# Comparison of Clinical Outcomes Following Minimally Invasive Lateral Interbody Fusion Stratified by Preoperative Diagnosis

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Minimally Invasive Maximum Results

Institute for Neurosurgical & Spinal Research
The INSPIRE Foundation

# Disclosures

- FDA off-label usage
  - rh-BMP2 (INFUSE, Medtronic Sofamor Danek)
  - CoRoent PEEK cage (NuVasive, Inc.)

- NuVasive, Inc.
  - Consultant
  - Honoraria/travel

# Introduction

- Lumbar fusion for:
  - Degenerative spondylolisthesis: well-accepted, good-excellent outcomes
  - DDD:  more controversial, fair–good outcomes
  - Revisions:  most difficult cases, fair outcomes
    - PLS
    - ASD

# Questions to Answer

- Is there value to an MIS lateral approach in these three groups, and can we detect differences in clinical improvements?
- Do such discrepancies exist in MIS vs. open surgery?
- Is there still value in performing surgery in controversial groups?
- MIS lateral approach may lead to better outcomes in all 3 groups, and may reduce the disparity in clinical improvements seen in open/posterior procedures

# Methods
## Study Overview

- Study Design
  - Prospective observational cohort
    - Prospective registry (data managed by PhDx)
  - Retrospective Review

- Inclusion Criteria
  - Consecutive patients treated between 2006-2011 (*n*=160)
  - Failure of conservative treatment
  - MIS lateral IBF at or above L4-5
  - Available for long-term follow-up

# Methods

## Indications for Surgery

- Degenerative spondylolisthesis (DS, *n*=68)
  - No previous surgery
  - Grade 1 or Grade 2
- Degenerative disc disease (DDD, *n*=20)
  - No previous surgery
  - Internal desiccation, >50% collapse, and/or Modic endplate changes
- Adjacent segment disease (ASD, *n*=26)
  - Instability/listhesis and/or disc degeneration
- Post laminectomy/discectomy (PLS, *n*=46)
  - Recurrent HNP, instability/listhesis, and/or disc degeneration

Revision (*n*=72)

# Methods

## Patient Samples

| | REVISION (*n*=72) | DDD (*n*=20) | DS (*n*=68) | p-value |
|---|---|---|---|---|
| **Follow-Up (months)** – *mean ± SD* | 14.5 ± 8.4 | 13.4 ± 8.9 | 15.0 ± 10.3 | 0.247 |
| **Age (years)** – *mean ± SD* | 61.6 ± 12.3 | 47.8 ± 10.2 | 63.3 ± 9.1 | **<0.001*** |
| **Female** – *n (%)* | 43 (59.7) | 12 (60.0) | 51 (75.0) | 0.132 |
| **BMI (kg/m$^2$)** – *mean ± SD* | 28.0 ± 4.5 | 27.7 ± 5.9 | 28.2 ± 5.4 | 0.894 |
| **Tobacco Use** – *n (%)* | 24 (33.3) | 9 (45.0) | 26 (38.2) | 0.604 |
| **Co-Morbidities Type** – *n (%)* | | | | |
| Diabetes | 20 (27.8) | 3 (15.0) | 13 (19.1) | 0.326 |
| Depression | 20 (27.8) | 3 (15.0) | 12 (17.6) | 0.255 |

# Methods

## Surgical Summary

| | REVISION (*n*=72) | DDD (*n*=20) | DS (*n*=68) | p-value |
|---|---|---|---|---|
| **Disc Levels Treated** – *mean ± SD* | 1.3 ±0.6 | 1.2 ± 0.5 | 1.1 ± 0.4 | 0.077 |
| **Add'l Post. Procedure** – *n (%)* | 61 (84.7) | 12 (60.0) | 68 (100.0) | **<0.001*** |
| Instrument. Only | 32 (44.4) | 8 (40.0) | 33 (48.5) | |
| Decomp. Only | 1 (1.4) | 0 (0.0) | 0 (0.0) | |
| Instrument. + Decomp. | 28 (38.9) | 4 (20.0) | 35 (51.5) | |
| **OR Time (min)** – *mean ± SD* | 195.4 ± 84.7 | 150.8 ± 69.6 | 156.7 ± 93.0 | 0.088 |
| **EBL (mL)** – *mean ± SD* | 77.6 ± 46.1 | 49.4 ± 35.9 | 75.7 ± 83.0 | 0.261 |
| **LOS (days)** – *mean ± SD* | 1.3 ± 0.8 | 1.1 ± 0.2 | 1.4 ± 1.0 | 0.233 |

# Methods
## Analysis

- Clinical Outcomes
  - ODI
  - NRS (LBP & LP)
  - SF-36 (PCS & MCS)
  - Patient satisfaction
- Analysis
  - Chi-squared/Fishers' Exact tests and one-way ANOVA
  - Post hoc Tukey's Range test for pairwise comparisons
  - Generalized linear mixed models with compound symmetric covariance structures
  - Significance accepted for

# Results

## Adverse Events

| | REVISION (*n*=72) | DDD (*n*=20) | DS (*n*=68) | Total (*n*=160) |
|---|---|---|---|---|
| **Major** | None | None | Myocardial infarction 1<br>**Total: 1 (1.5%)** | **1 (0.6%)** |
| **Minor** | Incidental durotomy 4<br>Transient DF weakness 3<br>Urinary retention 2<br>Anemia requiring transfusion 2<br>Vertebral body fracture 2<br>Superficial wound dehiscence 1 | UTI 1 | Superficial wound dehiscence 2<br>Urinary incontinence 1<br>Urinary retention 1<br>Anemia requiring transfusion 1 | **20 (12.5%)** |
| | **Total: 14 (19.4%)** | **Total: 1 (5.0%)** | **Total: 5 (7.4%)** | |

**p<0.001**

# Results

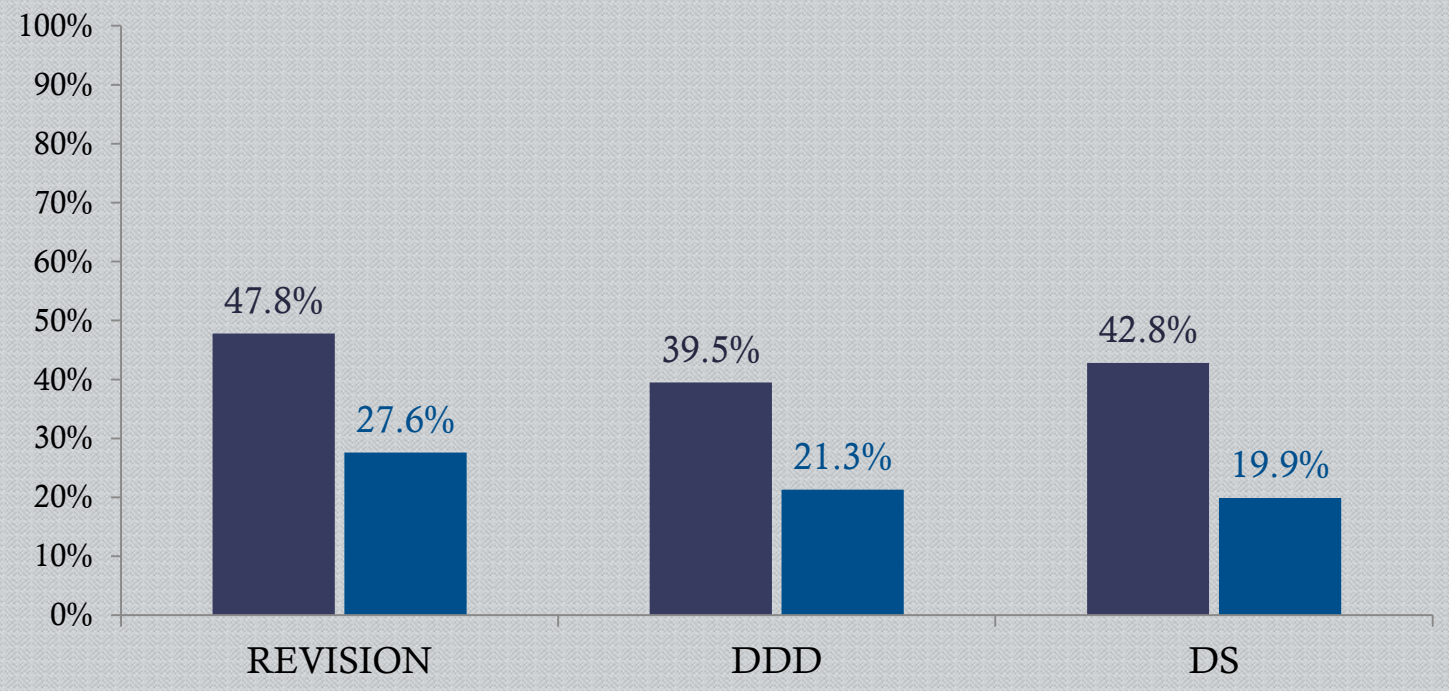
## Side Effects

| | REVISION (*n*=72) | DDD (*n*=20) | DS (*n*=68) | Total (*n*=160) |
|---|---|---|---|---|
| **Side Effects** | Approach-related thigh/groin pain 7<br>Hip flexion weakness 3<br>**Total: 10 (13.9%)** | None | Approach-related thigh/groin pain 14<br>Hip flexion weakness 9<br>**Total: 25 (36.8%)** | **35**<br>**(21.9%)** |

Resolved by 10 days to 6 months PO.

# Results

## Clinical Outcomes: ODI

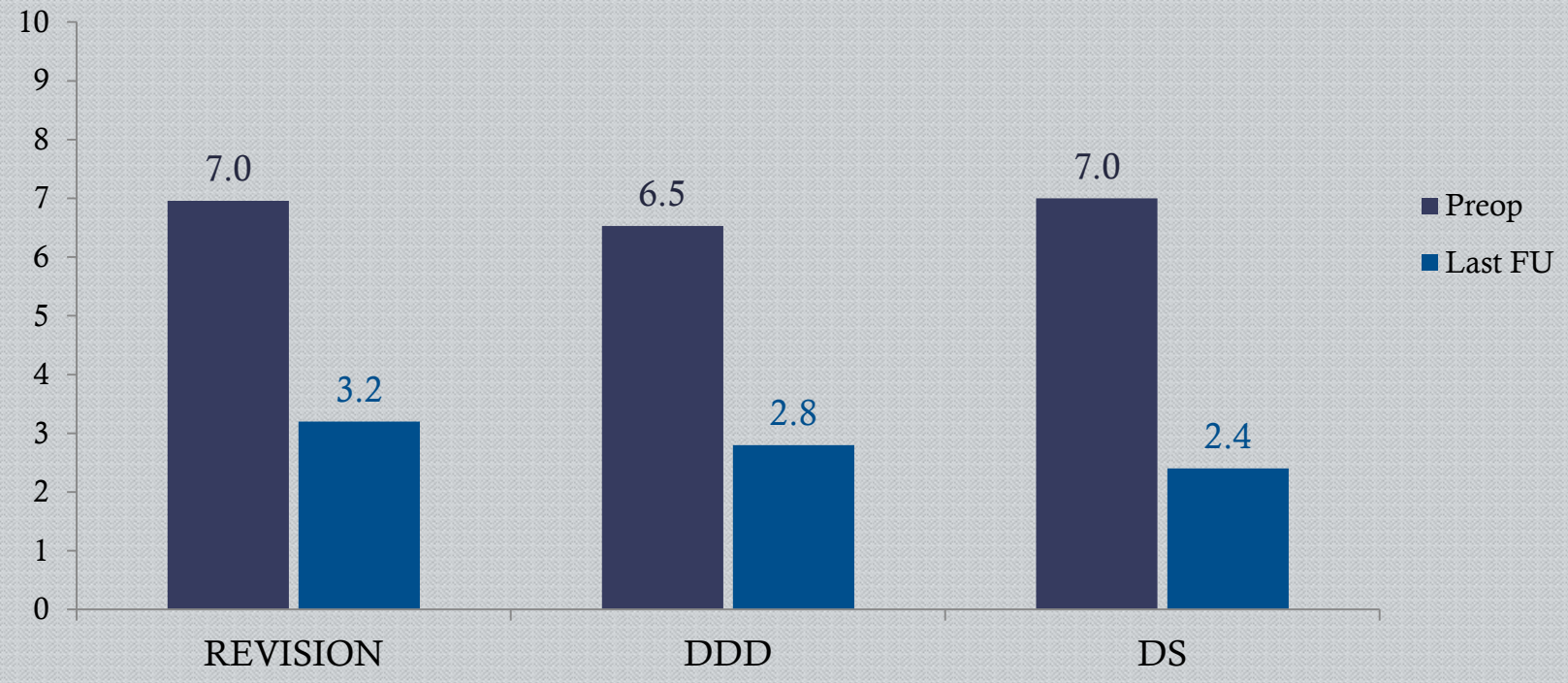



| | REVISION | DDD | DS | |
|---|---|---|---|---|
| **% Improvement:** | 42.3% | 46.1% | 53.5% | p = **0.025*** |

REVISION v. DS (p=**0.036***)

# Results

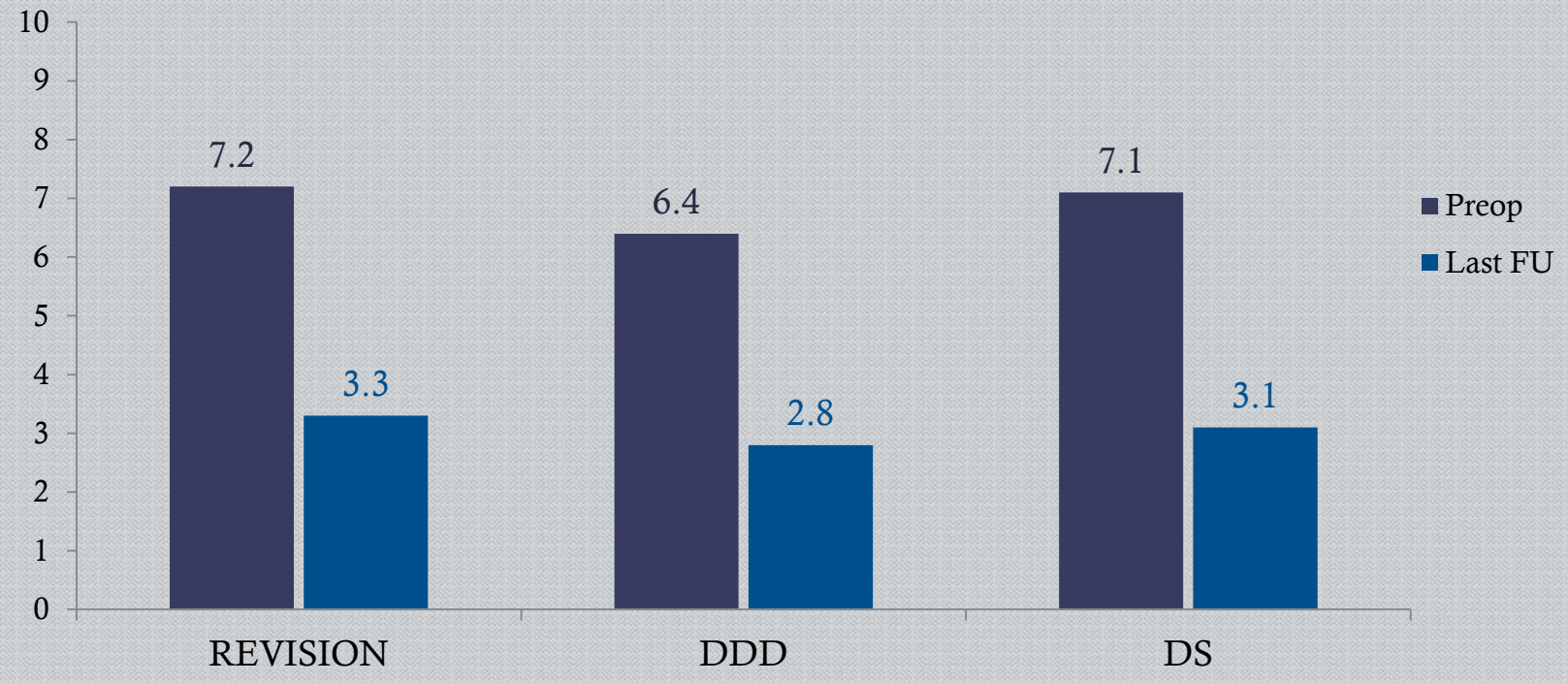
## Clinical Outcomes: NRS LBP




| | | | | |
|---|---|---|---|---|
| **% Improvement:** | 54.3% | 56.9% | 65.7% | p = 0.411 |

# Results

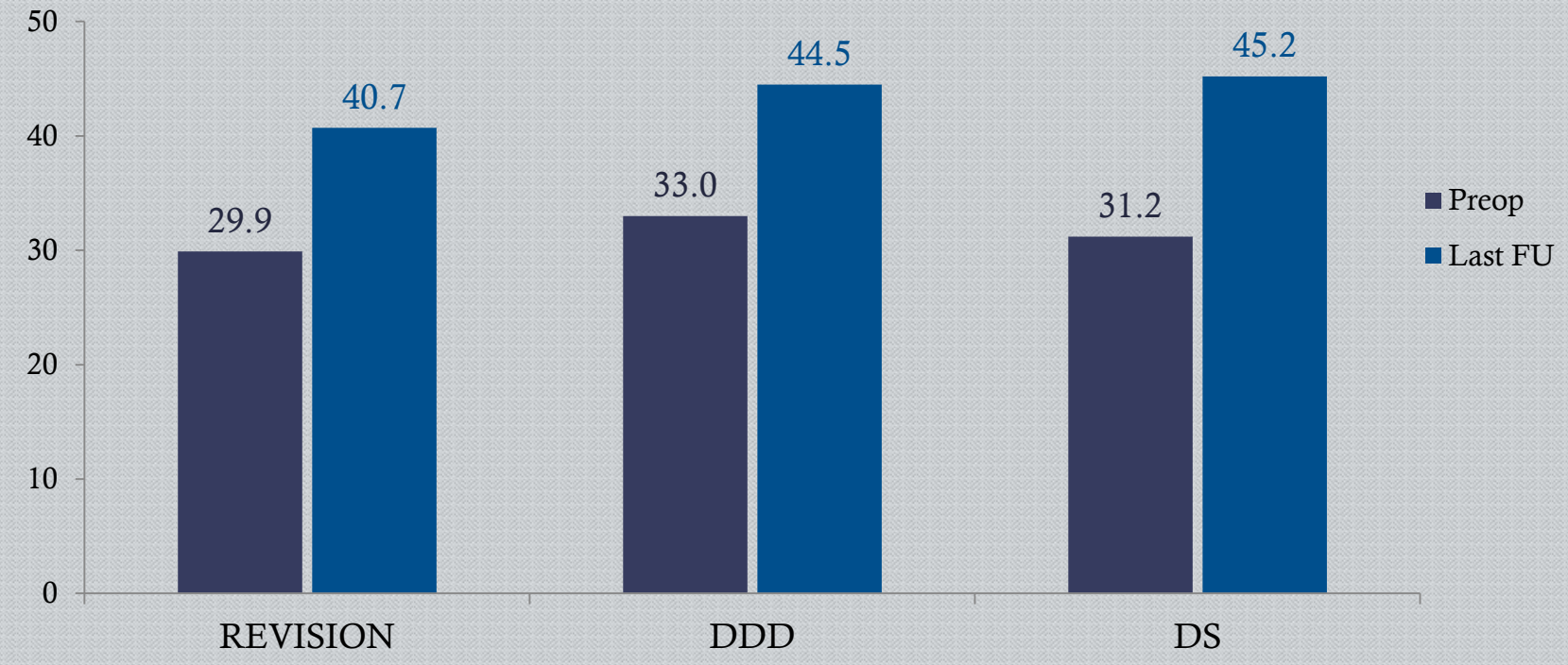
## Clinical Outcomes: NRS LP




| | | | | |
|---|---|---|---|---|
| **% Improvement:** | 54.2% | 56.3% | 56.3% | p = 0.486 |

# Results

## Clinical Outcomes: SF-36 PCS

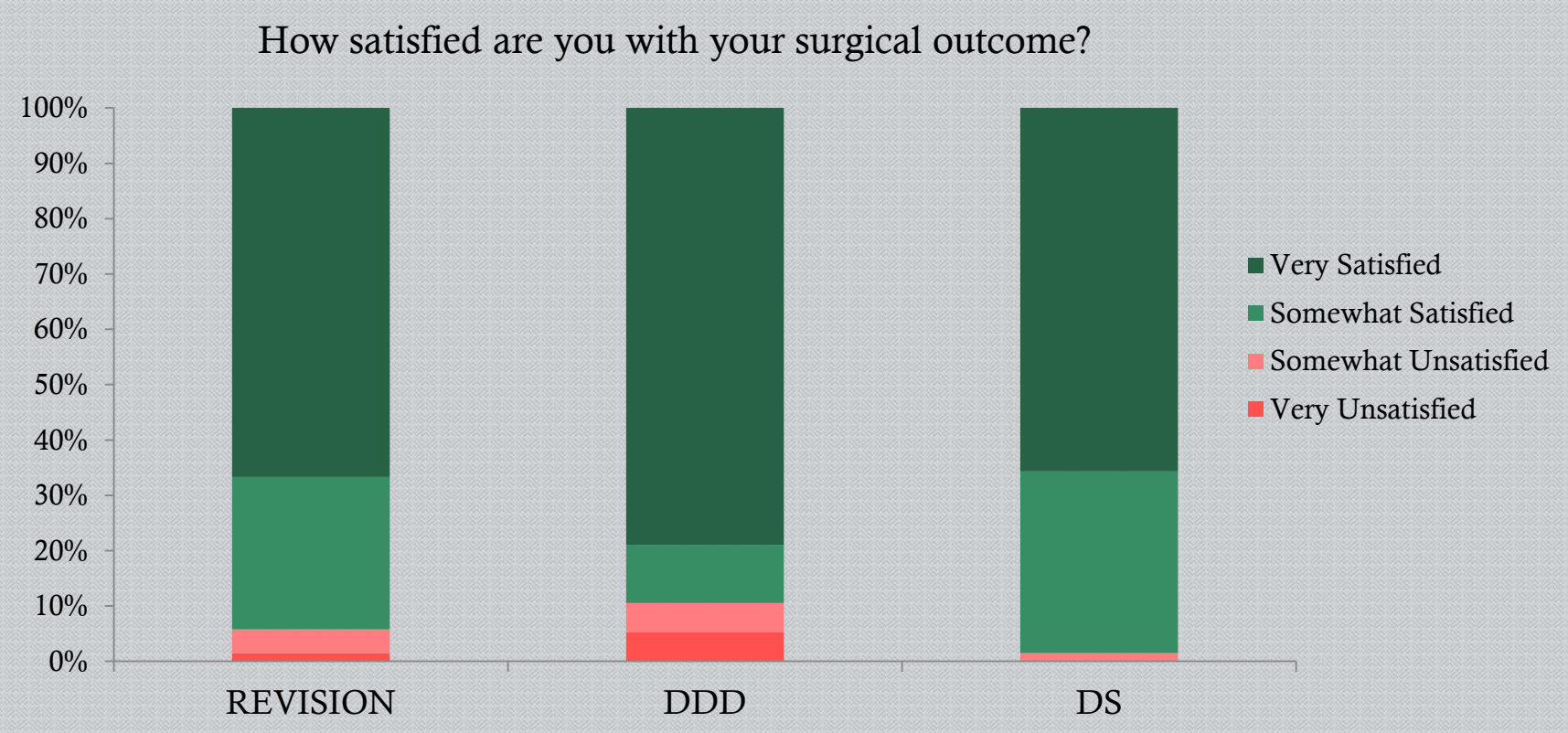



| | | | | |
|---|---|---|---|---|
| **% Improvement:** | 33.8% | 34.8% | 44.9% | p = **0.047*** |

REVISION v. DS (p=**0.037***)

# Results

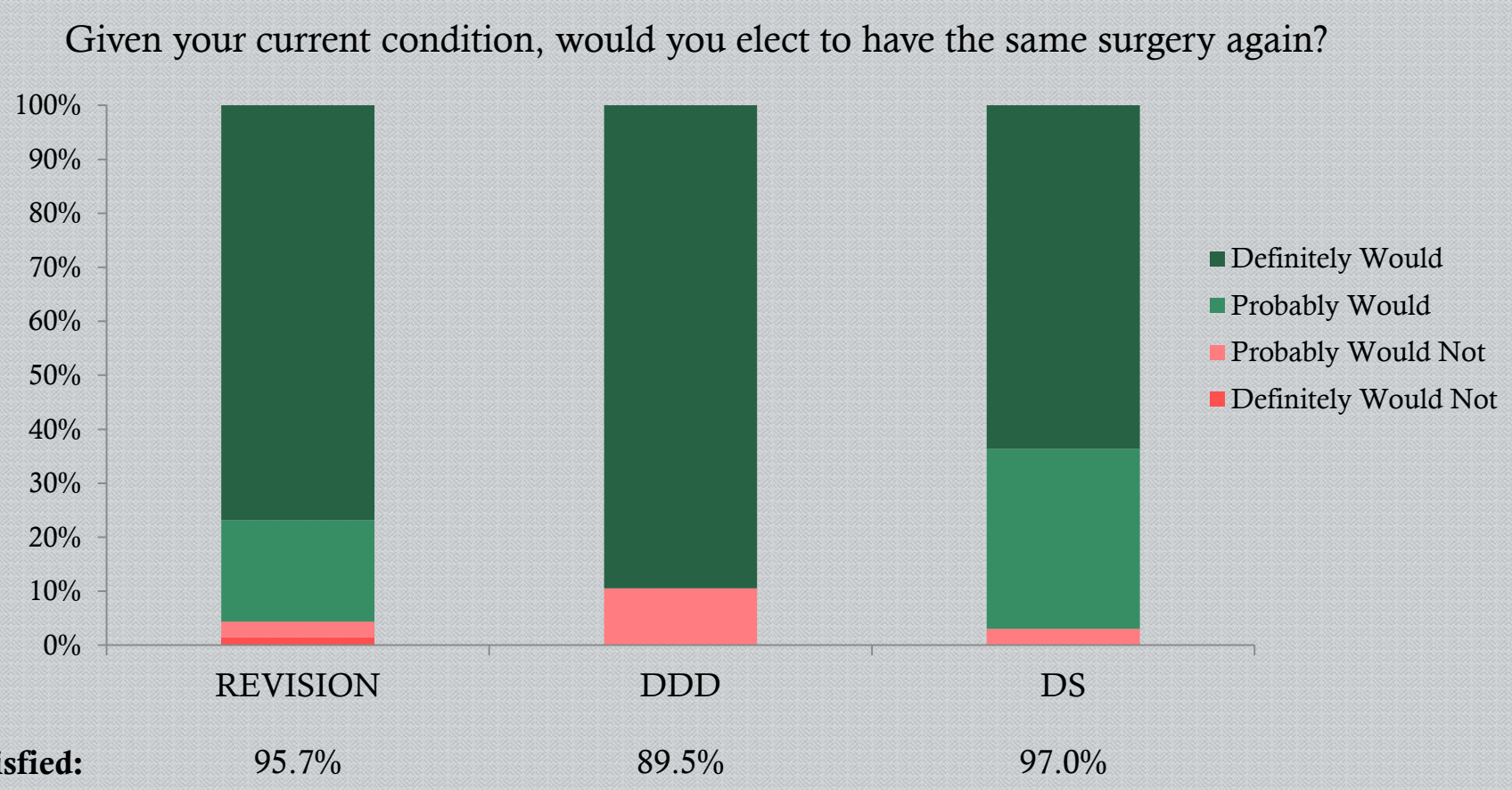
## Patient Satisfaction




| | REVISION | DDD | DS |
|---|---|---|---|
| **% Satisfied:** | 94.2% | 89.5% | 98.5% |

# Results

## Patient Satisfaction

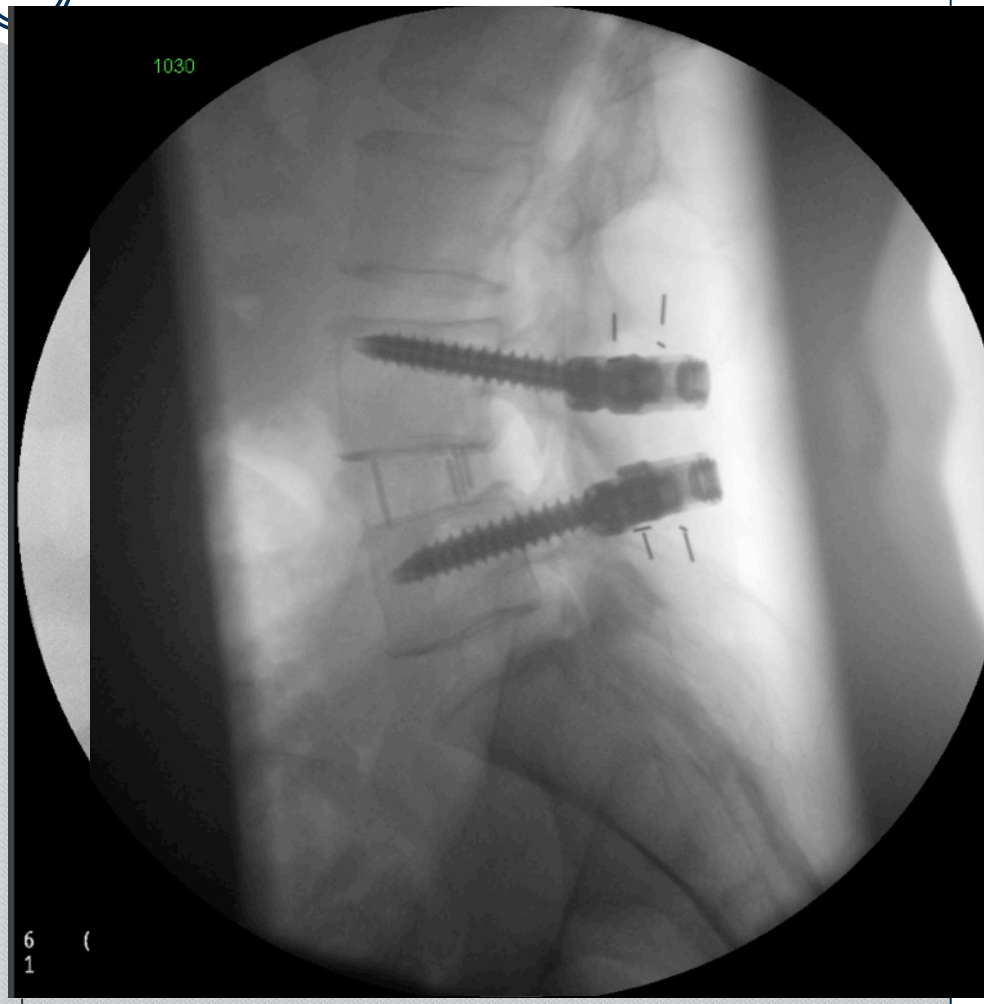



| | REVISION | DDD | DS |
|---|---|---|---|
| **% Satisfied:** | 95.7% | 89.5% | 97.0% |

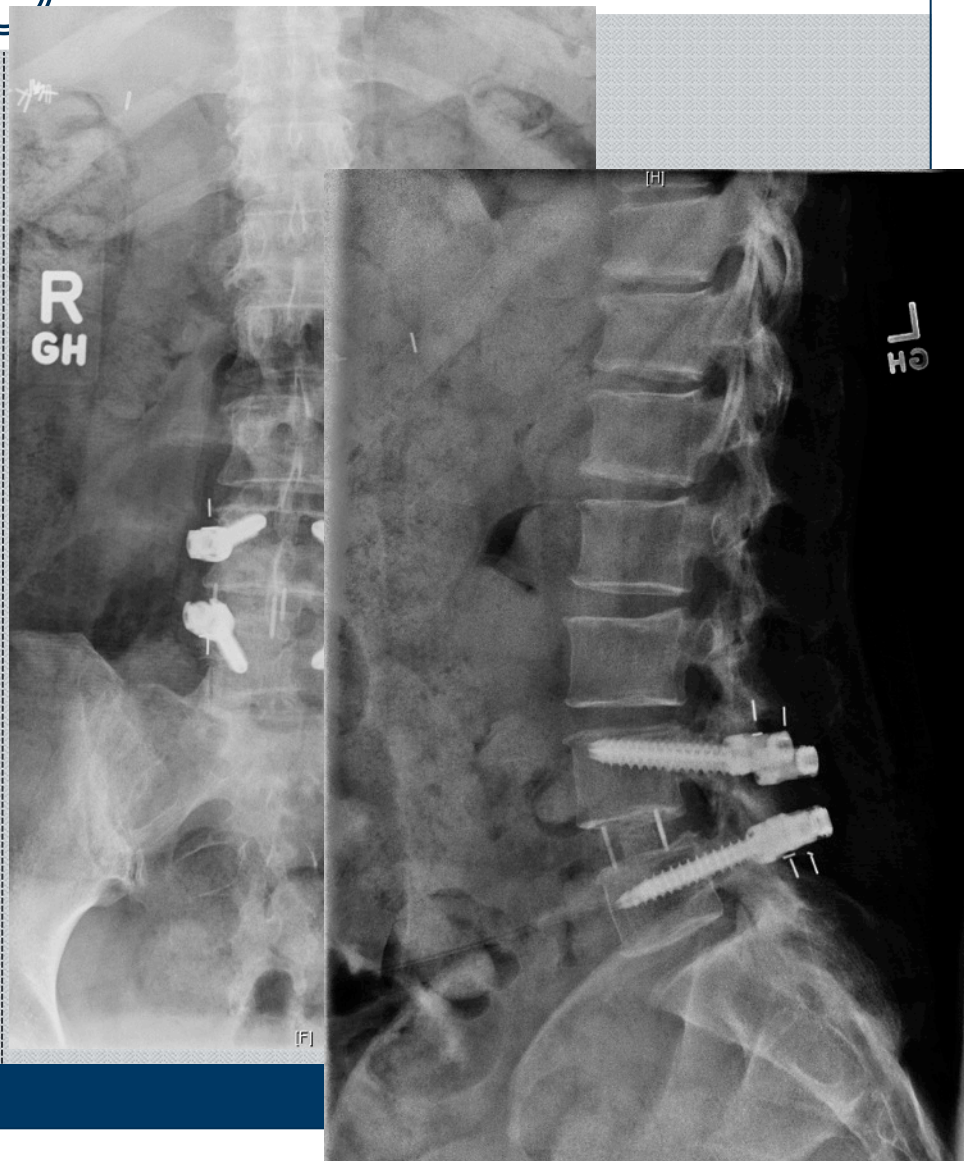
# Case Example: Degenerative Spondylolisthesis

- 66 y/o female
- CC:
  - 10 months progressively worsening LBP
  - Bilateral anterolateral thigh pain
  - Right quad weakness 4/5
- PMHx: DM, HTN, FM
- L4-5 spondylolisthesis
  - Grade I
  - L4-5 foraminal stenosis

- Procedure
  - L4-5 lateral IBF
  - L4-5 bilateral pedicle screws/rods

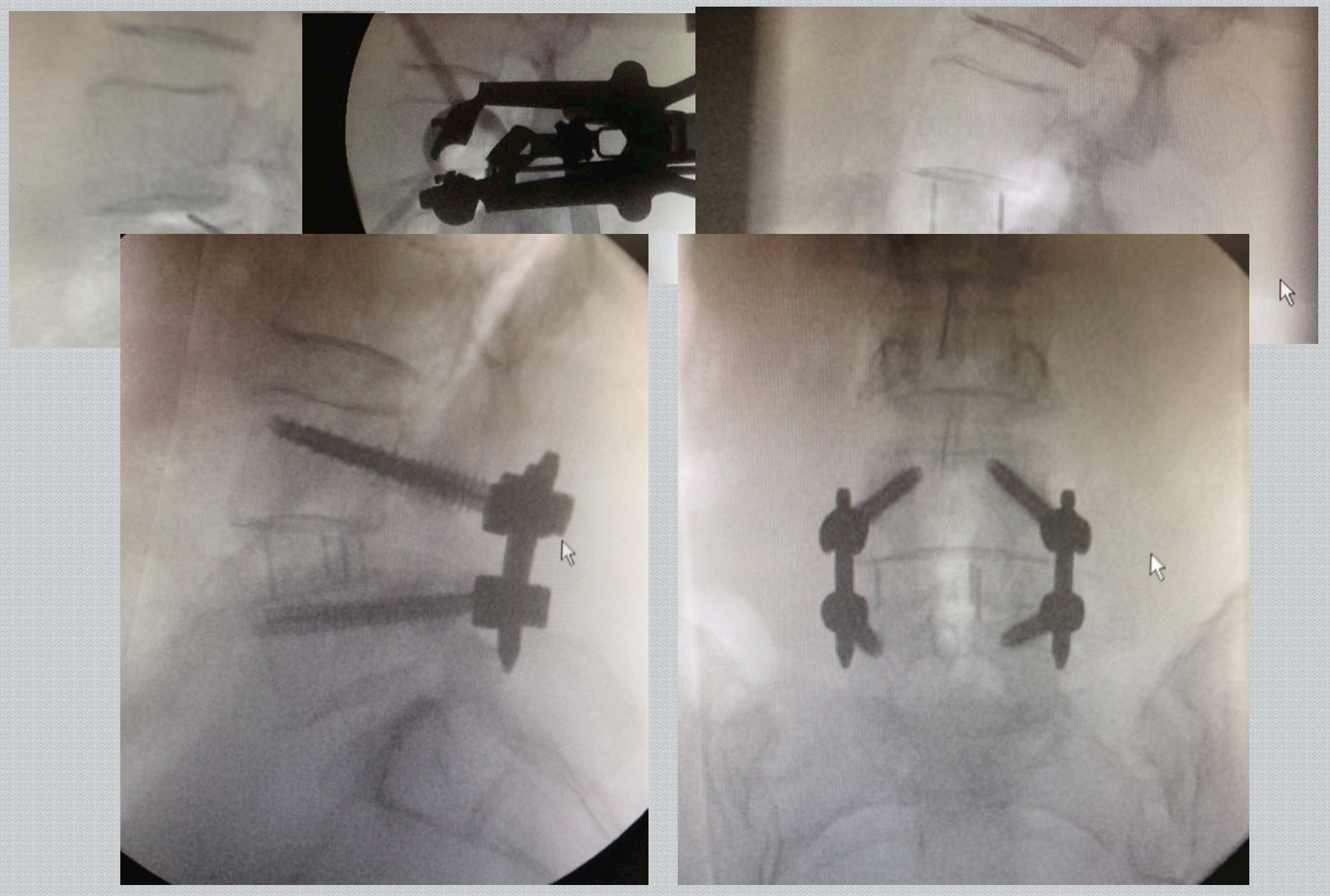


- Patient was discharged POD #1
- Pre-operative quad weakness resolved



- Patient was last seen at the 2 yr follow-up visit
- Outcomes
  - ODI 62 → 2
  - VAS LBP 10 → 0
  - VAS leg 10 → 8
  - PCS 26.4 → 57.9
  - MCS 33.5 → 54.4
- Patient satisfaction
  - Very satisfied with outcome
  - Definitely would do again

71 yo F years of LBP rad B/L LEs.  MRI mod stenosis, lat recess stenosis



# Case Example 3

## Degenerative Disc Disease

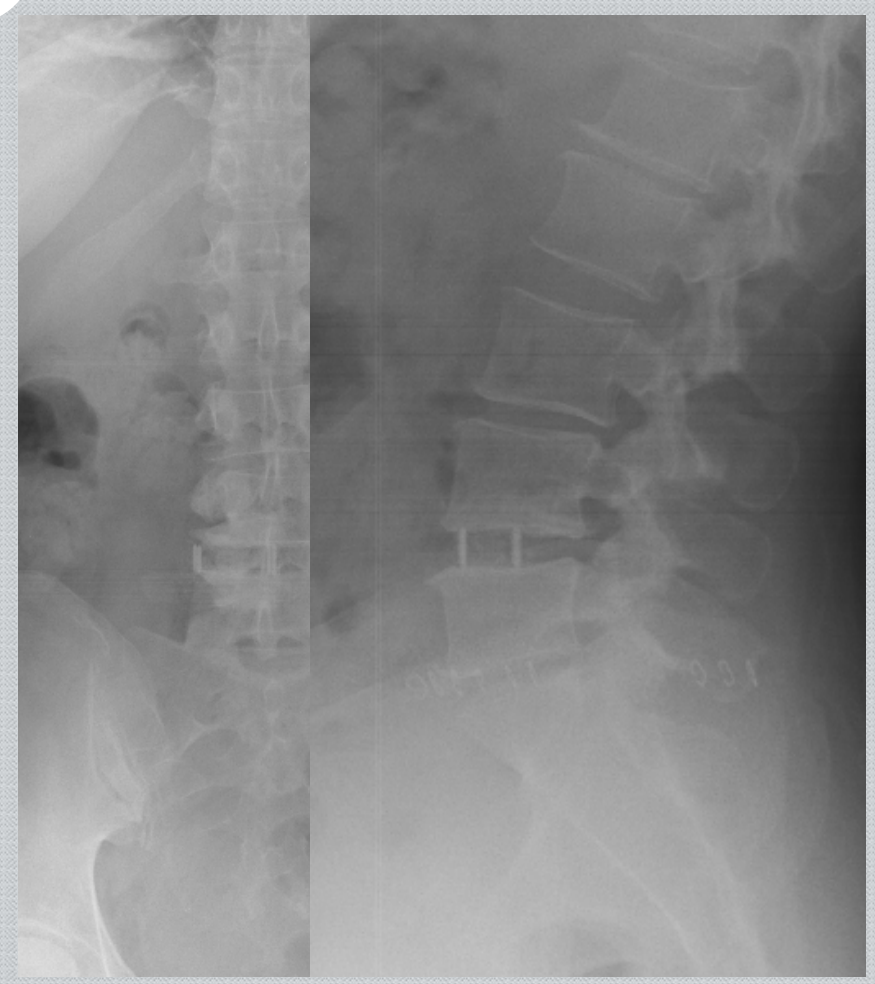
- 49 y/o female
- CC:
  - 7 MO LBP after work injury
- PMHx:
  - HTN
  - Depression
- L4-5 severe DDD
  - Disk space collapse
  - Modic endplate changes

# Case Example 3
## Degenerative Disc Disease

- Procedure
  - L4-5 lateral IBF
  - Standalone

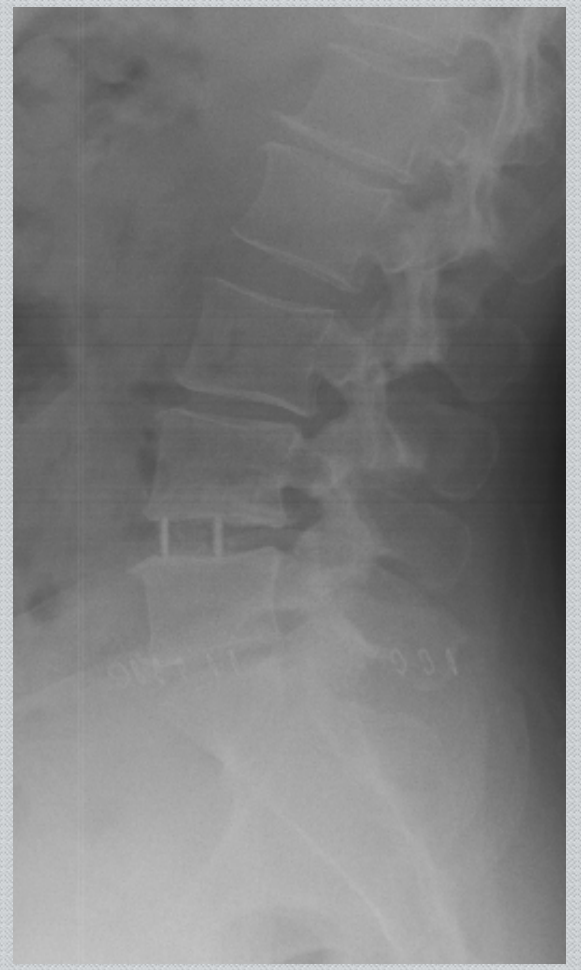
# Case Example 3
## Degenerative Disc Disease

- Patient was discharged POD #1



# Case Example 3

## Degenerative Disc Disease



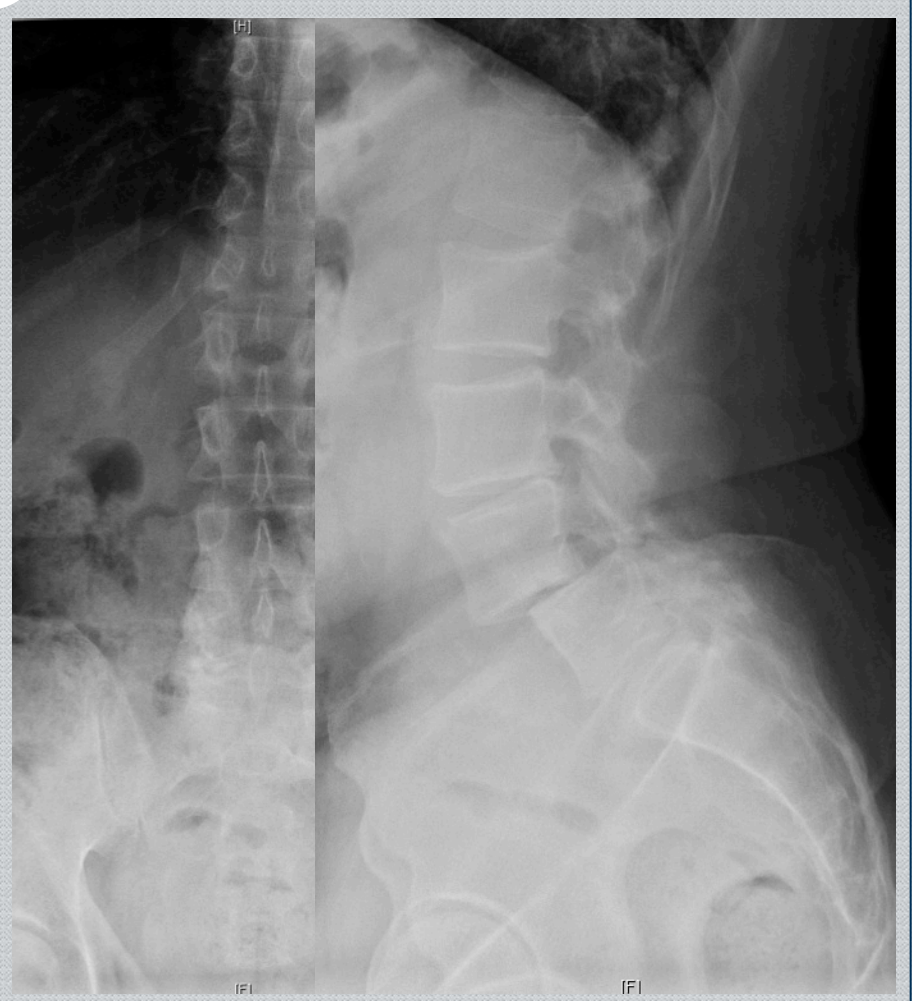
# Another DDD



L1
L2
L3
L4
L5

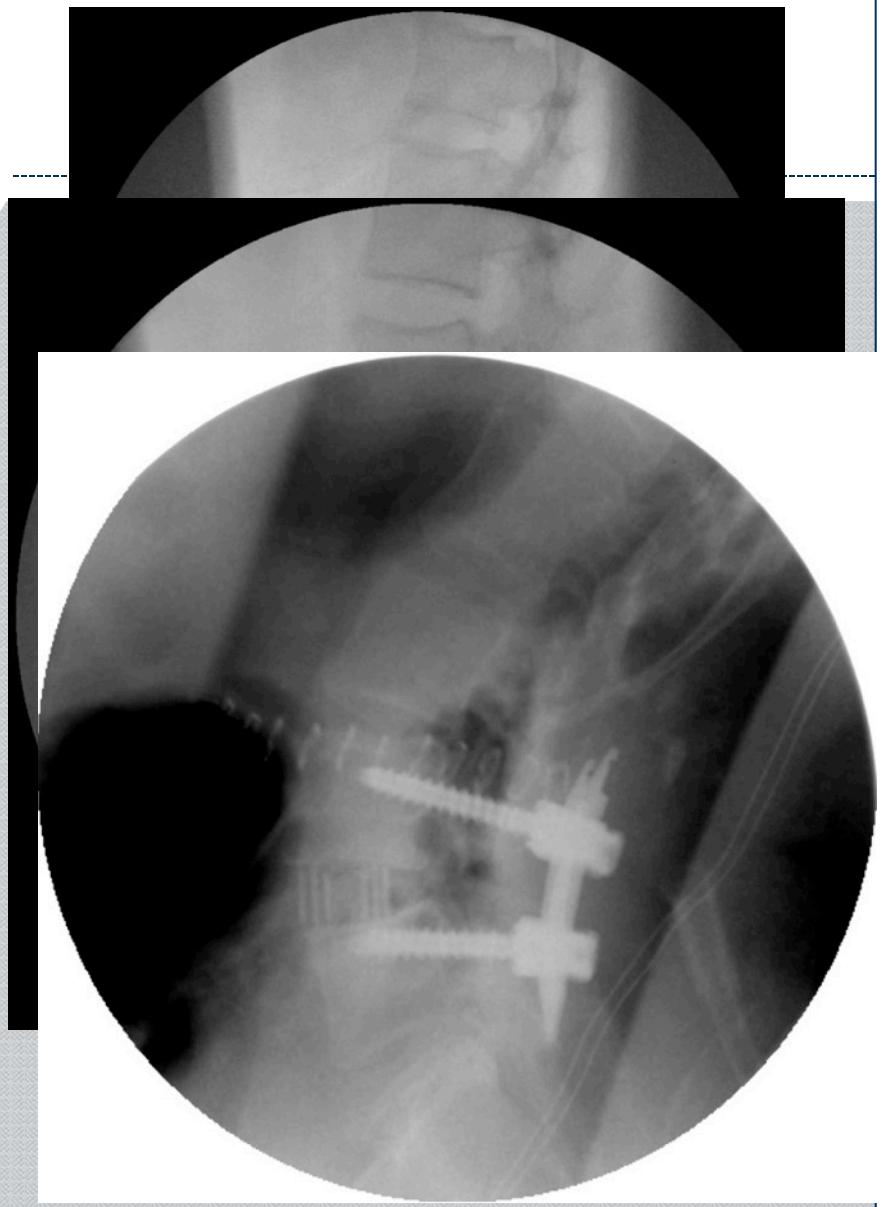
# Case Example: Post Lam syndrome (spondy)

- 58 y/o male
- CC/PMHx:
  - 2007: laminectomy + left facectectomy for LBP + bilat LE pain
  - Left LE improved, right did not
  - Repeat surgeries May + Aug 2008, no relief
- L4-5 PLS
  - Grade II spondylolisthesis
  - Instability on flex/ext



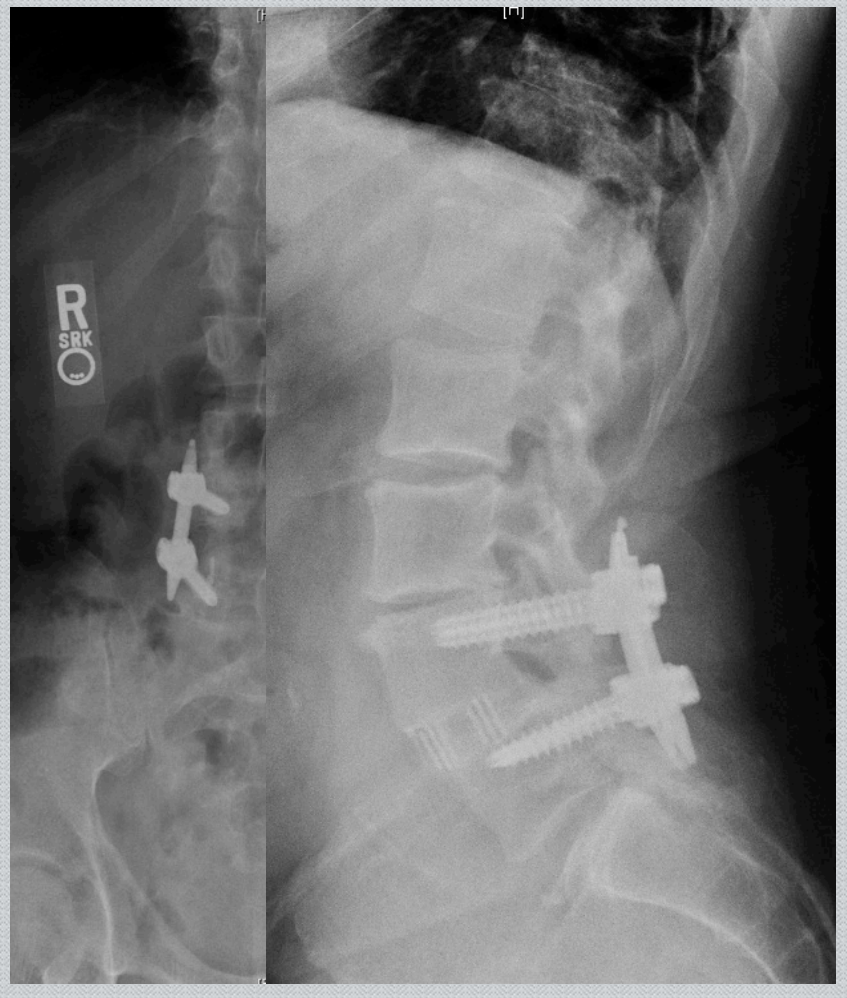
# Case Example 6
## Post-Laminectomy Syndrome

- Procedure
  - L4-5 Lateral IBF
  - L4-5 bilateral pedicle screws/rods

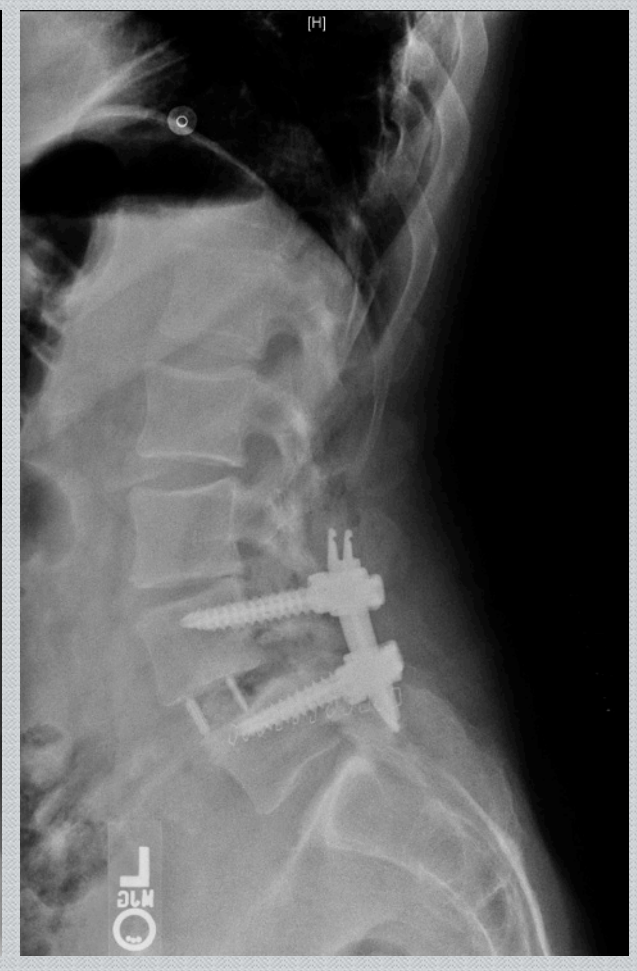


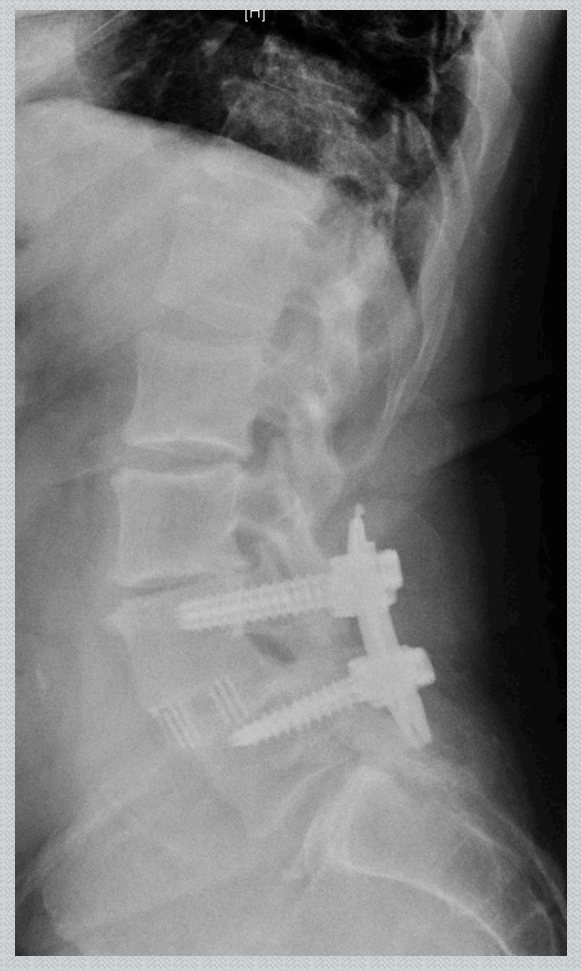
- Patient was discharged POD 1
- No new neurologic deficits or complaints

- Patient was last seen at the 4 yr follow-up visit
- Outcomes
  - ODI 32 → 2
  - VAS LBP 4 → 1
  - VAS leg 9 → 0
  - PCS 34.7 → 55.2
  - MCS 34.5 → 40.2
- Patient satisfaction
  - Very satisfied with outcome
  - Definitely would do again




[F]


[H]


[H]

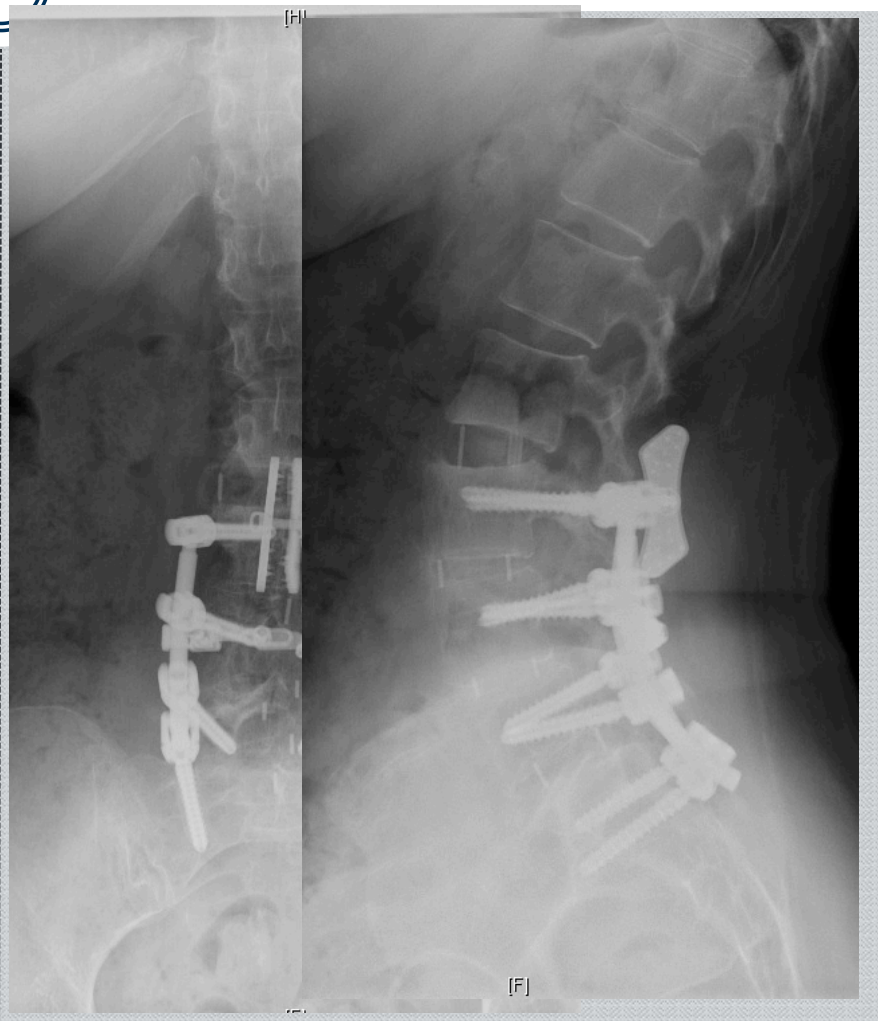
# Case Example: Adjacent Segment Disease

- 56 yo female
- CC/PMHx:
  - 2006: L3-S1 TLIF + bilateral pedicle screw/rod
  - Awoke with new right L4 radiculopathy
  - 6 months of new anterior thigh/groin pain
- L2-3 ASD
  - Retrolisthesis w/ instability on lateral bending
  - Persistent L4-5 right foraminal stenosis

- Procedure
  - L2-3 lateral IBF
  - L2-3 spinous process plate
  - L4-5 right decompression

- Patient was discharged POD #1
- No new neurologic deficits or complaints

- Patient was last seen at the 6 MO follow-up visit
- Outcomes
  - ODI 36 → 20
  - VAS LBP 9 → 5
  - VAS leg 9 → 7
  - PCS 26.3 → 40.2
  - MCS 43.1 → 62.7
- Patient satisfaction
  - Very satisfied with outcome
  - Definitely would do again




PRE


POST


LAST

# Discussion: Comparative Studies

ELSEVIER

The Spine Journal 9 (2009) 13–21

THE SPINE JOURNAL

2008 Outstanding Paper Award Runner-up

## Lumbar fusion outcomes stratified by specific diagnostic indication

Steven D. Glassman, MD[a,b,*], Leah Y. Carreon, MD, MSc[b], Mladen Djurasovic, MD[a,b], John R. Dimar, MD[a,b], John R. Johnson, MD[a,b], Rolando M. Puno, MD[a,b], Mitchell J. Campbell, MD[a,b]

[a]*Department of Orthopaedic Surgery, University of Louisville School of Medicine, 210 East Gray Street, Suite 900, Louisville, KY 40202, USA*
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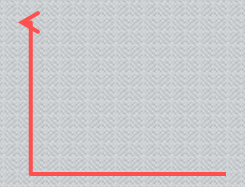
Received 4 January 2008; accepted 5 August 2008

# Discussion: Comparative Studies

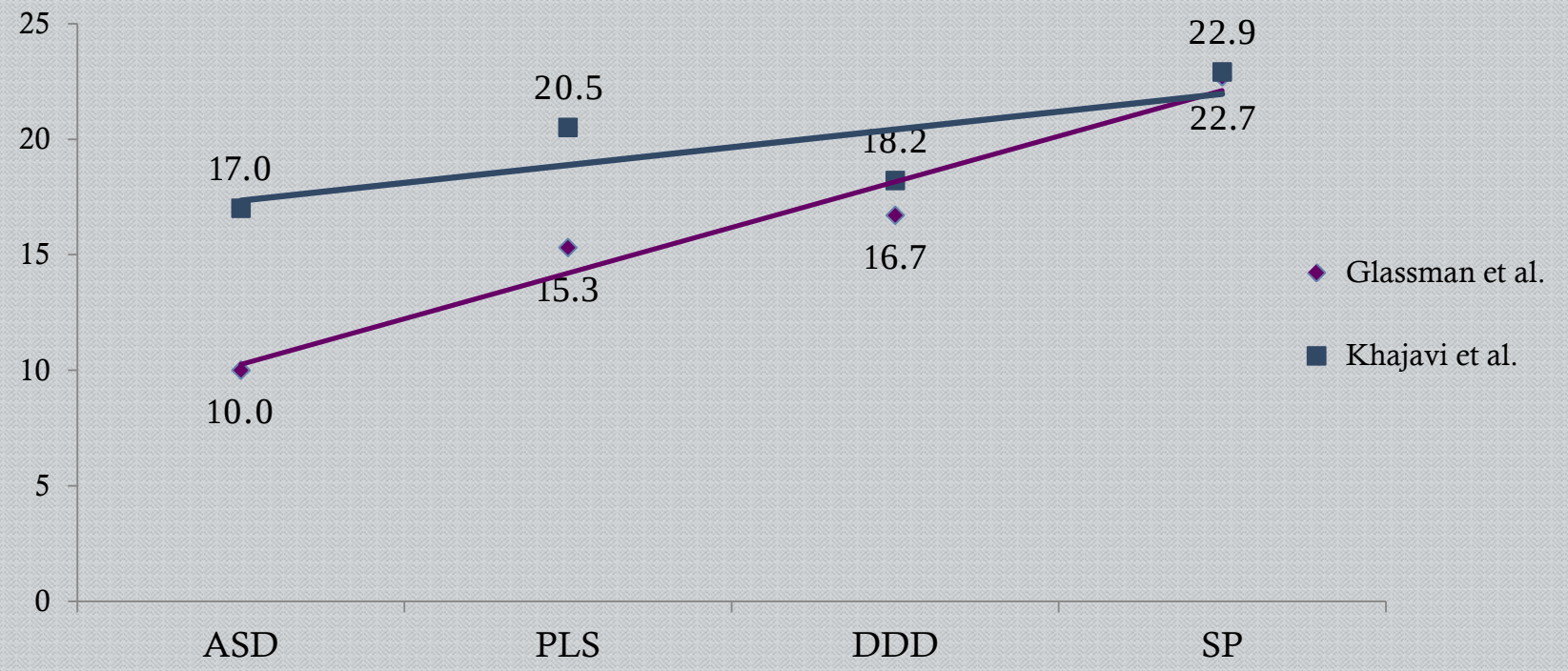
| | Glassman et al. | Khajavi et al. |
|---|---|---|
| Adjacent Segment | *n*=40 | *n*=26 |
| Post Decompression | *n*=67 | *n*=46 |
| Degenerative Disc | *n*=33 | *n*=20 |
| Spondylolisthesis | *n*=80 | *n*=68 |



Includes isthmic spondylolisthesis

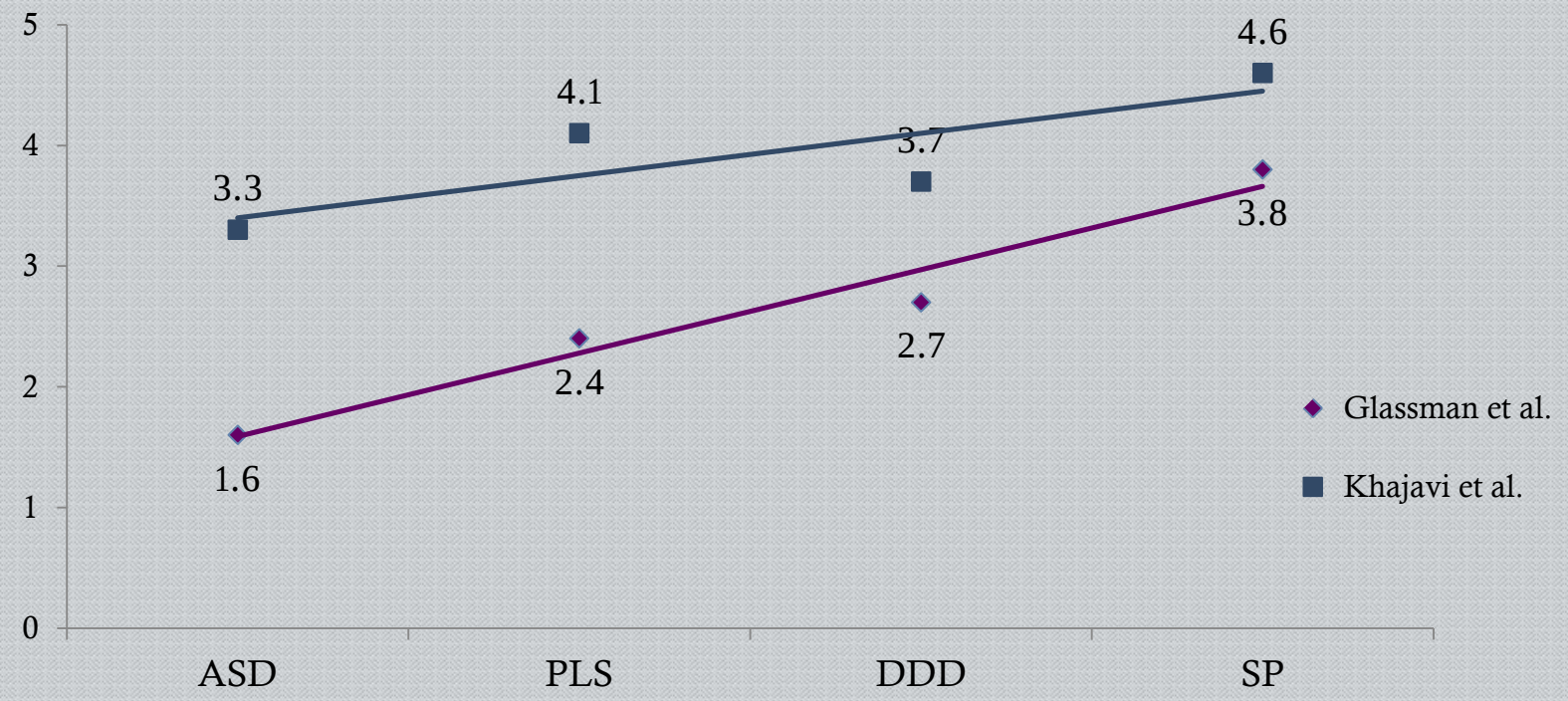
# Discussion: Net Improvement: ODI

Glassman SD, et al. "Lumbar fusion outcomes stratified by specific diagnosis indication" *Spine J.* 2009;9:13-21.



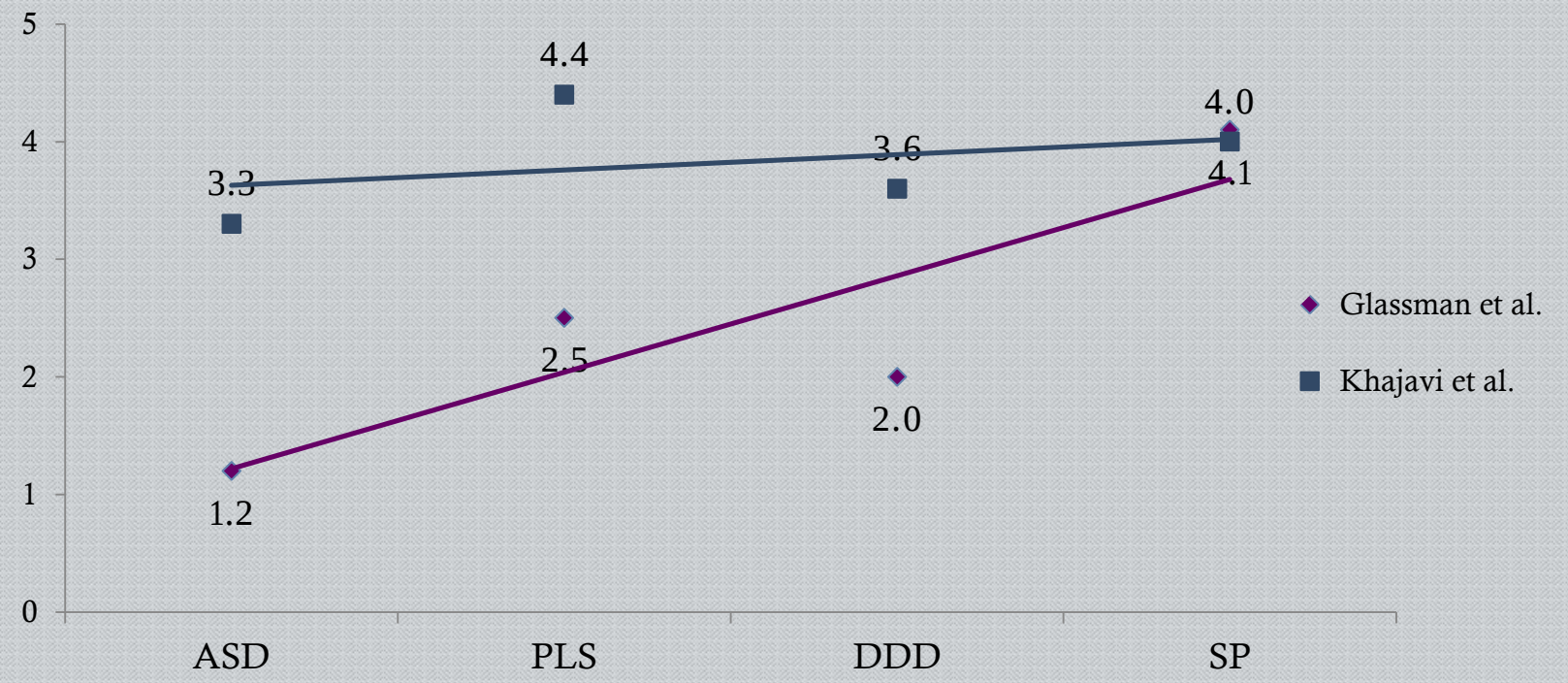
# Discussion: Net Improvement: NRS LBP

Glassman SD, et al. "Lumbar fusion outcomes stratified by specific diagnosis indication" *Spine J.* 2009;9:13-21.



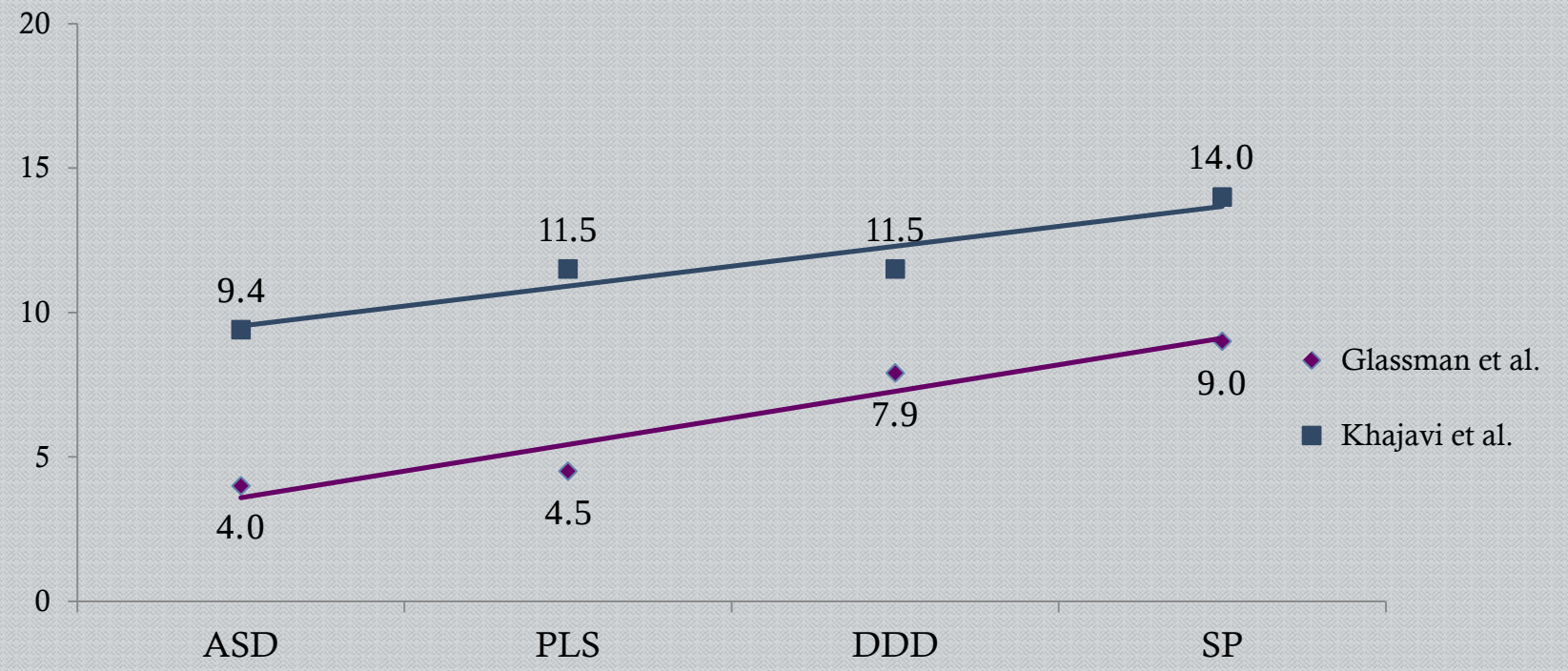
# Discussion: Net Improvement: NRS LP

Glassman SD, et al. "Lumbar fusion outcomes stratified by specific diagnosis indication" *Spine J.* 2009;9:13-21.



# Discussion: Net Improvement: SF-36 PCS

Glassman SD, et al. "Lumbar fusion outcomes stratified by specific diagnosis indication" *Spine J.* 2009;9:13-21.



# Clinical Outcomes: What do they mean?

- Statistically significant changes do not necessarily translate to significant improvement in clinical practice, and vice versa
- Problems with patient-reported outcomes
  - Actual state of health v. expectations
  - Recall bias
  - External factors
- Determination of "successful outcome"
  - Minimal clinically important difference (MCID)
  - Substantial clinical benefit (SCB)

# MCID vs. SCB

- MCID: The smallest change in clinical outcomes significant to clinician and patient
- SCB: Magnitude of improvement that a patient recognizes as substantial

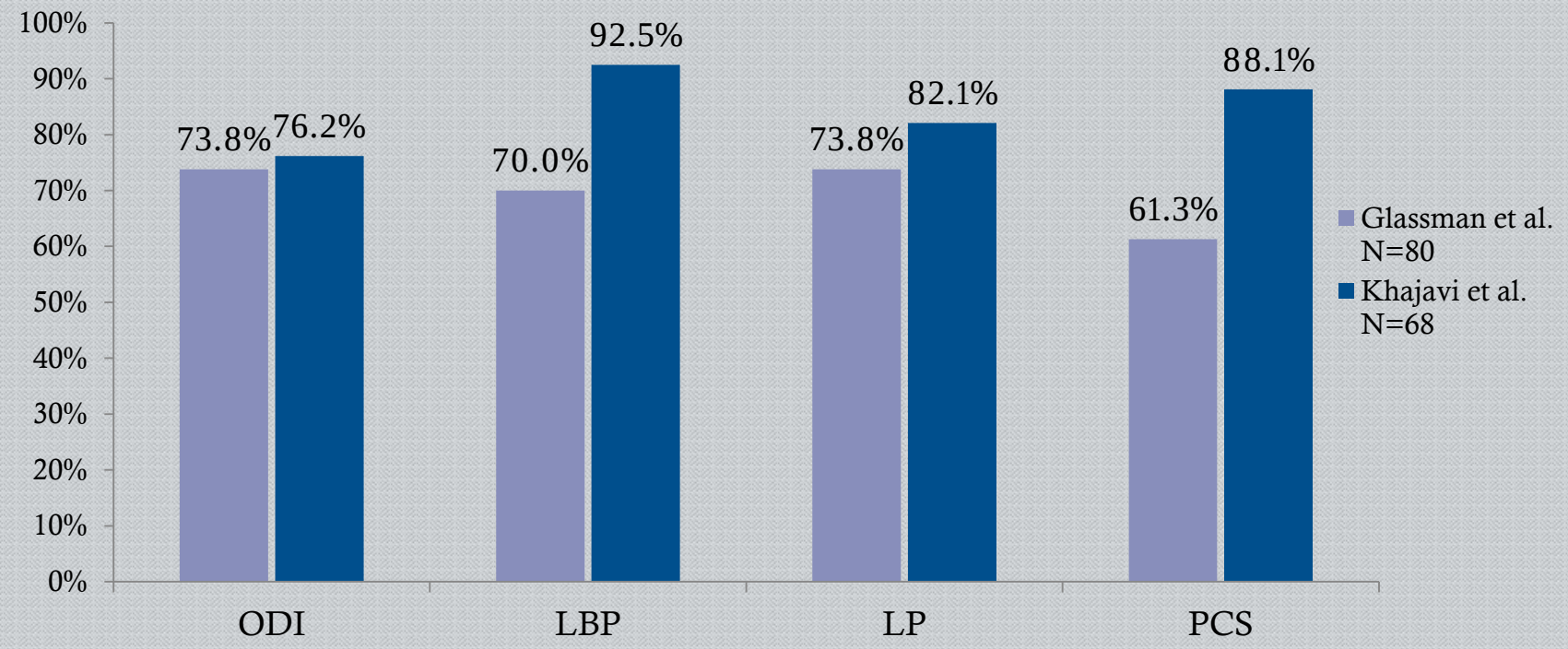
| | SCB[1] | | | MCID[2] |
|---|---|---|---|---|
| | % Improvement | Final Raw Score | Net Point Improvement | Net Point Improvement |
| ODI | 36.8% | <31.3 points | 18.8 points | 12.8 points |
| VAS LBP | 41.4% | <3.5 points | 2.5 points | 1.2 points |
| VAS LP | 38.8% | <3.5 points | 2.5 points | 1.6 points |
| PCS | 19.4% | ≥35.1 points | 6.2 points | 4.9 points |

[1]Glassman et al. *J Bone Joint Surg Am*. 2008;90:1839-47.

[2]Copay AG, et al. *Spine J*. 2008;8:968-74.

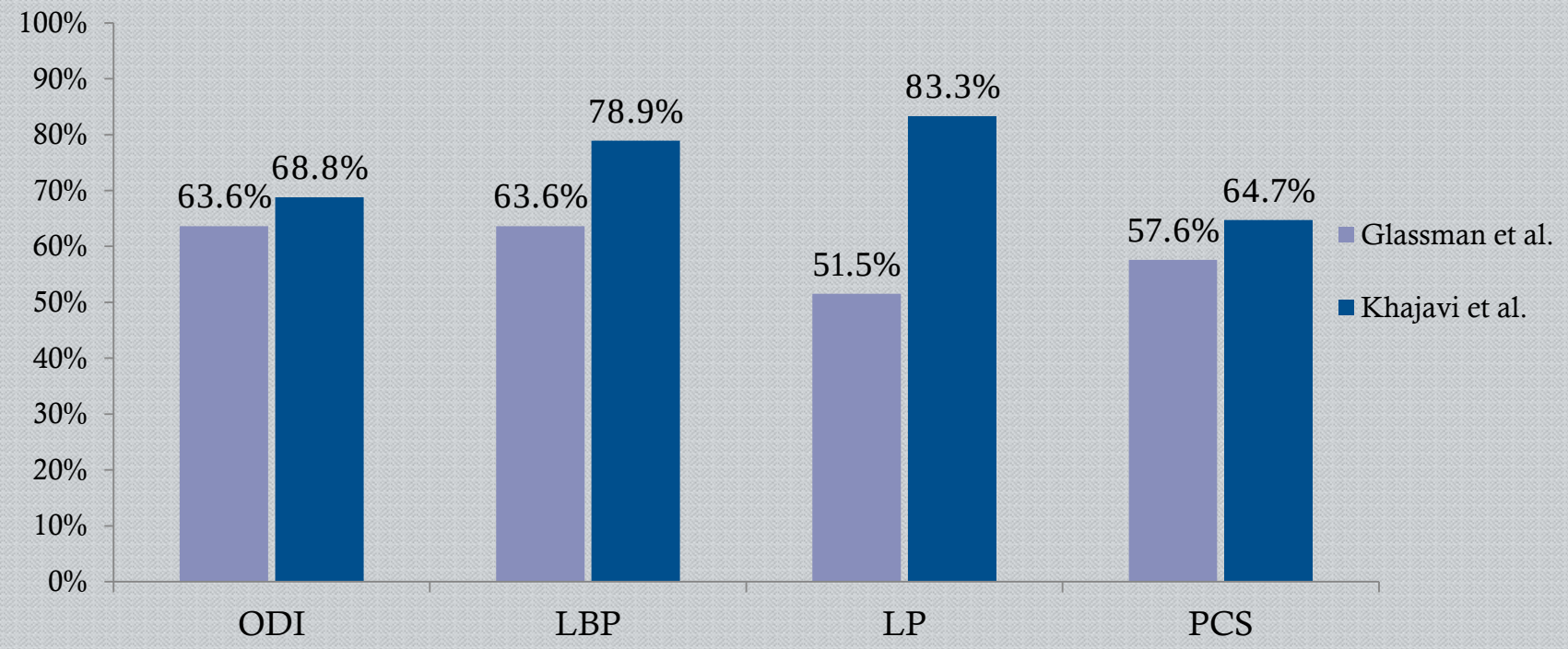
# MCID: Degenerative Spondylolithesis

Glassman SD, et al. "Lumbar fusion outcomes stratified by specific diagnosis indication" *Spine J.* 2009;9:13-21.



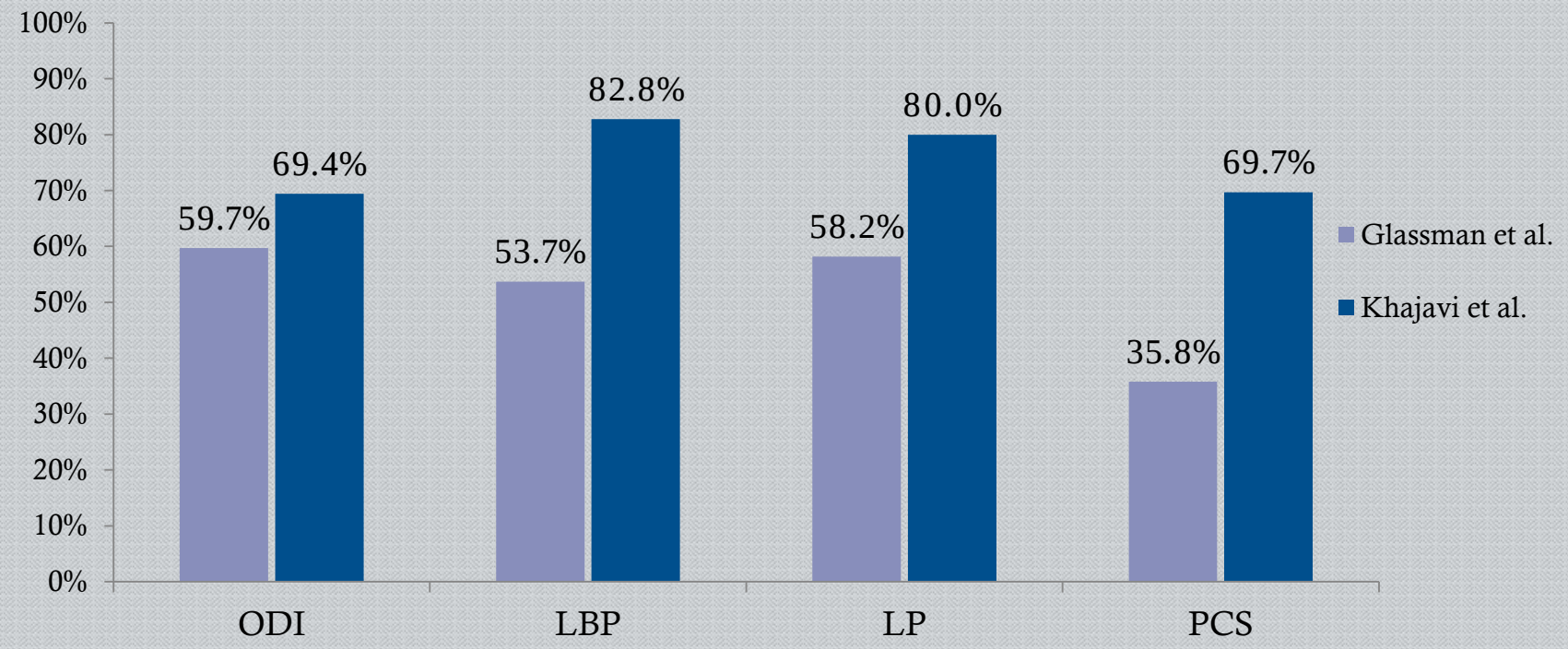
# MCID: DDD

Glassman SD, et al. "Lumbar fusion outcomes stratified by specific diagnosis indication" *Spine J.* 2009;9:13-21.



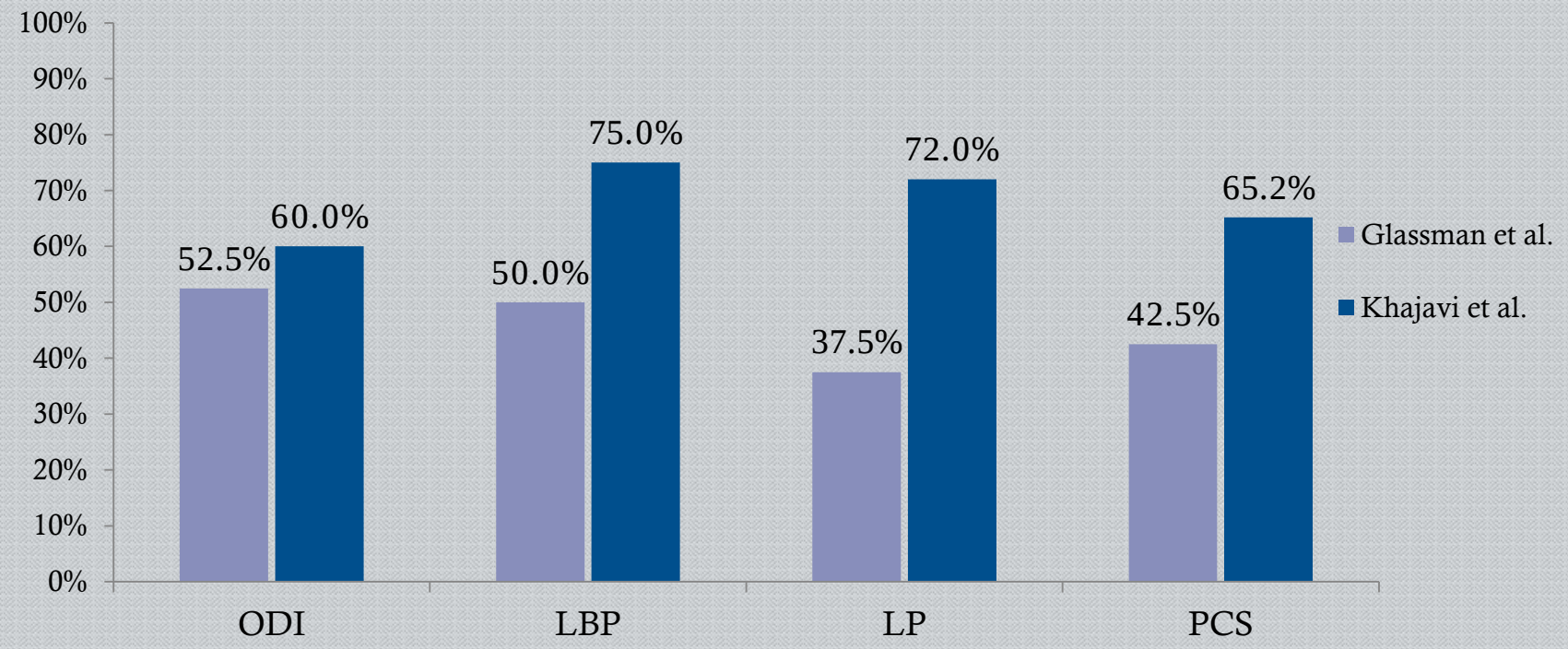
# MCID: Post laminectomy syndrome

Glassman SD, et al. "Lumbar fusion outcomes stratified by specific diagnosis indication" *Spine J.* 2009;9:13-21.

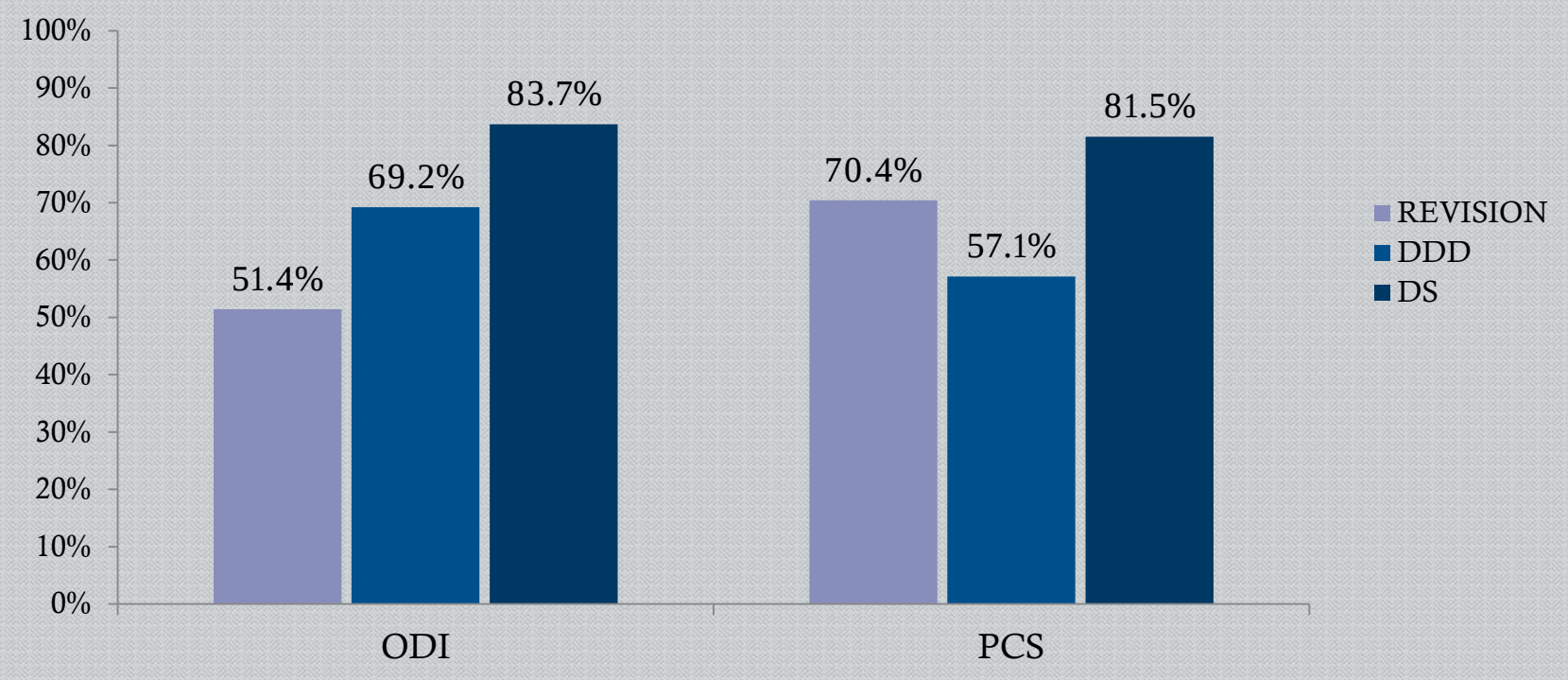


# MCID: Adjacent Segment Disease

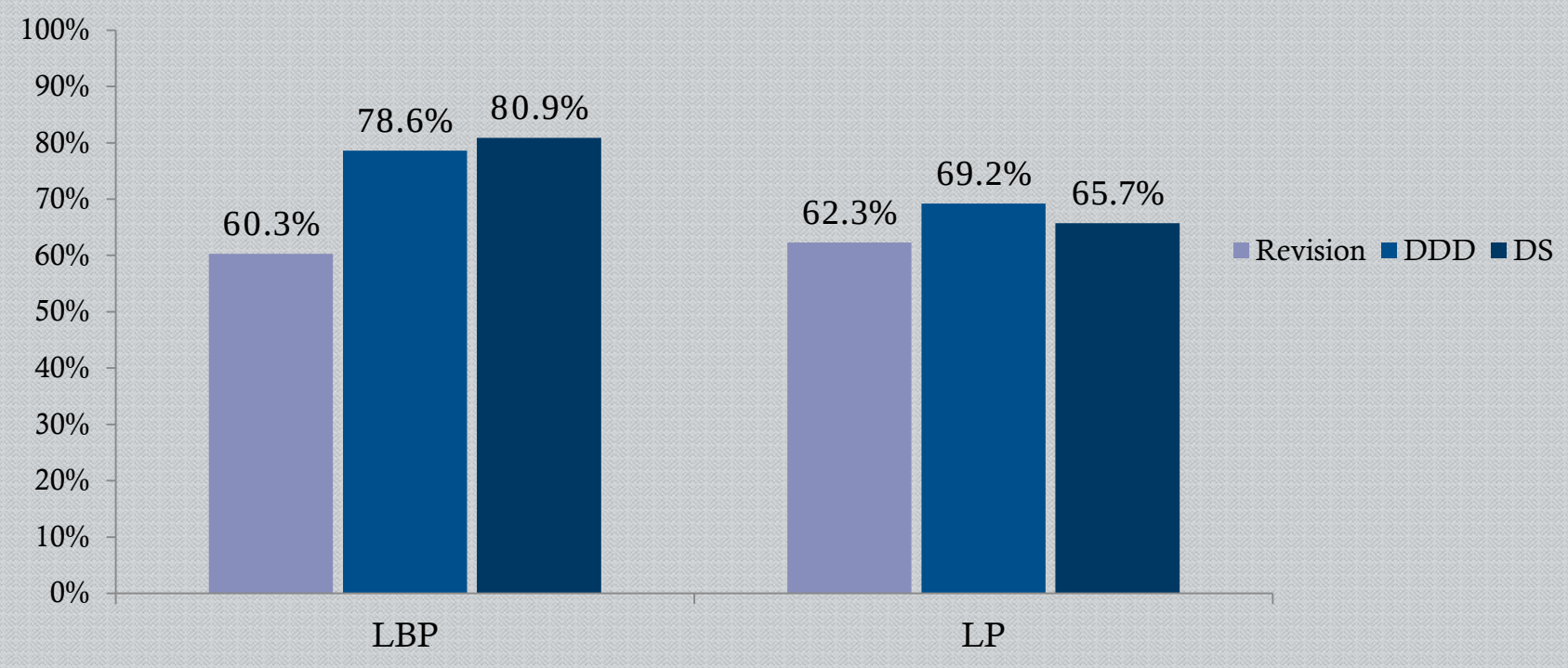
Glassman SD, et al. "Lumbar fusion outcomes stratified by specific diagnosis indication" *Spine J.* 2009;9:13-21.



# Substantial Clinical Benefit



# Substantial Clinical Benefit



# Complication comparison

- Khajavi et al.
  - Major 0.6%
  - Minor 12.5%
    - 5-7% for DDD and DS
    - 20% for revision
- Glassman et al.
  - Major 3-15%
  - Minor
    - 9% DDD
    - 37-45% for the other groups

Table 4
Incidence of complications in the different subgroups

| Diagnosis | Incidence of major complications | Incidence of minor complications | No. of patients with any complication |
|---|---|---|---|
| Spondylolisthesis | 12 (15.0%) | 32 (40.0%) | 36 (45.0%) |
| Instability | 0 (0.0%) | 7 (33.3%) | 5 (23.8%) |
| Stenosis | 4 (8.7%) | 18 (39.1%) | 16 (34.8%) |
| Scoliosis | 2 (11.8%) | 5 (29.4%) | 7 (41.2%) |
| Disc pathology | 1 (3.0%) | 3 (9.1%) | 3 (9.1%) |
| Nonunion | 3 (13.0%) | 4 (17.4%) | 7 (30.4%) |
| Postdecompression | 5 (7.5%) | 25 (37.3%) | 26 (40.3%) |
| Adjacent level | 2 (5.0%) | 18 (45.0%) | 16 (40.0%) |
| p Value | 0.447 | 0.788 | 0.771 |
| Total | 29 (8.7%) | 112 (33.7%) | 117 (35.2%) |

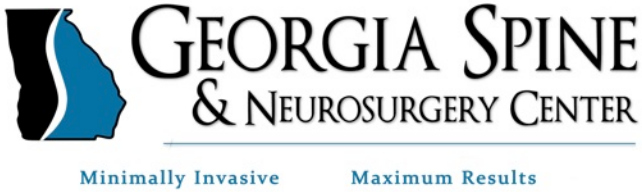
# Study Strengths / Limitations

- Strengths
  - All consecutive patients L1-5 included
  - Outcomes all prospectively collected
- Limitations
  - 160 patients still small, f/u < 2 years
  - Fusion definition based on x-rays, not CT
  - Classification of diagnosis difficult in some cases

# Conclusions

- MIS lateral IBF resulted in high clinical efficacy on pain, disability, and QOL measures across all indications
- Complication rates were low
- Our results compare favorably against traditional fusion approaches
- MIS techniques can drive outcomes for controversial indications (DDD, revision surgeries) towards that of "gold standard" (DS)

# Thank you!


GEORGIA SPINE
& NEUROSURGERY CENTER
Minimally Invasive
Maximum Results


INSTITUTE FOR NEUROSURGICAL & SPINAL RESEARCH
THE INSPIRE FOUNDATION

# Another DS Patient

# Recent spondy case


LATERA
ERE

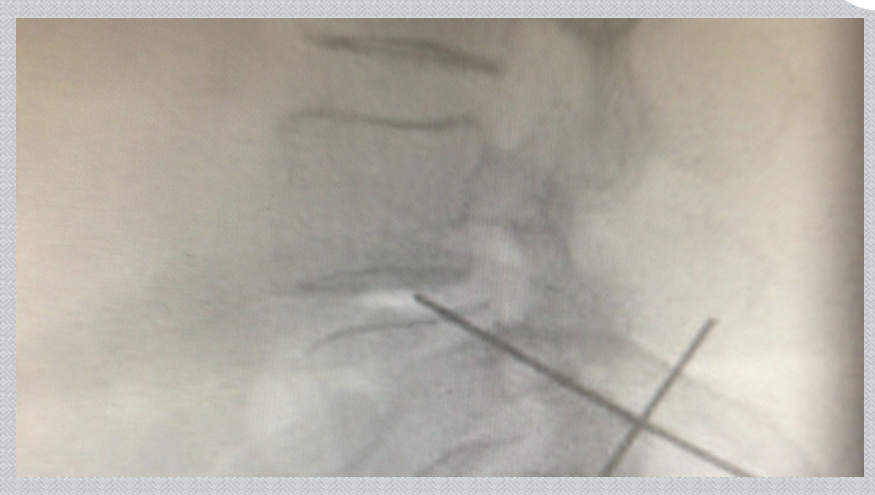
# Defining Substantial Clinical Benefit Following Lumbar Spine Arthrodesis

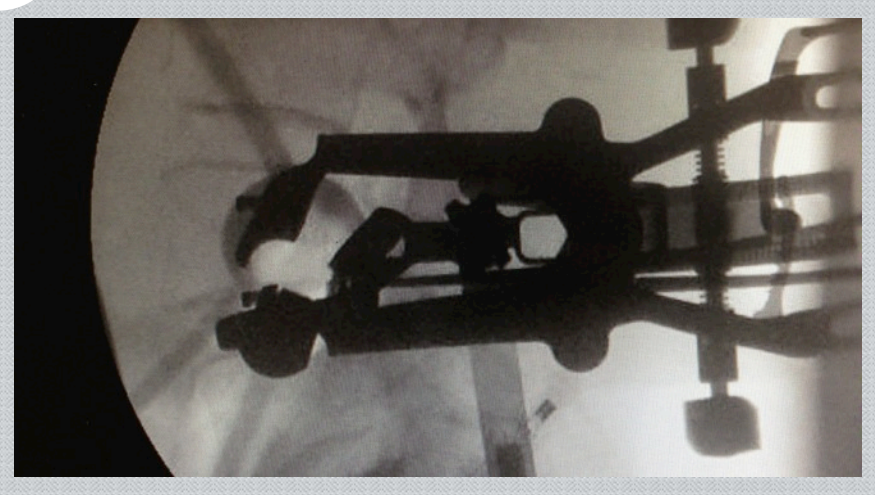
By Steven D. Glassman, MD, Anne G. Copay, PhD, Sigurd H. Berven, MD, David W. Polly, MD, Brian R. Subach, MD, and Leah Y. Carreon, MD, MSc

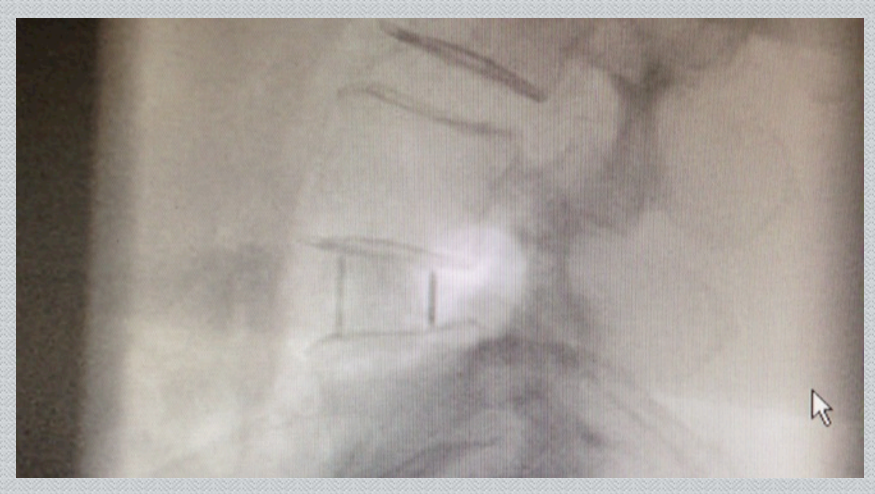
| | SCB[1] | | | MCID[2] |
|---|---|---|---|---|
| | % Improvement | Final Raw Score | Net Point Improvement | Net Point Improvement |
| ODI | 36.8% | <31.3 points | 18.8 points | 12.8 points |
| VAS LBP | 41.4% | <3.5 points | 2.5 points | 1.2 points |
| VAS LP | 38.8% | <3.5 points | 2.5 points | 1.6 points |
| PCS | 19.4% | ≥35.1 points | 6.2 points | 4.9 points |

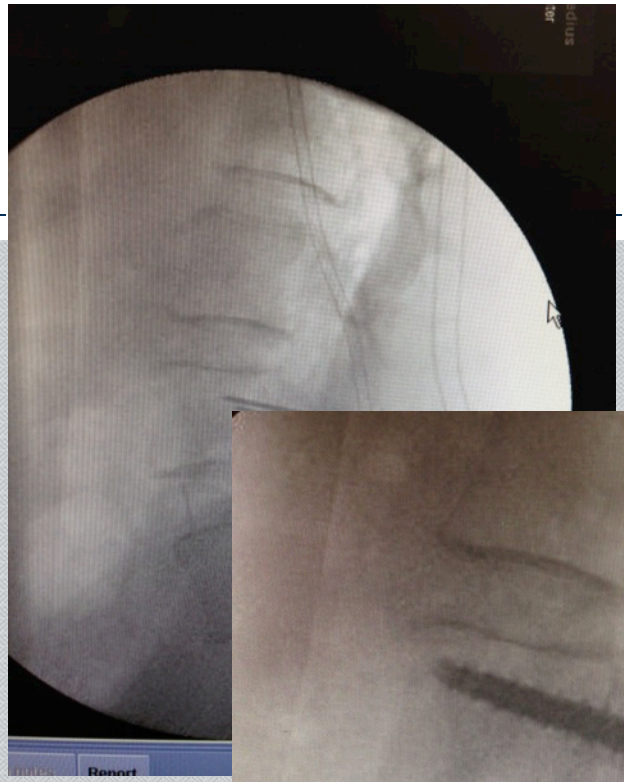
[1]Glassman et al. *J Bone Joint Surg Am*. 2008;90:1839-47.

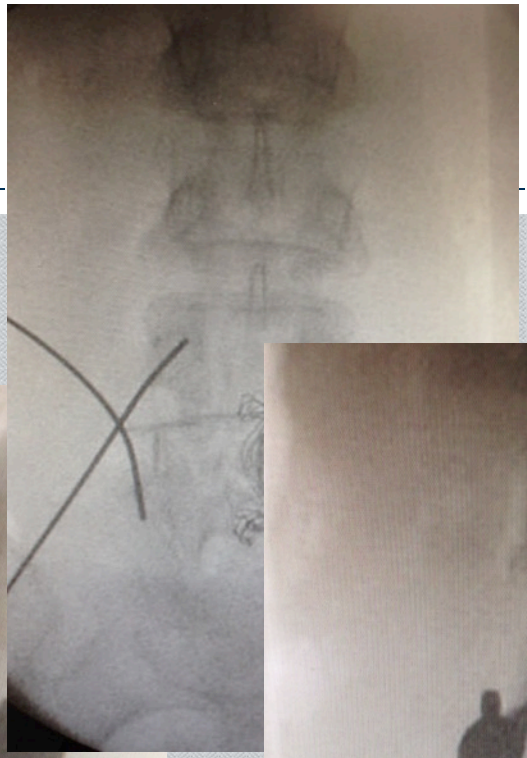
[2]Copay AG, et al. *Spine J*. 2008;8:968-74.

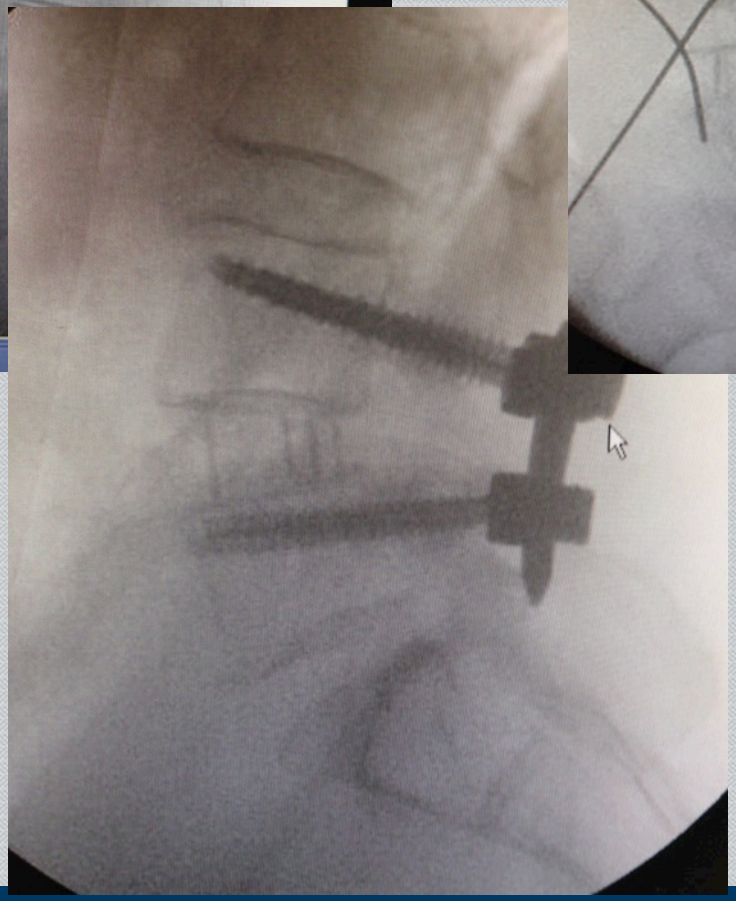


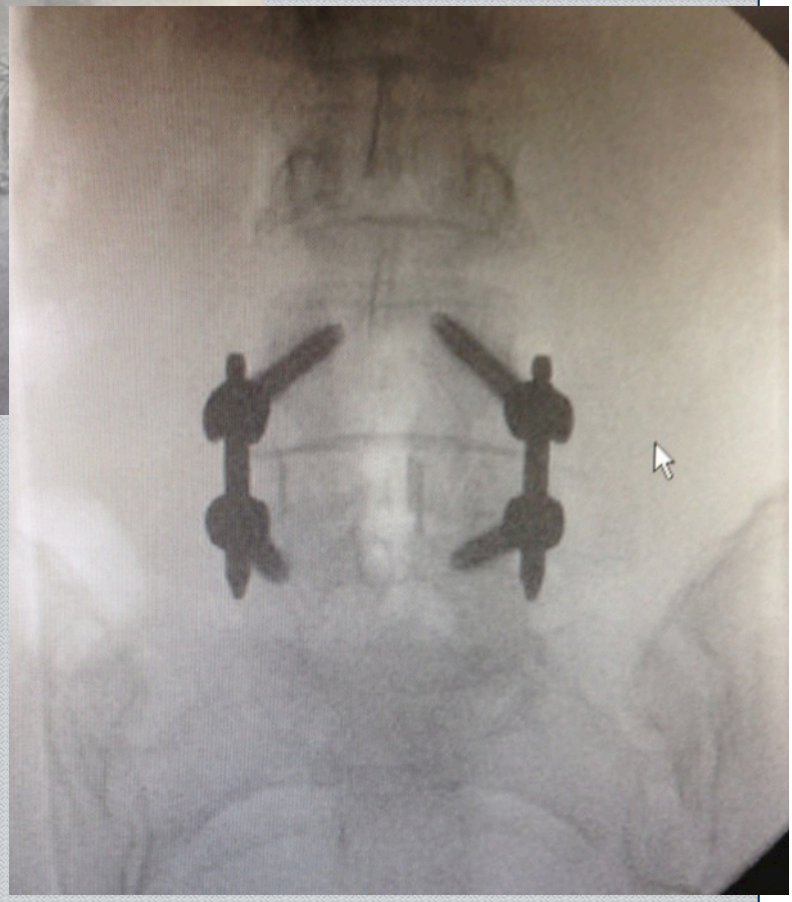


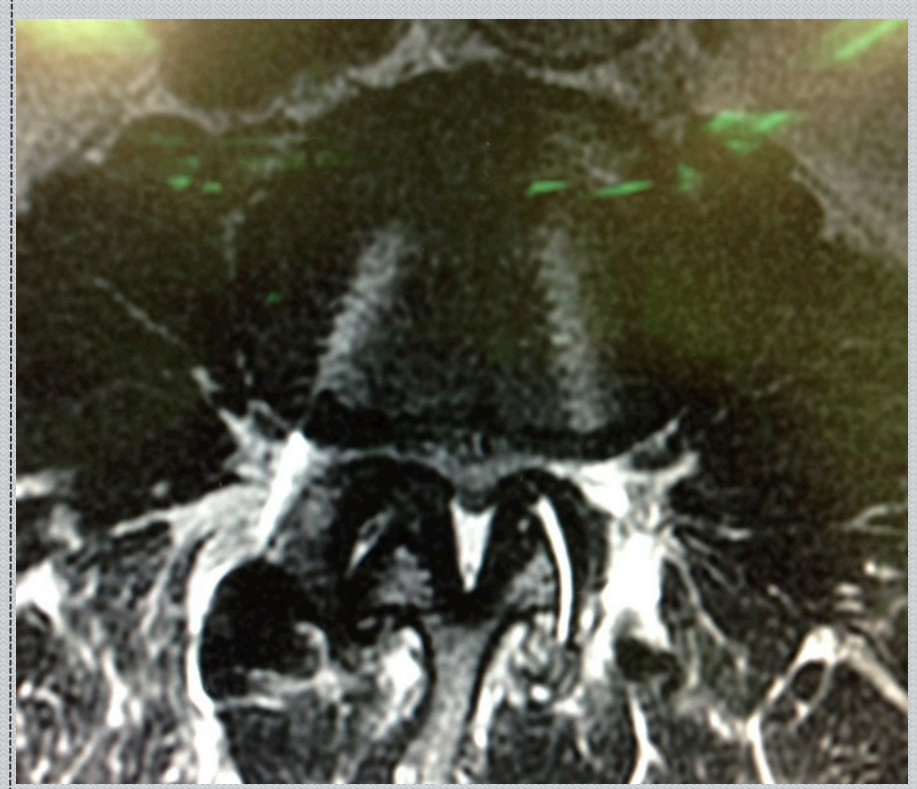



Report

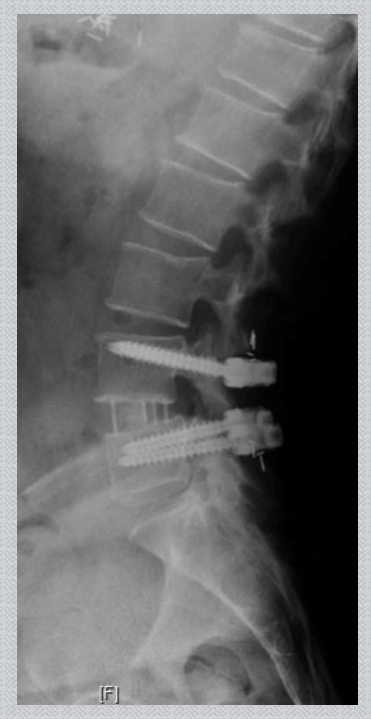













| | Pre | Intra | Post | Last |
|---|---|---|---|---|
| Slip (%) | 6.8mm (19.5%) | 1.8mm (5.2%) | 0.9mm (2.6%) | 2.4mm (6.9%) |
| SL | -17° | -22° | -21° | -22° |
| DH | 8.1mm | --- | 12.9mm | 13.9mm |
| FH | 18.2mm | --- | 19.6mm | 20.9mm |
| FW | 12.0mm | --- | 11.5mm | 12.3mm |
| FV | 198.6 | --- | 236.7 | 275.3 |