



Prospective Data Collection – Provider Perspective

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Science of Clinical Practice

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Disclosure

No Commercial Conflicts of Interest

Criticism/ Pressure from Government and Payers

Utilization of complex spinal fusion in the US increased 15 fold from 2002-2007.

- Deyo et al, JAMA 2010;303:1259-1265

The Cost of Spine Care in the US is now over 86 billion dollars/ year with over 300,000 spinal fusions performed annually.

Cost of Cancer in the US = 89 billion dollars/ year.

- Martin et al, JAMA 2008;299:656-664.

Where is the Evidence?

Lumbar Fusion Guidelines – Grade I Lumbar Spondylolisthesis with Spinal Stenosis

“Guidelines. There is insufficient evidence available to support a treatment guideline.”

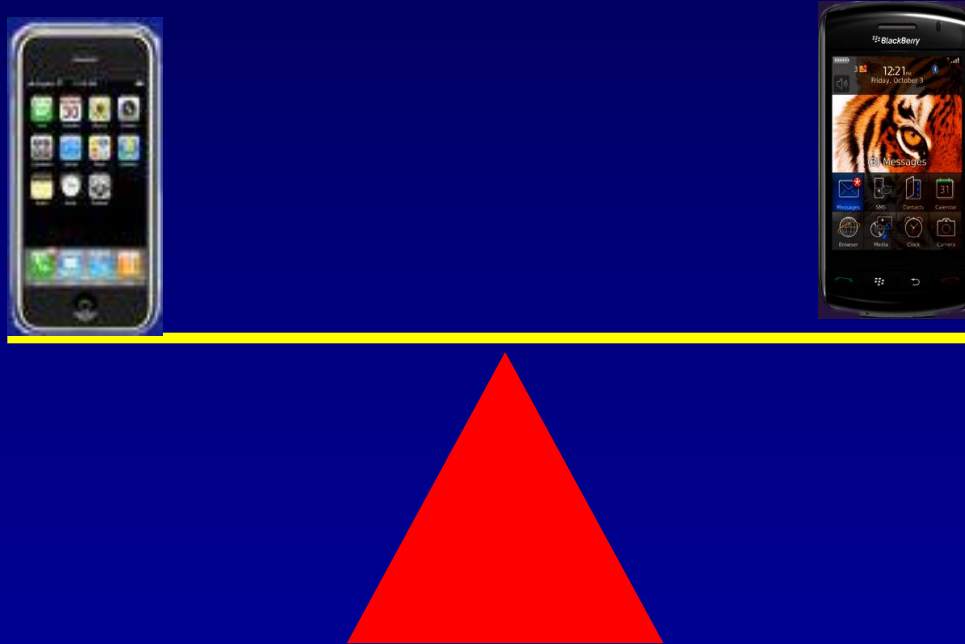
“The medical evidence regarding the use of pedicle screw fixation in this patient population is rated as Class III and is inconsistent”

- Resnick et al, J Neurosurg: Spine 2:679–685, 2005

Payers might limit access

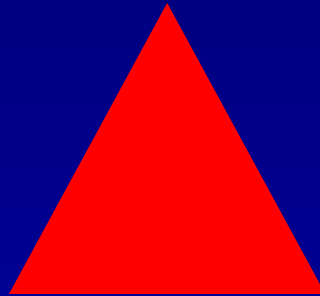
Several Third Party Payers (e.g. Blue Cross – Blue Shield of North Carolina) have begun (January, 2011) to limit patient access to lumbar spinal fusion citing a lack of evidence to support this treatment for patients with lumbar degenerative diseases.

Providers want data



**Patients think they have access to data
from the Internet and other sources**

All stakeholders need data



**Access to Quality Data and Cost
Preference Based on Value**

Administrative Databases

- Large administrative databases (e.g. National Inpatient Sample) containing vast amounts of patient data have increased our ability study quality with retrospective approaches
- Strength: Large numbers of patients from actual practice
- Weakness:
 - 1) Lack of outcomes detail
(i.e. no patient reported outcomes)
 - 2) Charges as a surrogate for costs

How do we as providers generate outcome data from actual clinical practice?

Types of Studies – RCT versus Registries

RCT represents the 'gold standard'

Limitations of RCTs (e.g. lack of equipoise, cross-overs, limited generalizability, etc.) have reduced enthusiasm for conducting more RCTs in surgery

Registries may represent a useful alternative when data is needed particularly on the value of treatments in actual practice

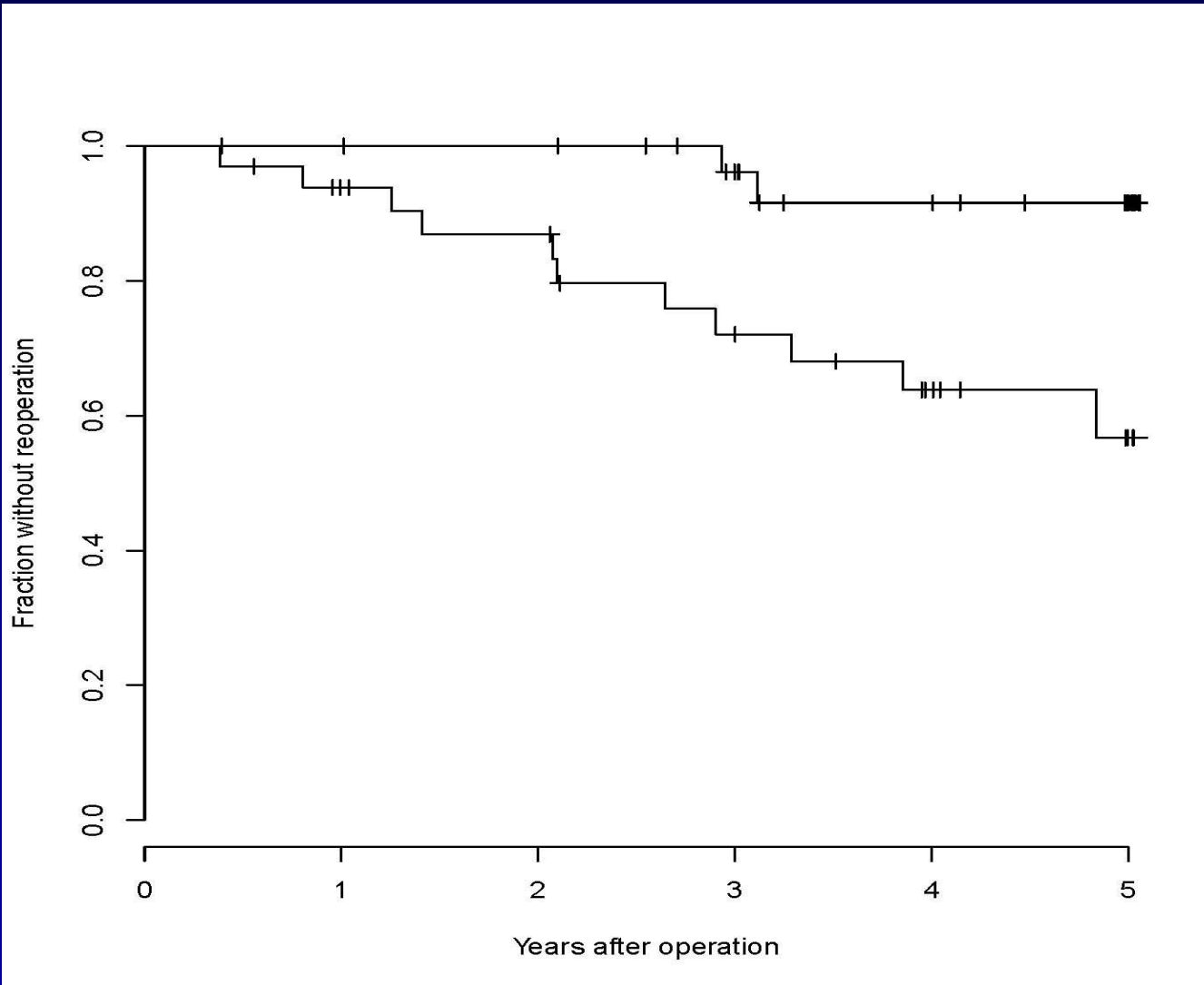
Meaningful Cost Data

- When your hospital says BMP is too expensive, for example, providers want local data comparing fusion with and without BMP
- When your hospital says you can not use a particular implant because it is too costly, providers need local data on the comparative costs and effectiveness of various options

Shared Decision Making

Providers and Patients could review actual data regarding a condition and make decisions together about treatment options

SLIP STUDY Actuarial Re-Ops

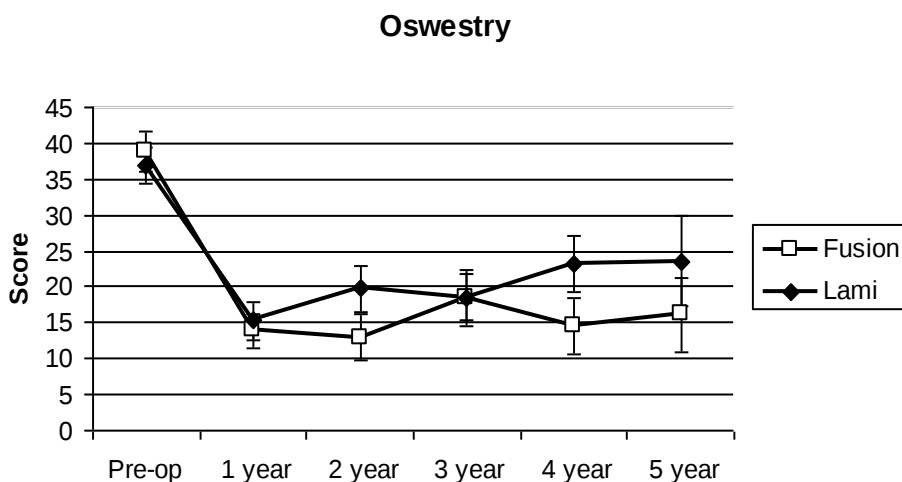


Fusion+Lami

Lami alone

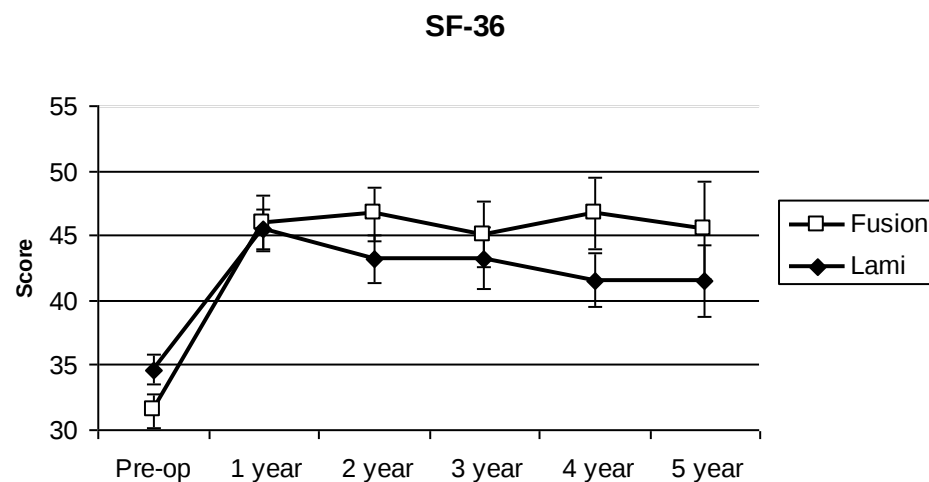
P=0.04

Comparative Outcomes: Fusion versus Lami



Oswestry
(Lower Score is Better)

P=0.071



PCS (SF36)
(Higher score is Better)

P=0.035

Shared Decision Making: Grade I Degenerative Spondylolisthesis



To Fuse or not to Fuse

- Work:
12 weeks vs 2 weeks
- Complications:
12% vs 5%
- Re-operation (5 year):
13% vs 33%
- Cost
\$85K vs \$20K

The Science of Community Practice?

The NPA is working on registry efforts to include the 'essential' elements to measure outcome and document effectiveness.

The Science of Community Practice?

Examples:

Neuropoint SD Study –

Lumbar discectomy and Single-level fusion for grade I spondylolisthesis

N2QOD –

Comprehensive risk-adjusted outcome assessment for lumbar spinal surgery in US

Proposed N2QOD Essential – 25 data elements

– focus upon ICD and CPT coding and EQ-5D



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Clinical Example: Lumbar Disc Herniation



- Lumbar Disc Herniation is the most frequent indication for spinal surgery in the US
- 15-fold regional variation in the US in utilization of surgery for herniated lumbar disc
- RCT - High degree of cross-over in the SPORT trial limited ability to compare surgical and non-surgical arms

Clinical Example: Grade I Degenerative Spondylolisthesis



- Degenerative lumbar spinal stenosis - most frequent indication for spinal surgery in patients >65
- 40% of patients have a degenerative slip
- Lack of high quality validated outcomes data regarding utility of different surgical approaches

Objective - Primary Aims

- 1) To establish a multi-center cooperative group that demonstrates 80% compliance in collecting 1-year outcomes data
- 2) To demonstrate the clinical effectiveness (SF-36 and ODI) of 2 common lower back procedures: lumbar discectomy & single level fusion

The Approach

To collect 200 unselected surgical patients (20 pts/ site) from 10-13 sites over 1 year with either:

- Symptomatic lumbar disc herniation
- or
- Symptomatic lumbar spondylolisthesis

Eligibility

Inclusion:

Age 18-80 years

- Lumbar Disc – 6 weeks
- Lumbar Stenosis with Spondylolisthesis – 3 months

Exclusion:

- Previous Surgery
- Significant (3/5) motor weakness
- Cancer, infection, or fracture
- Pregnancy

Outcomes Assessment

Health-related QOL – SF-36

Disease-specific outcome: ODI and VAS

**Pre-operatively and 30 days, and
3, 6, and 12 months post-operatively**

What is Success?

- Feasibility: At least **80% follow-up** at 1 year (primary outcome measure –SF36)
- Effectiveness: At least a **20 point** improvement using SF-36 physical function domain score at 1 year

Operational Matters

Three Investigators Meetings

- **Creation of Web-Platform**
- **Site IRB and Contract Approval**
- **Budget and Site Responsibilities**
- **Overall Study Manager**

Funded Study Budget

Personnel	\$ 0
Patient Care	\$ 0
Site Enrollment	\$ 90,000
SF-36 Licensing Fees	\$ 0
IRB Fees	\$ 20,000
NPA-Web Platform	\$ 78,000
Biostatistics (Yale)	\$ 12,000
Total	\$ 200,000

Two Major Flaws

Personnel	\$ 0
Patient Care	\$ 0
Site Enrollment	\$ 90,000
SF-36 Licensing Fees	\$ 0
IRB Fees	\$ 20,000
NPA-Web Platform	\$ 78,000
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Total	\$ 200,000

Site Responsibilities

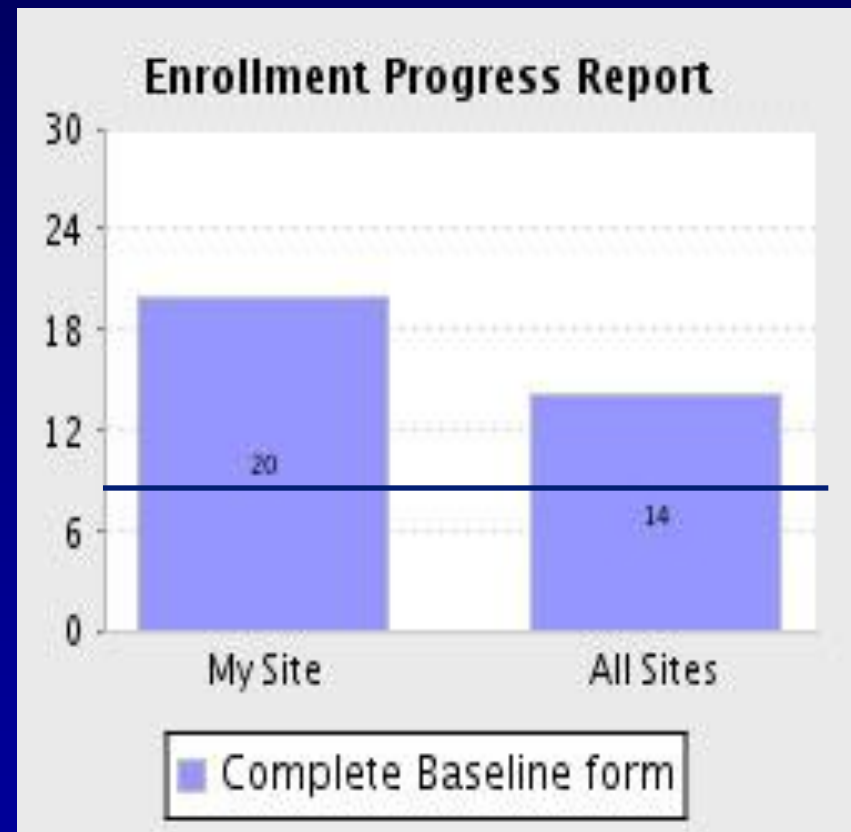
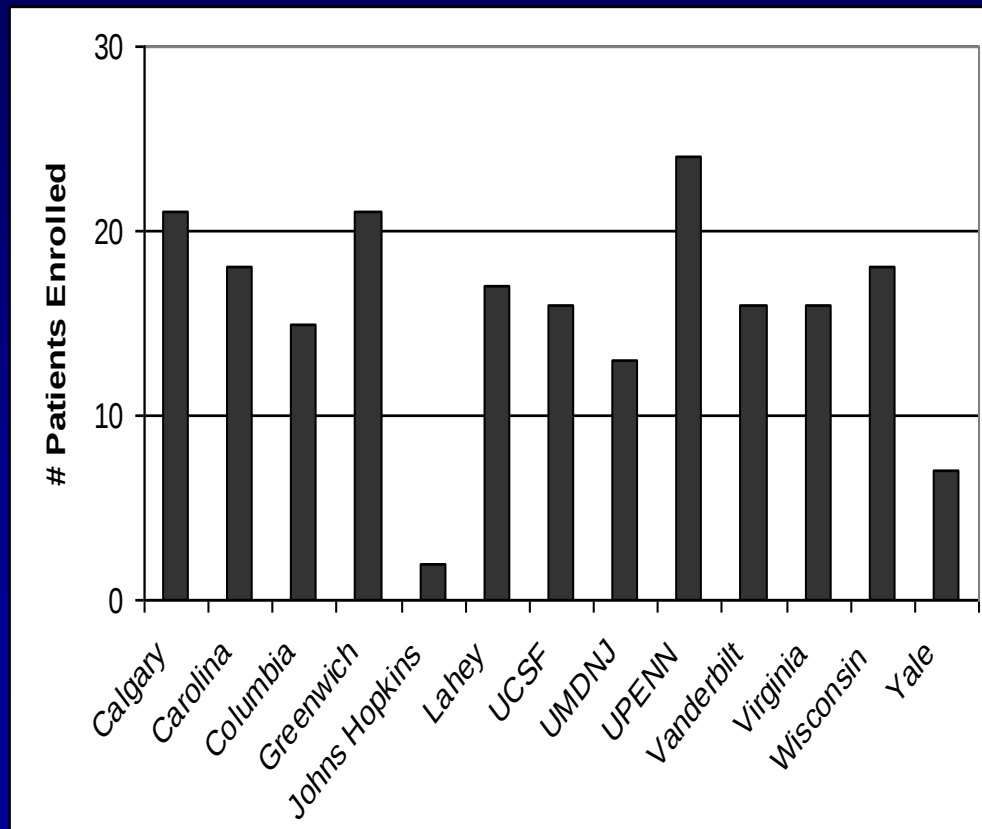
- Screen patients for enrollment
- Collect and enter baseline and operative data
- Force a change in culture – get both doctors and patients to get patient-reported outcome assessments completed on time
- IRB submission - up to \$ 2,500
- Patient Reimbursement \$ 100/ pt –
\$ 25 gift cards – 4 post-op visits
- Enroll 20 patients over 1 year

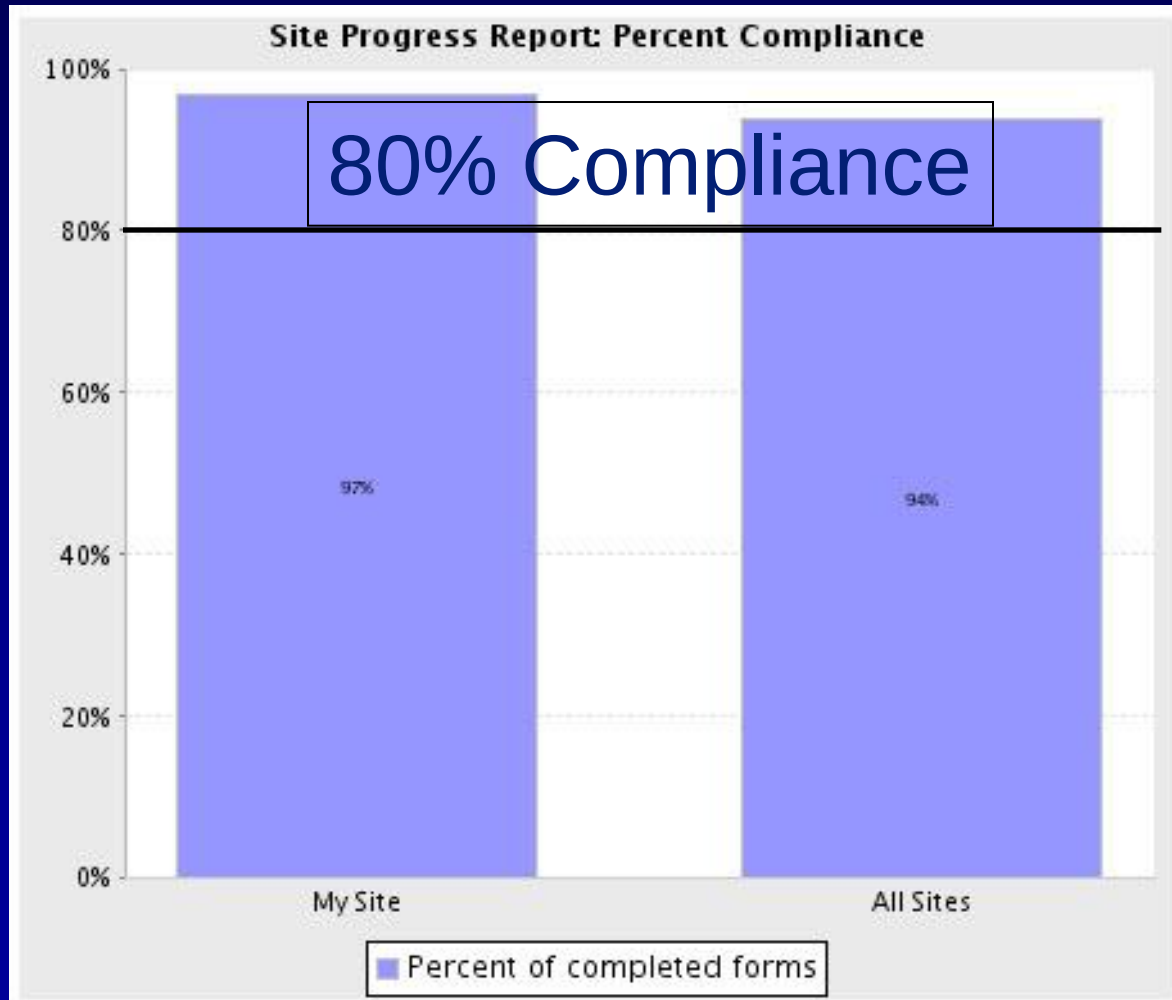
Site Costs

Personnel	\$ 12,000
Patient Care	\$ 0
Administrative Costs	\$ 6,000
Patient Reimbursement	\$ 2,000
IRB Fees	\$ 2,500
Total	\$ 22,500



Patient Enrollment (198 patients enrolled)





Quality Assessment



Complications – 30 days

Total = 12 complications – 6.1%

Disc Herniation & Grade I Spondy

4 wound infections

2 new post-op neurological deficits

4 re-operations (disc re-herniation)

1 symptomatic CSF leak

1 non-fatal cardiac arrest

Re-operations – 1 year

Total = 11 re-operations – 5.6%

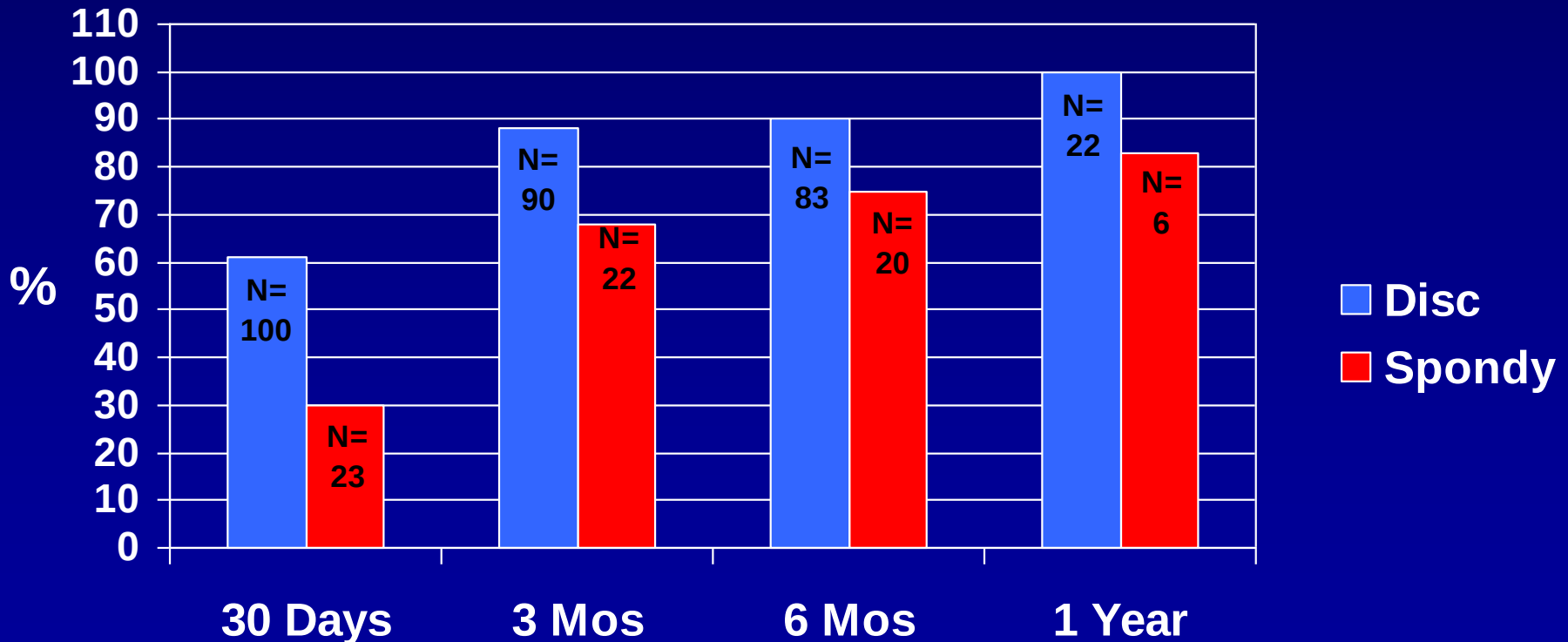
Ten re-operations were in the disc herniation cohort. One in the spondylolisthesis cohort. All were at the index level.

Return to Work

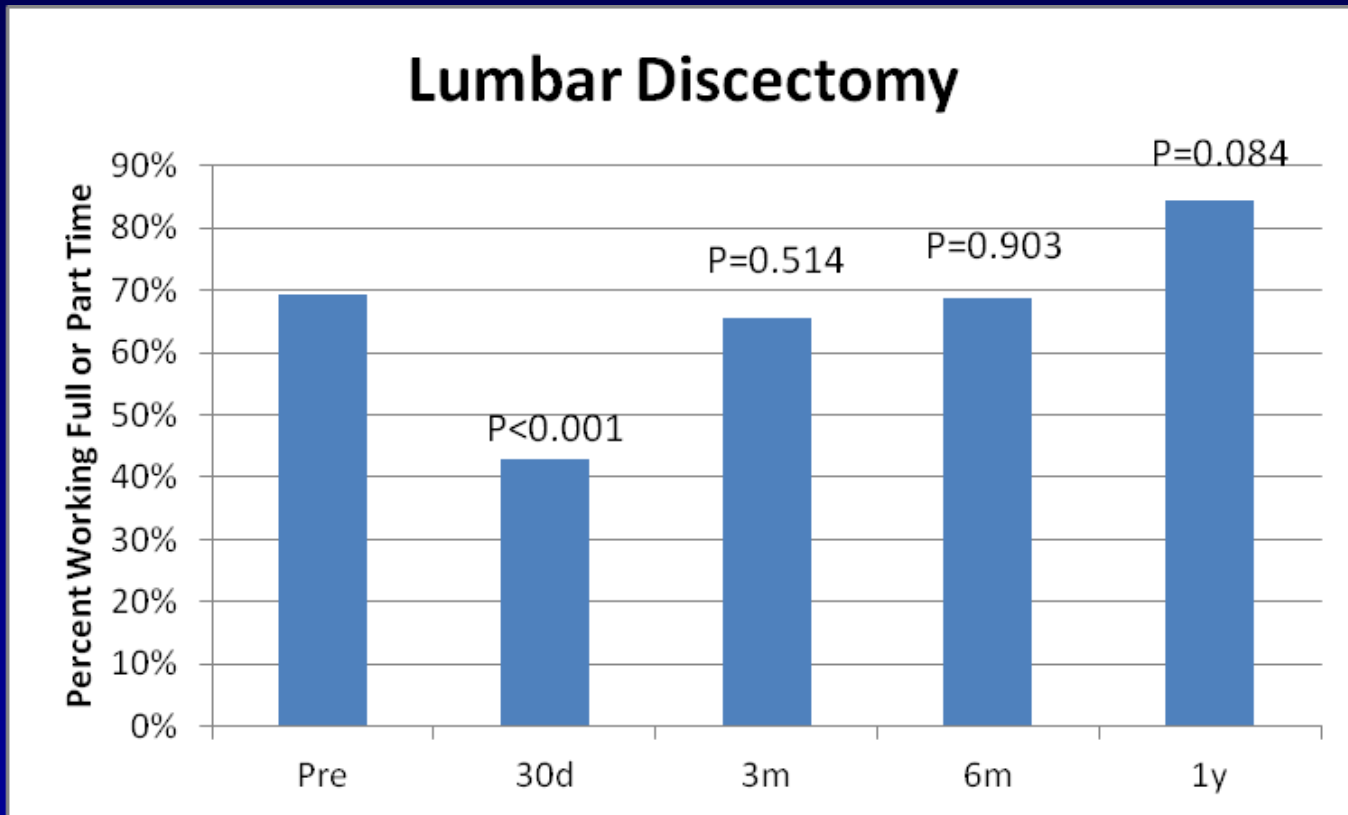
Pre-op Work Status	Total Group N=199	Disc N=153	Spondy N=46
Full Time	110	94	16
Part Time	19	12	7
No Work/Looking	3	1	2
No Work/Able	26	16	10
Disabled	41	30	11

Return to Work

>80% of Patients who were working pre-op
Return to Work by 1 Year

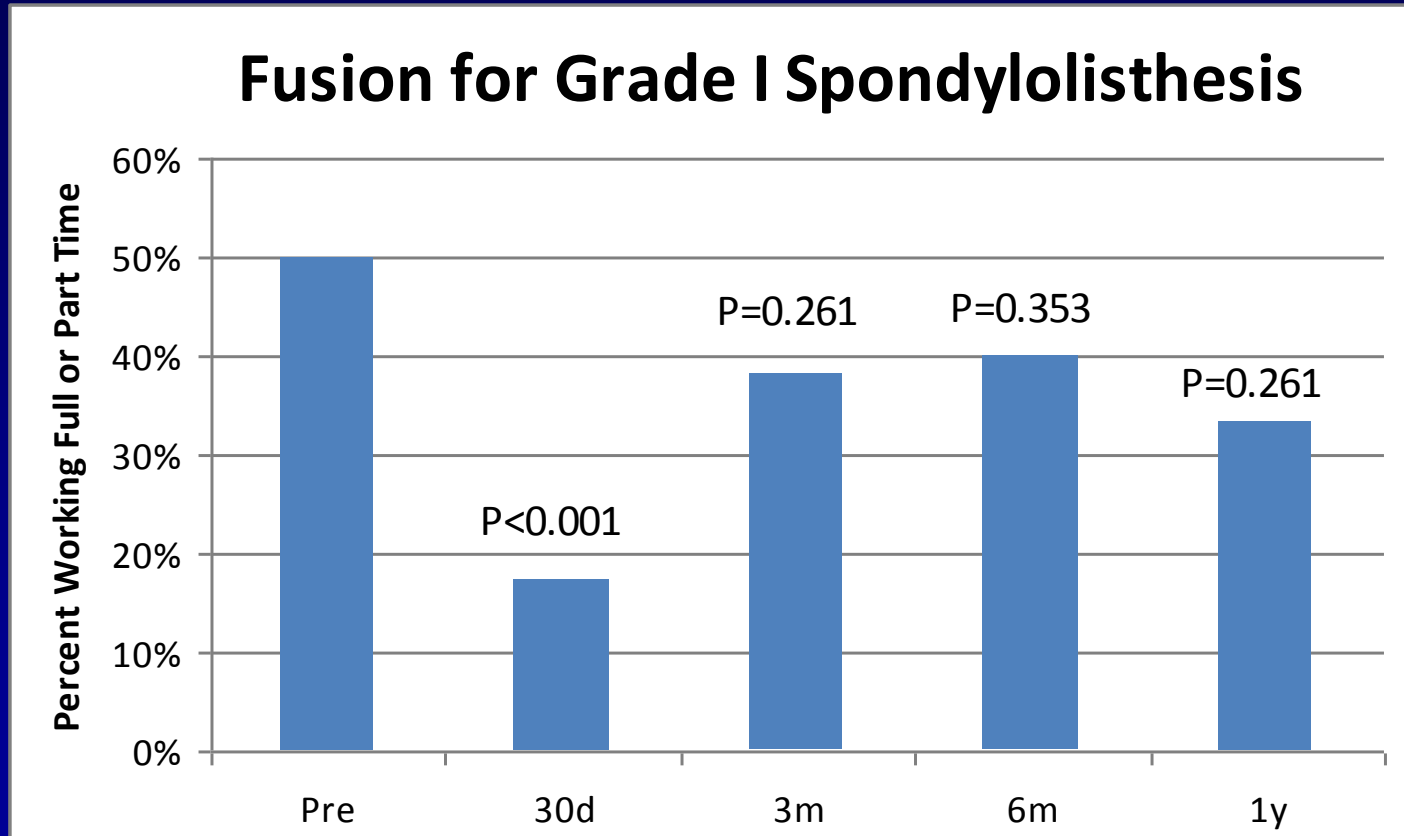


Return to Work

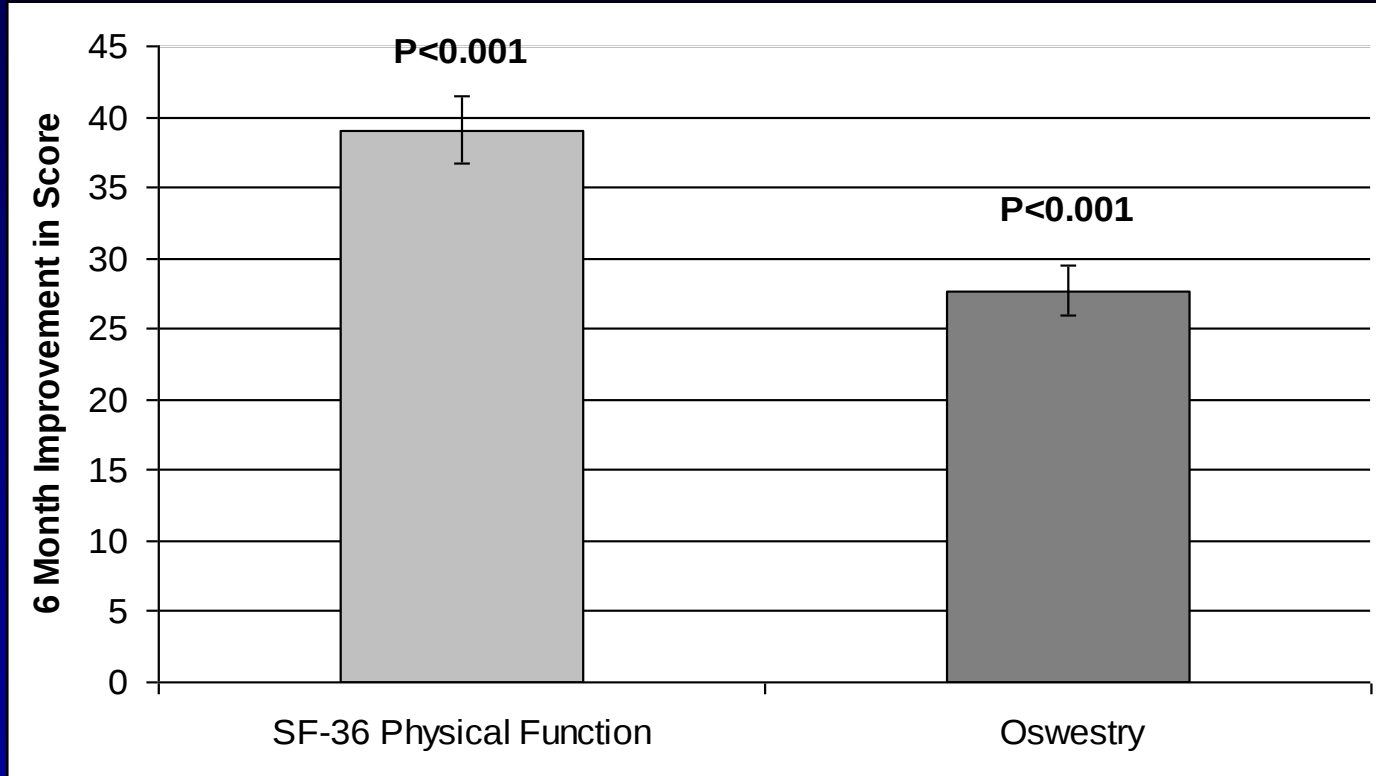


1 year: >80% of entire population is working

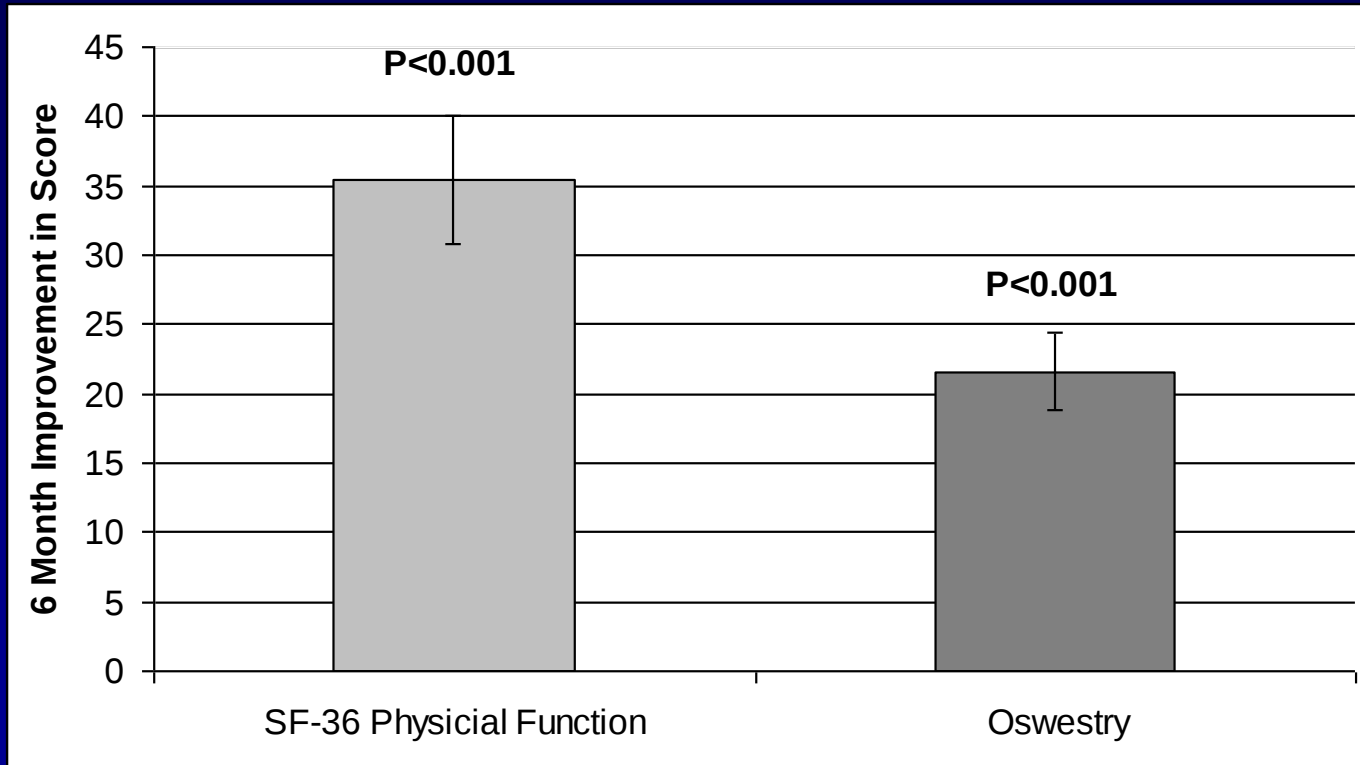
Return to Work



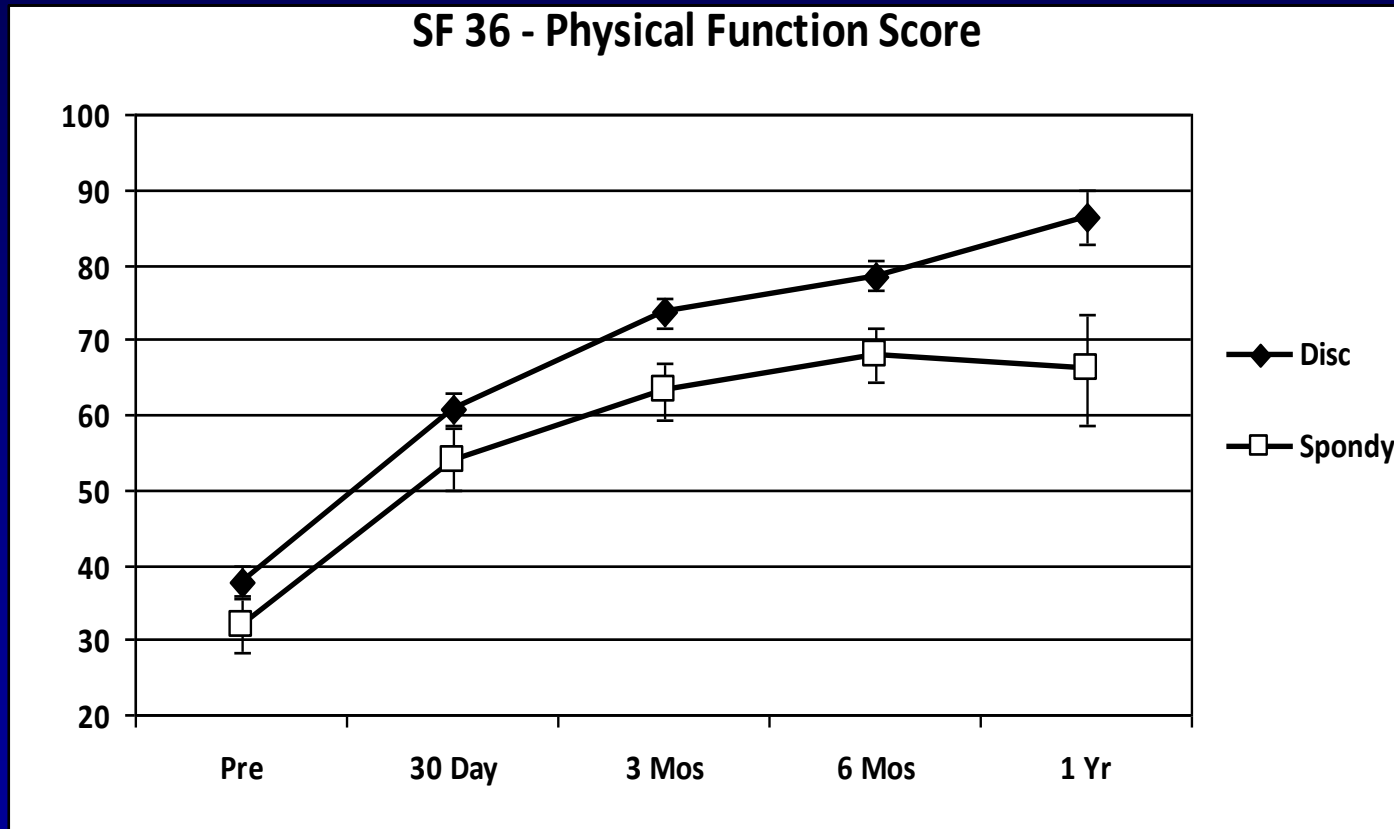
Different population – 50% working at baseline



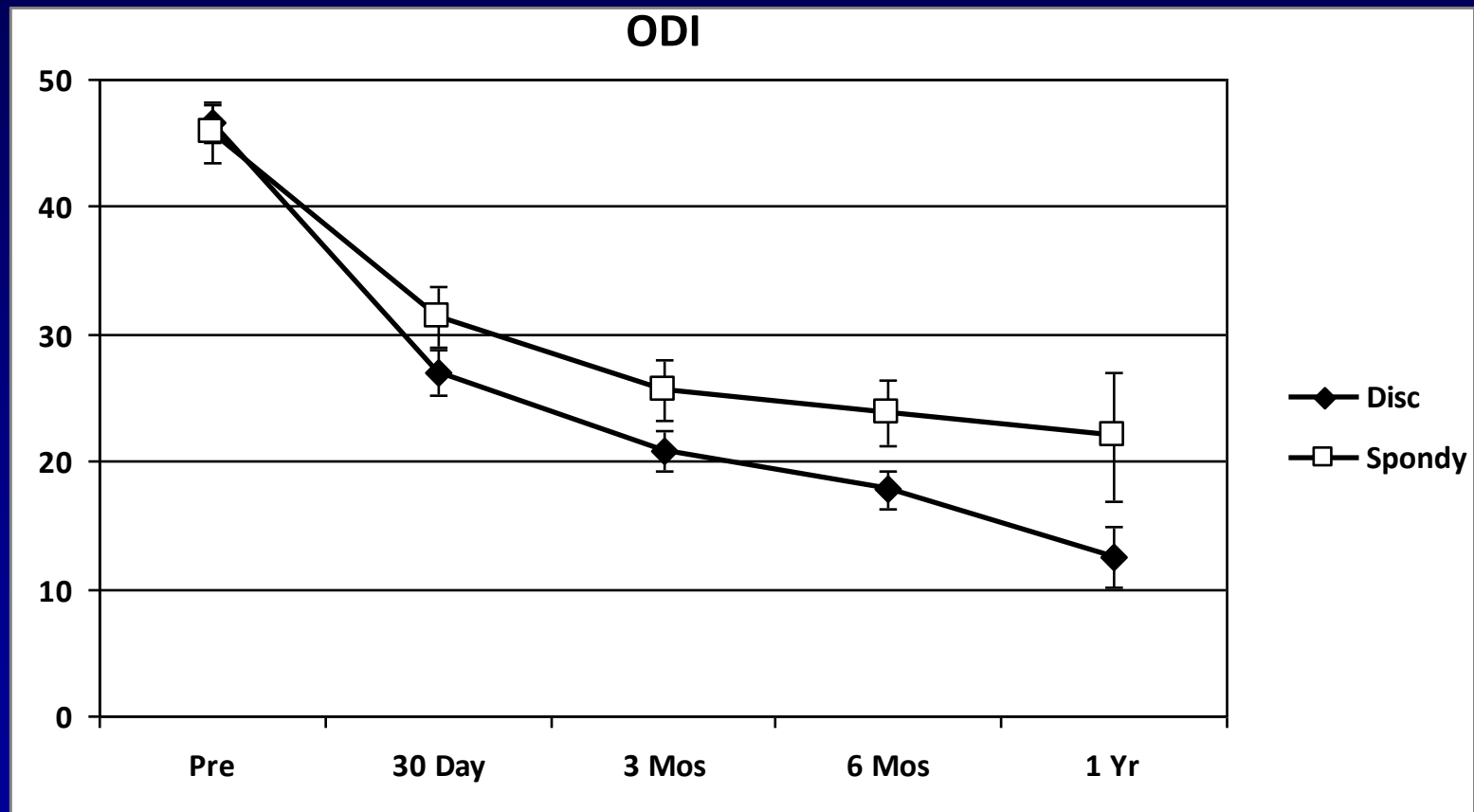
Lumbar Discectomy for Disc Herniation is Effective



**Lumbar Fusion for Grade I
Spondylolisthesis is Effective**



Improvement in SF-36 ($P < 0.001$; both groups)



Reduction in ODI ($P < 0.001$; both groups)

QALYs 1-year Analysis

	Disc N=153	Spondy N=46
QALYs Gained	.256	.208
Cost/QALY	\$ 79,051	\$ 153,548

Were we successful?

- Feasibility: At least **80% follow-up** at 1 year (primary outcome measure –SF36)
- Effectiveness: At least a **20 point** improvement using SF-36 physical function domain score at 1 year

Actual Study Budget

Personnel	\$ 186,000
Patient Care	\$ 0
Site Enrollment	\$ 72,150
SF-36 Licensing Fees	\$ 0
IRB Fees	\$ 21,800
NPA-Web Platform	\$ 89,564
Biostatistics (Yale)	\$ 798
Total	\$ 370,312

The Science of Community Practice

We must recognize that collection of patient-reported outcome will represent a culture change for neurosurgical practice

But, in order to do this, we must minimize impact of clinical work flow

Ultimately, we need strategies to measure outcome without a research coordinator FTE

So, How do we do this?

**Proposed N2QOD Essential – 25 data elements
– focus upon ICD and CPT coding and EQ-5D (QALYs)**

**Leverage EMR technology for data capture
and standardization**

Essential Elements

Demographics: Age, Gender, Date of Surgery

Co-Morbidities: CAD, Diabetes, Smoking
Status, BMI

Diagnosis: ICD-9 code – e.g. 756.12
(spondylolisthesis)

Treatment: CPT code – 22633 (TLIF), 63047
(decompression)

Outcome: ODI, EQ-5D, LOS, Return to Work

Extracting Data from the EMR System

- One recent innovative strategy has used natural language processing to search EMRs for complications.
- In a study of 2974 patients at VA medical centers – natural language processing had greater sensitivity and lower specificity than discharge coding for the identification of complications following surgery.
 - *Murff et al, JAMA, 2011*

Evaluating Safety

- Automated safety surveillance of National Cardiovascular CathPCI Clinical Registry April 2003-2007 in Massachusetts
- 74,427 consecutive coronary procedures
2 implantable devices (Taxus Express drug eluting stent and Angio-Seal STS vascular closure device) had higher than expected complication rates (MI and other vascular complications)

- *Resnic et al, JAMA, 2010*

Observational Medical Outcomes Partnership (OMOP)

- **A public-private partnership launched by the Foundation for the National Institutes of Health in partnership with PhRMA and the FDA**
- **Aim is to identify the most reliable methods for analyzing huge volumes of data drawn from heterogeneous sources**
 - **What can medical researchers learn from accessing new health care databases?**
 - **Could single approach be applied to multiple diseases?**

Current Challenges

- Different EHR Vendors classify and store data differently
- EPIC and Cerner are dominant and so that might represent an opportunity for standardizing EHR extraction strategies
- No matter what strategy is used, capturing health care and outcomes data will need to be accurate and verifiable

Conclusions

1. Providers want risk-adjusted outcome data with reliable cost data
2. Providers need strategies to collect these data to participate in national registries
3. Ultimately, work flow can not be disrupted and data must be extracted from the EHR
4. Patient-reported outcomes assessment must become part of our neurosurgical culture

Providers and Patients can use data to improve decision making

Useful practice data can improve the patient-doctor relationship and build trust



Thank You

