BACKGROUND: The ever-changing use of technology means that scientifically trained physicians must answer three pairs of questions before instituting any treatment\(^1\).

A.) What is the diagnosis and how is it validated?
B.) What is the natural history of that diagnosis and what are its treatment options?
C.) Is this treatment indicated for this diagnosis and does its risks justify its benefits?

Because spinal pain has many causes any test that accurately diagnoses the source of spinal pain offers an invaluable tool for making sure that the patient receives the correct treatment. Measuring the voltage amplitude necessary to cause a discernable nerve impulse depends on the effectiveness and clinical reliability of the technology. As such it offers important insights into what nerve causes pain in a given patient. A 2002 peer-reviewed study by Randall Cork, MD, PhD of Louisiana State University Pain Center studied the nerve conduction of pain fibers (pfNCS) with a device that had a 94.6% sensitivity in detecting lumbar nerve-root function pathology as confirmed by epidurograms\(^2\).

Unfortunately no prospective clinical studies demonstrate that the pfNCS improves the management and clinical outcomes of patients with spinal pain any better than other methods. Indeed, the Center for Medicare and Medicaid Services in 2004 concluded that prototype devices, which relied on the patient’s psycho physiological assessment (perception of a sensation) were unacceptable for Medicare coverage because: “there continues to be insufficient scientific and clinical evidence to consider the pfNCS test and device used in performing this test as reasonable and necessary”\(^3\).

The pfNCS uses electrical voltage applied at predetermined points that correspond to areas innervated by a specific nerve root\(^4\) to determine if that nerve root has a normal response to the current, a hyper response indicating increased sensitivity to the current, or a hypo response indicating impaired sensitivity of that nerve root. The use of a potentiometer precisely records from the nerve an objective increase of 20 millivolts or more a second or two before the patient feels a sensation generated by the pfNCS\(^5\). Thus theoretically, the pfNCS gives more than just a “psycho physiologic assessment” as to whether or not a given patient perceives pain.
**OBJECTIVE:** This study was undertaken to determine the effectiveness of the pfNCS in improving outcomes of patients suffering from cervical and lumbar pain. The pfNCS, (performed with a Neural-Scan™) employs a voltage regulated stimulus in conjunction with an objective measurement of the amplitude of the action potential known as a potentiometer.

Evaluating the *Sensitivity* of the test in determining what nerve generates a given patient’s pain as well as the *Specificity* of that test in reducing the patient’s pain while improving the patient’s function will demonstrate whether or not the use of the pfNCS is “reasonable and necessary.”

**METHODS:** For one year from August 1, 2008 until July 31, 2009 one hundred and fifty-one individual pfNCS electrodiagnostic examinations (EDX) were performed on a total of 124 different patients who were then followed for at least one month after receiving treatment. The patients’ age, sex, and clinical diagnoses as determined by history, physical findings and x-rays/MRIs/CT scans were recorded as were the results of the pfNCS. The pfNCS results demonstrated that a given nerve root had one of six responses; a normal, mild, moderate, marked, severe or very severe reaction.

- Normal results in patients with back or neck pain suggested a myofascial or other cause of the patient’s pain.
- Mild, moderate or marked abnormalities suggested a facet origin to the pain.
- Severe or very severe nerve root abnormalities suggested a discogenic pain generator.

All patients had their visual analog scale (VAS) and Oswestry Disability Index (ODI) measured and recorded before and after they received treatment. The treatment a given patient received depended on what the pfNCS showed to be the cause of the patient’s pain.

- If the results were negative the patient received conservative measures including physical therapy, medication and counseling where indicated.
- If the results showed mild, moderate or marked nerve root abnormalities then diagnostic medial branch facet joint blocks (MBB) were performed at the appropriate level according to ISIS Guidelines⁶,⁷ and medial branch facet rhizotomies performed when indicated.⁸,⁹
- If the results showed severe or very severe nerve root abnormalities then transforaminal lumbar epidural steroids injections (TF/LESI), lumbar epidural steroid injections (LESI) or cervical epidural steroid injections (CESI) were performed at the appropriate level.
- Some patients received other interventional techniques such as Sacroiliac (S/I) joint injections, pyriformis injections, percutaneous Disc Dekompressors™, or vertebroplasties.
The test results were then divided into three categories:

1.) pfNCS results that changed the treatment given to patient.
2.) pfNCS results that confirmed what the clinical findings suggested should be done.
3.) pfNCS results that did not influence the treatment given to a patient.

The treatment selected for a given patient was considered to have “helped” if the patient’s VAS was reduced by at least two points or 25% and/or the ODI was less than 40 and improved by at least 25%.\(^{10}\)

Many patients received either medial branch blocks (MBB) or rhizotomies, trans-foraminal lumbar epidural steroid injections (TF/LESI), or medical therapy (consisting of a combination of modalities including oral steroids, NSAIDs, analgesics, muscle relaxers, physical therapy (PT), and home exercise programs (HEP). Some patients received other interventional techniques including S/I joint injections, pyriformis injections, percutaneous disc dekompresors, or vertebroplasties; while a few received traditional interlaminar epidural steroids to their cervical or lumbar spine (CESI/LESI).

The overall average change in the VAS and ODI were determined in terms of

a.) all the patients,
b.) those patients helped by their treatment,
c.) those patients not helped by their treatment,
d.) those patients whose pfNCS changed the treatment,
e.) those patients whose pfNCS confirmed the treatment,
f.) those patients whose pfNCS did not influence the treatment,
g.) those patients who had MBB/Rhizotomies,
h.) those patients who had TF/LESI,
i.) those patients who had Medical therapy,
j.) those who patients had other interventional therapy, and
k.) those patients who had CESI/LESI.

In addition the patients were divided into those who had pfNCS of either the lumbar or cervical spinal regions and evaluated in terms of the treatment given to them and their response to treatment.
RESULTS:
One hundred and fifty one pfNCS were analyzed. The average age was 55.5 years with a range of 19 to 94. 59 males and 92 females tested. All who had a pfNCS done in this study had an average decrease in their VAS score of 49% and an average functional improvement in the ODI of 44%. One hundred and nineteen tests (79%) resulted in the helping the recipient of the test reduce on average their VAS by 74% and improve their function by 44%. Thirty two of the tests (21%) did not help the recipients who had on average increase in their VAS of 5% with an improvement in their function of only 7%. (See Table One)

<table>
<thead>
<tr>
<th>TABLE ONE RESULTS:</th>
<th>Total:</th>
<th>VAS:</th>
<th>ODI:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL pf-NCS:</td>
<td>151</td>
<td>49%</td>
<td>44%</td>
</tr>
<tr>
<td>PAIN DECREASED</td>
<td>FUNCTION IMPROVED</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pfNCS HELPED:</td>
<td>119</td>
<td>74%</td>
<td>44%</td>
</tr>
<tr>
<td>(79%) PAIN DECREASED</td>
<td>Function Improved</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pfNCS NO HELP:</td>
<td>32</td>
<td>5%</td>
<td>7%</td>
</tr>
<tr>
<td>(21%) *PAIN INCREASED</td>
<td>FUNCTION IMPROVED</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

____________________________________________________________________
CATEGORIES:

The 151 pfNCSs done had one of three influences on the treatment a given patient received. One:) 84 (56%) of the tests changed the treatment a given patient received. Two:) 53 (35%) of the tests confirmed what good clinical judgment recommended as appropriate treatment. Three:) 14 (9%) of the tests did not influence the treatment a given patient received.

The 84 pfNCSs were done on a total of 30 males and 54 females who had an average age of 56.9 years with a range in age of 19 to 94. Seventy two of these pfNCS (86%) helped patients have an average 75% decrease in their VAS and an average 42% improvement in their functioning.

The pfNCS changed the treatment plan by changing one or more of the following. Sixty-five of the pfNCSs (43%) changed the level selected to receive treatment. Seven of the pfNCSs (5%) changed the treatment the patient received. Four of the pfNCSs (3%) changed the diagnosis. And twelve of the pfNCSs (8%) changed the side that received treatment!! None of these twelve patients would have had the correct side of their pain generator treated without the use of the pfNCS. All twelve of these patients were helped by the treatment they received. On average, they had a 88% decrease in their VAS and a 54% improvement in their function!!.

Fifty three of the pfNCS (35%) confirmed what the history, physical findings, and diagnostic tests such as plain x-ray films, C.T. scans, and MRIs and were done on 25 males and 28 females with an average age of 54.3. Forty (75%) were helped
and 13 (25%) were not. The average patient in this group decreased their VAS by 55% and improved their ODI by 55%.

Fourteen of the pfNCS did not influence the treatment a given patient received. Six (43%) were helped anyway and 8 (57%) not helped. On average, those treated in this group had 42% decrease in their VAS and a 27% improvement in their ODI

**TABLE TWO: CATEGORIES**

1.) pfNCS CHANGED THE TREATMENT GIVEN TO THE PATIENT: (84 patients - 56%)

<table>
<thead>
<tr>
<th>SEX: MALES: 30</th>
<th>FEMALES: 54</th>
<th>AVERAGE AGE: 56.9</th>
<th>RANGE 14-94</th>
</tr>
</thead>
<tbody>
<tr>
<td>HELPED: 72 (86%)</td>
<td>NO HELP: 12 (14%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

THE pfNCS CHANGED THE TREATMENT BY CHANGING ONE OR MORE OF THE FOLLOWING:

A.) THE LEVEL:  65 PATIENTS (43% of the pfNCS done.)
B.) THE TREATMENT GIVEN: 7 PATIENTS (5% of the pfNCS done.)
C.) THE DIAGNOSIS: 4 PATIENTS (3% of the pfNCS done.)
D.) THE SIDE THAT GENERATED THE PAIN: 12 PATIENTS (8% OF THE pfNCS DONE.)***

*** This last point is extremely important to recognize since none of these 12 patients would have had the correct side of their pain generator blocked without the use of the pfNCS. The treatment chosen for these twelve patients helped them all by decreasing their average pain level by 88% and increasing their functioning by 54%.

ALL PATIENTS WHO HAD THEIR TREATMENT CHANGED BY THE USE OF pfNCS ON AVERAGE:

| VAS 64% Decreased Pain | ODI 36% Improved Function |

2.) pfNCS CONFIRMED TREATMENT GIVEN TO A PATIENT: 53 pfNCS (35%)

<table>
<thead>
<tr>
<th>Ave. Age</th>
<th>M</th>
<th>F</th>
<th>Total</th>
<th>VAS</th>
<th>ODI</th>
<th>HELPED</th>
<th>NO HELP</th>
</tr>
</thead>
<tbody>
<tr>
<td>53.5</td>
<td>25</td>
<td>28</td>
<td>53</td>
<td>55% Decreased</td>
<td>55.2% Improved</td>
<td>40 (75%)</td>
<td>3 (25%)</td>
</tr>
</tbody>
</table>

3.) pfNCS DID NOT INFLUENCE TREATMENT GIVEN TO A PATIENT: 14 pfNCS (9%)

<table>
<thead>
<tr>
<th>Ave. Age</th>
<th>M</th>
<th>F</th>
<th>Total</th>
<th>VAS</th>
<th>ODI</th>
<th>HELPED</th>
<th>NO HELP</th>
</tr>
</thead>
<tbody>
<tr>
<td>54.3</td>
<td>3</td>
<td>11</td>
<td>14</td>
<td>42% Decreased</td>
<td>27% Improved</td>
<td>6 (43%)</td>
<td>8 (57%)</td>
</tr>
</tbody>
</table>
PROCEDURES:
The pfNCS resulted in one hundred and fifty procedures or therapies being evaluated.

Forty percent of all the pfNCS (60) suggested that diagnostic medial branch blocks (MBB) should be done. These 60 MBB resulted in forty-four medial branch rhizotomies (MBR) being performed while sixteen of the MBB did not recommend that a MBR be performed. Twelve of the MBB gave such long term relief with just the use of local anesthetic that no MBR was needed. Four of the MBB failed to indicate that the patient would benefit from a MBR. Fifty (83%) of the procedures helped patients so treated while ten (17%) did not. The average patient in this group had a 63% decrease in their VAS and a 32% improvement in their ODI.

Thirty-four percent of all pfNCSs (51) suggested that TransForaminal Lumbar Epidural Steroid Injection (TF/LESI) should be done. These helped forty patients (78%), but did not help 11 patients (22%). The average patient in this group had a 46% decrease in their VAS and a 34% improvement in their ODI.

Thirteen percent of all pfNCS (19) suggested that patients should receive medical therapy. These conservative therapies helped ten patients (53%) who received them but did not help 9 (47%). The average patient in this group had 38% decrease in their VAS and a 26% improvement in their ODI.

Nine percent of all pfNCS (14) resulted in other treatments be given. These procedures included S/I joint injections, pyriformis injections, percutaneous Disc Dekompressors™, or vertebroplasties. Nine of these procedures (64%) helped but five (36%) did not. The average patient in this group had 65% decrease in their VAS and a 34% improvement in their ODI.

Four percent of all pfNCS (6) resulted in interlaminar epidural steroids being placed, three in the cervical spine (CESI) and three in the lumbar spine (LESI). Three of these procedures (50%) helped and three (50%) did not. The average patient in this group had a 65% decrease in their VAS and a 14% improvement in their ODI.
# TABLE THREE

**MEDIAL BRANCH BLOCKS or RHIZOTOMIES**  60 PROCEDURES (40% OF THE pfNCS)

<table>
<thead>
<tr>
<th>Type</th>
<th>Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Block Only</td>
<td>16</td>
</tr>
<tr>
<td>Rhizotomy</td>
<td>44</td>
</tr>
</tbody>
</table>

Sixteen diagnostic blocks, done to determine if the patient was a candidate for a rhizotomy showed that 12 had such long lasting relief with just local anesthesia that they did not need a rhizotomy. Four diagnostic blocks failed to help the patient indicating that a rhizotomy would not help.

<table>
<thead>
<tr>
<th>Helped</th>
<th>No Help</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 (80%)</td>
<td>10</td>
</tr>
</tbody>
</table>

**Change:**
- **VAS:** 63% Pain Decreased
- **ODI:** 32% Improved Function

**TRANSFORAMINAL/LUMBAR EPIDURAL STEROID INJECTIONS:** (TF/LESI)

<table>
<thead>
<tr>
<th>Procedures</th>
<th>51 (34% of All pfNCS)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Helped</th>
<th>No Help</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 (78%)</td>
<td>11 (22%)</td>
</tr>
</tbody>
</table>

**Change:**
- **VAS:** 46% Pain Decreased
- **ODI:** 34% Improved Function

**MEDICAL THERAPY:**  19 PROCEDURES (13% OF ALL pfNCS)

<table>
<thead>
<tr>
<th>Helped</th>
<th>No Help</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 (53)</td>
<td>9 (47%)</td>
</tr>
</tbody>
</table>

**Change:**
- **VAS:** 38% Decreased Pain
- **ODI:** 26% Improved Function

**OTHER INTERVENTIONAL PAIN TREATMENTS:** 14 PROCEDURES (9% OF ALL pfNCS)

<table>
<thead>
<tr>
<th>Helped</th>
<th>No Help</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 (64%)</td>
<td>5 (36%)</td>
</tr>
</tbody>
</table>

**Change:**
- **VAS:** 65% Decreased Pain
- **ODI:** 34% Improved Function

**CESI/LESI:**  6 PROCEDURES (4% OF ALL pfNCS)

<table>
<thead>
<tr>
<th>Helped</th>
<th>Not Helped</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 (50%)</td>
<td>3 (50%)</td>
</tr>
</tbody>
</table>

**Change:**
- **VAS:** 66% Decreased Pain
- **ODI:** 14% Improved Function
ANATOMIC LOCATION

Forty of the pfNCS were done for problems in the cervical spine (36%) and 111 for problems in the lumbar spine (64%) (see Table 4.)

**TABLE FOUR:**

<table>
<thead>
<tr>
<th>Location</th>
<th>Cumulative Results</th>
<th>By Procedure:</th>
<th>Medical</th>
<th>Other Interventions</th>
<th>CESI/LESI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total: 40</td>
<td>MMB/Rhizotomy</td>
<td>TF/LESI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cervical</td>
<td>Helped: 33, 29 [90%]</td>
<td>--</td>
<td>3 [60%]</td>
<td>--</td>
<td>1 [33%]</td>
</tr>
<tr>
<td></td>
<td>Not Helped: 7, 3 [10%]</td>
<td>--</td>
<td>2 [40%]</td>
<td>--</td>
<td>2 [67%]</td>
</tr>
<tr>
<td></td>
<td>Total: 111</td>
<td>30</td>
<td>51</td>
<td>16</td>
<td>3</td>
</tr>
<tr>
<td>Lumbar</td>
<td>Helped: 86, 24 [80%]</td>
<td>43 [84%]</td>
<td>10 [63%]</td>
<td>7 [64%]</td>
<td>2 [67%]</td>
</tr>
<tr>
<td></td>
<td>Not Helped: 25, 6 [20%]</td>
<td>8 [16%]</td>
<td>6 [37%]</td>
<td>4 [36%]</td>
<td>1 [33%]</td>
</tr>
</tbody>
</table>

The cervical spine pfNCS resulted in 32 MBB or rhizotomies being done, which helped 90% of these patients. Five patients had various forms of medical therapies which helped 60% of them. Three patients had a CESI done, one of which helped (33%).

Of the 110 pfNCS done for lumbar spine problems, fifty-one were TF/LESIs which helped 43 patients (84%). Thirty patients had MBB/Rhizotomies of their lumbar spine which helped twenty-four patients (80%). Sixteen had various forms of medical therapy including oral steroids and P.T. which helped ten patients (63%). Eleven patients had other forms of interventional treatments including S/I joint injections, pyriformis injections, percutaneous disc dekompressors procedures and vertebroplasties. Seven of these procedures helped (64%). Three pfNCS resulted in LESIs being done two of which helped (67%).
CONCLUSION: The use of pfNCS in this series of 151 tests showed that 84 of the tests done (56%) changed the treatment planned for the patient, 53 (35%) confirmed the planned treatment and 14 (9%) did not influence the treatment. The pfNCS changed the planned therapy by a combination of one or more of these factors;

1.) it demonstrates which level generated the patient’s pain when the MRI showed “multilevel degenerative disc and facet changes”; 
2.) it changes the diagnosis of the pain generator from the disc to the facet or vice versa; 
3.) it determines the best therapy for the patient or; 
4.) it confirms that the generator of a patient’s pain lies on the opposite side of the patient’s body. [One of the most satisfying moments in pain medicine comes after injecting a very small amount of local anesthesia precisely into the left side of a patient’s neck and seeing a few minutes later the patient climb off the table exclaiming that their right sided neck pain is gone!!]

The 84 scans that changed the planned treatment for a given patient helped 86% of these patients. By reducing these patient’s VAS by 63% and improving their function by 36% the data in this study offers clear and convincing “scientific and clinical evidence to consider the pfNCS EDX” as both a “reasonable and necessary” aid in helping all who wish to practice scientific and effective pain medicine.

If other studies confirm these findings then an important diagnostic tool will be available to greatly improve the surgical, interventional and medical treatment of spinal pain.
Bibliography:


3.) www.cms.hhs.gov/transmittal/Downloads/RISNCD.pdf


7.) ibid; pp.112-136.

8.) ibid; pp. 188-218.

9.) ibid; pp. 249-284.