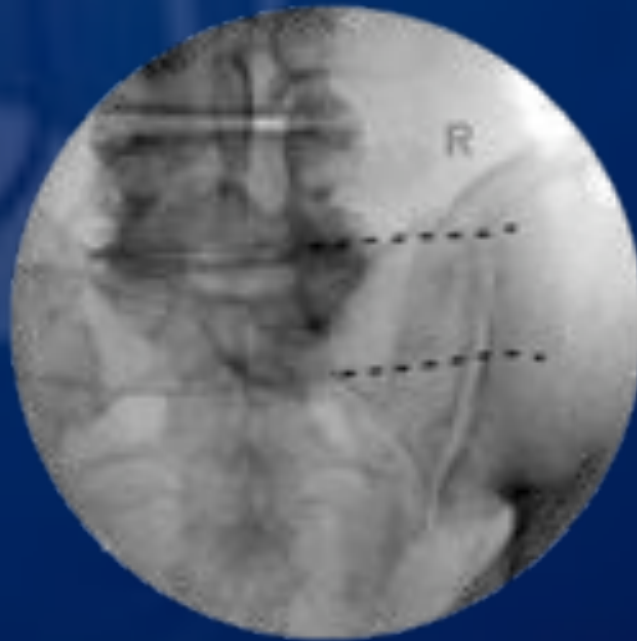


Neuromodulation: Capturing the Back

Dr Paul Verrills



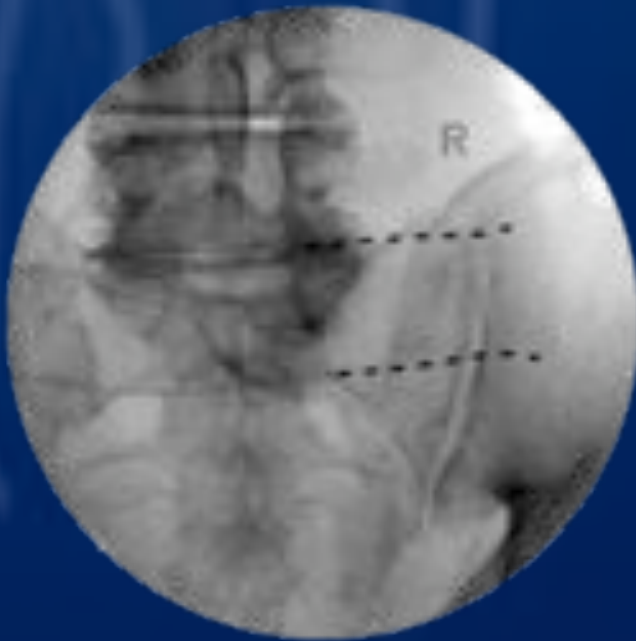
Institution: **Metro Spinal Clinic**
Melbourne, Victoria, Australia*



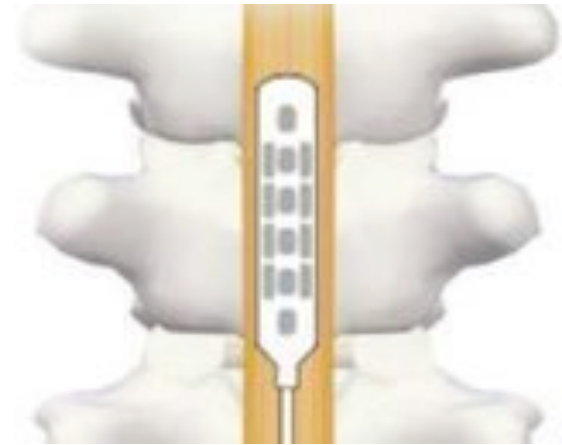
Disclosure: Travel support from Australian
Chapter of INS

Neuromodulation: Capturing the Back

- **Transverse Tripole Arrays**
- **Multiple Independent Current Control**
- **Peripheral Nerve Stimulation**



Transverse Tripolar Arrays



Thanks to Vytas Rupinskas
Sr. Mrktg Mgr. Leads & Accessories ANS

Science: Electrical Review



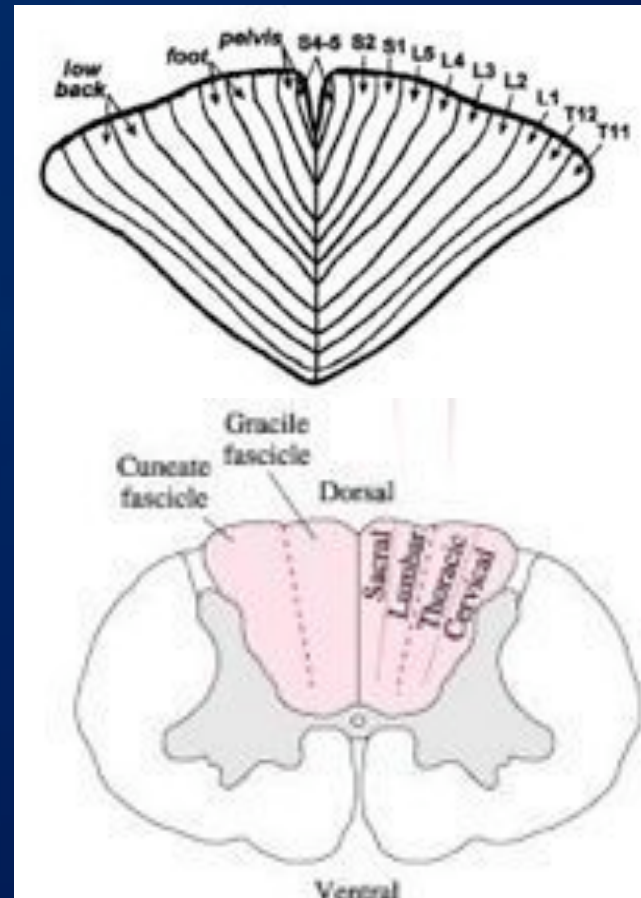
Data on Tripoles

- 1996: Struijk, Holsheimer. *Med & Biol Eng & Comput.*
- 1998: Struijk, Holsheimer et al. *IEEE*
- 1999: Slavin et al *Stereotactic Functional Neurosurgery*
- 2004: ANS introduces Tripole 8™ Paddle
- 2005 INS: Feler presentation
- 2005 INS: Hale presentation
- 2006 ASRA: Caraway poster
- 2006 NANS: Miyazawa and Prager poster
- 2006 Neuromodulation: Oakley article MDT's TTS (Transverse Tripolar System)
- 2006: over 3000 units

Science: Anatomy Key Points

- Where to target?¹
- Fibres start lateral and then move more medial as you go up the cord
- Density of the large target fibres decreases as the layers go up²
- Back is a challenge:
Target T8-T10¹

1. Barolat et al. *J Neurosurg.* 1993
2. Feirabend et al. *Brain.* 2002



Thoracic

Cervical
Spinal
Cord

Science: Anatomical Review

Lower Thoracic (approx. T9/T10)



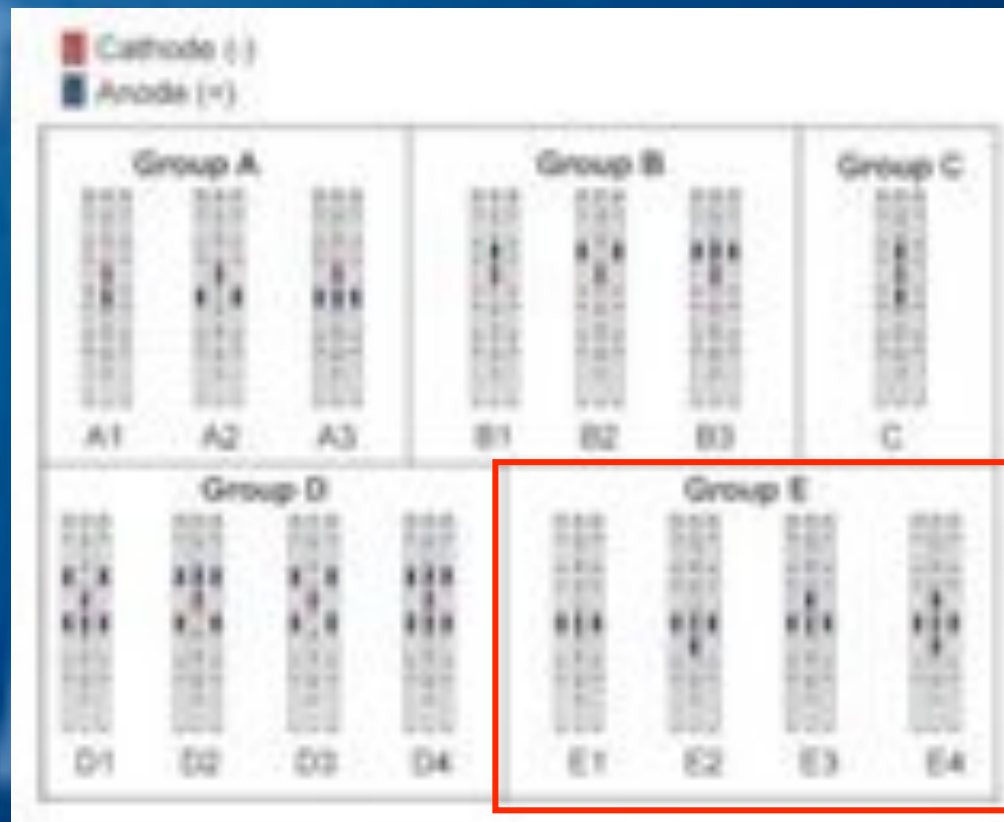
A Midline Single Cathode Offers Preferential Dorsal Column Recruitment with Spinal Cord Stimulation

David Caraway et al, Medtronic

- Configuration that offers the best DC selectivity is **transverse tripole**.
- Cathodes placed off the midline results in poorer dorsal column selectivity due to proximity of cathode to the dorsal roots.
- The voltage (VDC) necessary to activate one DC fibre at the midline and on the border of the white matter and CSF is highest with the transverse guarded tripole
- Using transverse tripoles gives the best selection of DC to DR fibre activation.

Guarded Cathode Arrays Allow Differential Spinal Cord Stimulation Effects

Gabi Miyazawa et al, Medtronic



Guarded Cathode Arrays Allow Differential Spinal Cord Stimulation Effects

Gabi Miyazawa et al, Medtronic

- Transverse Tripole (Group E) provided:
 - the best recruitment of DC vs DR fibres
 - highest usage range
 - however higher voltages were required to activate the first DC fibre
- The 4-8-4 array offers new patterns for paraesthesia coverage.

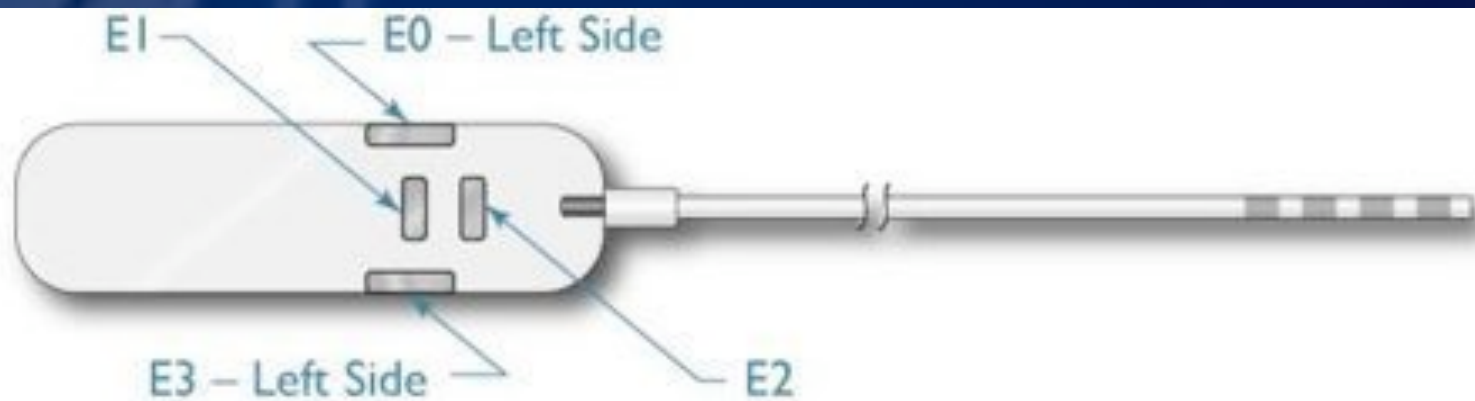
Science: Clinical Review

Oakley, J.C. et al. Transverse Tripolar SCS: Results of an International Multicenter study. *Neuromodulation*. 2006;9(3);192-203.

- 8 centers, 56 patients, 41 implanted
- 20 chose IPG w/quad, 21 chose dual channel RF w/TTS
- VAS scores dropped more for patients with TTS (32%) than conventional polarity (16%)

Science: Clinical Review

- Oakley Paper
 - TTS (Transverse Tripolar Stim) Implant
 - Lateral 0.5 mm wide x 10 mm long,
 - Central 1.5 mm long x 4.5 mm wide,
 - Lateral spacing 3 mm,
 - Longitudinal spacing 2.25 mm



Science: Clinical Review

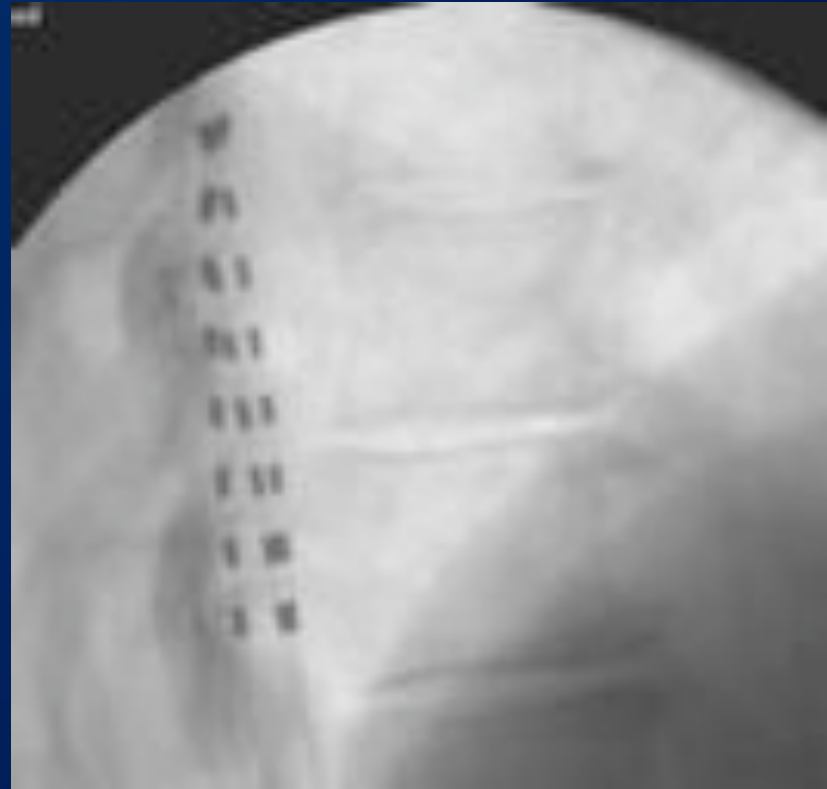
- Oakley Paper
 - “The system ... was noted to be very sensitive to ...physiologic midline.”
 - “The center electrode is 4.5 mm wide and if it is two or more millimeters off...it is over the dorsal root.”
 - “In finding the higher usage range ... we believe this indicates that the dorsal root fibres have an increased threshold as compared to dorsal column fibres due to the lateral anodal fields.”

Science: Clinical Review

- Oakley Paper
 - No attempt was made to specifically assess low back coverage or relief
 - Those observed to perceive paraesthesia in the low back, did not generally report pain relief
 - No statistically significant difference in outcomes between the 2 implanted groups
 - Between 53 – 61% reported “good” or “excellent” outcomes at 1 year

How to achieve a Tripole

- Perc Tripole™:
Two Quattrode® leads
and an Octrode® lead
 - Can be done by interventional pain management specialists
 - Can be difficult to align all three leads
- Paddle Lead
 - Requires a surgeon
 - Requires a laminectomy



ANS Tripole Family



16C

3214

8C

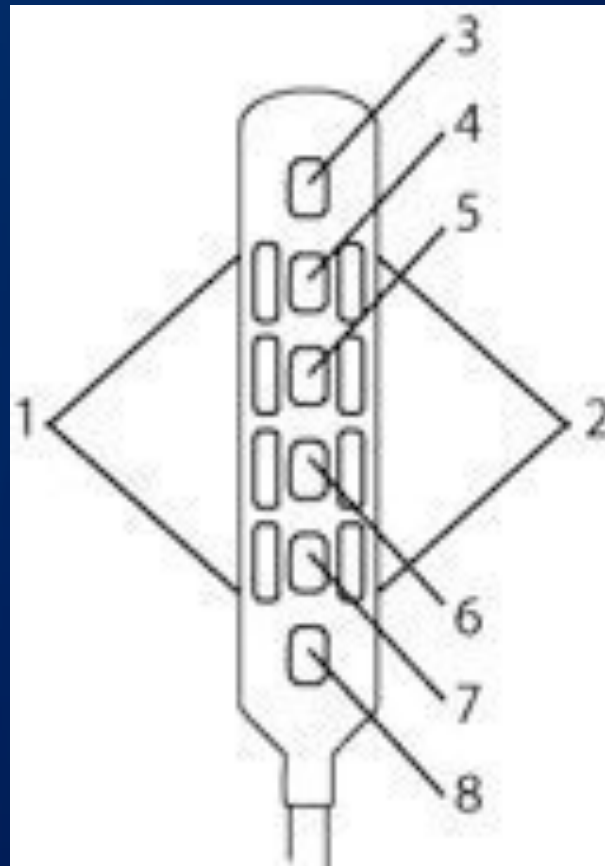
3210

8

3208

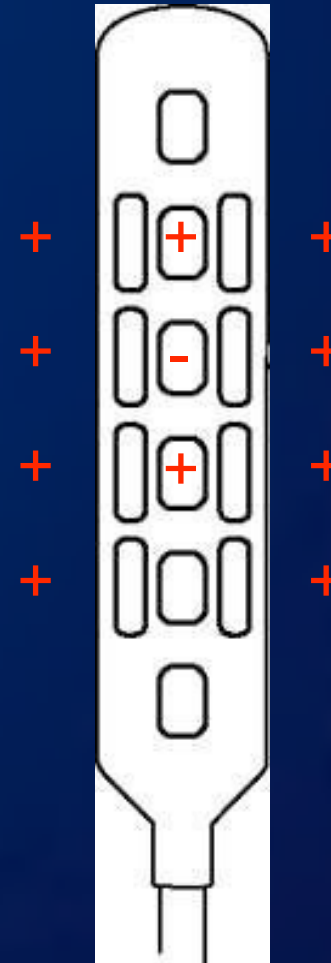
Lamitrode Tripole 8

- Array design

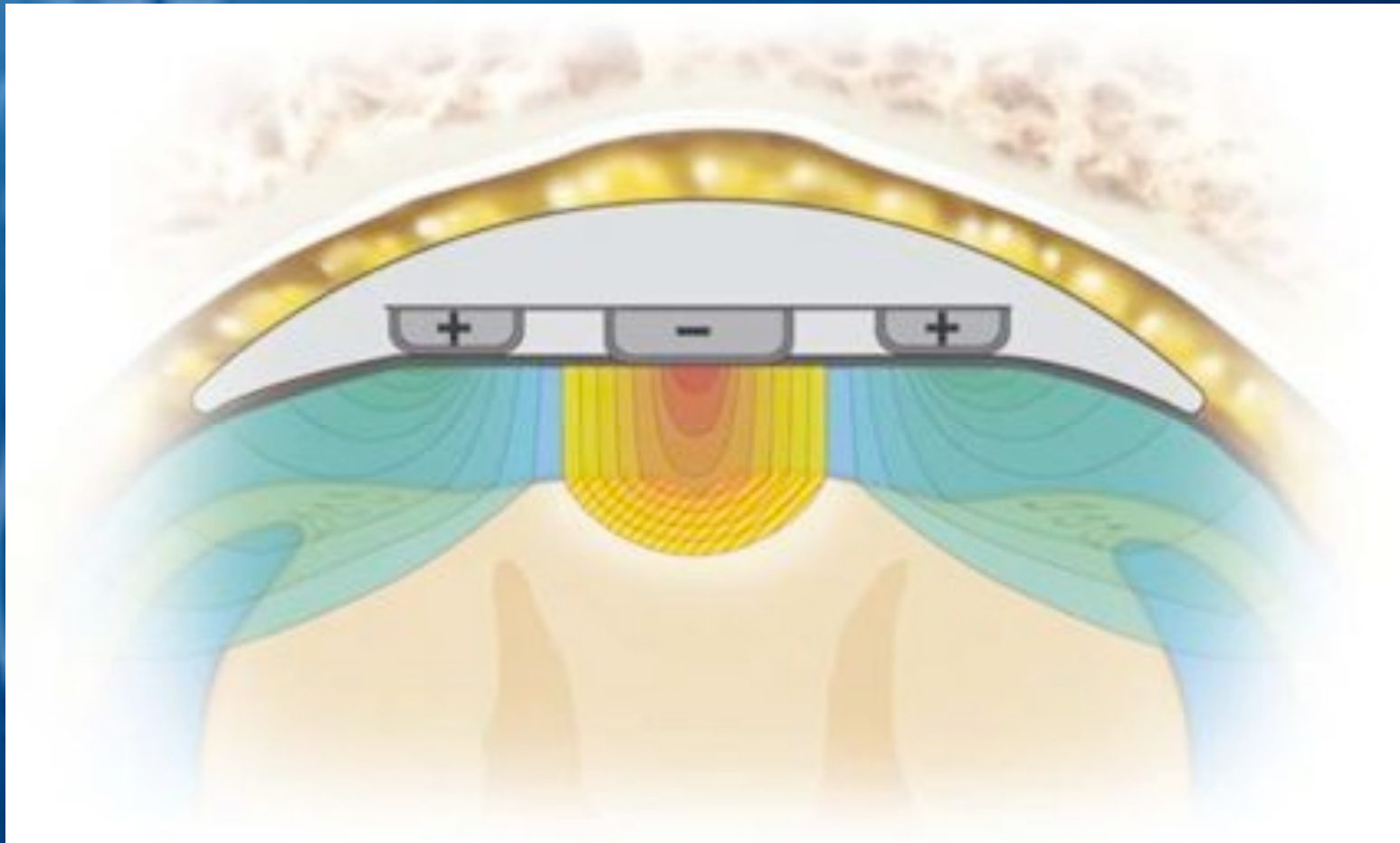


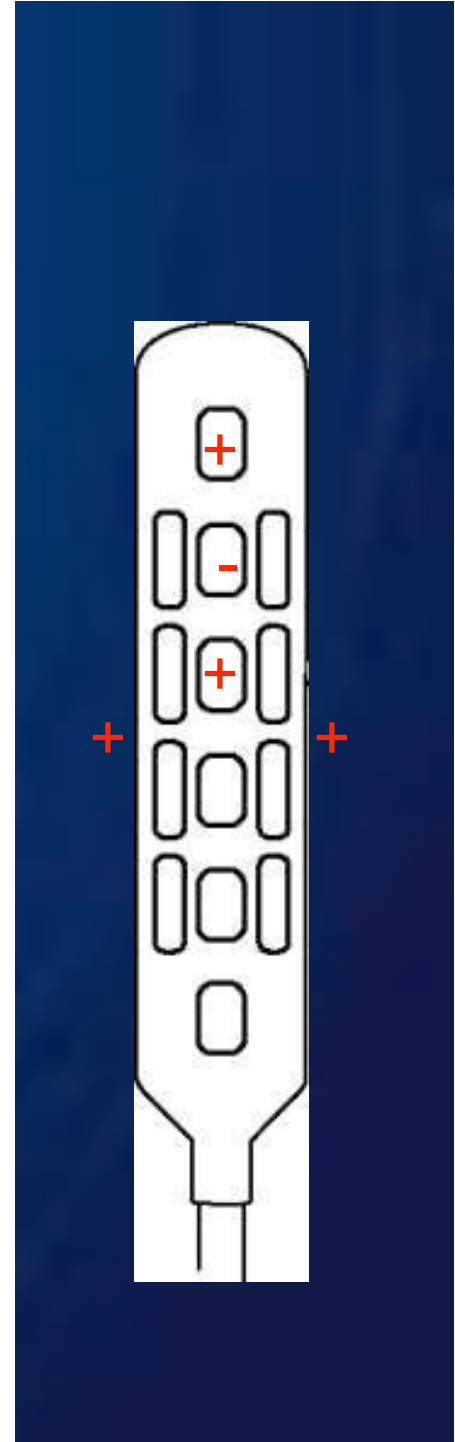
Anodal Blocking

- Limit root stimulation
- Focused targeting



Tripole™ C Paddle Lead





Financial Statement

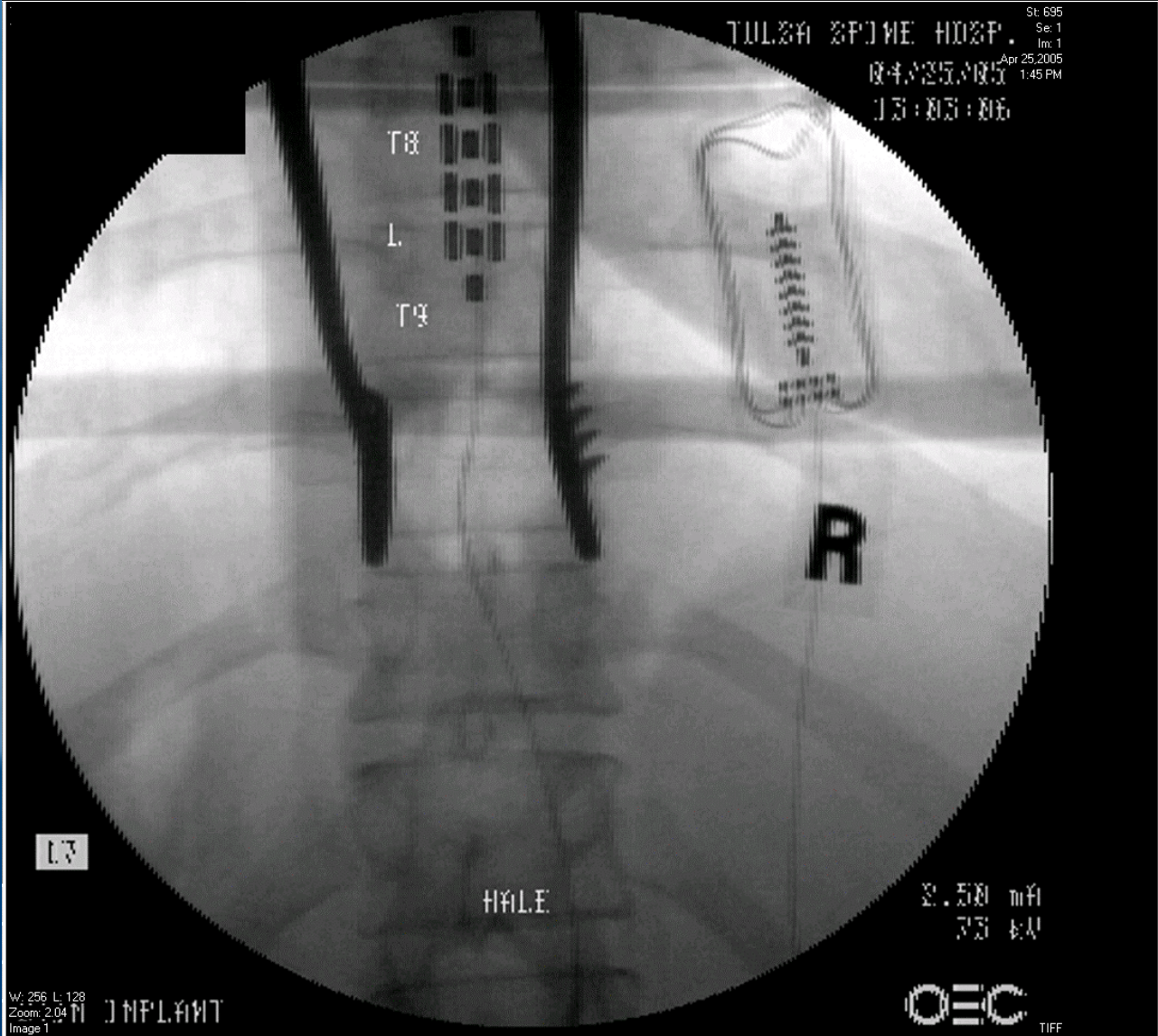
Income Statement
Period: 12/31/2010 to 12/31/2011
Currency: USD
Accounting Method: Accrual

Line Item	2010				2011				Change
	Revenue	Cost of Sales	Gross Profit	Operating Expenses	Revenue	Cost of Sales	Gross Profit	Operating Expenses	
1. Sales	100	0	100	0	100	0	100	0	0
2. Cost of Sales	0	0	0	0	0	0	0	0	0
3. Gross Profit	100	0	100	0	100	0	100	0	0
4. Operating Expenses	0	0	0	0	0	0	0	0	0
5. Operating Income	100	0	100	0	100	0	100	0	0

Financial Statement

Item	2018	2017	2016	2015	2014	2013
Revenue	100.0	100.0	100.0	100.0	100.0	100.0
Cost of Sales	(40.0)	(40.0)	(40.0)	(40.0)	(40.0)	(40.0)
Gross Profit	60.0	60.0	60.0	60.0	60.0	60.0
Operating Expenses	(20.0)	(20.0)	(20.0)	(20.0)	(20.0)	(20.0)
Operating Income	40.0	40.0	40.0	40.0	40.0	40.0
Interest Expense	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)
Income Before Tax	35.0	35.0	35.0	35.0	35.0	35.0
Income Tax	(10.0)	(10.0)	(10.0)	(10.0)	(10.0)	(10.0)
Net Income	25.0	25.0	25.0	25.0	25.0	25.0

Item	2018				2017				Total
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Revenue	25.0	25.0	25.0	25.0	25.0	25.0	25.0	25.0	100.0
Cost of Sales	(10.0)	(10.0)	(10.0)	(10.0)	(10.0)	(10.0)	(10.0)	(10.0)	(40.0)
Gross Profit	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	60.0
Operating Expenses	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)	(20.0)
Operating Income	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	40.0
Interest Expense	(1.25)	(1.25)	(1.25)	(1.25)	(1.25)	(1.25)	(1.25)	(1.25)	(5.0)
Income Before Tax	8.75	8.75	8.75	8.75	8.75	8.75	8.75	8.75	35.0
Income Tax	(2.50)	(2.50)	(2.50)	(2.50)	(2.50)	(2.50)	(2.50)	(2.50)	(10.0)
Net Income	6.25	6.25	6.25	6.25	6.25	6.25	6.25	6.25	25.0



Background

Study by: Gerald Hale, DO

Tulsa, Oklahoma, USA

- 23 patients
 - Previous back surgery FBSS - (96%)
 - Low-back & concurrent leg pain (96%)
 - Bilateral leg (4%)
- Psychological exam
- Successful trial
- Implanted Feb 2004–Feb 2005

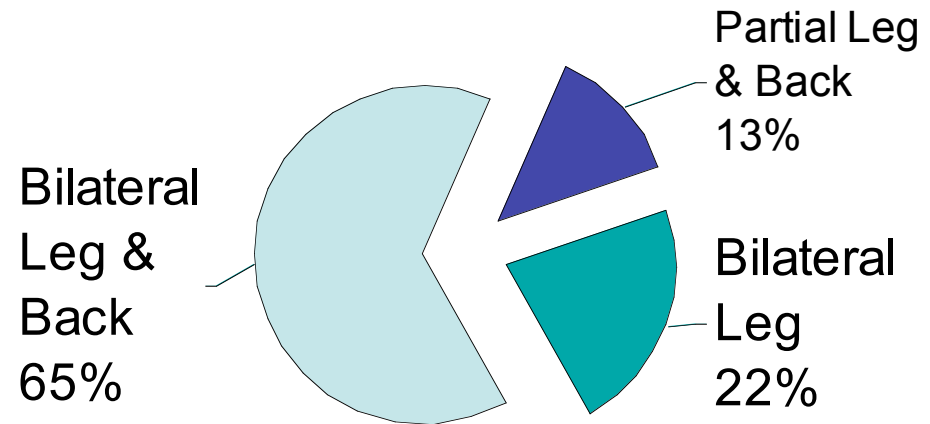
- Device
 - Tripole 8 (ANS)
 - Genesis IPG (ANS)
- Implanted by surgeon
 - MAC
 - Hemi-lamectomy
 - Tip at T8
- Initial programming in hospital

Demographics

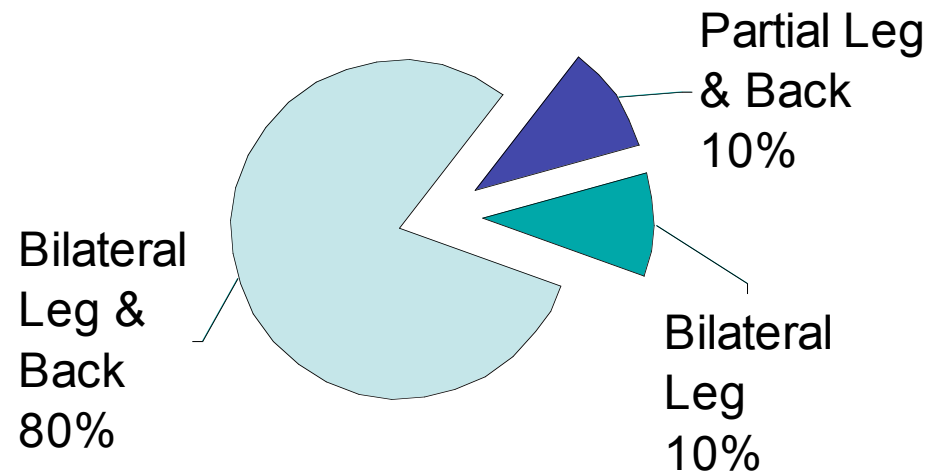
• Patients	23	100%
• Female	14	61%
• Male	9	39%
• Mean age (range)	58.9 (42-73)	
• Mean time in pain	11.7 years	
• VAS (range)	8.8 (7-10)	

Paraesthesia Coverage

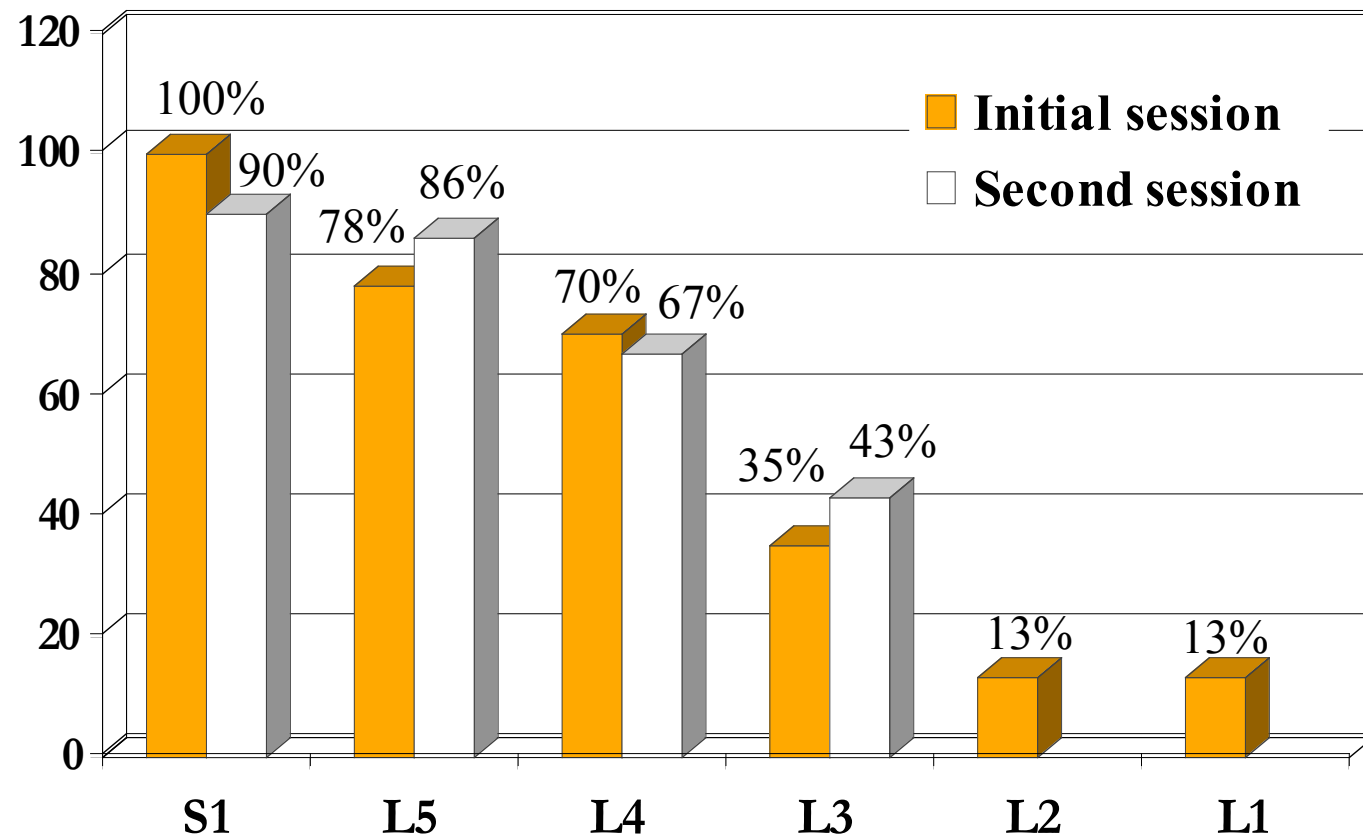
- Initial Programming

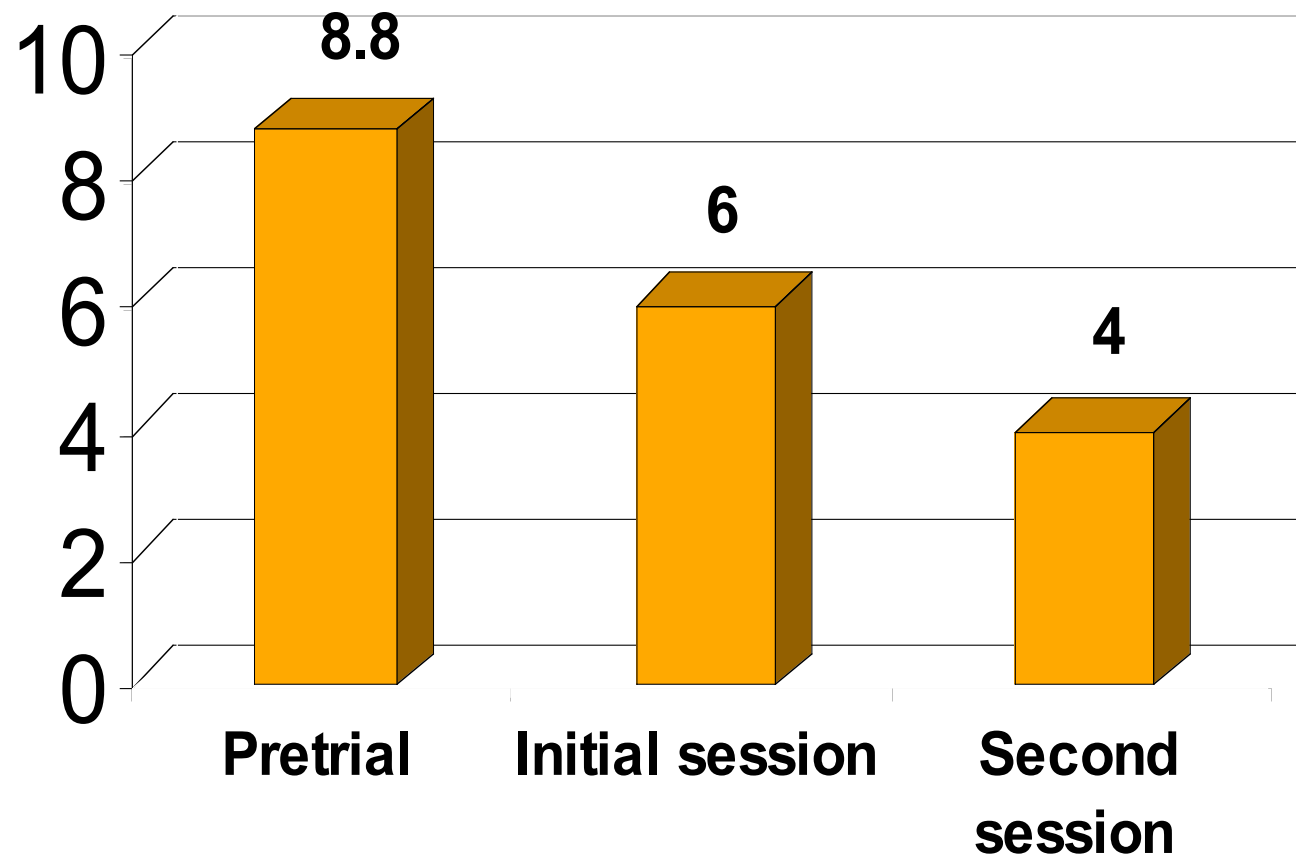


- 2nd Programming

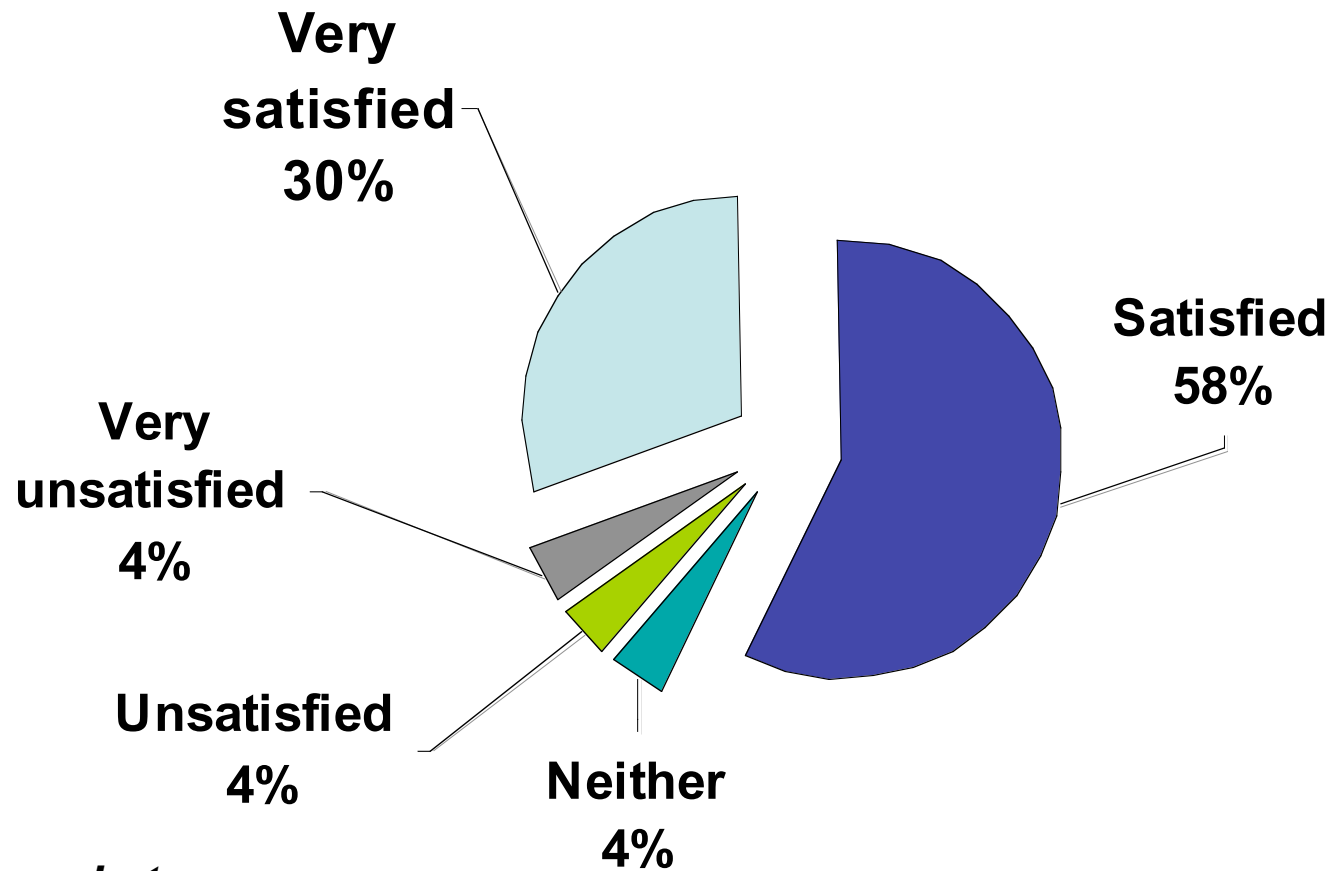


Back Coverage by Dermatome



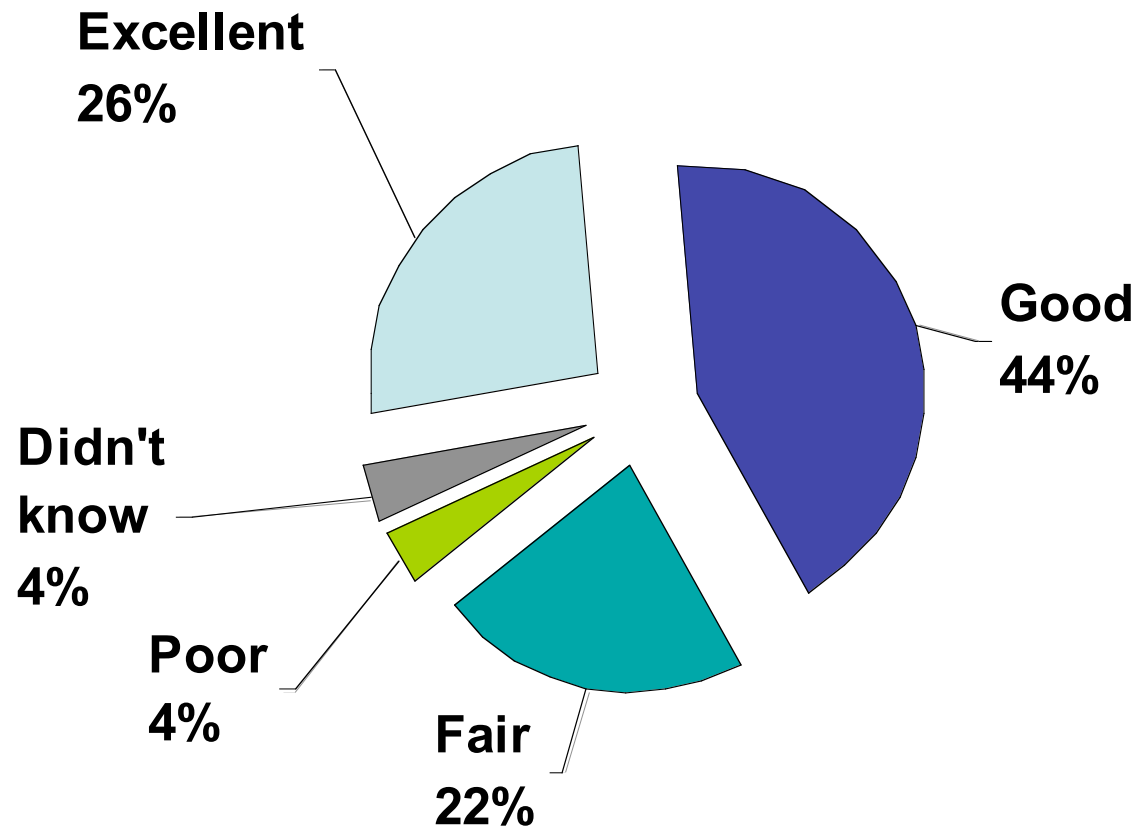


Patient Satisfaction



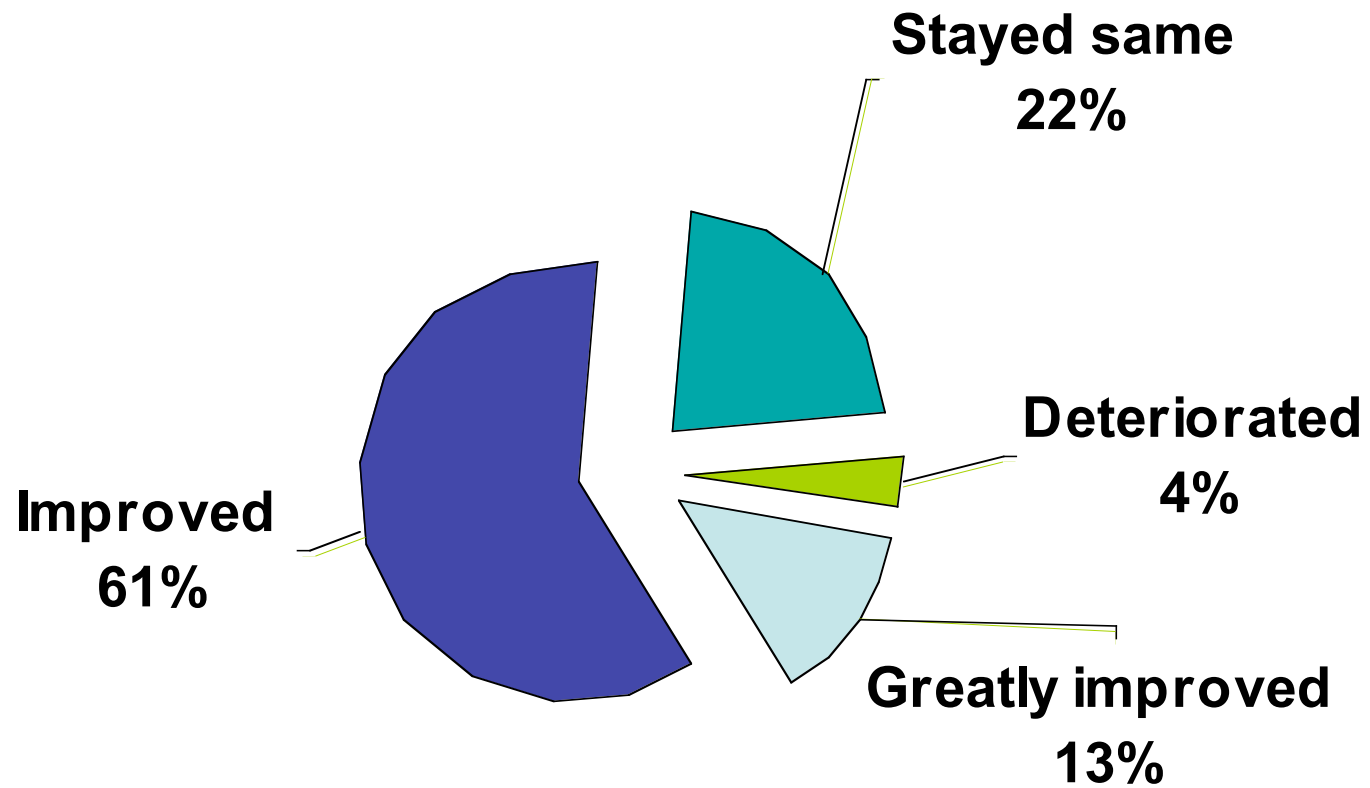
*Measured at
second session*

Overall Pain Relief



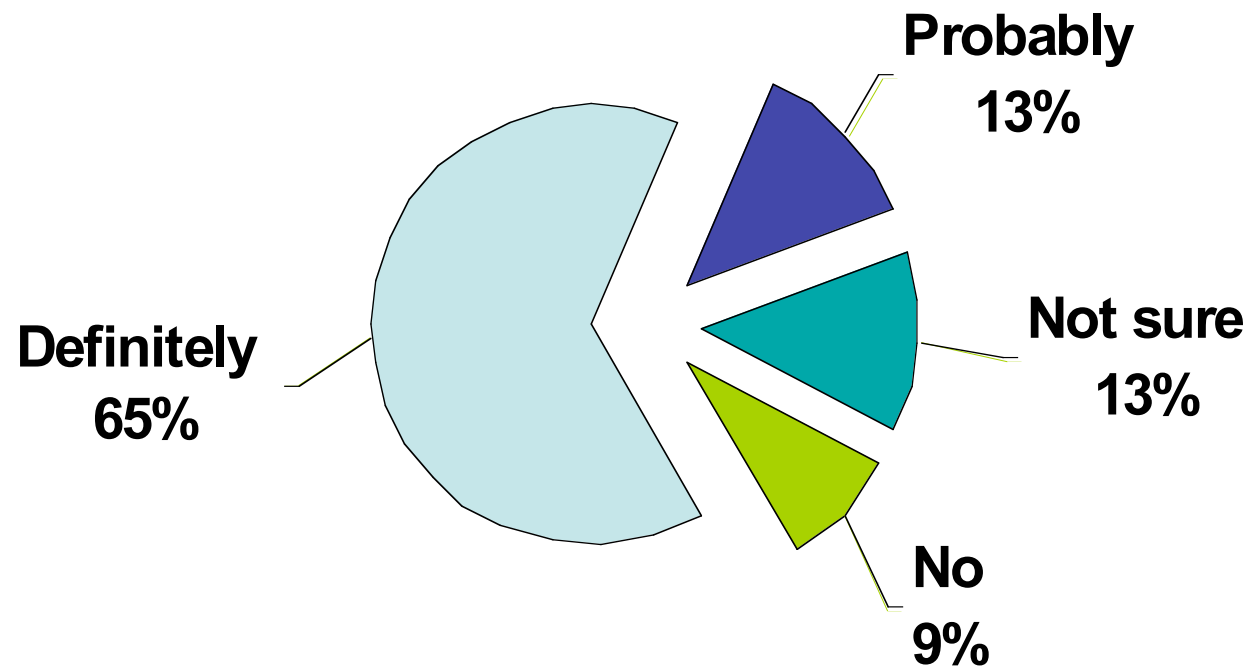
*Measured at
second session*

Quality of Life



*Measured at
second session*

Would choose to do procedure again?



*Measured at
second session*

Conclusion

- Provided broad coverage for the majority of patients
- Effectively relieved pain in high percentage of patients with low-back and concurrent leg pain
- Provided coverage at a higher dermatomal level compared to traditional leads
- Significant decrease in VAS scores
- Improved patient satisfaction and QOL ratings
- Prospective multi-center study needed to further validate

Spinal Cord Stimulation:

Multicentre SCS for Axial Low Back

Pain

- 259 Enrolled through 25 sites
- mean age 56 (+/-14)
- 50.4% female
- Duration – mean 14 years
- 226 trials – 76% positive
- Trial VAS man 6.6 pre to 3.9 ($P < 0.0001$)
- Average VAS reduction – 40%
- 159 implants

- Sponsored by Boston Scientific
- AAPM 2007 Thacker et al



Spinal Cord Stimulation:

Paraesthesia Coverage of Back Pain

**15 patients implanted
Boston Scientific
Precision™ SCS System**
- Metro Spinal Clinic

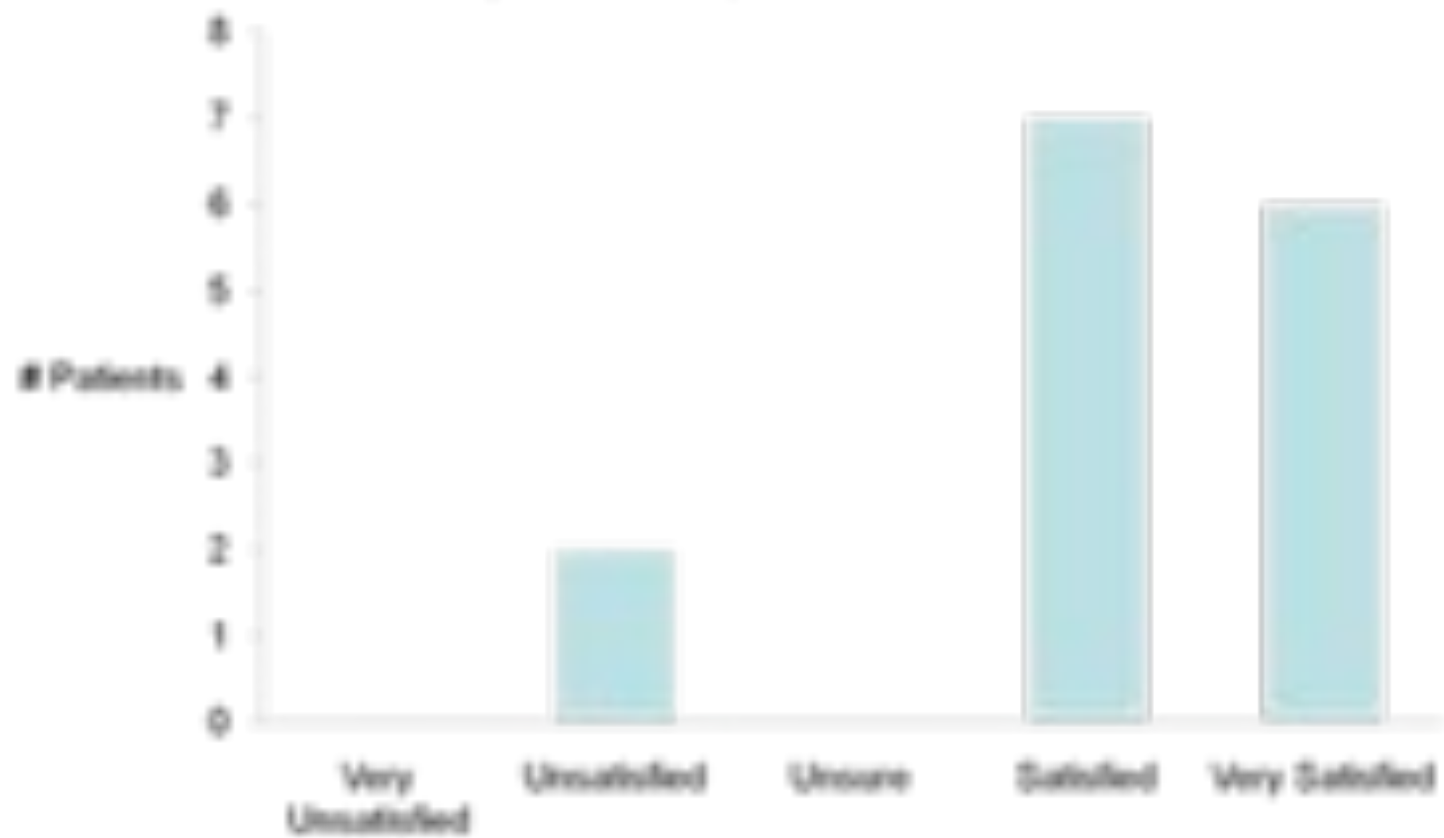


Phone survey: Stimulation coverage of back pain areas

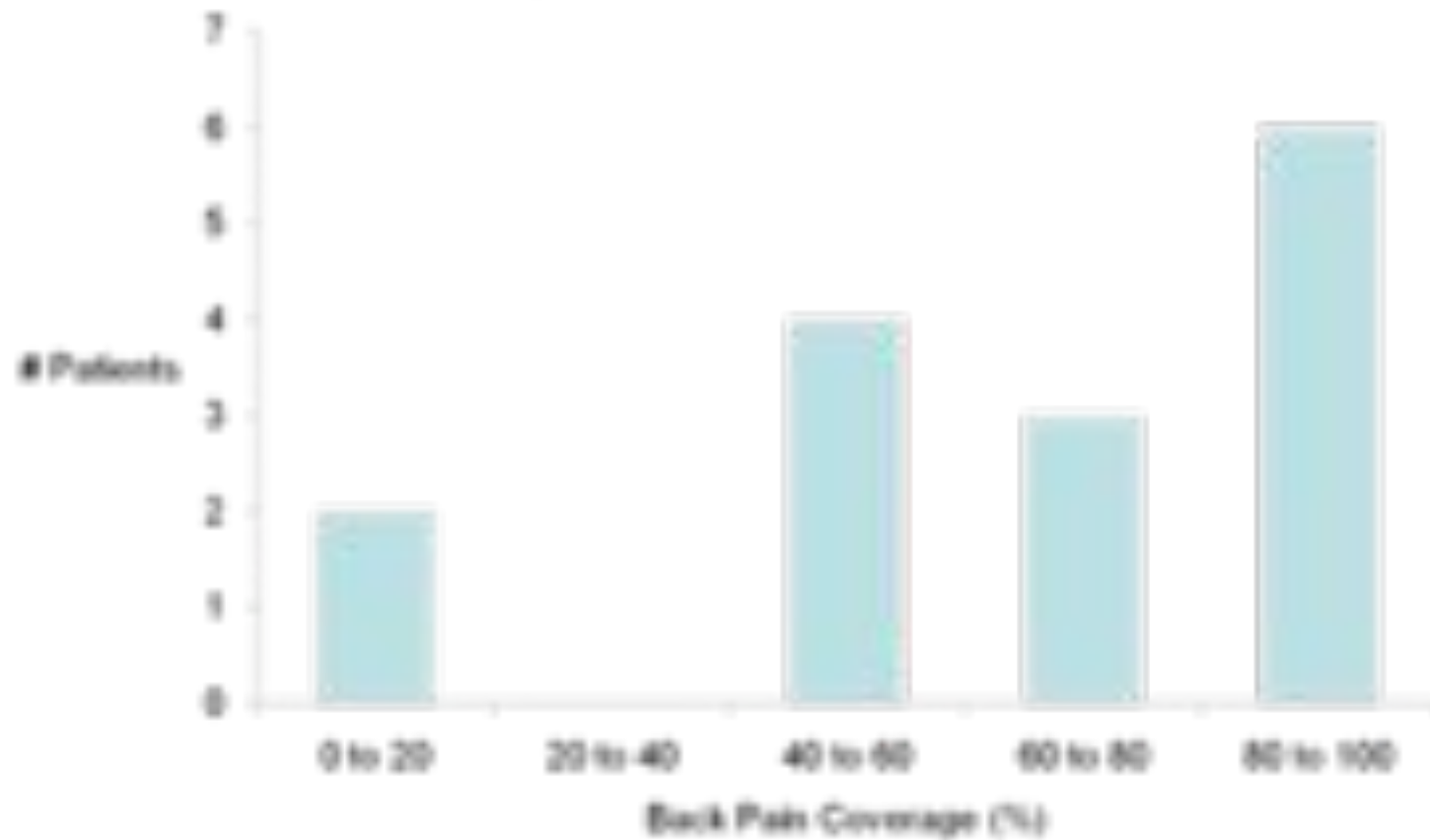
First 15 SCS patients implanted for back pain at Metro Spinal Clinic

Female	11			
Male	4			
	mean	SD	min	max
Age (years)	51	14	27	72
Days implanted	143	86	13	258

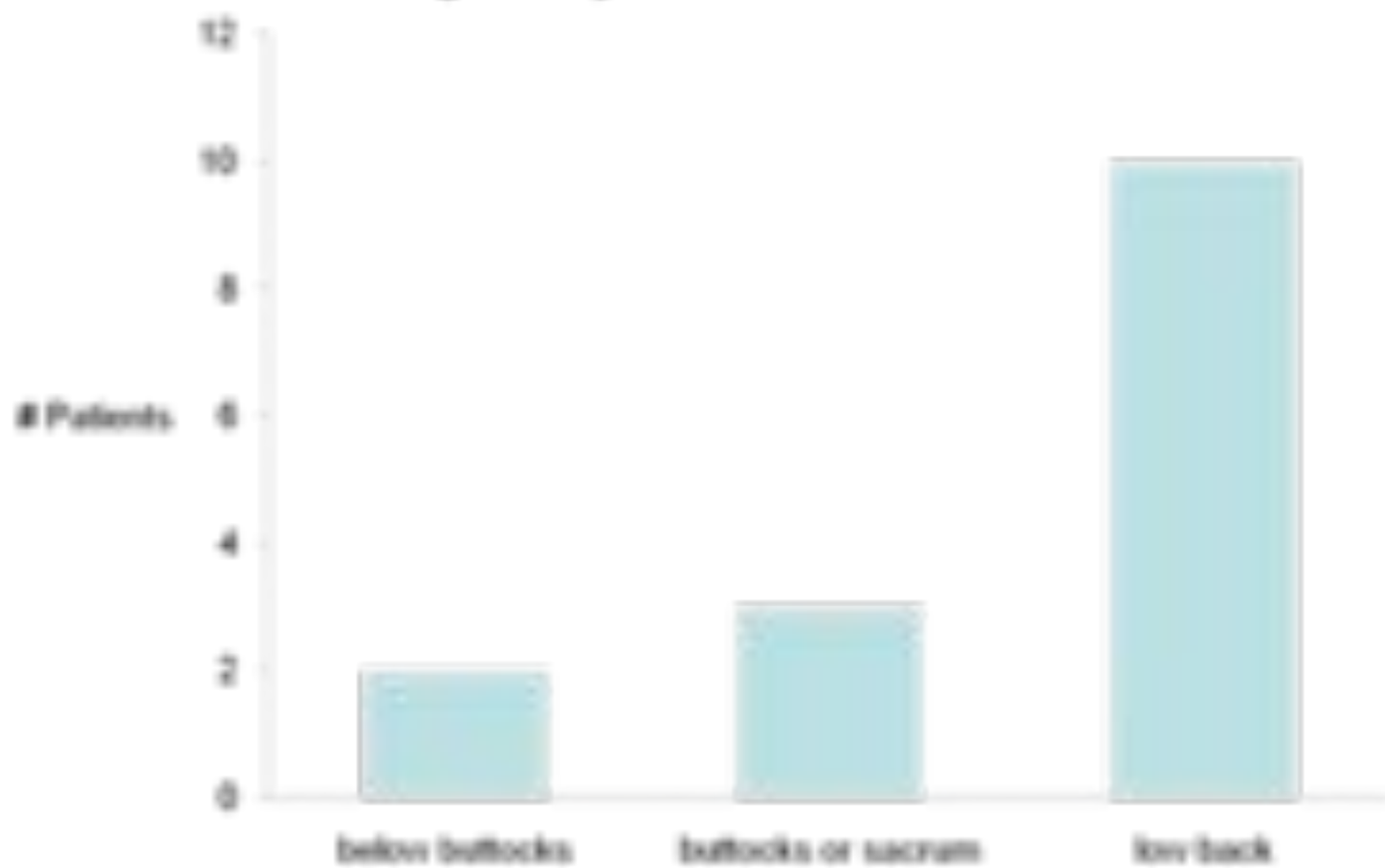
How would you rate the stimulation coverage of your back pain area?



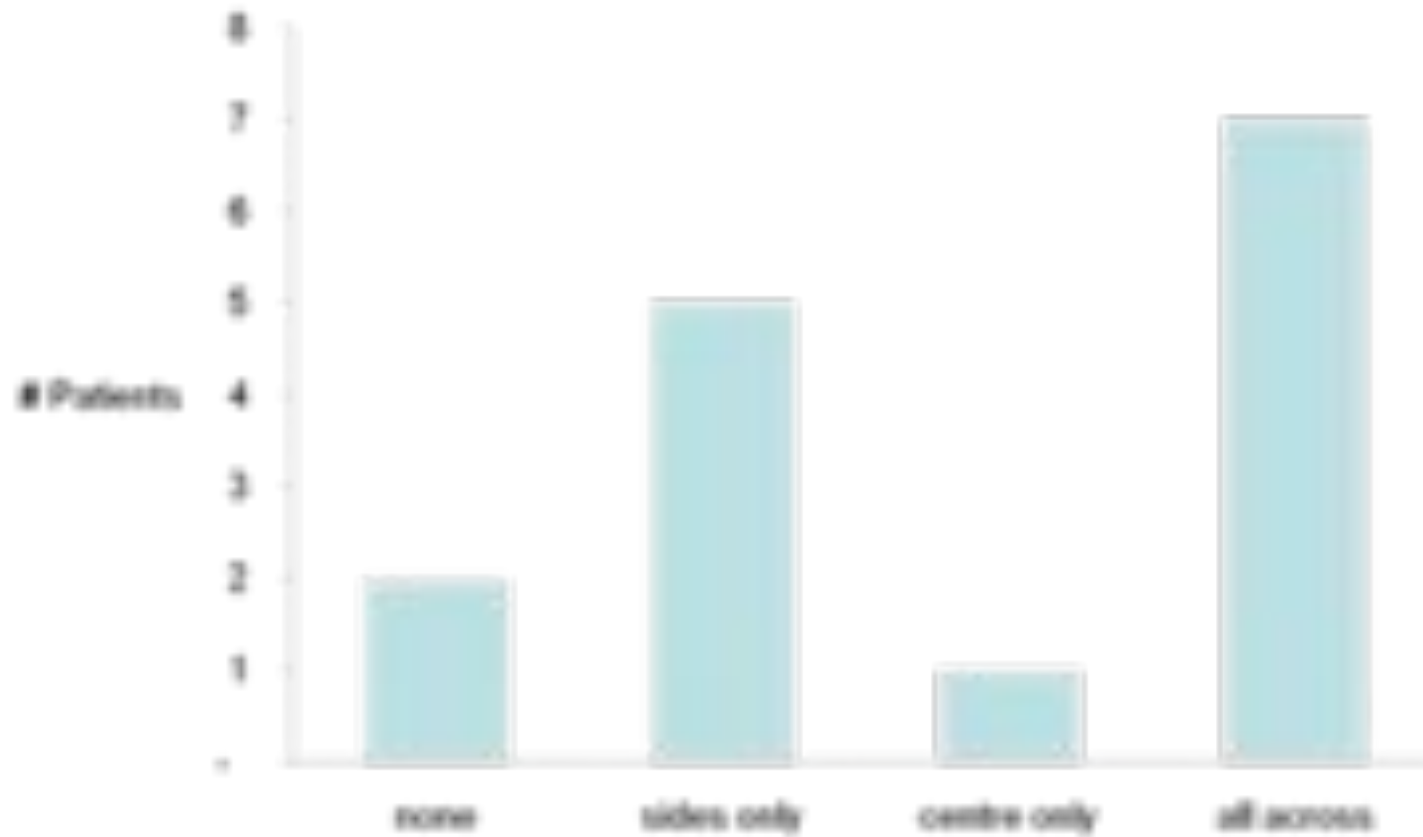
What percentage of your back pain area is covered by the stimulation?



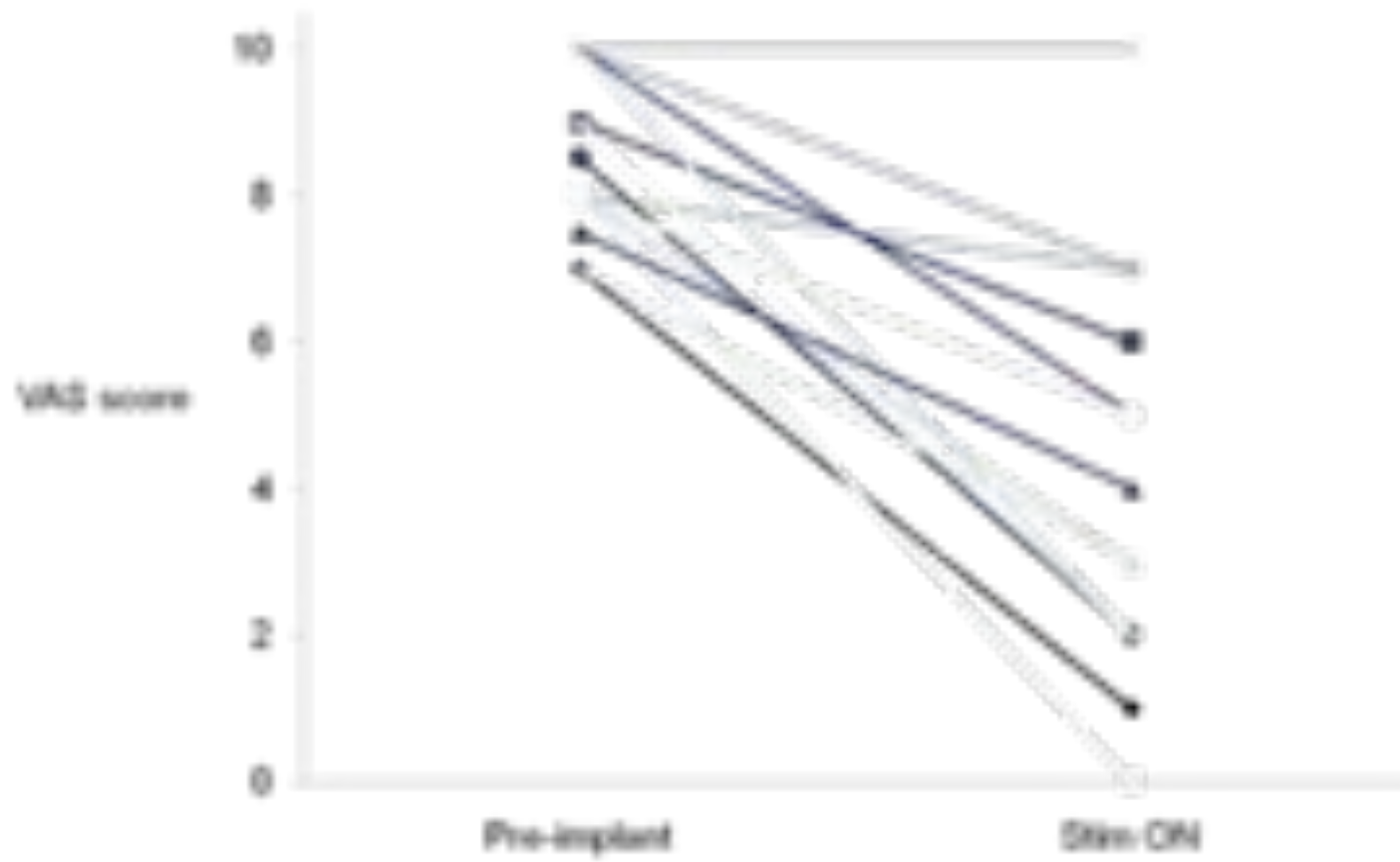
How "high" do you feel the stimulation?



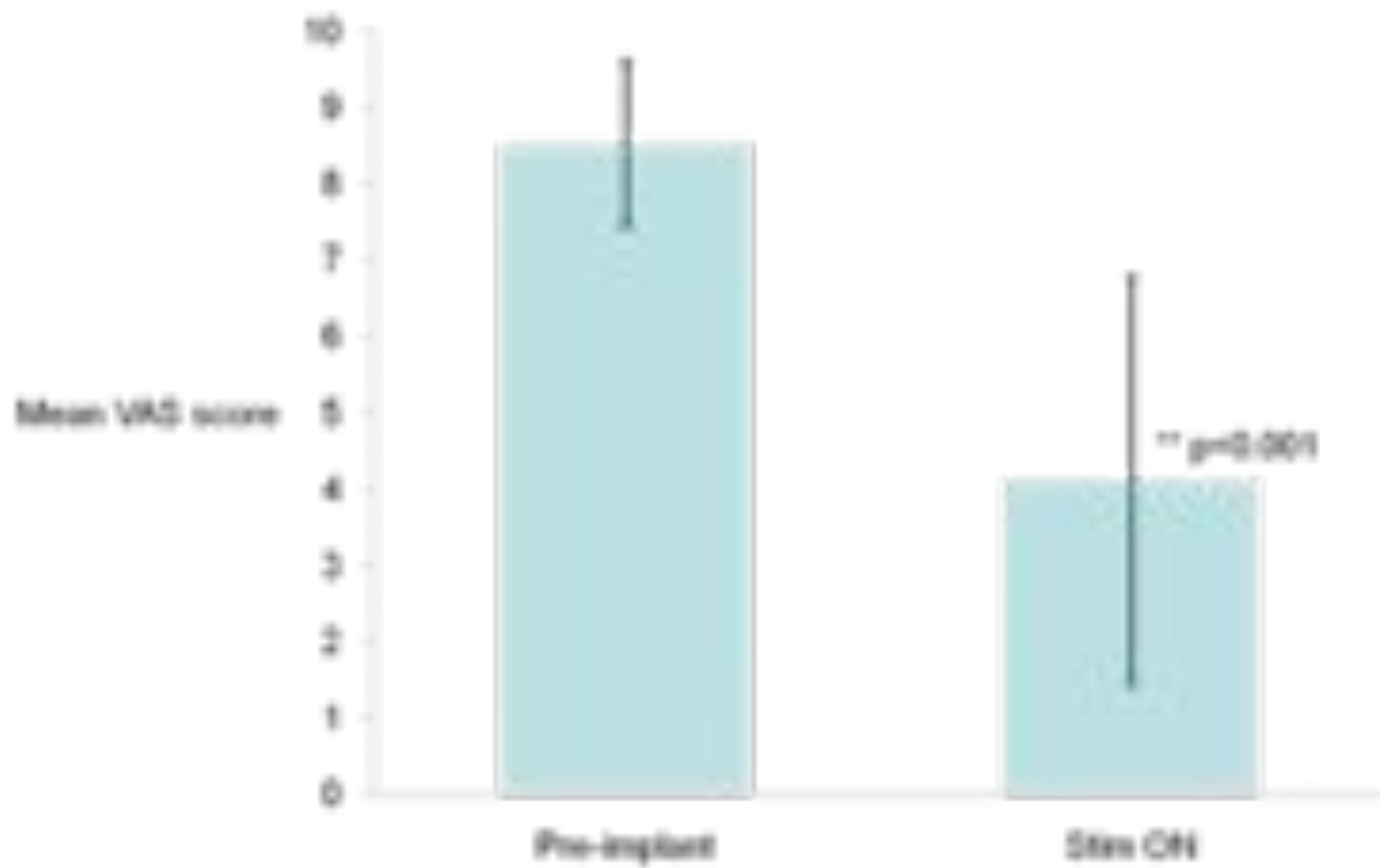
Does the stimulation spread across your back or buttocks?



VAS improvement



VAS Score for Pain



Programming

<i>Programming</i>	Mean	SD	Min	Max
Days since last programming	87	58	9	183
Days of programmer data*	55	67	1	238
Usage (hours/day)	17.4	6.2	4.7	23.6
Programs (Number used/day)	1.6	0.4	1.0	2.7

*IPG collects and stores program usage and battery data every 4 hours, which is then downloaded to the Clinician's Programmer at each visit.

- Each **Patient** can have 1-4 "Programs" to change as needed with the Remote Control
- Each **Program** can have 1-4 "Stimulation Areas" delivering stimulation pulses sequentially
- Each **Area** can have different electrode configurations, current amplitude, pulse width and frequency
- Each of the **16 electrodes** can be independently controlled to deliver a fixed percentage of the total anodal (+ve) or cathodal (-ve) current

Sample programs

Pt 8 SB

Area 1

Level : 3.7 mA
Pulse Width : 1000 μ S
Rate : 90 Hz

- 31	- 53
- 5	- 11
+ 40	+ 44
+ 8	+ 8

Area 2

Level : 3.9 mA
Pulse Width : 640 μ S
Rate : 90 Hz

- 42	
- 58	
	+ 72
+ 28	

Most recent programs for these patients consisting of 1-4 Areas.
Each electrode can be programmed to deliver 0-100% of total current.

Sample programs

Pt 7 LG

1 BODY

Level : 6.7 mA

Pulse Width : 300 μ S

Rate : 60 Hz

	+ 100
	- 100

Sample programs

Pt 10 CB

low back

Level : 4.8 mA
Pulse Width : 550 μ S
Rate : 60 Hz

+ 66	+ 23
+ 7	+ 4
- 73	- 27

r)back

Level : 5.4 mA
Pulse Width : 550 μ S
Rate : 60 Hz

+ 56	+ 3
+ 38	+ 3
- 93	- 7

lwr back

Level : 7.5 mA
Pulse Width : 550 μ S
Rate : 60 Hz

+ 47	+ 25
- 66	- 34
+ 12	+ 16

Sample programs

Pt 11 IJ

back
Level : *.9 mA*
Pulse Width : *1000 μ S*
Rate : *60 Hz*

	- 100
	+ 50
	+ 50

L)calf
Level : *1.4 mA*
Pulse Width : *600 μ S*
Rate : *60 Hz*

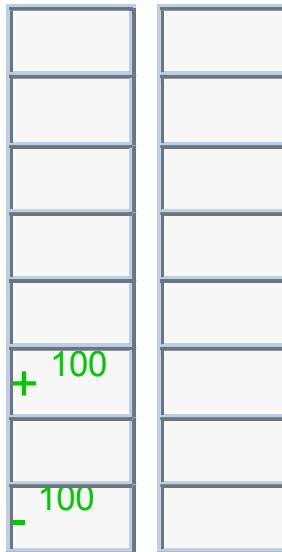
	+ 81
	+ 19
	- 100

Sample programs

Pt 4 PP

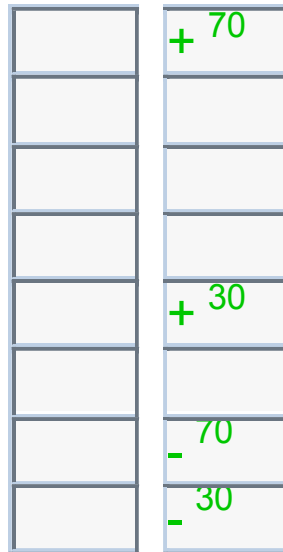
1 BODY

Level : 7.5 mA
Pulse Width : 550 μ S
Rate : 60 Hz



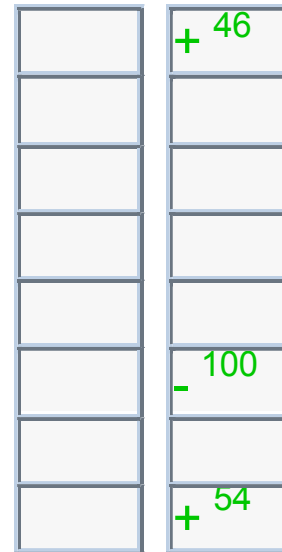
r)LEG GO

Level : 5 mA
Pulse Width : 550 μ S
Rate : 60 Hz



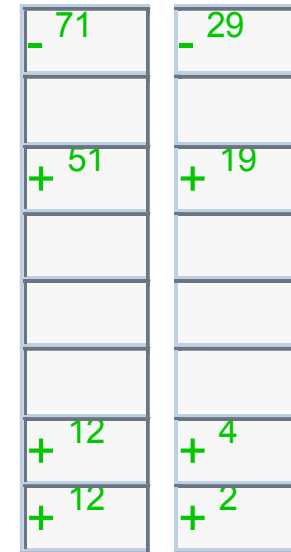
R)leg+

Level : 5.7 mA
Pulse Width : 550 μ S
Rate : 60 Hz

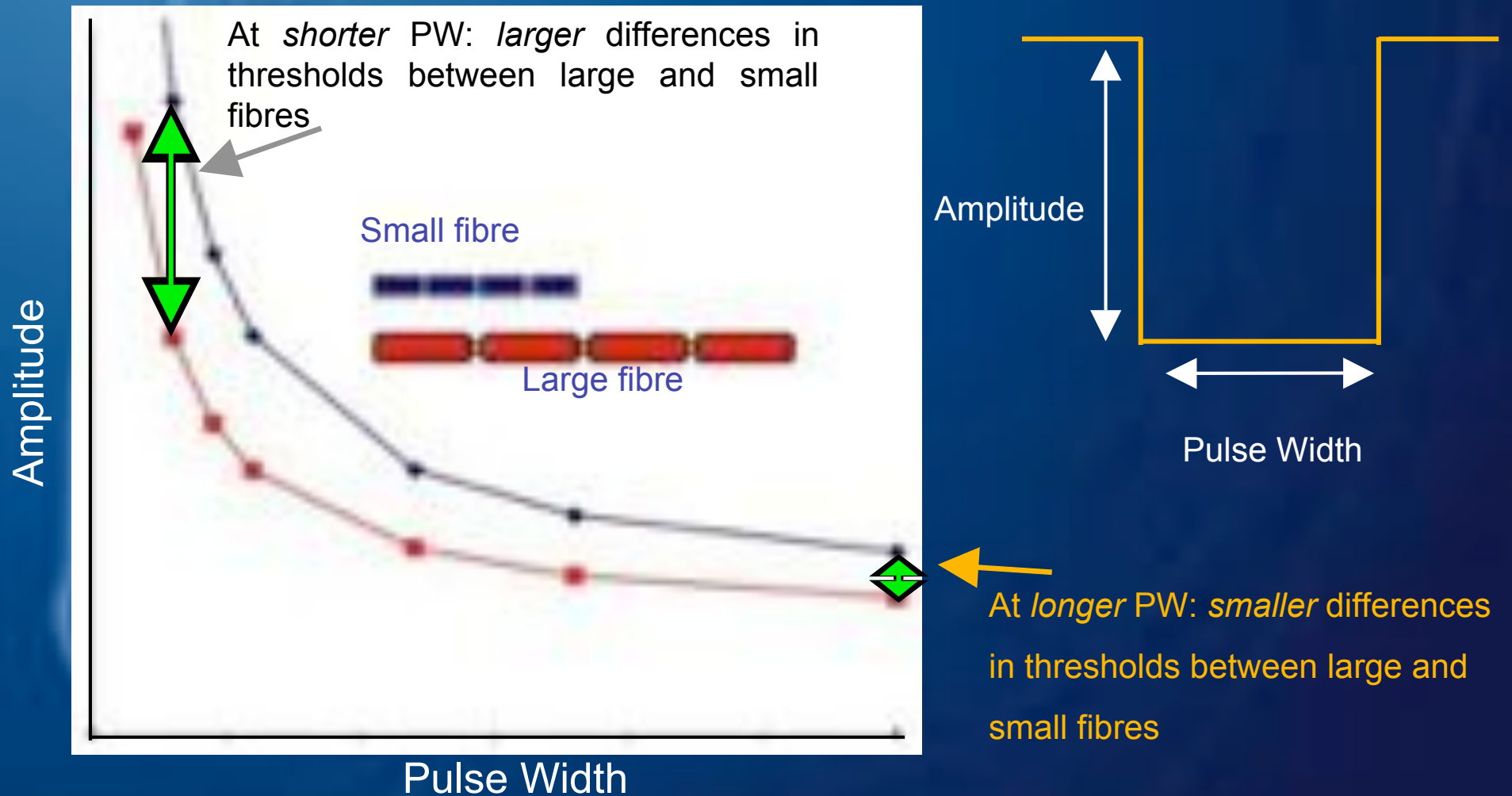


top L)l

Level : 4.6 mA
Pulse Width : 550 μ S
Rate : 60 Hz



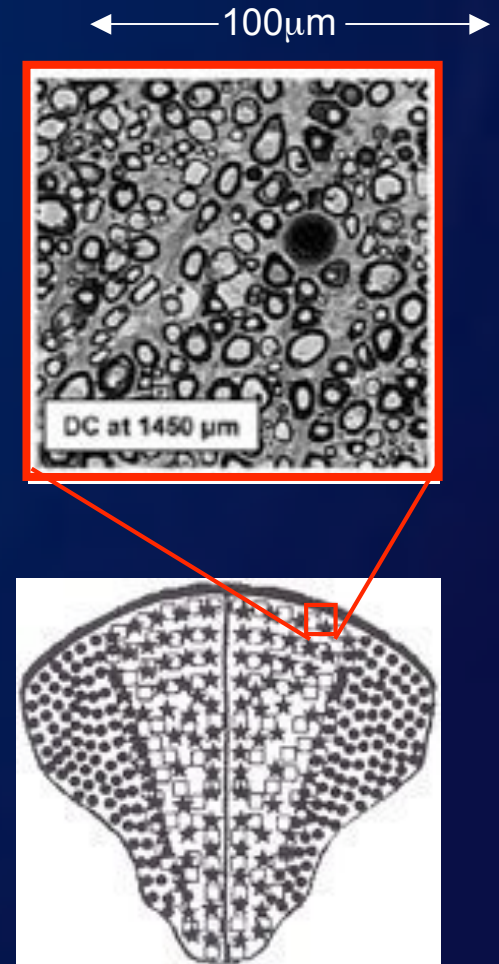
Pulse Width: Background



Strength-duration curve for large and small nerve fibres

Pulse Width: Background

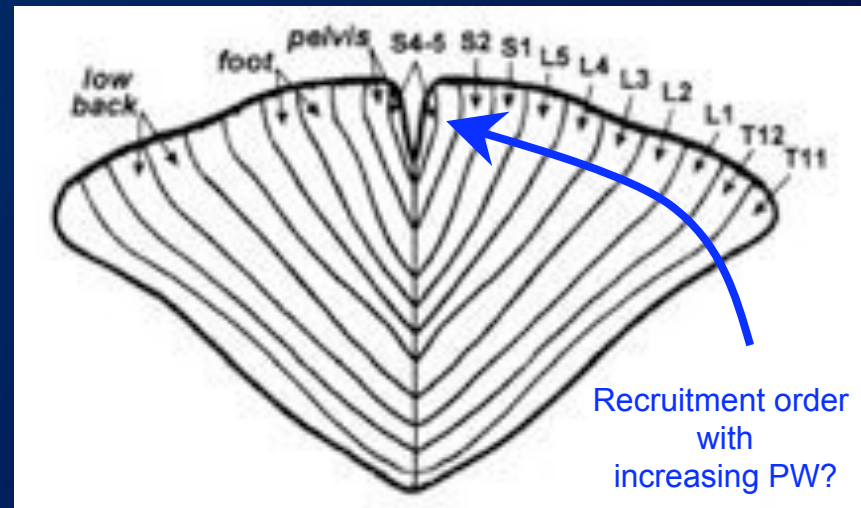
- In the superficial DC, ~85% of fibres are smaller than 7 μm and <1% are larger than 10 μm (Feirabend et al, 2004).
- Longer PW values promote the activation of smaller diameter fibres relative to larger diameter fibres, as found in other neurostimulation applications (Gorman and Mortimer, 1983).
- ***In SCS, longer PW may increase the number of fibres activated*** and thereby increase the likelihood of generating paresthesia in broader dermatomal regions (Meyerson, 1997).



Source: Feirabend et al,
Brain 2004

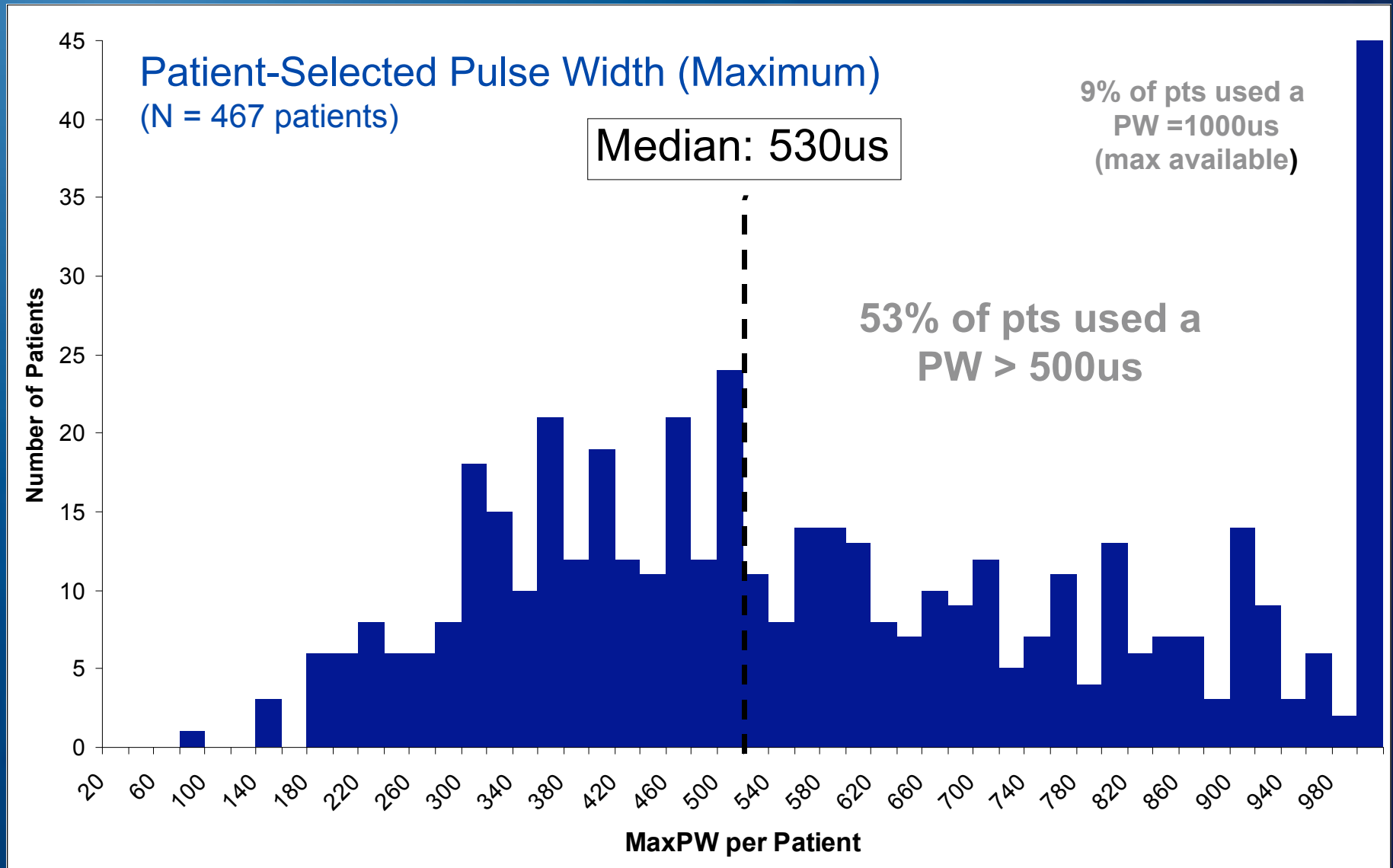
Pulse Width: Discussion

- Paresthesia Coverage with PW
 - More DC activation
 - Hypothesis:
 - Fibre size and density are smaller in more medial DC's *
 - Increased PW allows greater recruitment of smaller fibres



*Feirabend et al, *Brain* 2004

Pulse Width: Background

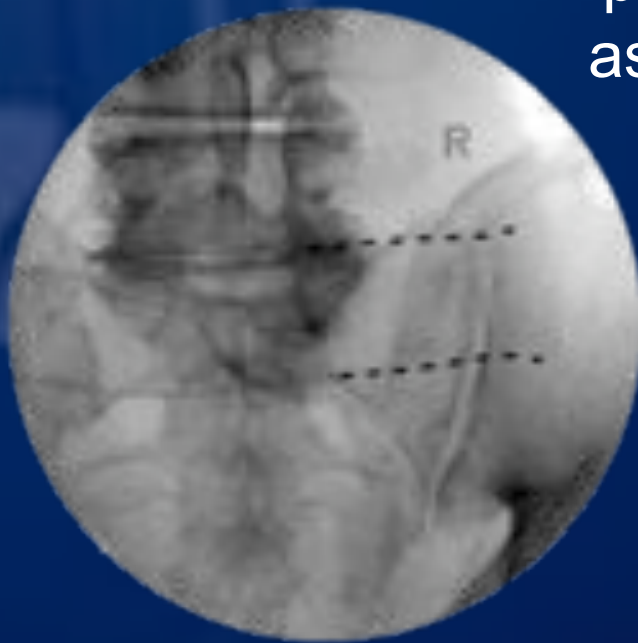


Source: Gould B, Bradley K. *Pain Medicine*. 2006; 7(2): 205.

Peripheral Nerve Field Stimulation:

A novel treatment in chronic low back pain
and failed back surgery syndrome

AIM: to evaluate the usefulness of peripheral nerve field stimulation as a treatment option for patients with chronic low back pain and failed back surgery syndrome.



MATERIALS & METHOD

- n=13
- 11 met the diagnostic criteria for failed back surgery syndrome (FBSS)
- Questionnaire used to assess outcomes including:
 - pain indices, post-operative changes in analgesic use and the overall level of patient satisfaction
 - questionnaire response rate - 93% (13/14)
- Average follow-up time = 7 months.

DEMOGRAPHICS

- Mean patient age:
61.3 \pm 10.4 (range 42-80 years)
- 7 females / mean age 56 \pm 7
years
- 6 males /mean male age 67 \pm 11

SELECTION CRITERIA

- Clear low back pain with a neuropathic or combined somatic (nociceptive) & neuropathic pain component.
- Failure to respond to other conservative treatments (including medications, psychological therapies, rehabilitation and pain management programs).
- Previous failure of, or ineligibility for surgical procedures (including fusions or radiofrequency neurotomy (RFN)).
- Psychological clearance (including drug addictions, major depression and similar severe disorders that might impact on successful treatment).
- Clearly defined, discrete focal area of pain, e.g. commonly a “band” of approximately 1 to 2 hands spans over the low back.
- Informed consent

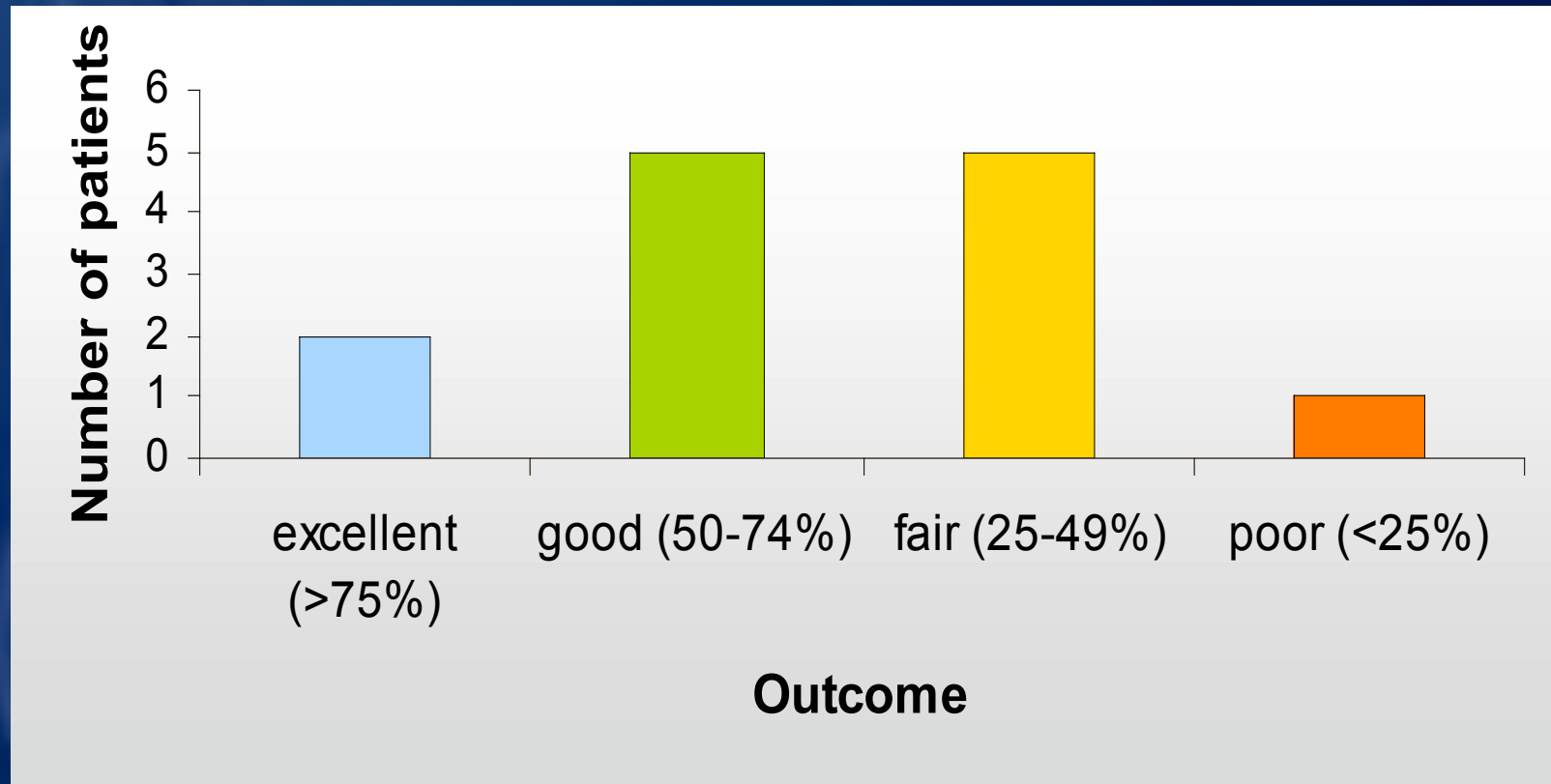
POSITIVE TRIAL

- 55% of clinic patients responded positively to the neuromodulation trial period and proceeded to permanent implantation of Peripheral Stimulator

POSITIVE TRIAL CRITERIA

- Patients proceeding beyond the trial to implantation of PNFS must meet the following criteria:
 1. Defined as halving of original pain levels, with stimulation covering most of the painful area.
 2. Report a reduction in reliance on analgesics.
 3. Report an improvement in 'valued' activities of daily living (ADL).

PERCENTAGE PAIN RELIEF of ORIGINAL PAIN



MEAN VAS

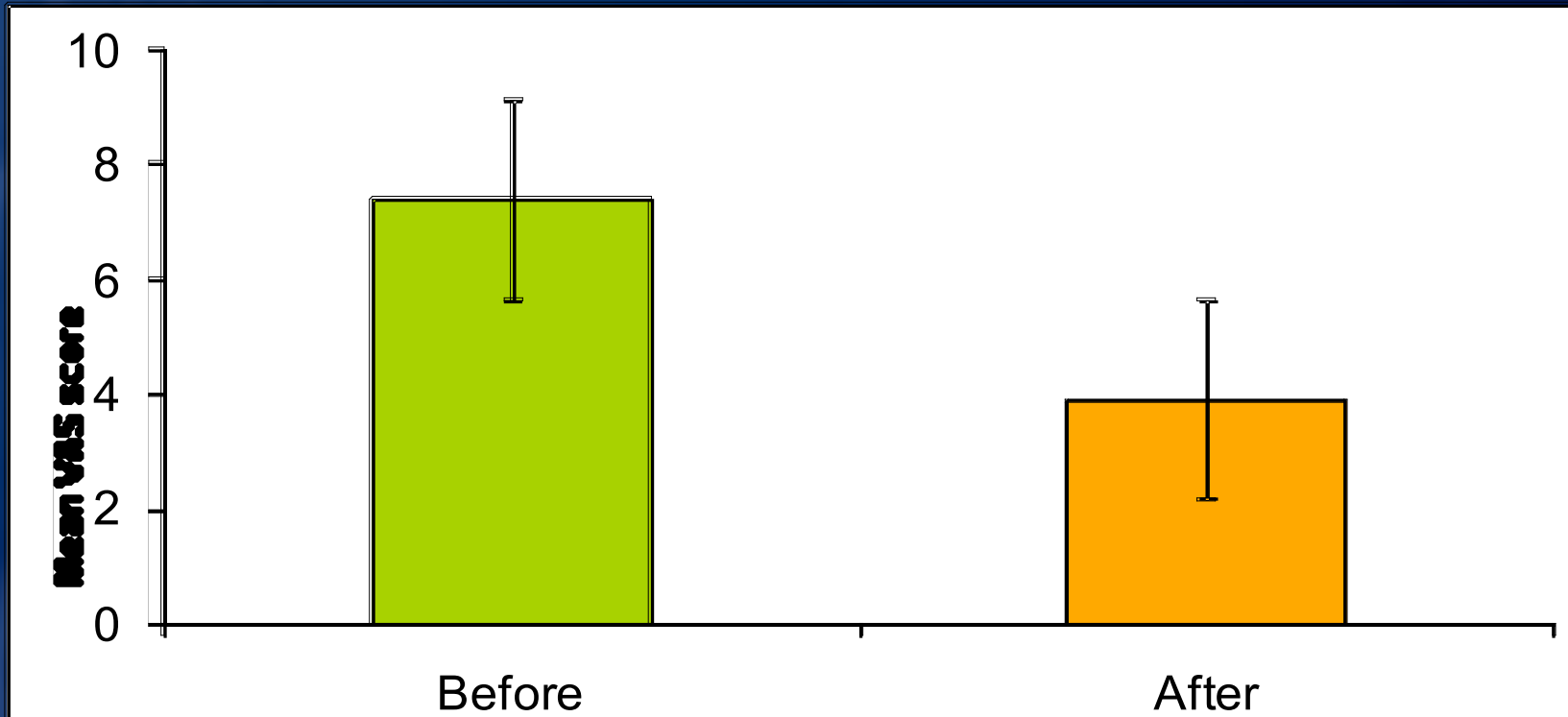


Figure 2. Patient pain relief as a result of PNFS, where pain relief is expressed as the mean VAS recorded both pre and post PNFS.

ANALGESIC USE

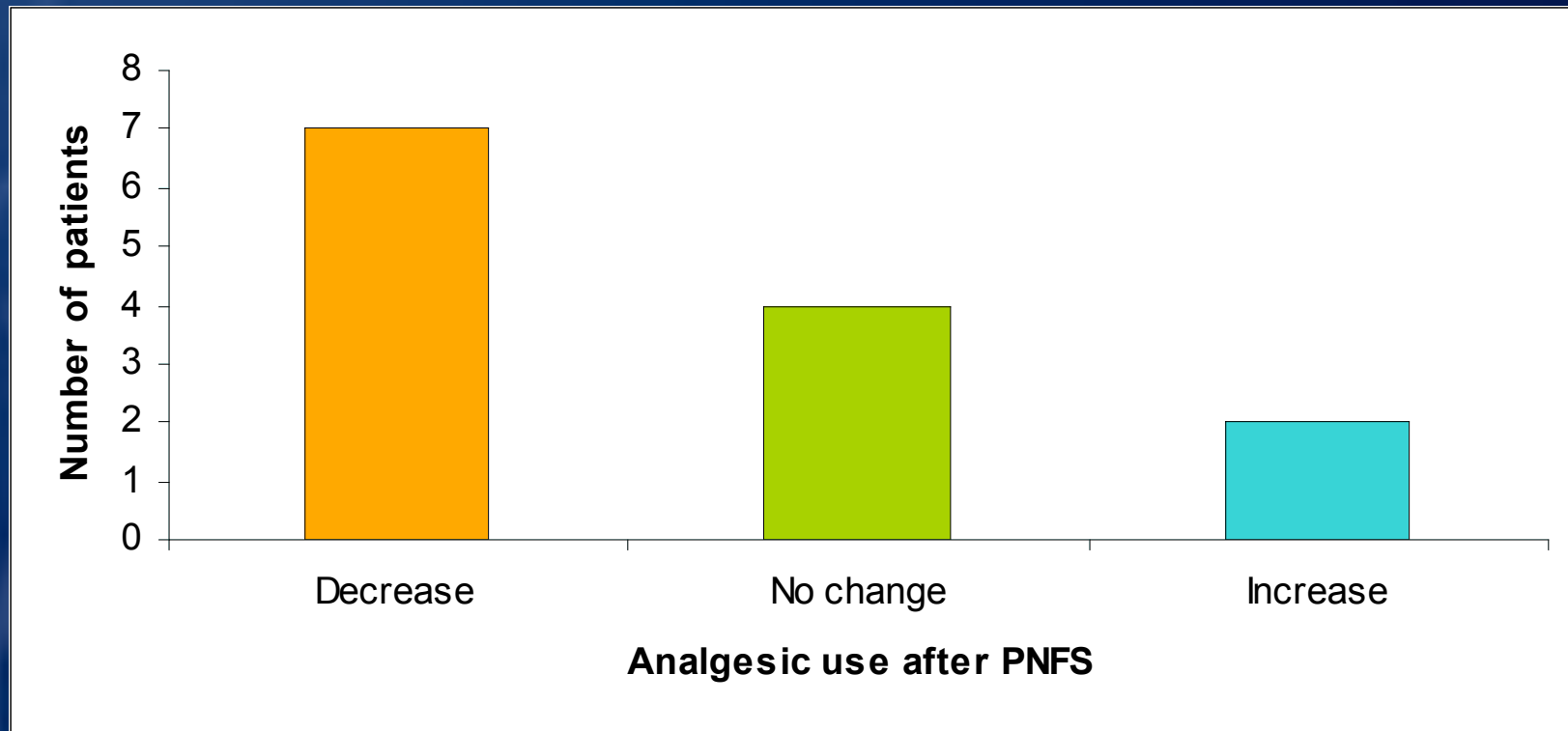


Figure 3. Patient need for medication following PNFS.

PATIENT SATISFACTION



CONCLUSIONS

- Where PNS for chronic low back and FBSS was successful, it improved pain by an average of 4.18 VAS points.
- An overall improvement of 50.06% ($\pm 21.8\%$) on original pain levels was observed after PNFS.
- More than half the patients reported a decrease in analgesic use after PNFS.
- More than 75% patients were satisfied with the procedure.
- This study demonstrates PNS is a safe, reversible and effective treatment option for patients suffering chronic low back pain.