Peripheral Nerve Field Stimulation for Chronic Low Back Pain

Falling dusk or the dawn of a new technique?

W. Porter McRoberts, M.D.
Medical Director, Interventional Spine and Pain Medicine
Holy Cross Orthopedic Institute, Holy Cross Hospital, Fort Lauderdale, Florida.

Disclosures

• The use of SCS devices for peripheral nerve stimulation is off label.

• Research support
  • St. Jude, Vertos, Anulex

• Consulting
  • St. Jude
  • Medronic-Sanofi Aventis
  • Bioness
  • Vertos
Goals of the Talk

- A summary of role of PNfS in treatment of CLBP
- Theory regarding effect of PNFS
- Anecdotal evidence
- Case series and prospective evidence
- Implant and programming techniques
- Pit falls, weaknesses, complications
- Reimbursement Issues
- Concerns regarding abuse and failures

All Fluff and Puff?
PNfS Theory

- Dendritic analogy (Barolat)
- Melzack and Wall
- Wall and Sweet (1967)
- “Gate” mechanism in dorsal horn
- Close the gate with preferential stimulation of large, (A-beta) fibers
- Preventing transmission of small (A delta and C) fibers

Peripheral Subdermal placement of Stimulating Electrodes
Why PNfS?
“The technologies which have had the most profound effect on human civilization have usually been simple.” - Freeman Dyson

- There exists no optimal treatment for FBSS or CLBP
- Despite recent studies, (Abejon / Mironer et al.) re SCS and LBP, there remain difficult to stimulate regions central and axial trunk
- SCS excels at treatment of radicular, buttock and neuropathic pain
- Historically, SCS is challenged in the treatment of axial, (especially high lumbar) and nociceptive pain
- Most studies suggest decay of effect over time for axial LBP
- Areas are progressively more difficult to stimulate the more central and cephalad they exist
- SCS poor at selective stimulation of small areas of pain
- It is arguably the the safest neuromodulation implant modality

Topographical representation of the dermatomes in the dorsal columns of the T11 segment.
Adapted from Smith and Deacon (1984). L = lumbar; S = sacral; T = thoracic.
Maximum Dept of Stim: the outer 0.3%

- Häggqvist: dorsolateral columns (DLCs) hold a substantially higher density of large fibres (up to 18 µm) than the DCs.

_Holsheimer et al., 1991_: large dorsal spinocerebellar tract fibres are also likely to be activated by SCS.

“Taking into account that the maximum stimulus allowed in SCS exceeds the perception threshold by 40%, the maximum depth at which large DC fibres can be activated would be 0.2–0.25 mm.“

Statistical comparisons between fibre populations of size group A(f) ≥70 µm² of all para-sagittal areas in the superficial dorsal column (DC0–300) of the male specimen.
Smaller anatomic window for paresthetic LB coverage.
Origins of PNfS
Krames, Barolat, Goroszeniuk

Initial work and anecdotal evidence

 Likely Teo Goroszeniuk et al.

Subcutaneous Neuromodulating Implant
Targeted at the Site of Pain.

6th World Congress of International Neuromodulation Society
June 2003, Madrid, Spain.

Published 2006

Regional Anesthesia

PSFS - STS TARGET
Permanent Implantation

Pain duration 8 years
Severity 6 - 9 VAS
Rx - MF

September 2001
August 2002

Goroszeniuk, Kethar, Hermes
Reg Anesth Pain Med 2006;31:3. March
Who has published on PNfS

- Abejon, David; Amrani, Jacob; Barkow, Stehen H; Barnard, Adele; Barolat, Gincarlo; Beasley, Ralph; Berardoni, Nicole; Berger, Jeffrey; Bernstein, Clifford A; Bhattachar, Sunima; Bittar, R.G.; Boyce, Zachary; Burcher, Abram H; Cairns, Kevin D; Carayannopoulos, Alexios; Colpain, M Elkan; Cross, Nancy E; Davids, Heather R; Davis, Bennett E; Day, Miles; Deery, Timothy; Desai, Mehul; Done, Ivan; Doust, Matthew W; Falco, Frank J E; Fiabi, Katharina; Ford, Theodore; Franzini, Angelo; Fuchs, Wolfgang; Georgiou, Loukas; Goroszeniuk, Tedor; Goyal, Gaurav N; Gupta, Deepak; Hamann, Wolfgang; Hayek, Salim M; Heinze, Georg; Huntington, Marc A; Hutcheson, J; Ilias, Wilfried; Jacobs, Lisa; Jano, Roopesh; Jasper, Josep F; Joshi, Jaydeep R; Karasev, Sergey A; Kloor, Alexandra; Kothari, Sandesh; Kounouseki, Irene; Krames, Elliot S; Kress, Hans G; Kutsch, Jason P; Kumar, Sandeep; Kumar, Sunil; LaTourette, Philippe C; Lepheart, James; Lempart-Cohen, Chevy; Levy, Robert M; Likar, Rudolf; Lipoy, Eugene G; Loening, Nadia; Lynch, Paul H; Mccenery, Michael H; McJunkin, Tony L; McRoberts, W Porter; Messina, Giuseppe; Mironer, Y; Mishra, Sema; Mitchell, Bruce; Mozés-Balla, Eva-Maria; Munawar, Naureen; Neoh, Dianisso; Nersyan, Hrachya; Neuhold, Josef; O'Callaghan, James; Onyewu, Obi; Paicurs, Richard M; Panaretou, Evangelia; Panourias, Ioannis G; Papastergiou, Dimitrios; Papavassilopoulos, Theonymfni; Pinter, Michaela; Rana, Shiv Pratap; Resch, Beth E; Ricciard, Benedette; Roche, Martin; Rodemer, Grant F; Sakas, Damiano E; Sanders, Sarah; Sander, Georgios; Sato, Katzenschlager, Sabine; Satterthwaite, John R; Sinclair, Chantal; Sites, Brian; Slavin, Konstantin V; Smolinski, Andrew; Stanton-Hicks, Michael; Steinw, Lisa J; Stinson, Lawrence W Jr; Tamimi, Mazin A; Teddy, P; Turley, Todd W; Ushiloy, Surja Prasad; Verrills, Paul; Vivian, David; Vrabal, Alan; Weism, Christian; Yakovlev, Alexander E; Yakovleva, Victoria E; Zhu, Jie; Zompolas, Vassilios

Subcutaneous Neuromodulating Implant Targeted at the Site of Pain, Goroszeniuk T et al. Regional Anesthesia and Pain Medicine; Mar/Apr 2006

- Case series of 3 pts
- STN 1-2 hrs/ day=12-24 hrs relief
- F/U
  - 36mo- 95% relief
  - 26mo off all Rx
  - Not Reported
- Low Hz Frequency, low PW (100ms)
PNfs efficacious in sites other than low back

- Barolat G
  - Peripheral subcutaneous stimulation for intractable abdominal pain, Progress in Neurologic Surgery 2011
- Desai et al.
  - Successful Peripheral Nerve Field Stimulation for Thoracic Radiculites following Brown-sequard Syndrome, Neuromodulation, 2011
- Goyal et al.
- Kouroukli et al.
  - Peripheral Subcutaneous Stimulation for the treatment of intractable post-herpetic neuralgia: two case reports and literature review. Pain Practice, 2009
- McJunkin et al.
  - An Innovative case Report Detailing the Successful treatment of post-thoracotomy syndrome with peripheral nerve field stimulation. Neuromodulation, 2009
- McRoberts et al.
  - Novel approach for peripheral subcutaneous field stimulation for the treatment of severe, chronic knee joint pain after total knee arthroplasty. Neuromodulation, 2009

PNfs efficacious in sites other than low back

- Paicus et al.
- Upadhyay et al.
  - Successful treatment of and intractable post herpetic neuralgia using peripheral nerve field stimulation. American Journal Hospital Palliative Care, 2009
- Buiten et al.
- Kothari et al.
  - Peripheral percutaneous stimulation for refractory angina pectoris. Regional Anesthesia Pain Medicine 2004
- Goroszeniuk et al.
Peripheral Nerve Field Stimulation in the Treatment of Postlaminectomy Syndrome after Multilevel Spinal Surgeries
Yakovlev AE, Resch BE, Yakkovleva VE, Neuromodulation, 2011

- Serial case series of 18 patients with PLS failing CMM
- All trialed and then implanted with 4-quadrapolar arrays

<table>
<thead>
<tr>
<th>Case</th>
<th>Opioid use before implant</th>
<th>Gender</th>
<th>Pain duration before implant (M)</th>
<th>Pre-procedure WAS (0-10)</th>
<th>1 month post-implant WAS (0-10)</th>
<th>2 month post-implant WAS (0-10)</th>
<th>Opioid use after implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Yes</td>
<td>F</td>
<td>15</td>
<td>7</td>
<td>2</td>
<td>1</td>
<td>Decreased</td>
</tr>
<tr>
<td>2</td>
<td>Yes</td>
<td>M</td>
<td>13</td>
<td>6</td>
<td>3</td>
<td>1</td>
<td>Decreased</td>
</tr>
<tr>
<td>3</td>
<td>Yes</td>
<td>M</td>
<td>18</td>
<td>9</td>
<td>2</td>
<td>1</td>
<td>Unchanged</td>
</tr>
<tr>
<td>4</td>
<td>Yes</td>
<td>M</td>
<td>24</td>
<td>8</td>
<td>3</td>
<td>2</td>
<td>Decreased</td>
</tr>
<tr>
<td>5</td>
<td>Yes</td>
<td>F</td>
<td>15</td>
<td>8</td>
<td>2</td>
<td>2</td>
<td>Stopped</td>
</tr>
<tr>
<td>6</td>
<td>Yes</td>
<td>M</td>
<td>17</td>
<td>7</td>
<td>3</td>
<td>1</td>
<td>Stopped</td>
</tr>
<tr>
<td>7</td>
<td>Yes</td>
<td>F</td>
<td>18</td>
<td>8</td>
<td>3</td>
<td>2</td>
<td>Stopped</td>
</tr>
<tr>
<td>8</td>
<td>Yes</td>
<td>M</td>
<td>19</td>
<td>9</td>
<td>4</td>
<td>2</td>
<td>Stopped</td>
</tr>
<tr>
<td>9</td>
<td>Yes</td>
<td>M</td>
<td>14</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>Decreased</td>
</tr>
<tr>
<td>10</td>
<td>Yes</td>
<td>M</td>
<td>30</td>
<td>7</td>
<td>3</td>
<td>1</td>
<td>Stopped</td>
</tr>
<tr>
<td>11</td>
<td>Yes</td>
<td>F</td>
<td>26</td>
<td>8</td>
<td>2</td>
<td>2</td>
<td>Stopped</td>
</tr>
<tr>
<td>12</td>
<td>Yes</td>
<td>M</td>
<td>14</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td>Stopped</td>
</tr>
<tr>
<td>13</td>
<td>Yes</td>
<td>M</td>
<td>16</td>
<td>9</td>
<td>3</td>
<td>2</td>
<td>Stopped</td>
</tr>
<tr>
<td>14</td>
<td>Yes</td>
<td>M</td>
<td>28</td>
<td>8</td>
<td>3</td>
<td>2</td>
<td>Stopped</td>
</tr>
<tr>
<td>15</td>
<td>Yes</td>
<td>M</td>
<td>15</td>
<td>7</td>
<td>2</td>
<td>1</td>
<td>Stopped</td>
</tr>
<tr>
<td>16</td>
<td>Yes</td>
<td>F</td>
<td>42</td>
<td>8</td>
<td>4</td>
<td>3</td>
<td>Decreased</td>
</tr>
<tr>
<td>17</td>
<td>Yes</td>
<td>F</td>
<td>32</td>
<td>6</td>
<td>2</td>
<td>2</td>
<td>Unchanged</td>
</tr>
<tr>
<td>18</td>
<td>Yes</td>
<td>F</td>
<td>24</td>
<td>7</td>
<td>3</td>
<td>2</td>
<td>Stopped</td>
</tr>
</tbody>
</table>
Peripheral Nerve Field Stimulation in the Treatment of Postlaminectomy Syndrome after Multilevel Spinal Surgeries
Yakovlev AE, Resch BE, Yakkovleva VE, Neuromodulation, 2011

Results:
- 4 patients had SCS systems pre-operatively and were unsuccessful
- 89% able to decrease or stop opioids
- Average duration of pain before implant: 21.5 months
- Average VAS Pre-implant: 7.45
- Average VAS One month: 2.61
- Average VAS Twelve month: 1.67
Methods

- **Study Design**
  - IRB-approved, prospective, randomized, controlled crossover study

- **Two phases**
  - **Phase I (Trial): 4 Week**
    - Patients rotated through the four arms including minimal (placebo) and standard stimulation in 4 to 8 day intervals
    - If a patient had a 50% reduction in pain at the end of Phase I, they proceeded to Phase II
  - **Phase II: 52 Week**
    - Permanent implantation of the device system (Eon™ IPG; Octrode™ or Quattrode™ leads; St. Jude Medical Neuromodulation Division, Plano, TX)

- **Outcomes**
  - **Pain**
    - Patient asked to classify their pain relief as excellent, good, fair, poor or none
    - SF-McGill Pain Questionnaire (SF-MPQ)
    - Patient reported pain relief
  - **Quality of life**
    - SF-36
Implant Technique

Two to four leads implanted in the painful area in the subcutaneous tissue.

Leads placed along the main axis of the pain.

Patient Demographics (N=30)

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>51.6 ± 12.8 years</td>
</tr>
<tr>
<td>Range</td>
<td>31-78 years</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male: n (%)</td>
<td>19 (63.3%)</td>
</tr>
<tr>
<td>Female: n (%)</td>
<td>11 (36.7%)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>Caucasian: n (%)</td>
<td>30 (100%)</td>
</tr>
<tr>
<td><strong>Work Status</strong></td>
<td></td>
</tr>
<tr>
<td>Not Working: n (%)</td>
<td>13 (43.3%)</td>
</tr>
<tr>
<td>Retired: n (%)</td>
<td>6 (20.0%)</td>
</tr>
<tr>
<td>Currently Working: n (%)</td>
<td>11 (36.7%)</td>
</tr>
</tbody>
</table>
Trial Phase: SF-McGill Pain Questionnaire

Percentage of Patients

Excellent/Good | Fair | Poor/None
---|---|---
Minimal Stimulation (n=29) | Subthreshold (n=29) | Low Frequency (n=30) | Standard Stimulation (n=30)

Present Pain Index Score

Baseline | Minimal Stimulation | Subthreshold | Low Frequency | Standard Stimulation
---|---|---|---|---

Permanent Phase:
4/12/24/52 wk follow-up

Percentage of Patients

<table>
<thead>
<tr>
<th>Time</th>
<th>Excellent/Good</th>
<th>Fair</th>
<th>Poor/None</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 Weeks (n=22)</td>
<td>60</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>12 Weeks (n=23)</td>
<td>60</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>24 Weeks (n=22)</td>
<td>60</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>52 Weeks (n=19)</td>
<td>60</td>
<td>20</td>
<td>20</td>
</tr>
</tbody>
</table>

Permanent Phase: 4/12/24/52 wk follow-up

Present Pain Index Score

Baseline 4 Weeks 12 Weeks 24 Weeks 52 Weeks
Permanent Phase: 4/12/24/52 wk follow-up
## Summary and Conclusions

- At 52 weeks, 68.4% of patients reported their pain relief as 50% or greater.
- Average VAS dropped from ~8/10 to <4/10 at 52 weeks.
- All components of the SF-MPQ were positively impacted at 4, 12, 24, and 52 weeks post-implant.
- Quality of life as measured by the SF-36 was relatively unaffected at 4, 12, 24, and 52 weeks post-implant.
- PNS appears to be a promising modality for the treatment of chronic, intractable back pain.

---


- One hundred consecutive patients receiving PNFS for the treatment of chronic craniofacial, thorax, lumbosacral, abdominal, pelvic, and groin pain conditions.
- LBP: 21 patients.
- Private Clinic, Melbourne Australia.

- Average pain reduction of 4.2 +/- 2.5 VAS
- VAS: Pre avg 7.4 +/- 1.7 ➔ avg 3.2 +/- 2.3 p≤0.00
- Follow-up period of 8.1 +/- 4.7 months (range 1–23 months)
- Overall 72% of patients reduced their analgesic use following PNFS
- Patients receiving a lumbosacral PNFS for chronic low back pain reported a significant reduction in disability following treatment, as determined by the Oswestry Disability Index
- Of the 100 cases, no long-term complications were reported


- Adverse Event: Frequency
  - Lead infection: 1
  - Hardware Erosion: 7
  - Hardware Migration: 2
  - Leads too Superficial: 3
  - Leads too Tight: 1
  - Hardware Failure: 2
  - TOTAL: 16
Falco et al.: Cross Talk: A New Method for Peripheral Nerve Stimulation. An Observational Report with Cadaveric Verification
Pain Physician 2009; 12:965-983

Objective: to determine if cross talk (CT), electrical circuit creation between PNfS leads (as opposed to just electrodes) was clinically possible across large painful areas.

Objective: To evaluate clinical efficacy on PNfS-CT.

Objective: To confirm presence of CT in a cadaveric model.

18 consecutive patients

- Axial, regional pain

- Variables
  - Presence or absence of stim between leads
  - Tolerability
  - Stimulation region
  - Lead orientation
  - Lead montage
  - Inter-lead distance
  - Pain relief from PNfSCT compared to PNfS without CT
Descriptive Data

- 13 females, 5 males
- Age 29-82 yrs 56 yrs mean
- Pain duration 2 mo-35 years, 8.4 avg
- Pure neuropathic pain: 3 patients
- Pure nociceptive pain: 5 patients
- Mixed pain: 10 patients
- 14/18 tried and failed TENS, but responded to PNfSCT>PNfS

Outcome Data

- Inter lead distance: 5.5 to 34.25cm avg 19.2 cm
- PRE implant NRS:7-10 with 9.1 avg
- POST implant NRS:0-3 with 1.2avg
- 3 patients required revision
  - Battery flip, lead migration, burning paresthesia 2/2 superficial lead position
  - All revised successfully
Electrical Circuits in the Periphery

- Questions:
  - How does the current flow?
  - How large can the paresthetic field be?
    - Without cross talk or with cross talk?
  - Does paresthesia density relate to pain relief?
  - Can paresthetic density be quantified?

How deep to go?

<table>
<thead>
<tr>
<th>Case</th>
<th>Min Depth</th>
<th>Max Dept</th>
<th>Avg Depth</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10</td>
<td>22</td>
<td>15.1</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>9</td>
<td>7.1</td>
</tr>
<tr>
<td>5</td>
<td>4</td>
<td>7</td>
<td>5.6</td>
</tr>
<tr>
<td>6</td>
<td>10</td>
<td>15</td>
<td>12.6</td>
</tr>
<tr>
<td>Mean</td>
<td>6.5</td>
<td>12.2</td>
<td>9.2</td>
</tr>
<tr>
<td>S. Dev</td>
<td>2.8</td>
<td>5.8</td>
<td>3.9</td>
</tr>
</tbody>
</table>
Depth and orientation of lead placement
Leads found at approx 4mm to 12mm depth

The electric resistivity of human tissues (100 Hz–10 MHz): a meta-analysis of review studies
T J C Faes, H A van der Meij, J C de Munck and R M Heethaar
Department of Clinical Physics and Informatics, Institute for Cardiovascular Research, University Hospital Vrije University, PO Box 7057, 1007 MB Amsterdam, The Netherlands

Table 1. The calculated mean values and 95% confidence intervals of resistivities for various tissues, as well as the number of resistivities involved in the calculations, the number of primary sources and the water content (water content from Pethig and Kell (1981, p 952).

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Water content (%)</th>
<th>Number of studies</th>
<th>Number of resistivities</th>
<th>Resistivity (Ω cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>Bladder</td>
<td>1</td>
<td>2</td>
<td>447</td>
<td>288–693</td>
</tr>
<tr>
<td>Blood</td>
<td>3</td>
<td>7</td>
<td>151</td>
<td>120–191</td>
</tr>
<tr>
<td>Bone</td>
<td>1</td>
<td>4</td>
<td>124 x 10⁶</td>
<td>91 x 10⁵–169 x 10⁶</td>
</tr>
<tr>
<td>Breast</td>
<td>1</td>
<td>4</td>
<td>339</td>
<td>269–463</td>
</tr>
<tr>
<td>Fat</td>
<td>12.5</td>
<td>2</td>
<td>3850</td>
<td>3046–4868</td>
</tr>
<tr>
<td>Heart</td>
<td>2</td>
<td>5</td>
<td>175</td>
<td>133–231</td>
</tr>
<tr>
<td>Kidney</td>
<td>78.5</td>
<td>3</td>
<td>711</td>
<td>160–378</td>
</tr>
<tr>
<td>Liver</td>
<td>75</td>
<td>1</td>
<td>342</td>
<td>206–396</td>
</tr>
<tr>
<td>Lung</td>
<td>81.5</td>
<td>1</td>
<td>157</td>
<td>122–202</td>
</tr>
<tr>
<td>Muscle (longitudinal)</td>
<td>75.5</td>
<td>2</td>
<td>171</td>
<td>135–216</td>
</tr>
<tr>
<td>Muscle (transverse)</td>
<td>1</td>
<td>2</td>
<td>240</td>
<td>155–372</td>
</tr>
<tr>
<td>Muscle (transverse)</td>
<td>1</td>
<td>2</td>
<td>675</td>
<td>435–1047</td>
</tr>
<tr>
<td>Ovary</td>
<td>2</td>
<td>7</td>
<td>224</td>
<td>144–347</td>
</tr>
<tr>
<td>Skin</td>
<td>68</td>
<td>2</td>
<td>329</td>
<td>255–424</td>
</tr>
<tr>
<td>Spleen</td>
<td>78.5</td>
<td>2</td>
<td>405</td>
<td>307–535</td>
</tr>
<tr>
<td>Testis</td>
<td>1</td>
<td>2</td>
<td>145</td>
<td>93–224</td>
</tr>
<tr>
<td>Thyroid</td>
<td>1</td>
<td>2</td>
<td>183</td>
<td>118–283</td>
</tr>
<tr>
<td>Tibia (cancellous)</td>
<td>50</td>
<td>6</td>
<td>464</td>
<td>369–507</td>
</tr>
<tr>
<td>Tibia (cortical)</td>
<td>8</td>
<td>1</td>
<td>17,583</td>
<td>12,289–25,157</td>
</tr>
<tr>
<td>Tongue</td>
<td>1</td>
<td>2</td>
<td>333</td>
<td>215–517</td>
</tr>
<tr>
<td>Uterus</td>
<td>1</td>
<td>6</td>
<td>219</td>
<td>170–282</td>
</tr>
</tbody>
</table>
Inter-electrode distance correlates with area of paresthesia

A = + and – are two most proximal electrodes on same lead
B = + and – are separated by one electrode on same lead
C = + and – are most distant on the same lead
D = + and – are the most distant in the array (across 2 leads)
E = – is the most distant electrode from the IPG and + IS the IPG

Figure 4. Number of areas of paresthesia resulting from each electrode configuration.
POSTER SESSIONS | Peripheral Nerve Stimulation

Lumbar Nerve Field Stimulation for Chronic Lumbar Pain—A Standardized Approach for Therapeutic Success (90)
Christian Voel, University Hospital Düsseldorf, Düsseldorf, Germany; Jason Perrin, University Hospital Düsseldorf, Düsseldorf, Germany; Stefan Schu, University Hospital Düsseldorf, Düsseldorf, Germany; Jan Vesper, University Hospital Düsseldorf, Düsseldorf, Germany

Objective: Chronic lumbar pain remains a difficult to address symptom in spite of advances made in electrode design and implantation techniques for DBS. Trials with subcutaneous electrodes implanted within or around the painful area sometimes produce additional pain relief, yet many often fail to elicit pain relief. Recently we introduced electro-acupuncture mapping as a test tool for PNS. Its application to determine efficacy and optimal stimulation sites ensures proper patient selection.

Methods: 10 patients (6 male, 4 female) with therapy-resistant and stable chronic lumbar pain underwent electro-acupuncture mapping twice and subsequent subcutaneous electrode implantation for trial. During the mapping procedure a pattern of acupuncture needles was placed subcutaneously to cover subcutaneous branches of the segmental rami dorsales. Thresholds and effects of 300 μs impulses at 90 Hz were recorded at different sites. A positive test result resembles paresthesia and numbness within the pain area provoking lasting pain relief for more than 1 hour. Two electrodes (4 or 8 contacts) were placed at sites of optimal test stimulation.

Results: Electro-acupuncture mapping revealed optimal stimulation sites for lateral to the pain area in proximity to a region where segmental cutaneous branches surface. Perception thresholds between 0.3 mA and 0.6 mA with a comfort range of ±0.1 mA indicated stimulation sites in proximity of a peripheral nerve. With relatively low stimulation intensity a confluent field of paresthesia across the midline was observed. Lasting and additional pain relief after implantation could be seen in 9 out of 10 treated patients. The superior effect relies on 2 electrodes. Cycling stimulation ensures stable pain control. Mean pain reduction is 80%. Mean follow-up is 12 months.

Conclusion: Electro-acupuncture mapping is a suitable noninvasive test method for lumbar nerve field stimulation and improves therapeutic efficacy. Our results indicate that the effect of lumbar nerve field stimulation itself relies on peripheral nerve stimulation at subcutaneous branches of the segmental rami dorsales. By standardizing approach and patient selection lumbar nerve field stimulation provides predictable and lasting pain control in our series. If our results could be reproduced in a larger trial, lumbar nerve field stimulation yields potential as a secure therapeutic option for chronic lumbar pain as a standalone therapy or in combination with DBS.

PNfS Programming Options

- + - + - Across the lead = High amplitudes required for perception
- Single bipolar + - on the lead = low amplitudes for same perception, but small “credit card” area of paresthesia
- “Cross Talk” = Bipole across two PNfS leads = low amplitudes, large area of paresthesia, ? Diminished paresthetic density
- “Flow Programming” = (Krames) Bipole across an epidural lead and peripheral lead
- Peripheral cathode, IPG as anode
- 3A1C interpolated
Why doesn’t PnFS work?

- Wrong patient, wrong pain
- Wrong electrode location, wrong orientation
- Wrong electrode depth or technique
- Wrong trial time length or objectives (shotgun wedding?)
- Poor programming
- Lead migration?
- Scarring and impedance changes
- Utilization of a product with sub-optimal design

"Government is the art and science of running the circus from the monkey cage."
-H.L. Mencken

On January 1, new CPT Category III codes will be implemented to report peripheral subcutaneous field stimulation.

- CPT Category III codes are a set of temporary codes that allow data collection for emerging technologies, services and procedures. These codes are intended to be used to substantiate widespread usage or to provide documentation for the Food and Drug Administration (FDA) approval process.
- The CPT Category III codes may not conform to the usual CPT code requirements as follows:
  - Services or procedures must be performed by many health care professionals across the country.
  - FDA approval must be documented or be imminent within a given CPT cycle.
  - The service or procedure has a proven clinical efficacy.
  - The service or procedure must have relevance for research, either ongoing or planned.
- The presence of Category III codes requires that providers use these rather than a less specific Category I unlisted or other code when performing peripheral subcutaneous field stimulation.
- There are no relative value units (RVUs) assigned to these codes. The lack of RVUs means that there are no payments established for the physician procedures. The physician will need to negotiate payment directly with every payer. Because a national RVU is not present, payment will typically be established on a case-by-case/payer-by-payer basis. In many instances, a payer will not allow for coverage and payment because of policy considerations associated with the status of such codes. Today, the vast majority of payers cover and reimburse for PNS. Given the implementation of Category III codes on January 1, it is uncertain how they will handle PNS.
- The existing Category I CPT codes for Peripheral Nerve Stimulation 64555, 64575, 64585, 64590, 64595 are intended only for use when targeting specific peripheral nerves as compared to the new Category III codes which describe targeting a field of pain.
In Summation

- New codes may actually preserve technique from abuses and thus ensure its existence in future
- PNfS works in carefully selected patients when appropriately applied
- Least invasive, possibly safest implantable neuromodulation option for low back pain
- Nascent science, nascent techniques
- SCS/PNfS may the the future, if there is a future...
- “Great things are done when men and mountains meet.”
  —William Blake