# IDET™ Procedure

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*Bones and Spine*

# Agenda

- Indications for Use
- Patient Selection
- Patho-anatomy
- Procedure Overview (video)
- Post-Operative Care
- Effects of Thermal Energy
- Clinical Efficacy
- Coding and Cost

# IDET™ Indications for Use

- Spine Cath Intradiscal Catheter was initially cleared for market and use by the FDA in March 1998

- Indicated for chronic, symptomatic patients diagnosed with annular disruption of contained herniated discs

# Patient Selection

- Appropriate Diagnostics
  - MRI
    - evidence of herniation or HIZ
  - Discography
    - low pressure with production of a negative level
    - presence and location of tears or fissures
    - identify painful level
  - Post Discography CT
    - visualization of pathology
    - helps develop treatment strategy

# Patient Selection

- Axial/referred low back pain of at least 3 months
- Eight weeks of conservative care
- Sitting intolerance
- Preserved disc height (≥ 40%)
- Motivated/No psych involvement

# Potential Exclusionary Criteria

- Sequestered or extruded disc material into neural foraminal space (severe herniation)
- Nerve root/thecal sac impingement
- Moderate to severe spinal stenosis
- Segmental instability or slippage (spondylolisthesis)
- More than 3 levels
- Previous fusion at requested level
- Pregnant women

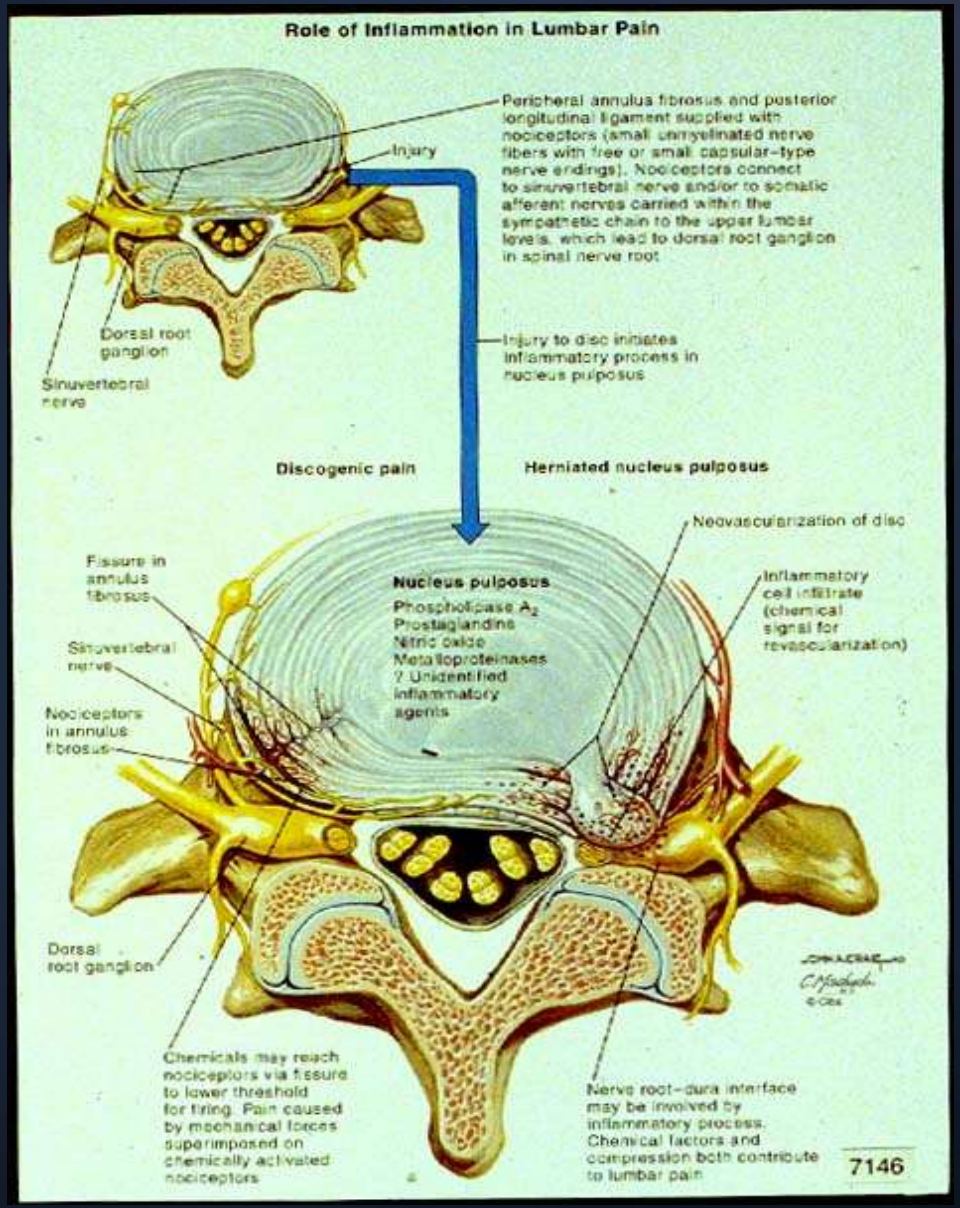
# Pathoanatomy of Discogenic Pain

- Degeneration of the disc often results in:
  - Annular fissures (90% occur posteriorly)
  - Ingrowth of unmyelinated nerve fibers (nociceptors)
  - Ingrowth of granulation tissue which is innervated and vascularized

# Pathoanatomy of Discogenic Pain

- Pain produced is often result of:
  - Enzymes (substance P) leaking out of the nucleus into the fissure
  - Irritates the nociceptors and innervated granulated tissue

- Referred to as chemical sensitization

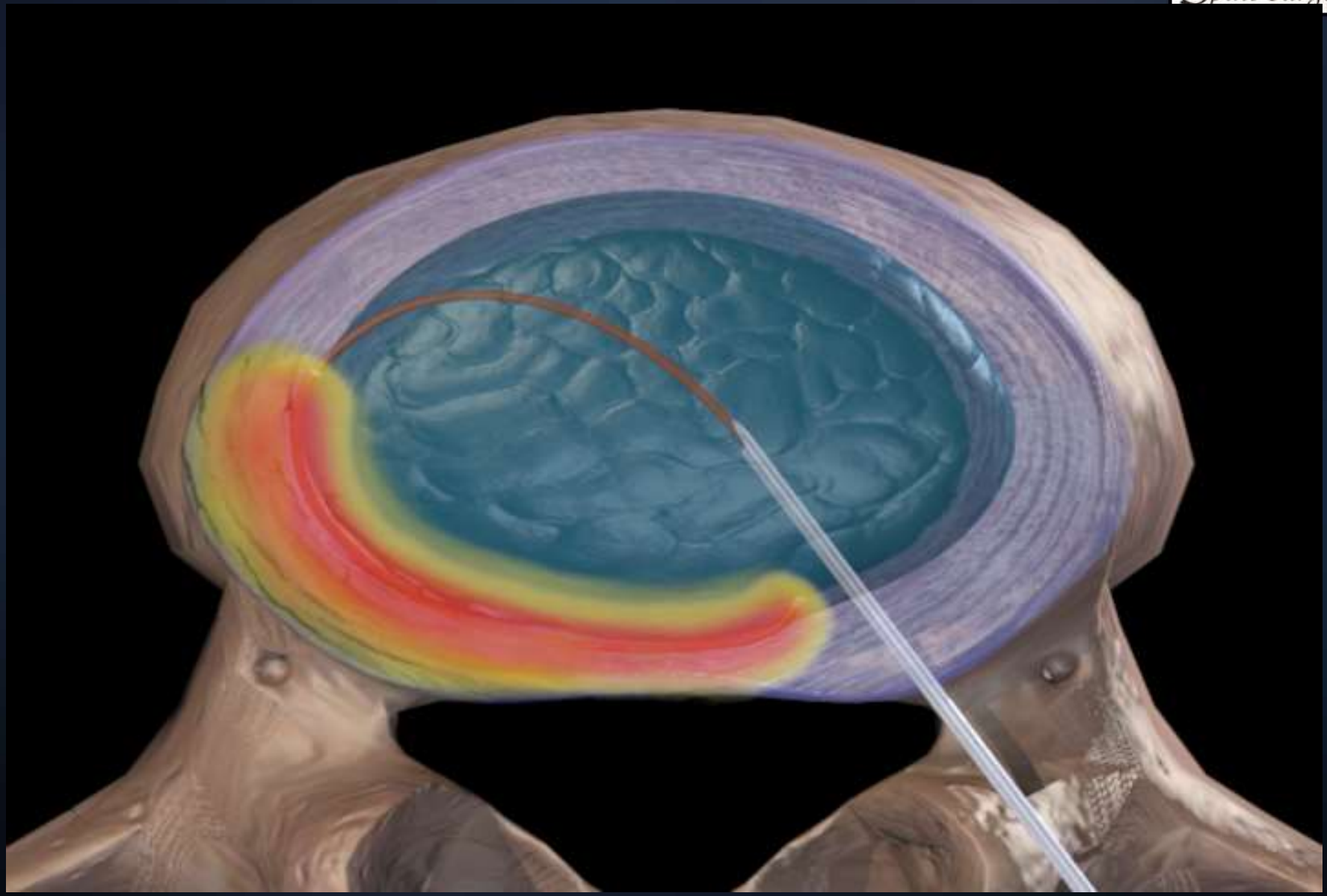


# Treatment Options

- Conservative treatment
  - pain medication
  - exercise
  - epidural or facet injections
- IDET™ procedure
- Fusion

# IDET™ Procedure Overview

- Equipment Used
  - SpineCath® Intradiscal Catheter
  - Needle Introducer, 17 gauge
  - OR-50 S ElectroThermal™ Generator
- Approximately 40,000 procedures (12/02)
- More information available at www.idetonline.com



# Post-Operative Care

- Pain may increase 1-7 days post-op
- At approximately 6-12 weeks, begin feeling better
- Begin PT exercises at approximately 8-12 weeks
- No heavy lifting until at least 3 months

# Post-Operative Care

- 0-6 Weeks:
- Lumbar corset
- Walking, Gentle leg stretching
- Limited sitting (20-45 minutes)
- No bending or stretching
- 6-12 Weeks:
- Basic stabilization, no spine mobilization
- No traction, manipulation or deep massage

# Post-Operative Care and RTW

- 12-16 Weeks:
- Exercise progression with spine stabilization
- Swimming program, bike riding
- Return to Work Expectations:
- Sedentary office work
  - 1-2 weeks post-operatively (dependent on patient's pain tolerance)
- Heavy work
  - 4-6 months

# Effects of Thermal Energy

- Modifies tissue
  - May break heat sensitive hydrogen bonds thus denaturing collagen
- May denervate unmyelinated nerve fibers (nociceptors)

# Optimum Temperature

- Validation studies confirm temperatures
  - Safe temperature in epidural space ~ 40 degrees
  - Heat dissipates as it is absorbed by the annulus
  - Tissue modification = 60-75 degrees C

- Temperature does not ablate, destroy or burn the disc (no presence of phagocytic cells)

# Other Heat-Mediated Modalities

- Radiofrequency (RF)
  - Saline is best medium
  - Straight needle
- Laser
  - No heat sensor
  - Costly

# IDET™ Benefits

- Minimally invasive
- Temperature controlled
- Navigable catheter with broad heating zone
- Radio-opaque and visual proximal markers to confirm catheter location in the disc
- No tissue impedance
- Outpatient procedure; home same day

# Physician Specialties

- Approximately 3,400 physicians trained
  - Orthopedic Spine
  - Neurosurgery
  - Neurology
  - Anesthesia/Pain Management
  - Physiatry
  - Interventional Radiologist

# IDET™ Physician Training

- National and regional courses
- Will not recommend utilization of IDET™ procedure until course is completed
- Workshops are conducted by physicians who have performed at least 50 procedures

# IDET™ Clinical Studies

# Summary of Publications

- Total Publications 20
  - Case Studies 3
  - Technique 6
  - Clinical Outcomes 9
  - Non-clinical 2

# Summary of Peer-Reviewed Published Data

| Author/ Publication | Saal, Saal Spine, 2002 | Karasek, et.al., The Spine Journal, 2002 | Pauza, et.al., ISIS 2002 |
|---|---|---|---|
| **Follow Up** | 24 months | 24 months | 6 months |
| **Patients** | 58 | 53 (36 IDET patients) | 64 |
| **VAS Improvement** | 3.1 Points (Mean) | 8.0 pretreatment to 3.0 at 24 months | 2.4 Points (Mean) |
| **Favorable Outcome** | 81% Phys. Function*<br>78% Bodily Pain*<br>(* > 7 point) | 57% of patients with 50% pain relief | Phys. Function for low PF pts., mean 32.4 points. Bodily Pain, mean 17.3 points. Oswestry, 10.9 decrease |
| **Return to Work** | Private Pay: 97%<br>WC: 83% | Post IDET: 74% | Not Reported |
| **Complications** | None | None Reported | Not Reported |

# A Randomized, Prospective, Double-Blind, Placebo Controlled Trial Evaluating the Efficacy of Intradiscal Electrothermal Annuloplasty (IDET™) For the Treatment of Chronic Discogenic Low Back Pain:

## 6-month Outcomes

Kevin Pauza, Susan Howell, Paul Dreyfuss, John Peloza, and Kathryn Park

International Spine Injection Society
Austin, TX 2002

# Pauza K et al.
## *ISIS, 2002*

## Methods

64 patients, 3:2 Randomization during procedure

Placebo procedure included needle placement and simulated treatment

Outcome measures: VAS, SF-36 BP and PF, Beck, Oswestry

Blinded observers conducted all follow up and post procedure management

Unblinding at 6 mos. post procedure

# Pauza K et al.
## *ISIS, 2002*

Average age: 41 years
Duration of pain > 2yrs:  77%
Employed or homemaker: 84%
Manual labor: 65%
No difference in pretreatment pain scores between groups

# Pauza K et al.
## *ISIS, 2002*

Statistically significant improvement in pain demonstrated by the IDET™ treatment group compared to placebo

Greater improvement in pain levels in treated group evidenced by 3 outcome measurements:

- Visual Analog Scale (VAS)
  - 36% improvement
- Bodily Pain (BP) Scale of the SF-36
- Oswestry Disability Index

# Pauza K et al.
## *ISIS, 2002*

Randomized, double-blind nature of the study eliminates the potential for bias

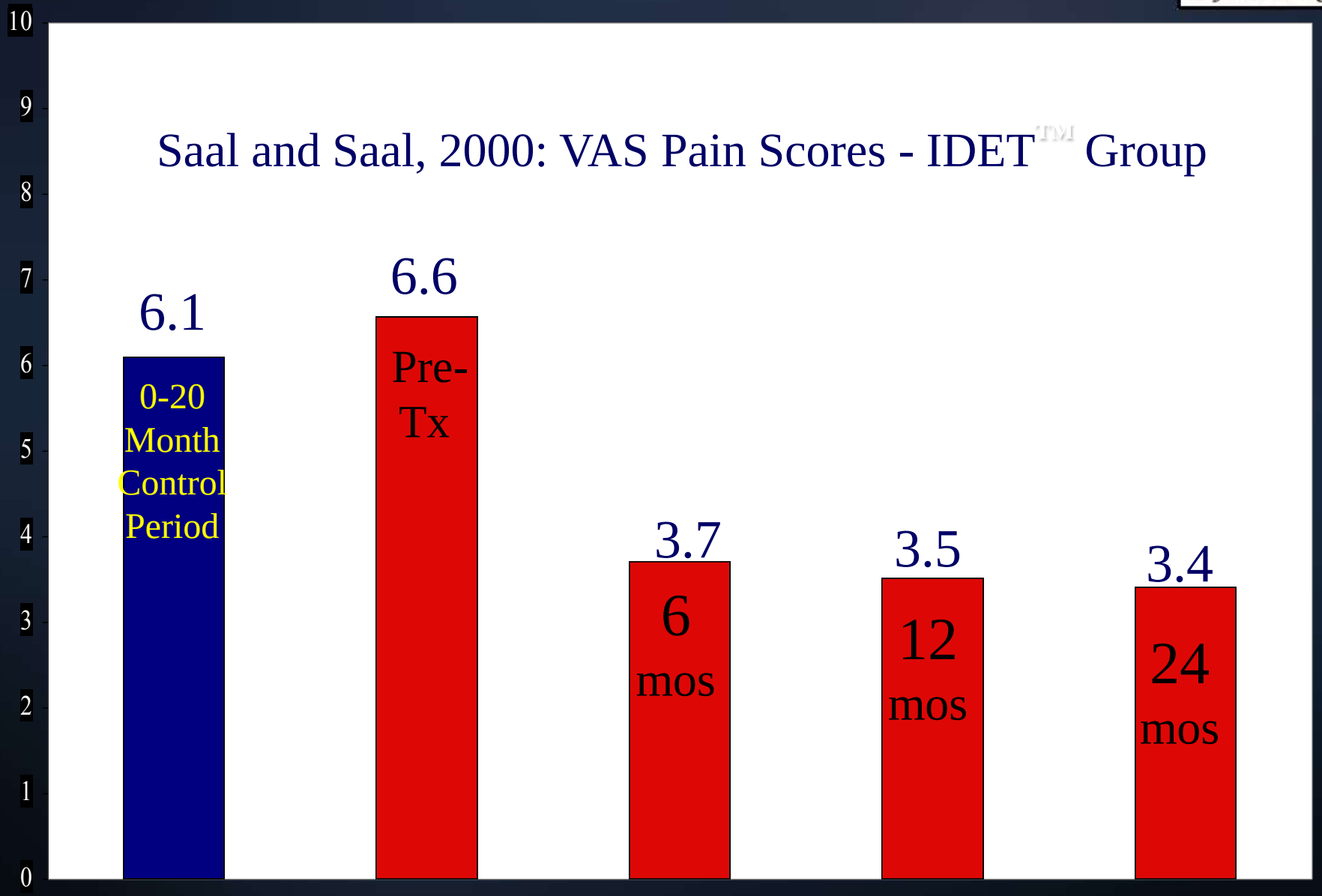
- Extremely objective and of the highest scientific value
- Investigators did not receive benefits from any commercial parties

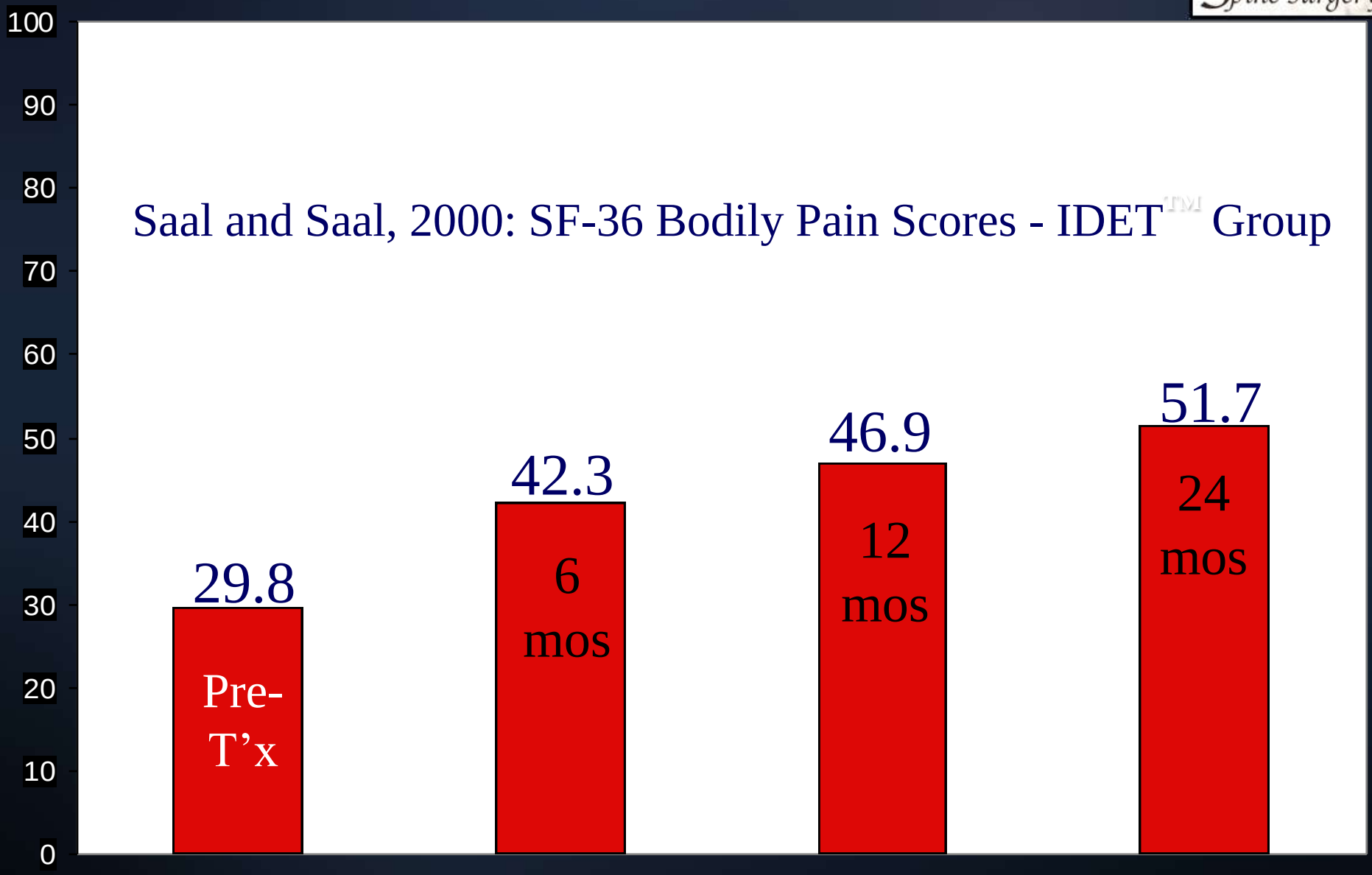
# Saal JA and Saal JS
# *Spine, May 2002*

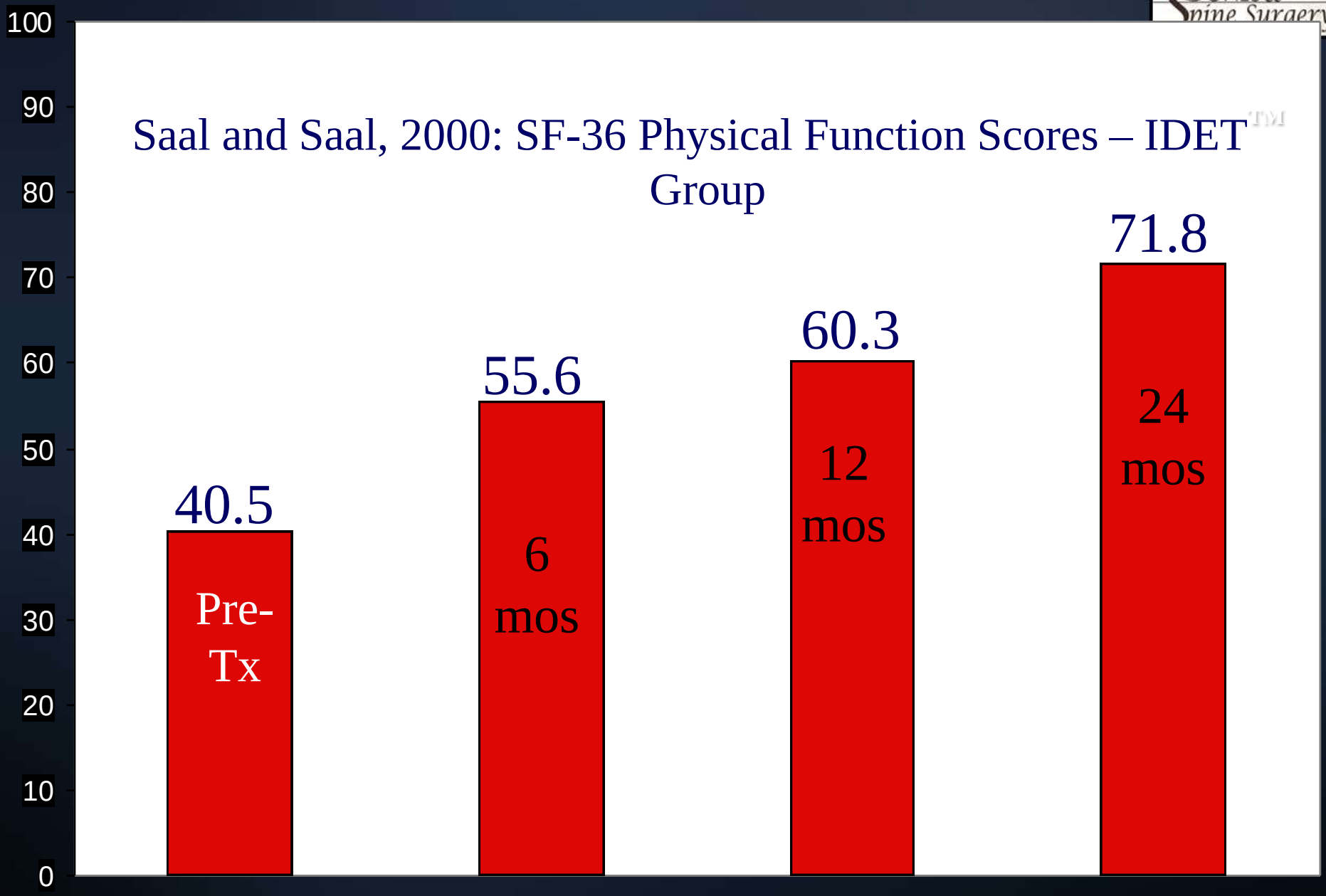
- 62 IDET™ Patients
- 29 Control Patients who declined or deferred IDET for non-physiological reasons
- Observation period: 0-20 months pre-IDET
- Mean follow up: 28 months (12-35 months)

# Saal JA and Saal JS
# *Spine, May 2002*

- IDET™ Group Results (pre-IDET vs. 24 months)
  - VAS Change: 3.2 pts. (p= .0001)
  - SF-36 Bodily Pain Change: 21.9 pts. (p= .0001)
  - SF-36 Physical Function Change: 31.3 pts. (p= .0001)
- Control Group Results (during 28 month observation)
  - Mean VAS: 5.9 (± 1.95)
  - No Trend Change


Saal and Saal, 2000: VAS Pain Scores - IDET™ Group
10
9
8
7
6
5
4
3
2
1
0
6.1
0-20 Month Control Period
6.6
Pre-Tx
3.7
6 mos
3.5
12 mos
3.4
24 mos


Saal and Saal, 2000: SF-36 Bodily Pain Scores - IDET™ Group
100
90
80
70
60
50
40
30
20
10
0
29.8
Pre-T'x
42.3
6 mos
46.9
12 mos
51.7
24 mos


Saal and Saal, 2000: SF-36 Physical Function Scores – IDET Group
100
90
80
70
60
50
40
30
20
10
0
40.5
Pre-Tx
55.6
6 mos
60.3
12 mos
71.8
24 mos

# Bogduk and Karasek
## ***The Spine Journal*, October 2002**

- 53 patients met highly selective criteria for
- IDET™ Procedure
- 36 patients received IDET™ Procedure
- 17 patients denied coverage formed control group
- 24 month follow up

# Bogduk and Karasek ***The Spine Journal*, October 2002**

- Control group results: (3 month follow up)
  - 1 patient resolved pain
  - 3 patients obtained modest improvement
  - 4 remained same
  - 9 worsened
  - 7/15 working vs. 10/15 pre study

# Bogduk and Karasek ***The Spine Journal*, October 2002**

- Treatment group results (12 month follow up)
  - 32 of 36 IDET™ patients obtained relief of pain
  - Median VAS decreased from 8.0 to 3.0
  - 23% of IDET™ patients achieved complete relief of pain

# Bogduk and Karasek ***The Spine Journal*, October 2002**

- 27/33 working at 12 month follow up
- Concomitant reduction in opioids
- Median 41% improvement on Oswestry scores

# Maurer P, Squillante, D
## *ISIS 2002*

- 81 patients treated , 12-24 month follow up
- 58% male; 71% were ages 18-44
- 60% had 1 disc treated; 40% had 2 discs treated; 3% had 3 discs treated
- 78% overall success rate
  - (≥ 2 point increase on VAS or ≥ 10 point increase in BP or PF)

# Maurer P, Squillante, D
## *ISIS 2002*

**Outcomes from Success Group:**

- VAS Change: 4.5 ($p<.0001$)
- SF-36 Bodily Pain Change: 47 ($p<.0001$)
- SF-36 Physical Function Change: 40.2 ($p<.0001$)
- Sitting Change: 58.6 ($p<.0001$)
- Standing Change: 53.6 ($p<.0001$)
- Walking Change: 51.2 ($p<.0001$)
- Success vs. failure independent of gender, smoking history, number of discs treated, or worker's compensation

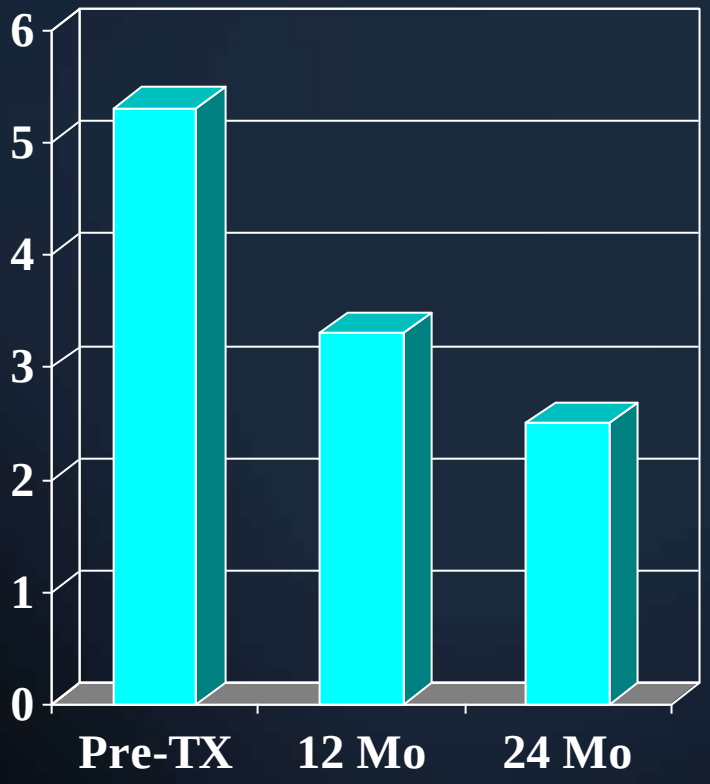
# Wetzel, Andersson et. al. *NASS 2001, ISIS 2002*

- Multi-center, prospective cohort study initiated in 1998
- 74 patients, 24 month follow up
- 64% females; average age 42.6
- 74% single level disc; 26% 2 levels treated
- 88% would choose the same treatment for their back pain
- RTW:  61% vs. 23% pre-op

# Wetzel, Andersson et. al.

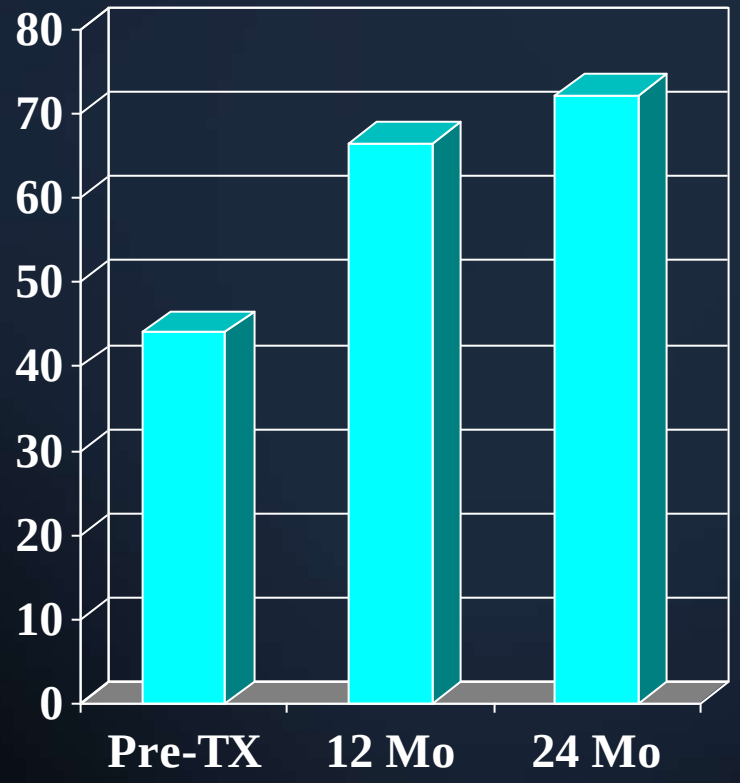
*NASS 2001, ISIS 2002*

VAS




- 2.6 +/- 2.5 decrease in VAS at 24 months
- ($p < 0.0001$)

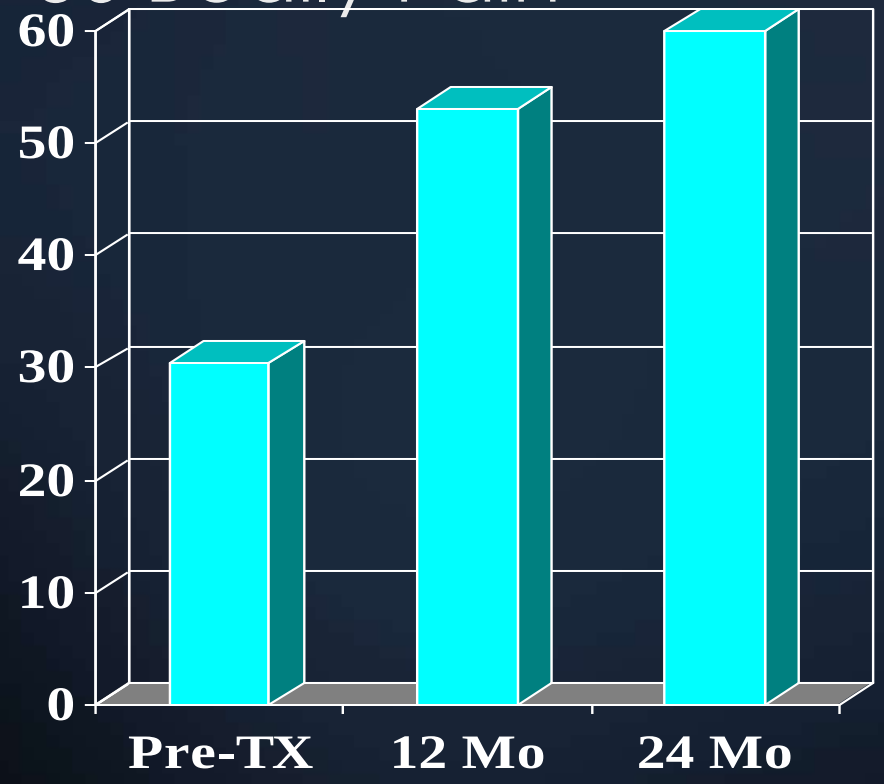
# Wetzel, Andersson et. al.
## *NASS 2001, ISIS 2002*
## SF-36 Physical Function




- 27.5 +/- 25.2 increase at 24 months ($p < 0.0001$)

# Wetzel, Andersson et. al.
## *NASS 2001, ISIS 2002*

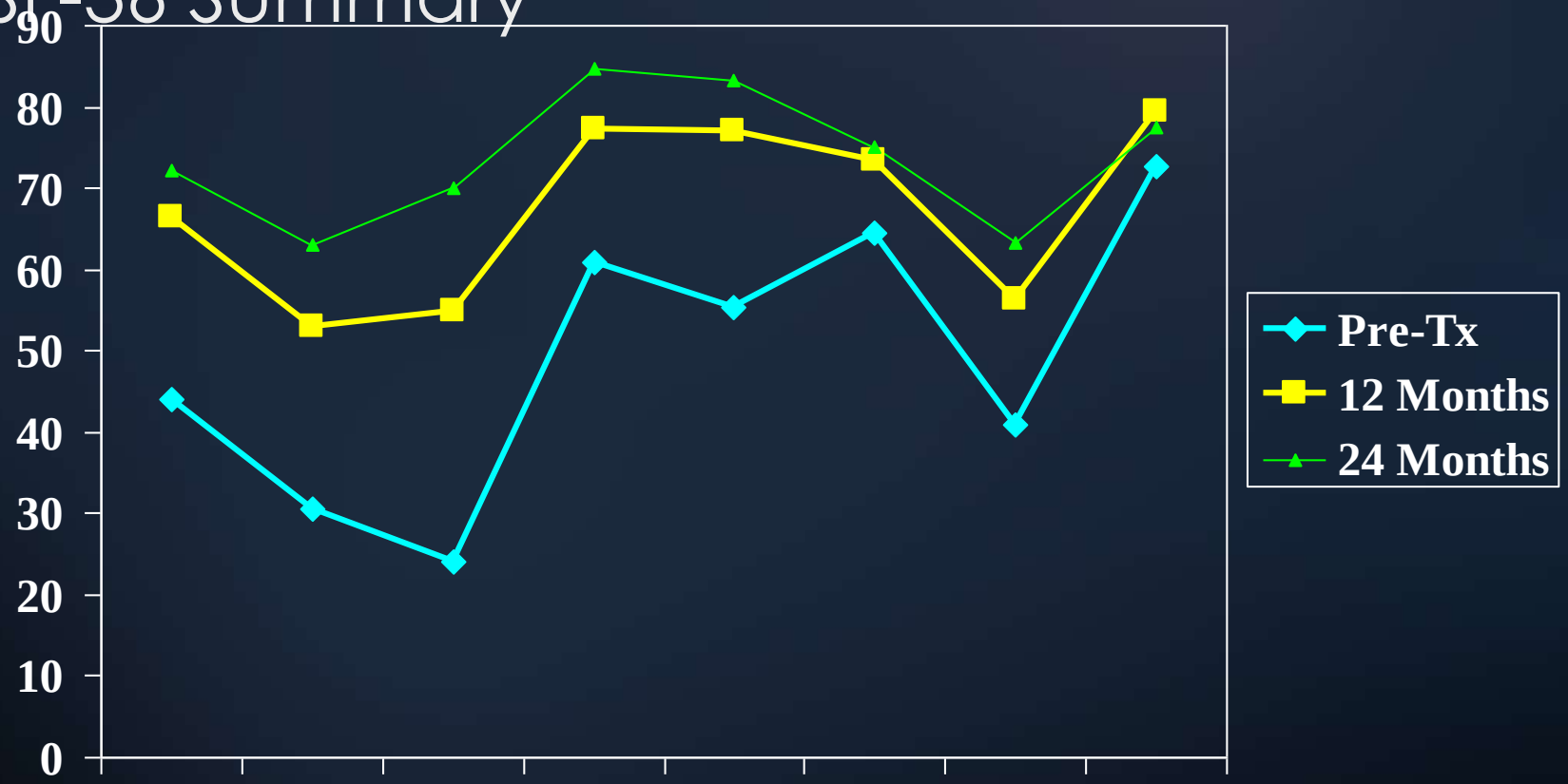
SF-36 Bodily Pain




- 30.8 +/- 21.0 increase at 24 months ($p < 0.0001$)

# Wetzel, Andersson et. al.
## *NASS 2001, ISIS 2002*

SF-36 Summary




Significant improvement in all but RE and GH.

# Lagattuta FP et al *AAOM 2000*

- Review of 122 patients with IDD treated with IDET™ procedure in 3 centers to determine necessity of fusion and RTW
- Follow up: 6-18 months
- Four of 122 (3.2%) of patients required fusion in follow up period
- RTW: 3 patients retired, 5 applied disability, 12 did not return to work, 100 released to work

# Possible Procedural Codes

- 64999 Unlisted Procedure, nervous system
- 22899 Unlisted Procedure, spine

# Possible Procedural Codes

- HCPCS
- S2370 IntraDiscal ElectroThermal Therapy, single interspace
- S2371 IntraDiscal ElectroThermal Therapy, each additional interspace

# Possible Product Code

- 99070  Miscellaneous Surgical Supply
-

# Average Costs for Single Level

- Average physician reimbursement
  - $1,800-$3,000
- Average facility reimbursement
  - $2,000-$5,000
  - Cost of standard catheter is $1,095
- Total Cost $6k-$11k vs. Fusion?