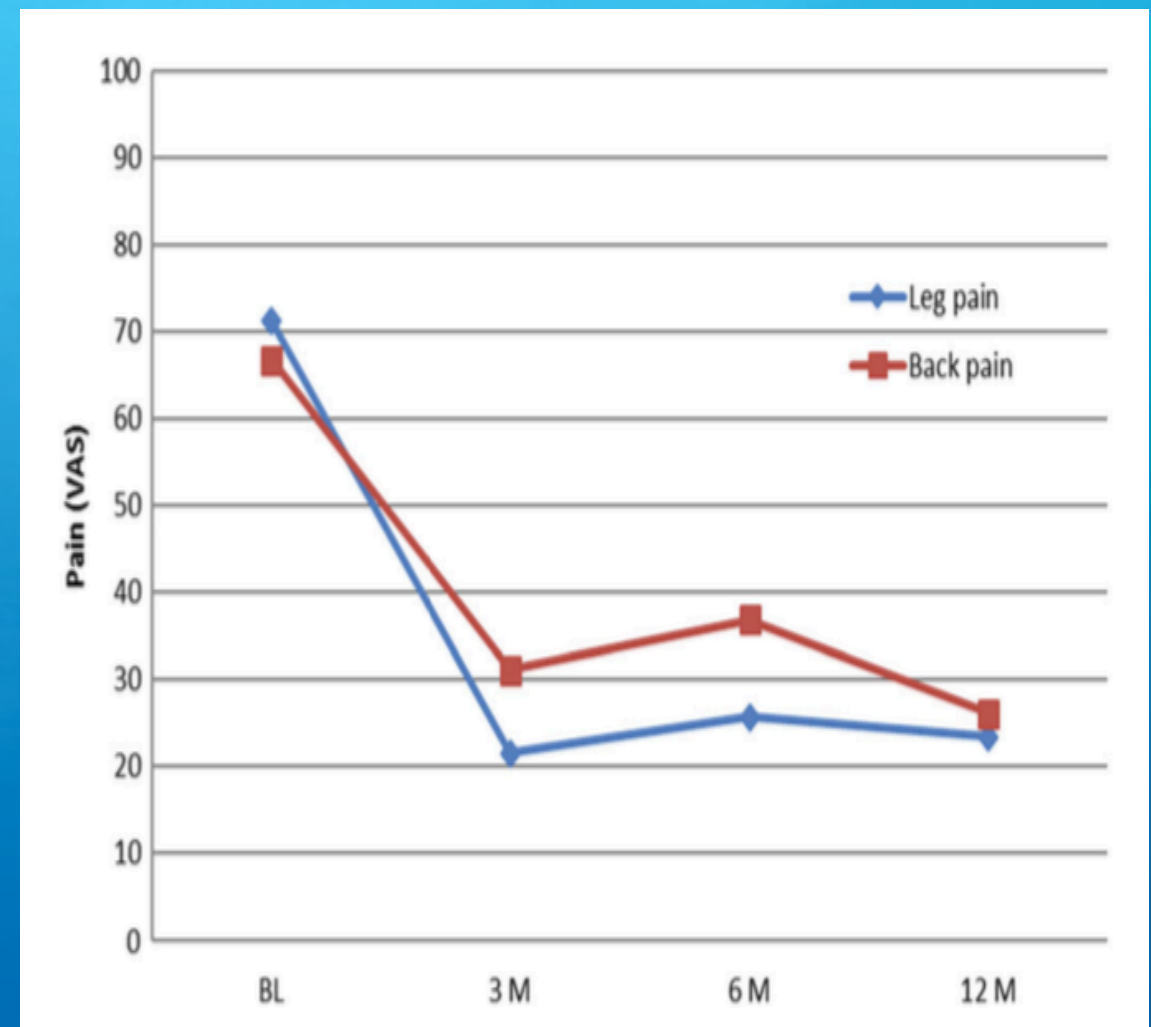
# BACK PAIN - NEWER MODES

High-Dose Spinal Cord Stimulation for Treatment of Chronic Low Back Pain and Leg Pain in Patients With FBSS, 12-Month Results: A Prospective Pilot Study  
Hamm-Faber et al Neuromodulation 2020; 23: 118–125

High density mode

n=11 (Pilot study)

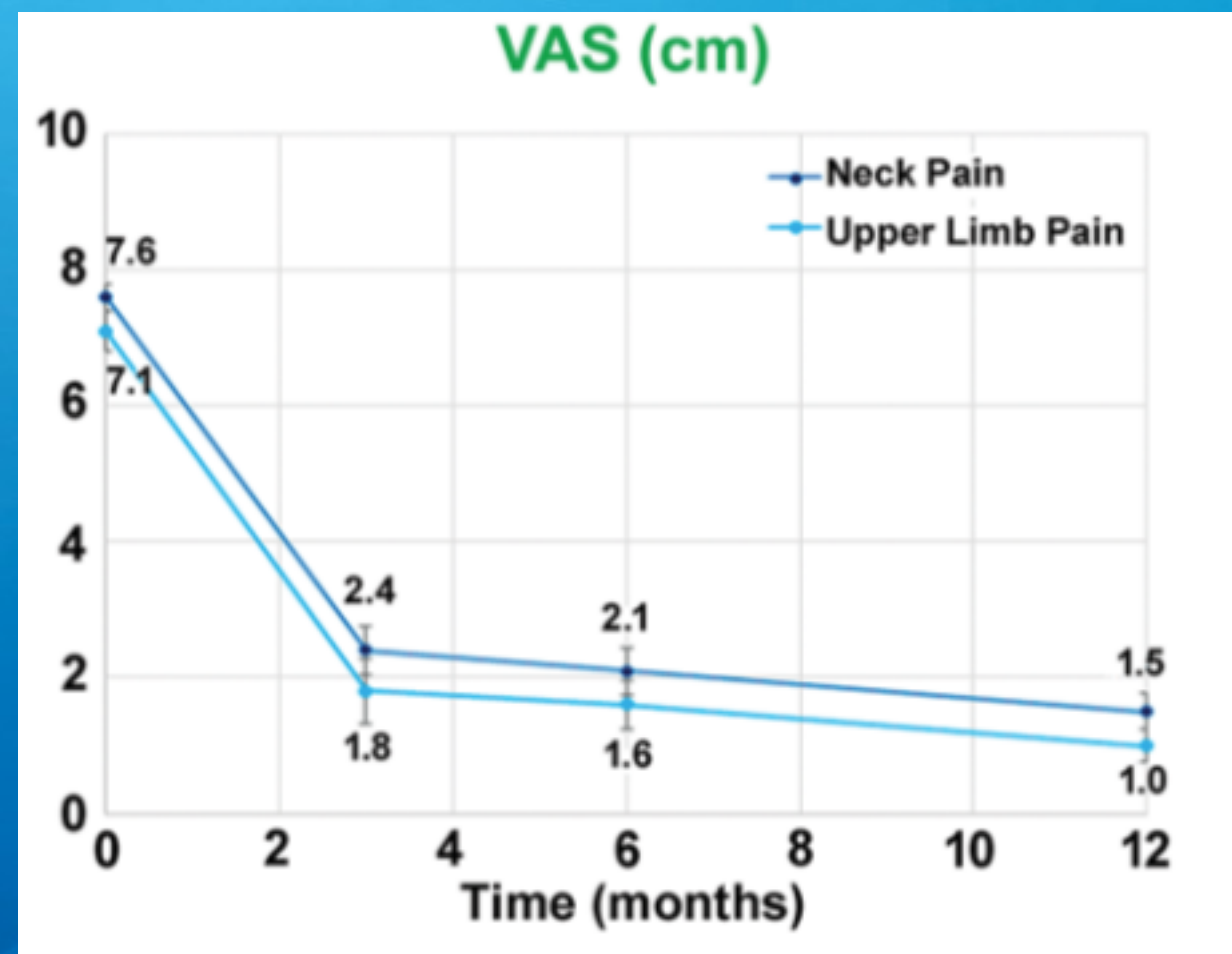
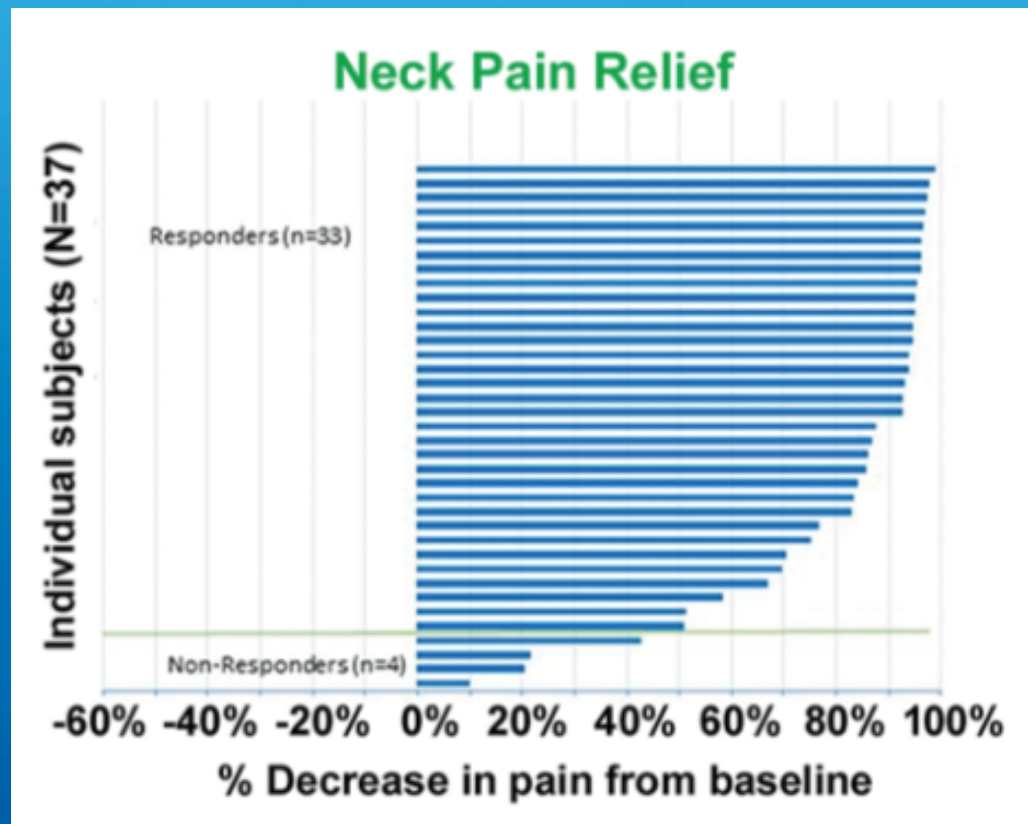
84% responder rate



# NECK PAIN

Less well studied, tonic modes less effective. HF promising.

High-Frequency Spinal Cord Stimulation at 10 kHz for the Treatment of Combined Neck and Arm Pain: Results From a Prospective Multicenter Study  
Amirdelfan et al Neurosurgery 0:1–11, 2019



# CRPS



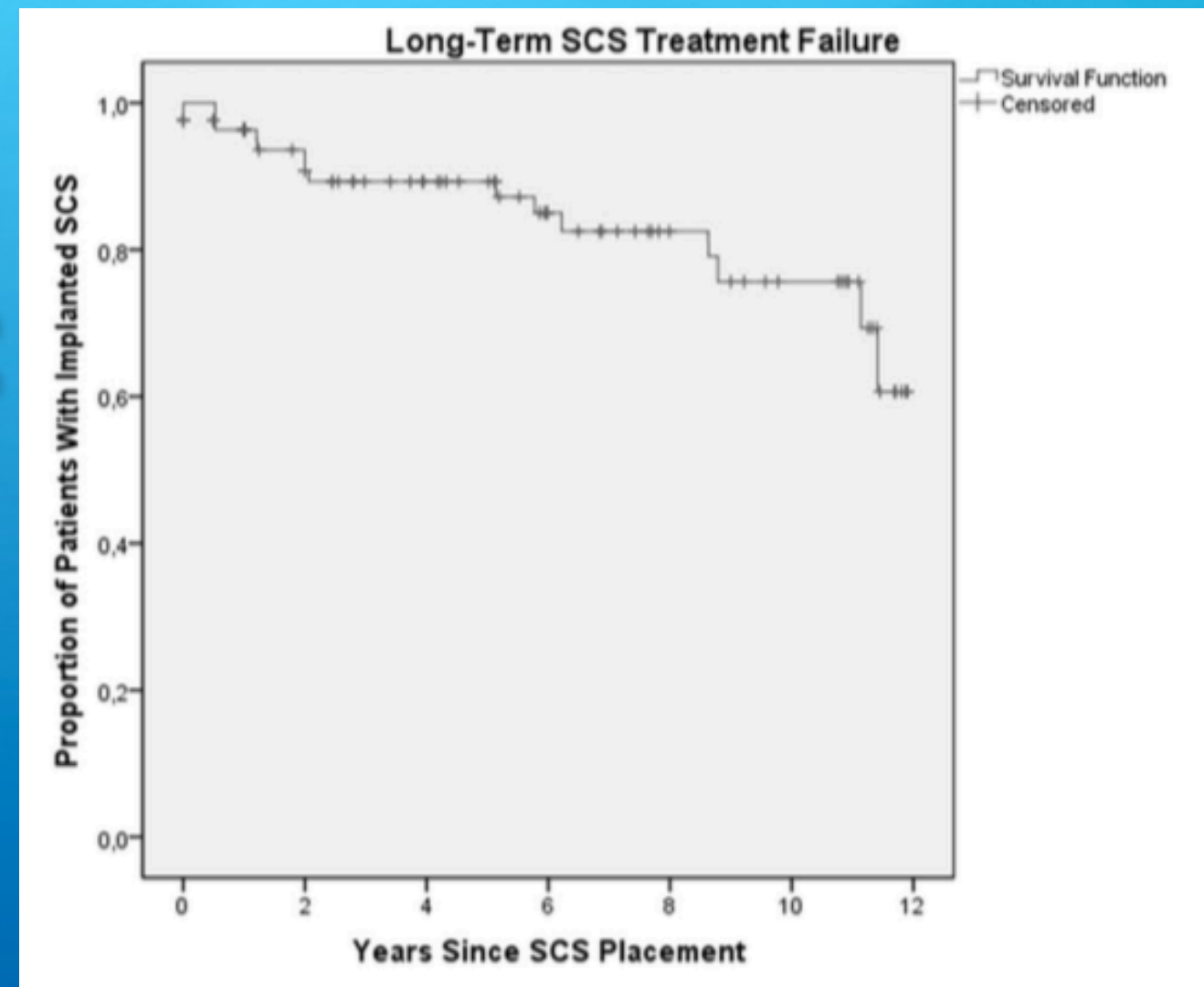
Difficult to treat condition

Strong evidence base for SCS

Spinal Cord Stimulation for Complex Regional Pain Syndrome Type I: A Prospective Cohort Study With Long-Term Follow-Up  
Geurts et al Neuromodulation 2013; 16: 523–529

Older study, older technology

Still showed prolonged benefit.







# PROCEDURES (TRIALS AND IPG's)

# WORKUP

Not a first line treatment generally

Needs good assessment:

- OT / Physio
- Clinical Psychology

# THE PROCEDURE

Many have significant co-morbidities.

Anaesthetic considerations:

- Most are quite sensitised
- Prone position
- On table testing.



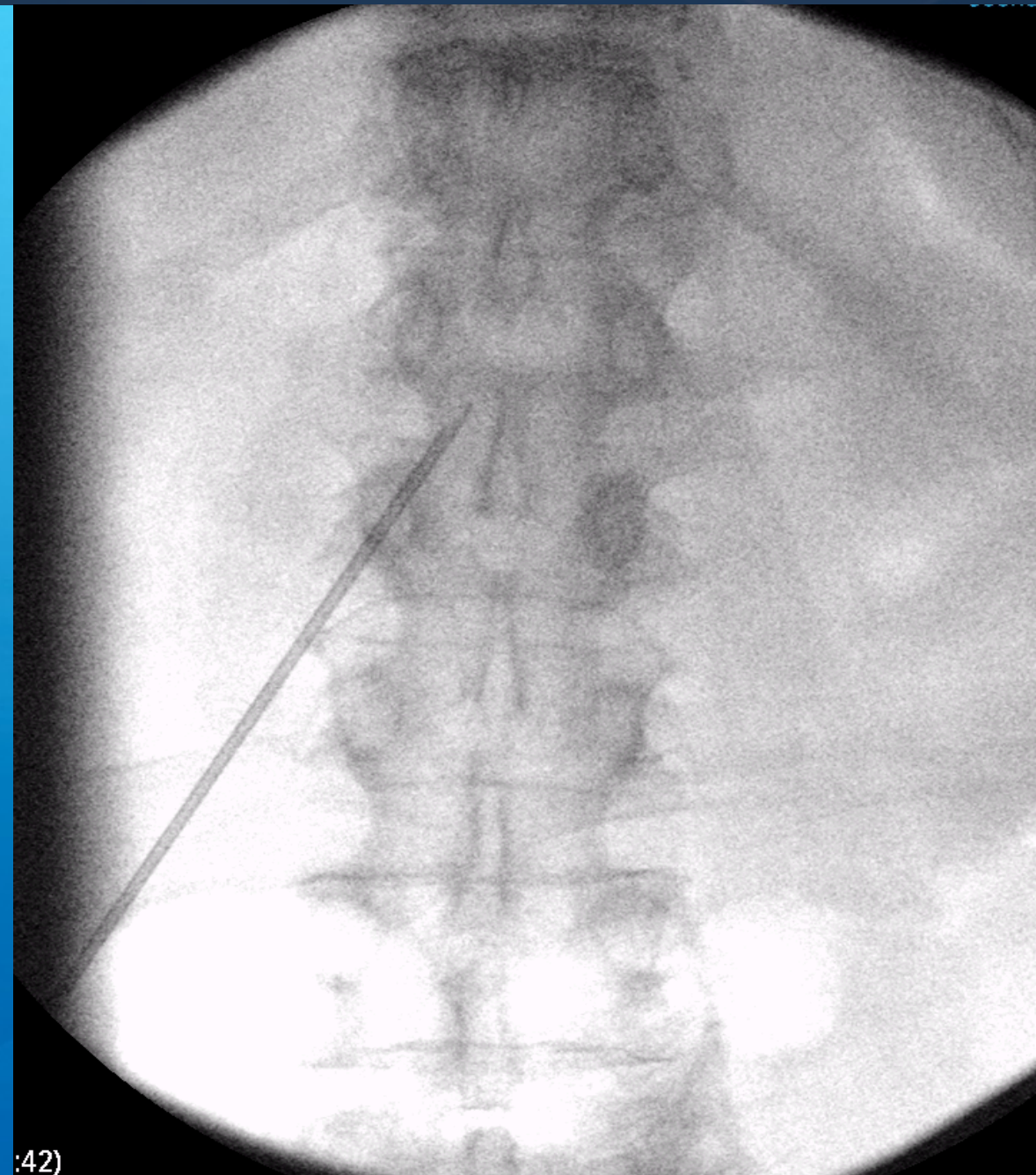


# TECHNICAL DETAILS - TRIALS

Shallow approach to epidural space

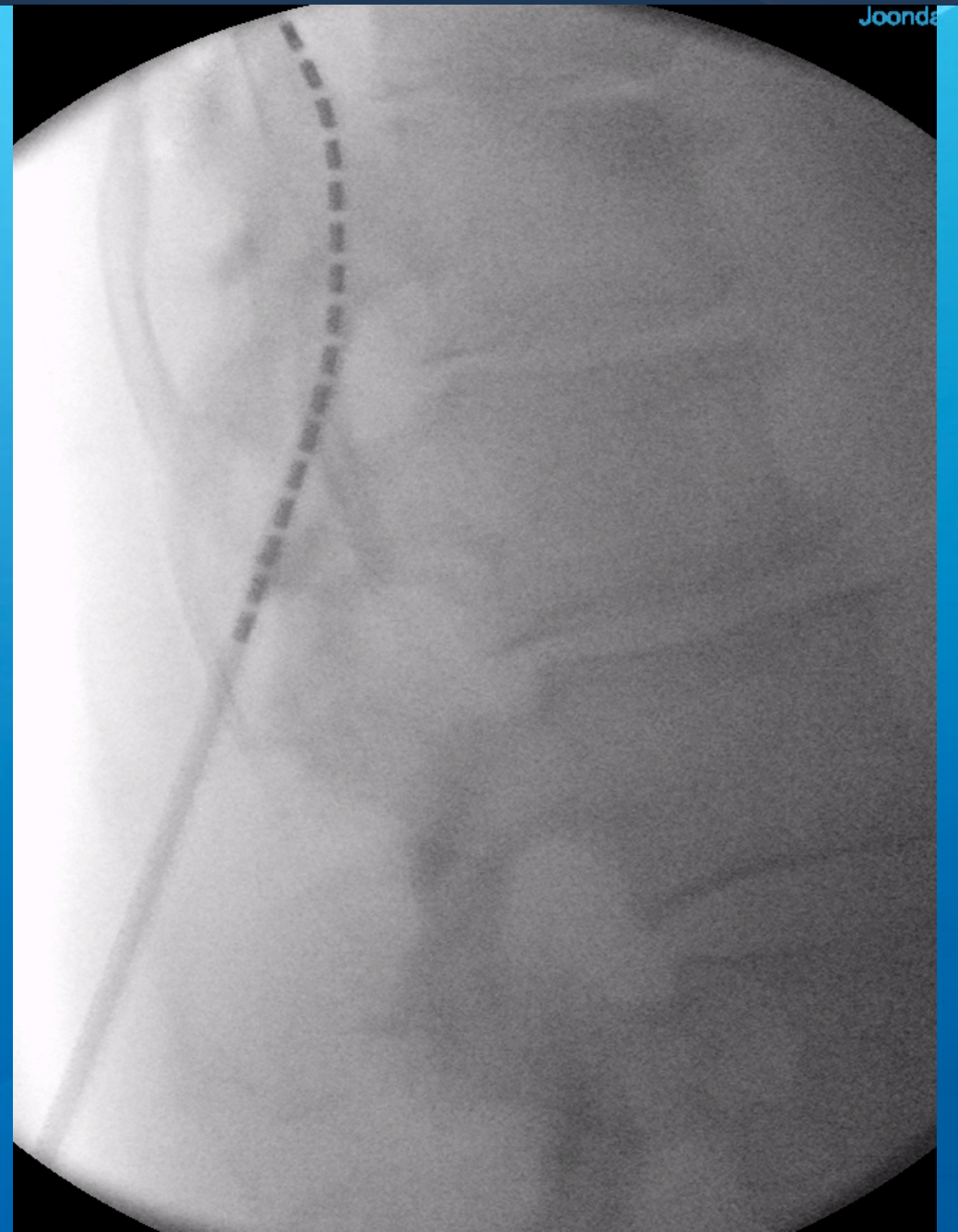
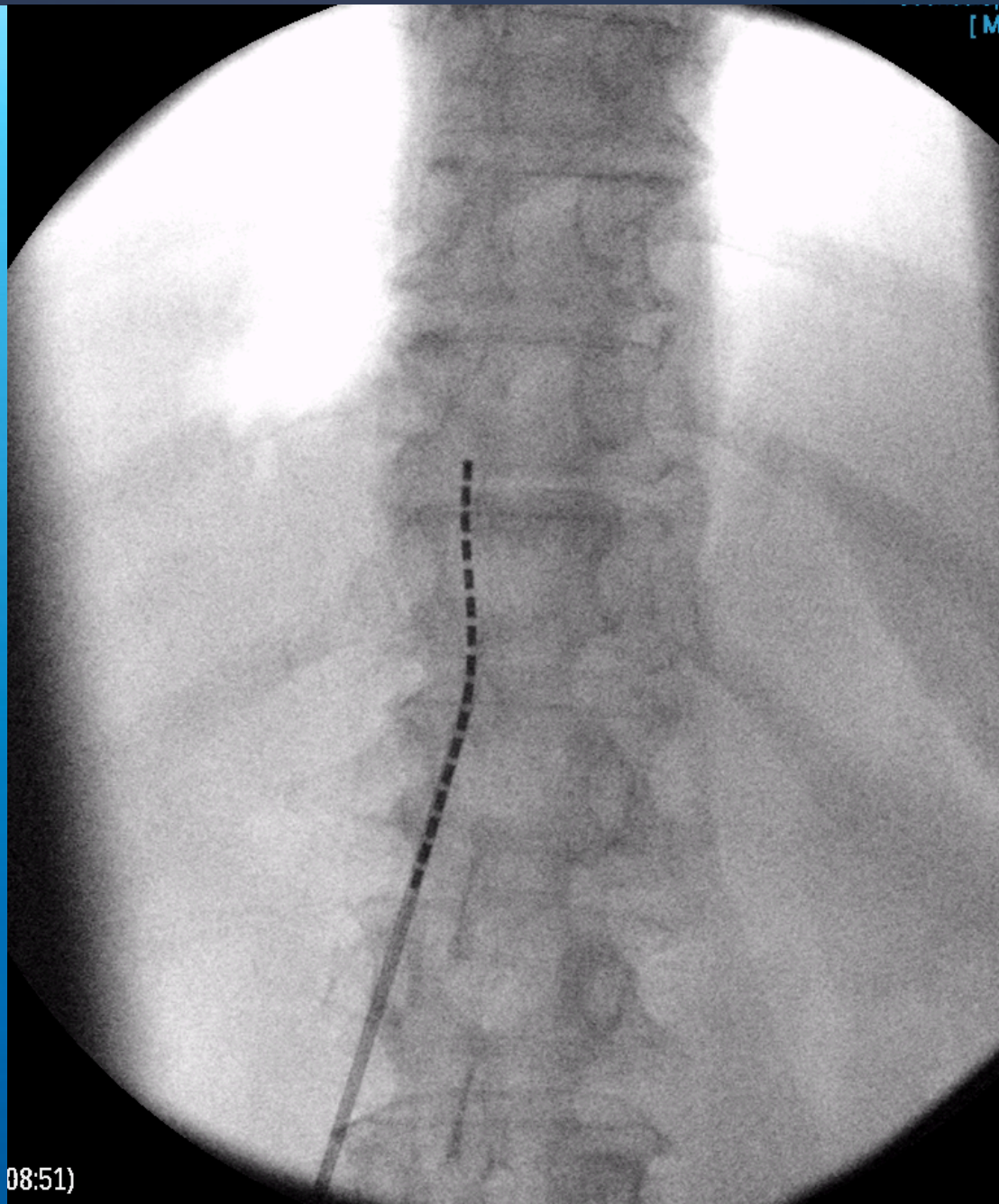
- Small skin puncture for tunnelling

Entry point usually high lumbar



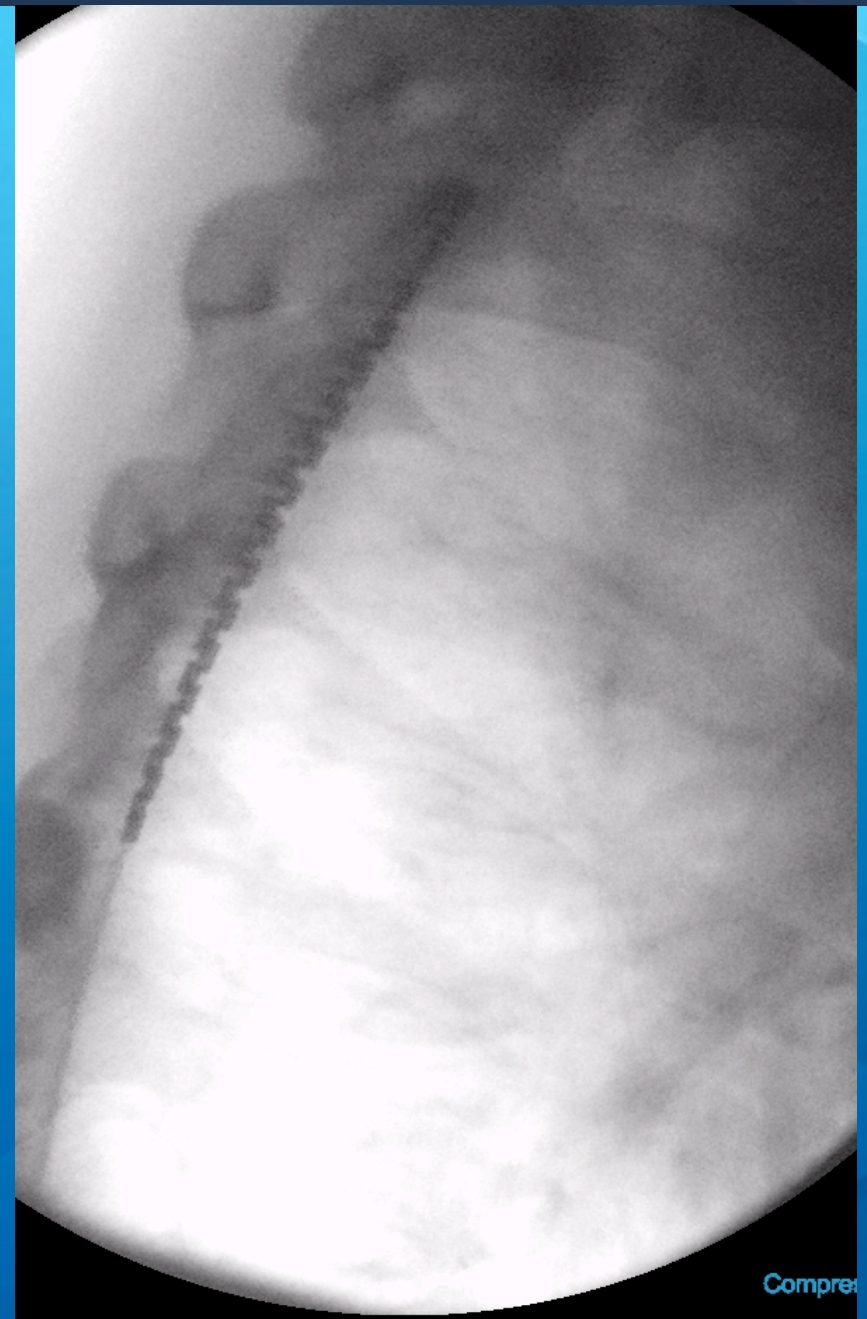
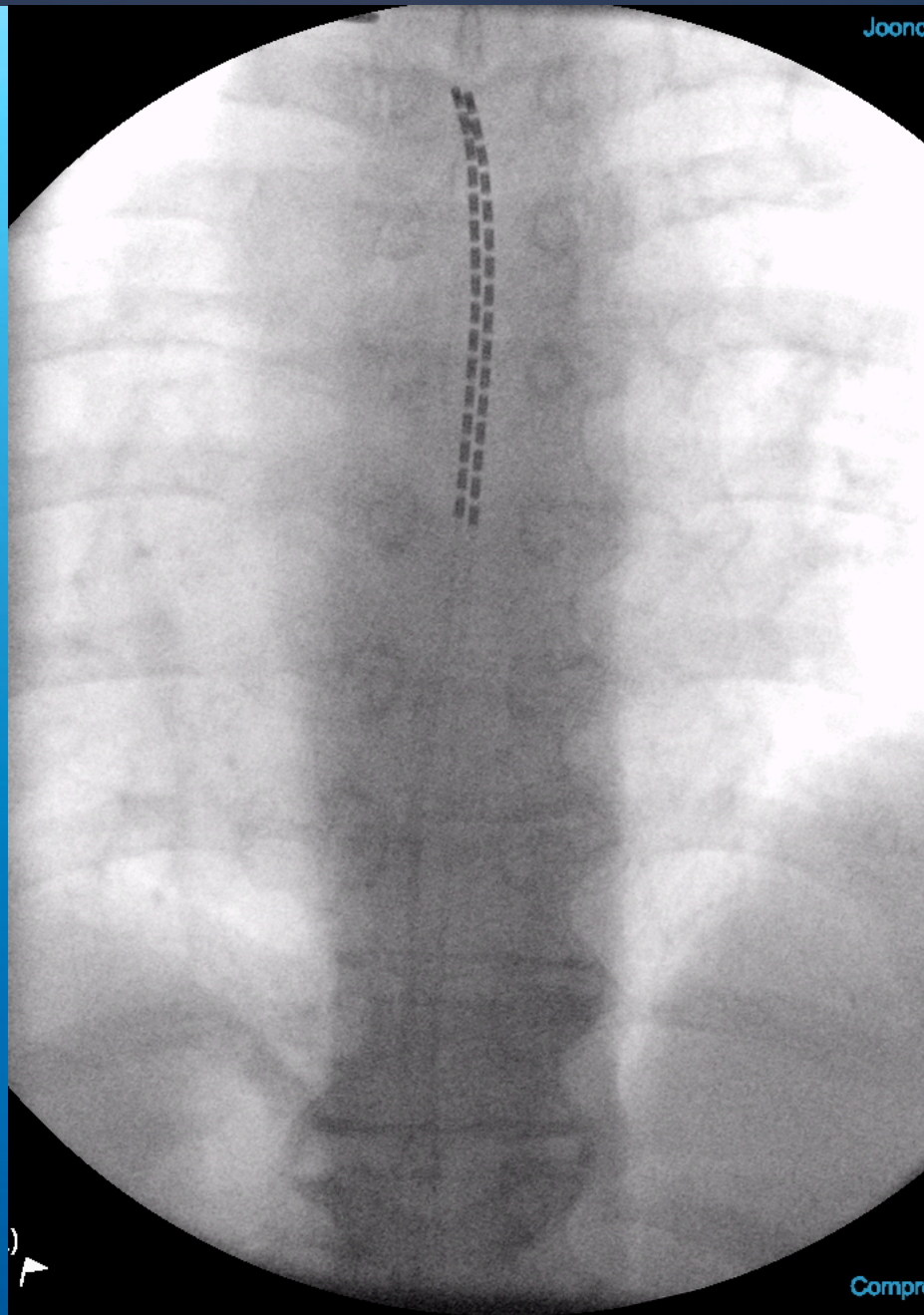


# TECHNICAL DETAILS - TRIALS





# TECHNICAL DETAILS - TRIALS





# THE TRIAL

Typically 2+ weeks

Trialling multiple modes

Requires teamwork between patient, technician and pain medicine

Try to establish:

- Does the device work (ie., >50% pain relief) in a sustained way.
- Where the target is for the leads
- Can you do a primary cell or do you need rechargeable system

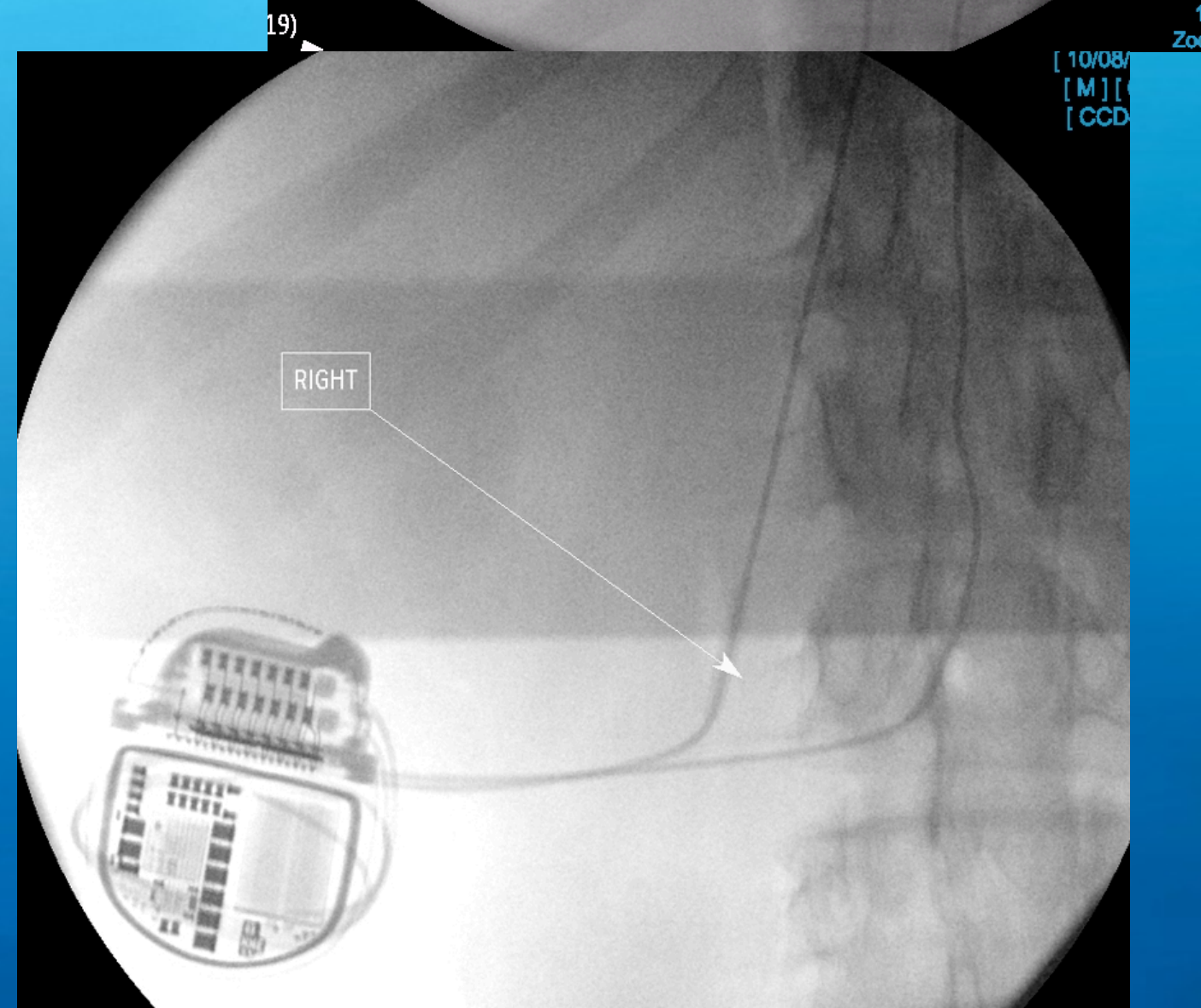
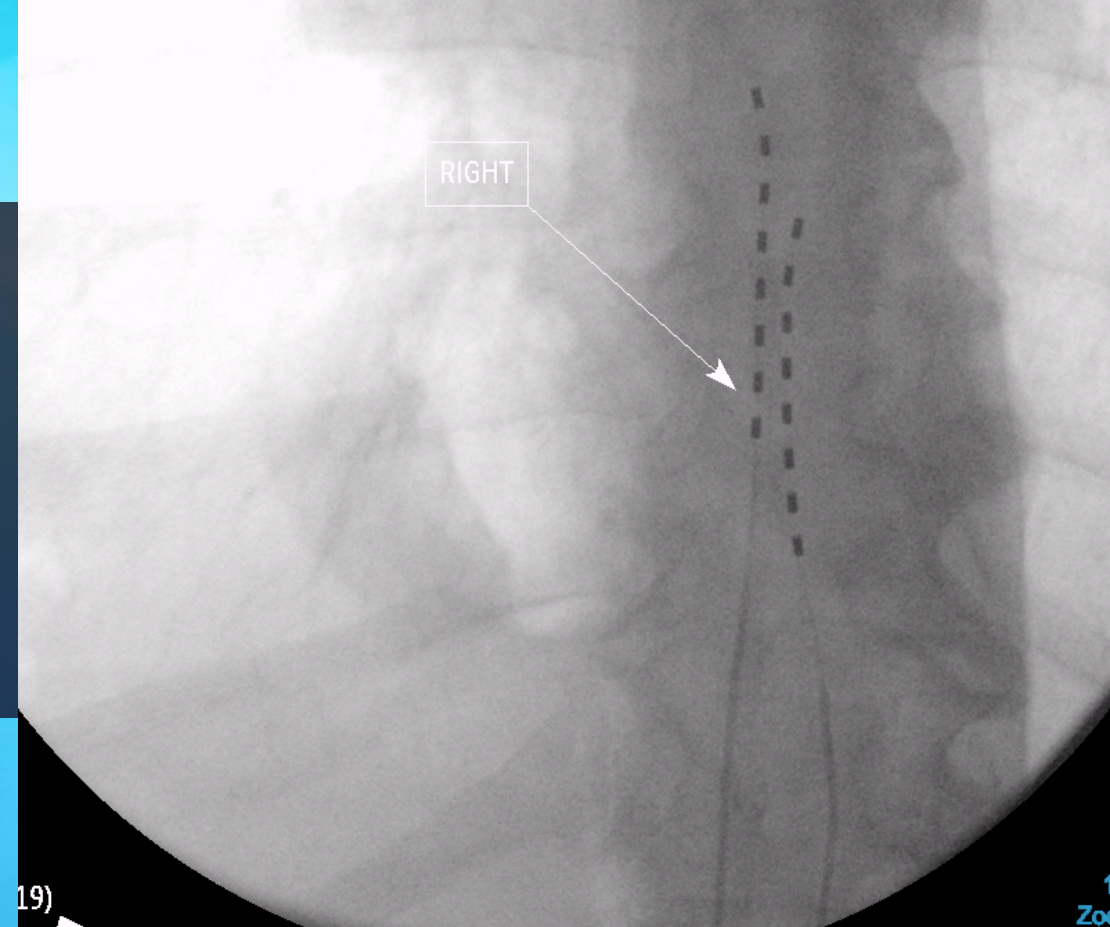
# PERMANENT SYSTEM

Similar to trial.

Can often do under GA.

Surgical incisions for device

- Generally sore
- Overnight admission





# AFTER THE IPG

Some limitations for first couple of months.

- Have to recover from surgery
- Hopefully can wind down any opioids or other pain meds.

Rehabilitation begins here.



# JOONDALUP EXPERIENCE

# JOONDALUP EXPERIENCE



## Indications

- Lumbar back pain 35%
- Pelvic Pain 19%
- Complex Regional Pain Syndrome (17%)
- Neuropathic foot or knee pain 15%
- Thoracic pain 6% (wedge #, post thoracotomy pain)
- Vasculitis 4%

# COMPLICATIONS

Repositioning of IPG/leads - 3 (6%)

Infection (superficial) - 2 (4%)

- 1 confirmed S Aureus.
- No device infections.

Skin reaction to dressings - 2 (4%)

Other - (? coincidental) Hemorrhagic CVA



# CASE PRESENTATION - KH

70 y.o. lady, severe vasculitis, PVD

Seen by APS for 2 months to control intractable ischaemic pain

- Steroids
- antineuropathics, opioids, ketamine
- Percutaneous sympathectomy without benefit.

Was considering amputation of feet for pain management.

# CASE PRESENTATION

Ultimately referred to SCGH for trial leads

Dramatic improvement.

- Mobilising around ward
- Major reduction in PRN usage
- Legs turned pink.

Went on to permanent IPG (Primary cell)

Still difficult to manage

# SUMMARY

What is neuromodulation

Evidence base

Procedures:

- Trials and IPG insertions.

- Joondalup experience

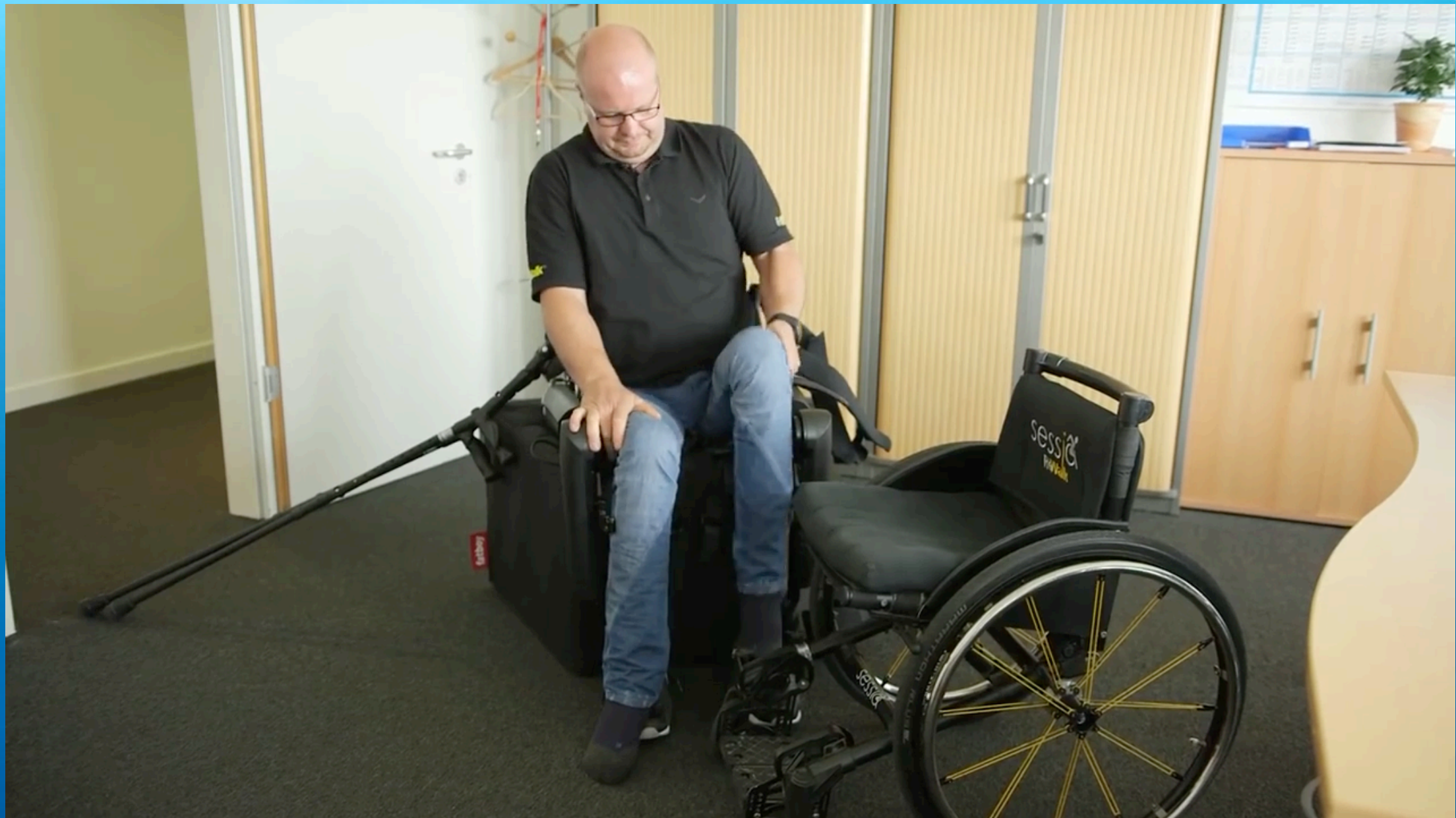
The Future



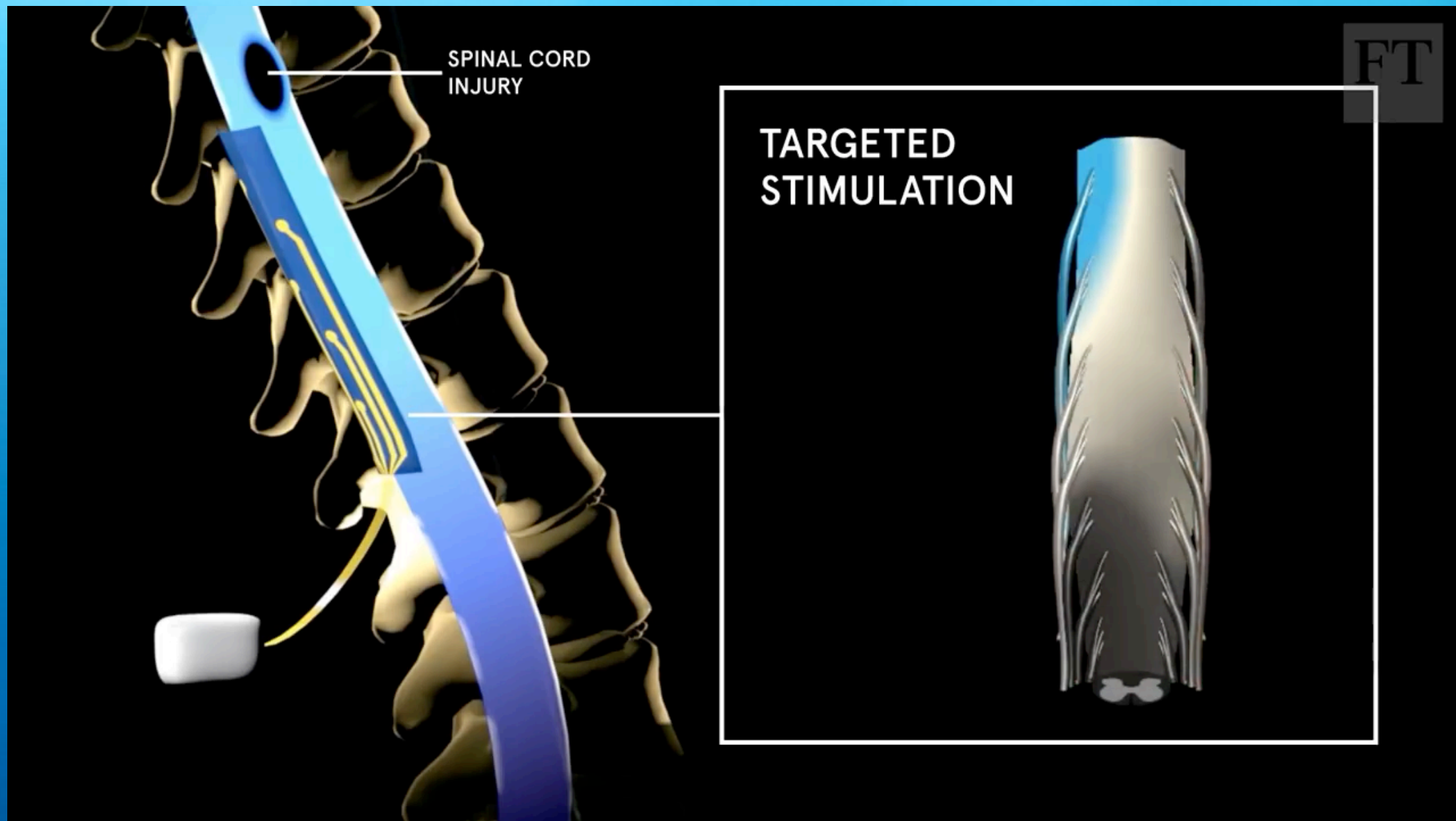


THE FUTURE

# PARALYSIS



# SCS FOR MOTOR CONTROL





# UNEXPECTED RESULTS

**Without electrical stimulation  
after 5 months of treatment**



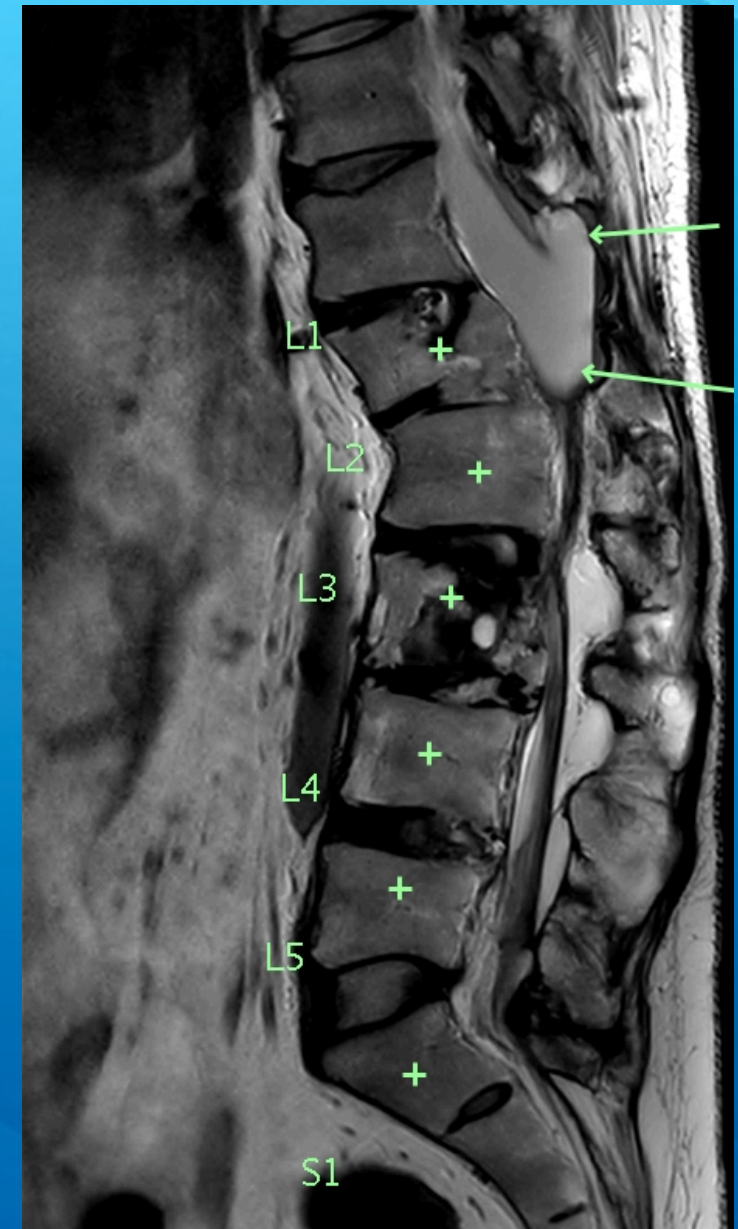


# THE FUTURE

So probably going to see more of these down the track..

Not just for pain.

- Distal vessel vascular disease
- Spinal cord injury?



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Definitions and demographics

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The Future