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

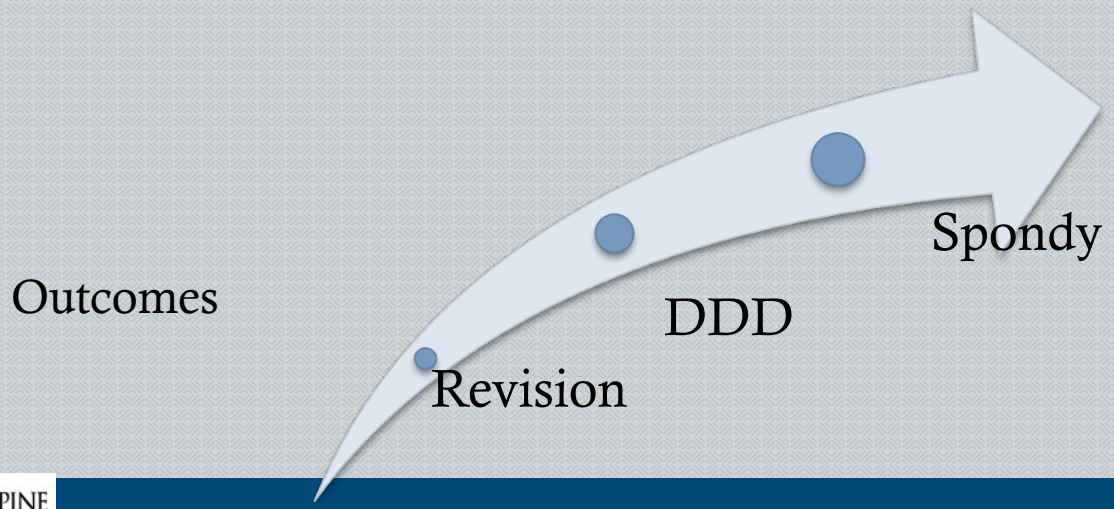
- The following presentation was given at ISASS in Miami 2014, and the paper has been submitted for publication.
- It covers all consecutive patient treated with minimally invasive lumbar fusions at L4-5 or above that fall into 1 of the 4 diagnoses given. It excludes all L5-S1 cases, all scoliosis cases and cases with a primary diagnosis of tumor, fracture, disctitis, pseudoarthrosis
- See the methodology section of the website for more details.

Disclosures

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

- NuVasive, Inc.
  - Consultant
  - Honoraria/travel

- Lumbar fusion for:
  - Degenerative spondylolisthesis: well-accepted, good-excellent outcomes
  - DDD: more controversial, fair–good outcomes
  - Revisions: most difficult cases, poorer 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 discrepancies in outcomes between the groups exist in MIS vs. open surgery? To the same extent?
- Is there still value in performing surgery in controversial groups?

Methods
Study Overview

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

- Inclusion Criteria
  - Consecutive patients treated between 2006-2011 (*n*=160)
  - MIS lateral IBF at or above L4-5
  - Failure of conservative treatment
  - 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 $p \leq 0.05$

Results

Adverse Events

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

p<0.001

No cases of non-union, infection, DVT/PE, or unplanned return to OR,

Results

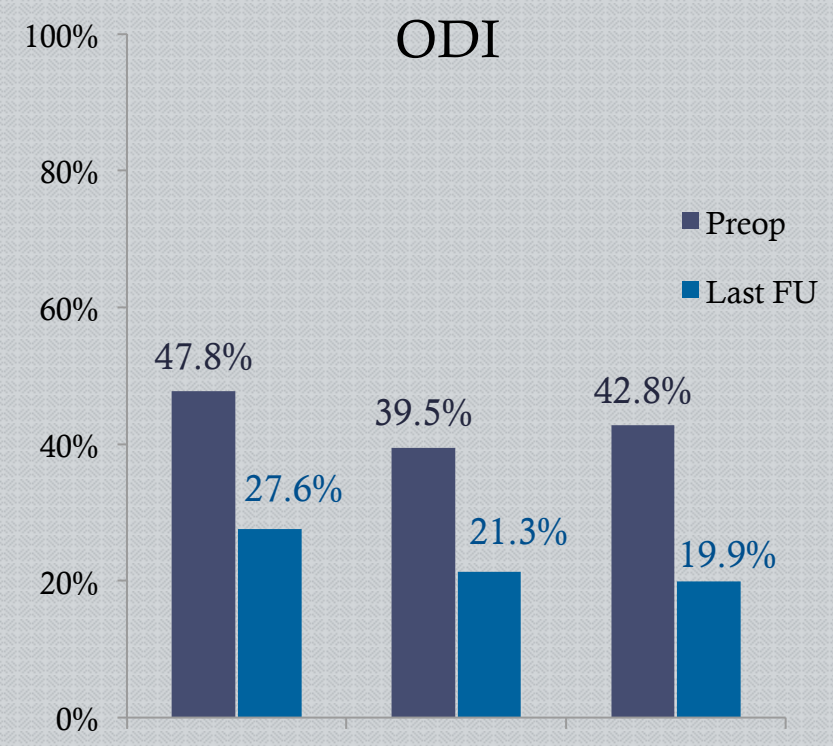
Side Effects

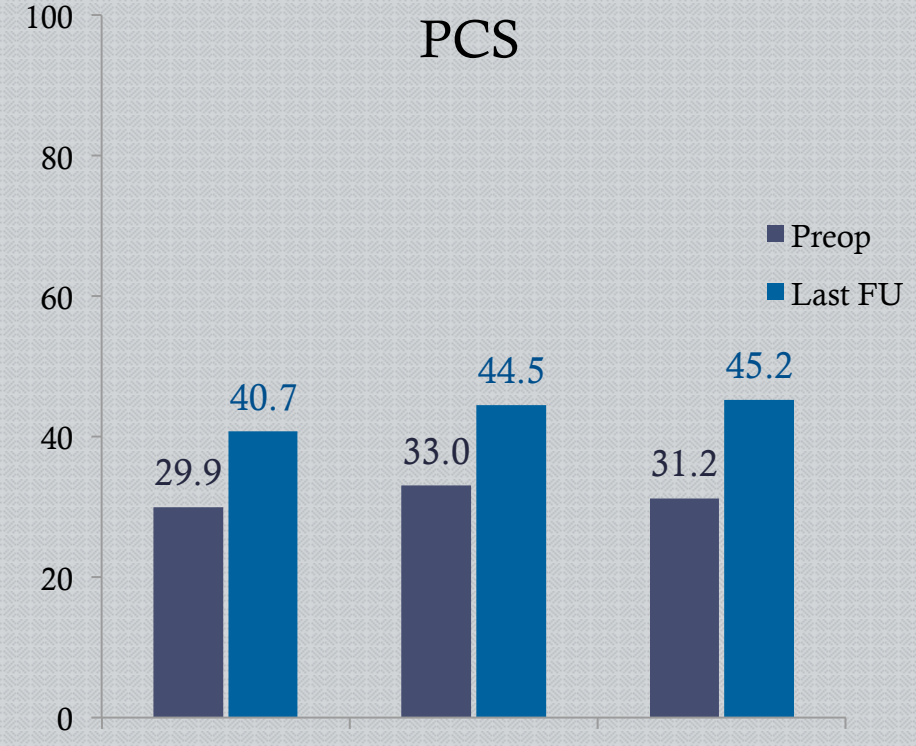
	REVISION (*n*=72)	DDD (*n*=20)	DS (*n*=68)	Total (*n*=160)
Side Effects	Approach-related thigh/groin pain 7 Hip flexion weakness 3 **Total: 10 (13.9%)**	None	Approach-related thigh/groin pain 14 Hip flexion weakness 9 **Total: 25 (36.8%)**	**35** **(21.9%)**

Resolved by 10 days to 6 months PO

Results

Clinical Outcomes: ODI & SF-36 PCS





% Improve: 42.3% | 46.1% | 53.5%

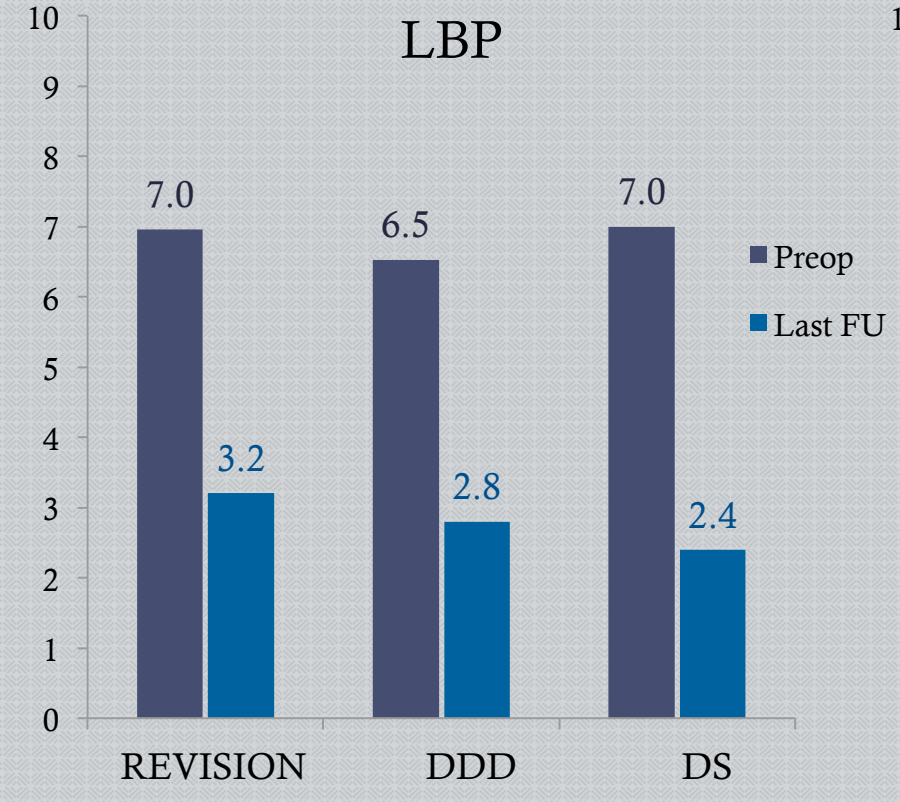
p = **0.025***

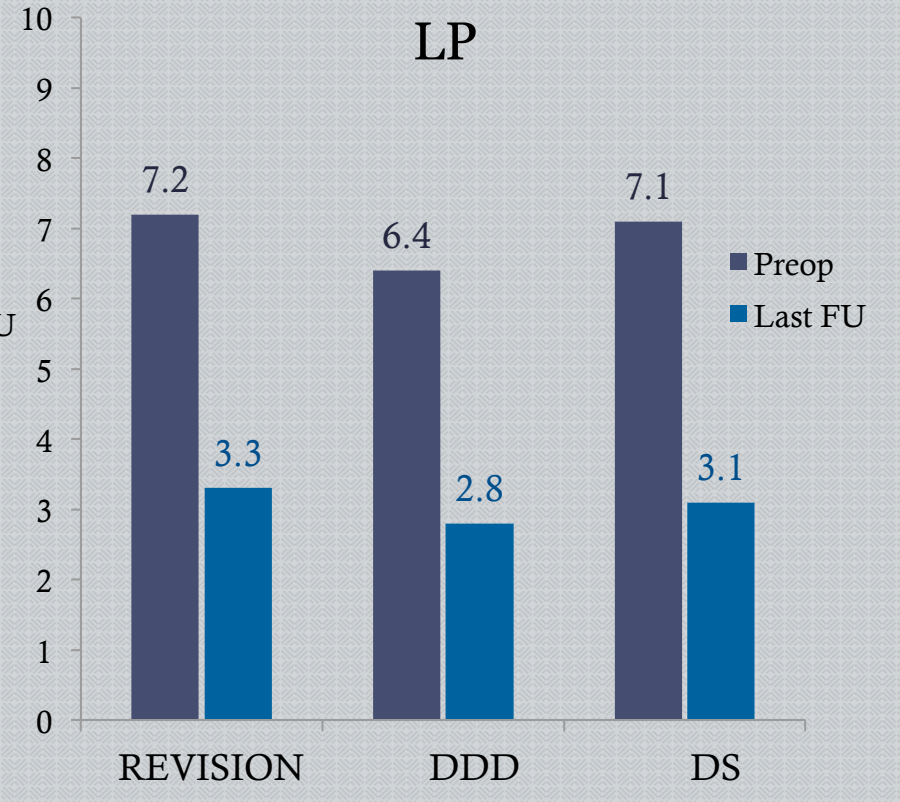
33.8% | 34.8% | 44.9%

p = **0.047***

Results

Clinical Outcomes: LBP & LP





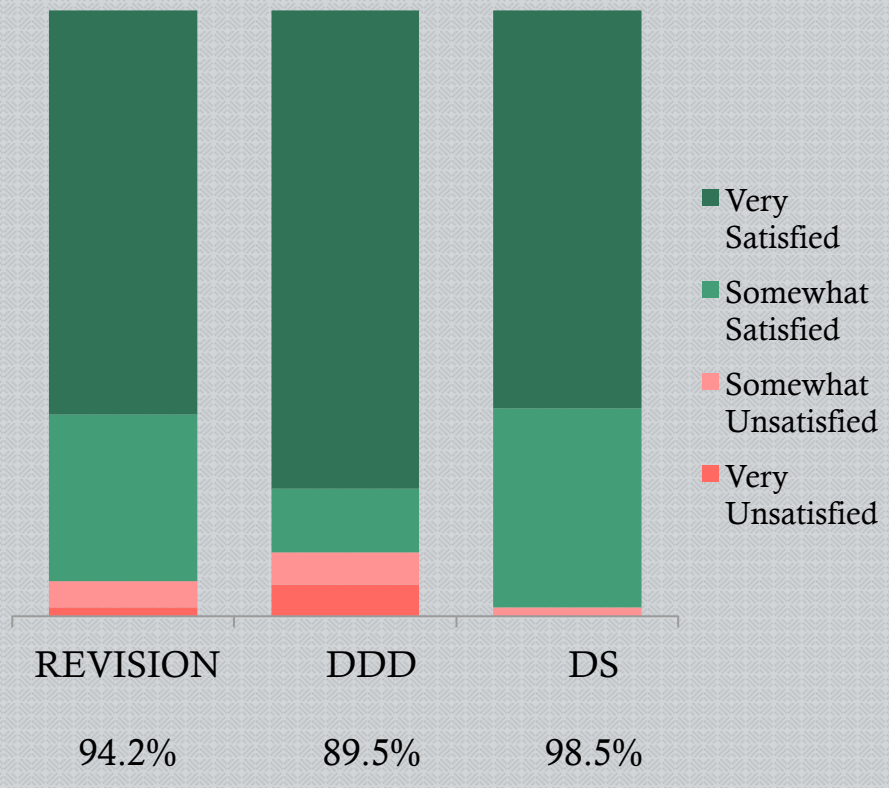
	REVISION	DDD	DS
% Improve:	54.3%	56.9%	65.7%
		p = 0.411	

	REVISION	DDD	DS
	54.2%	56.3%	56.3%
		p = 0.486	

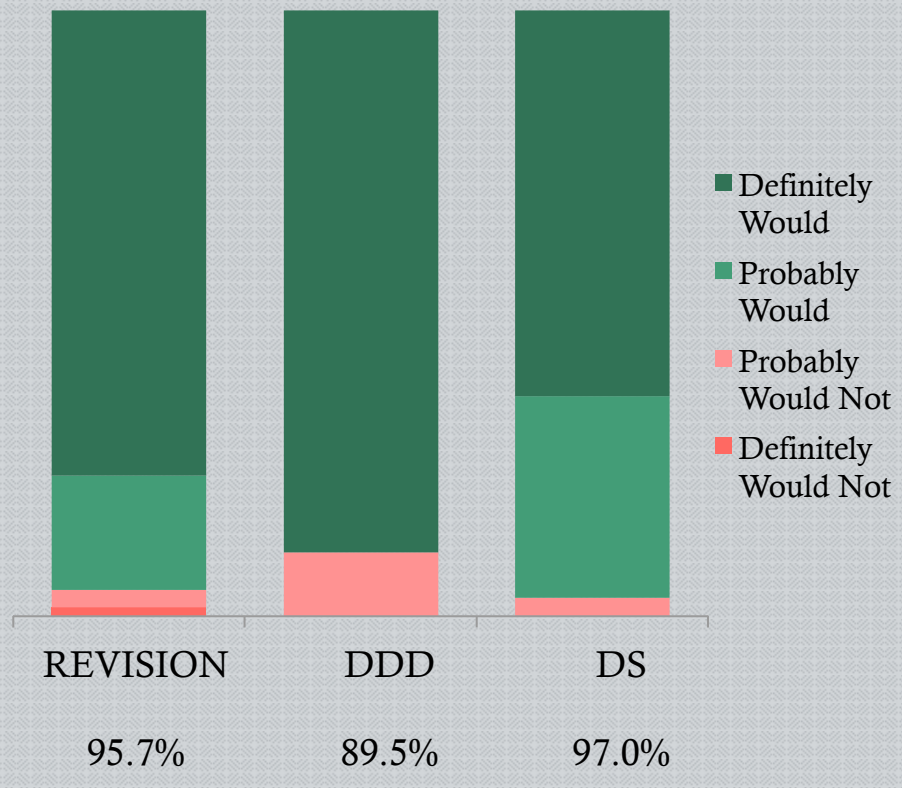
Results

Patient Satisfaction

How satisfied are you with your surgical outcome?

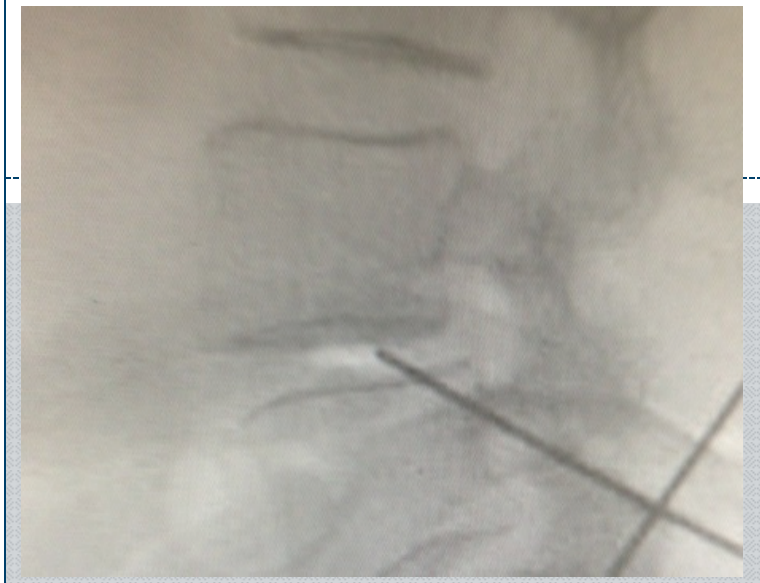


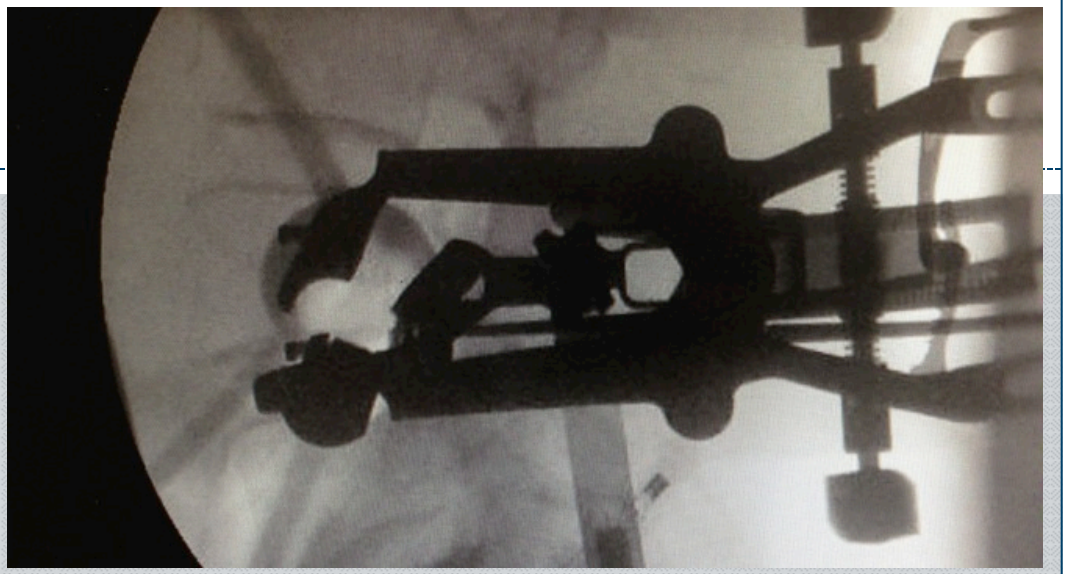
Given your current condition, would you elect to have the same surgery again?

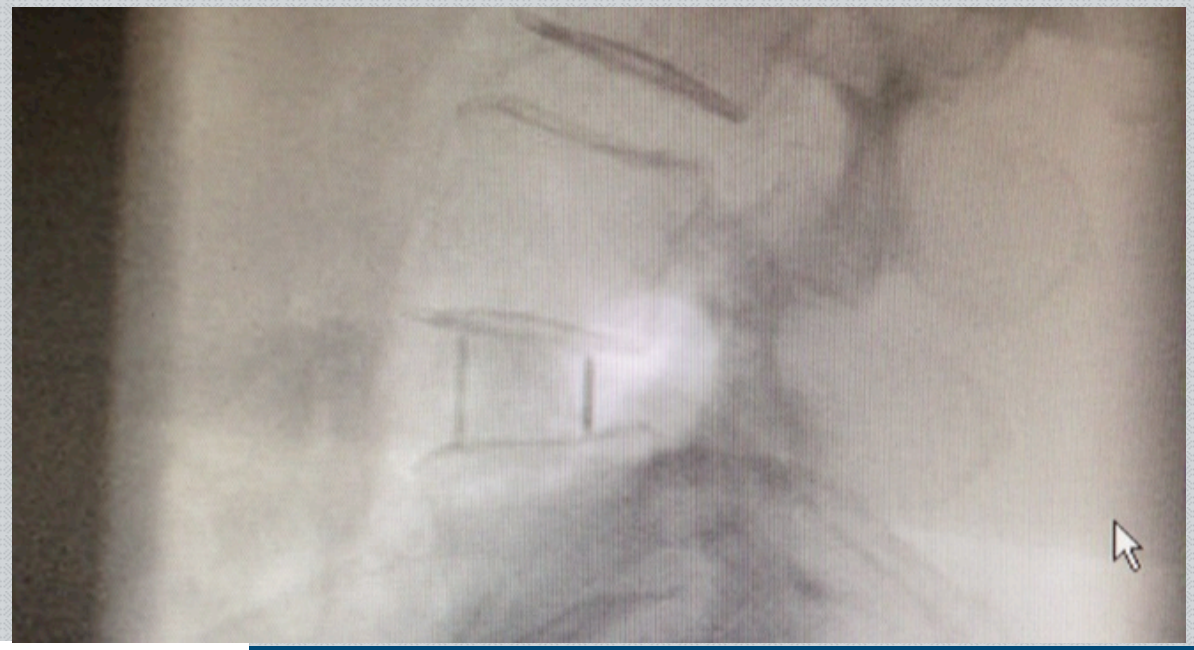


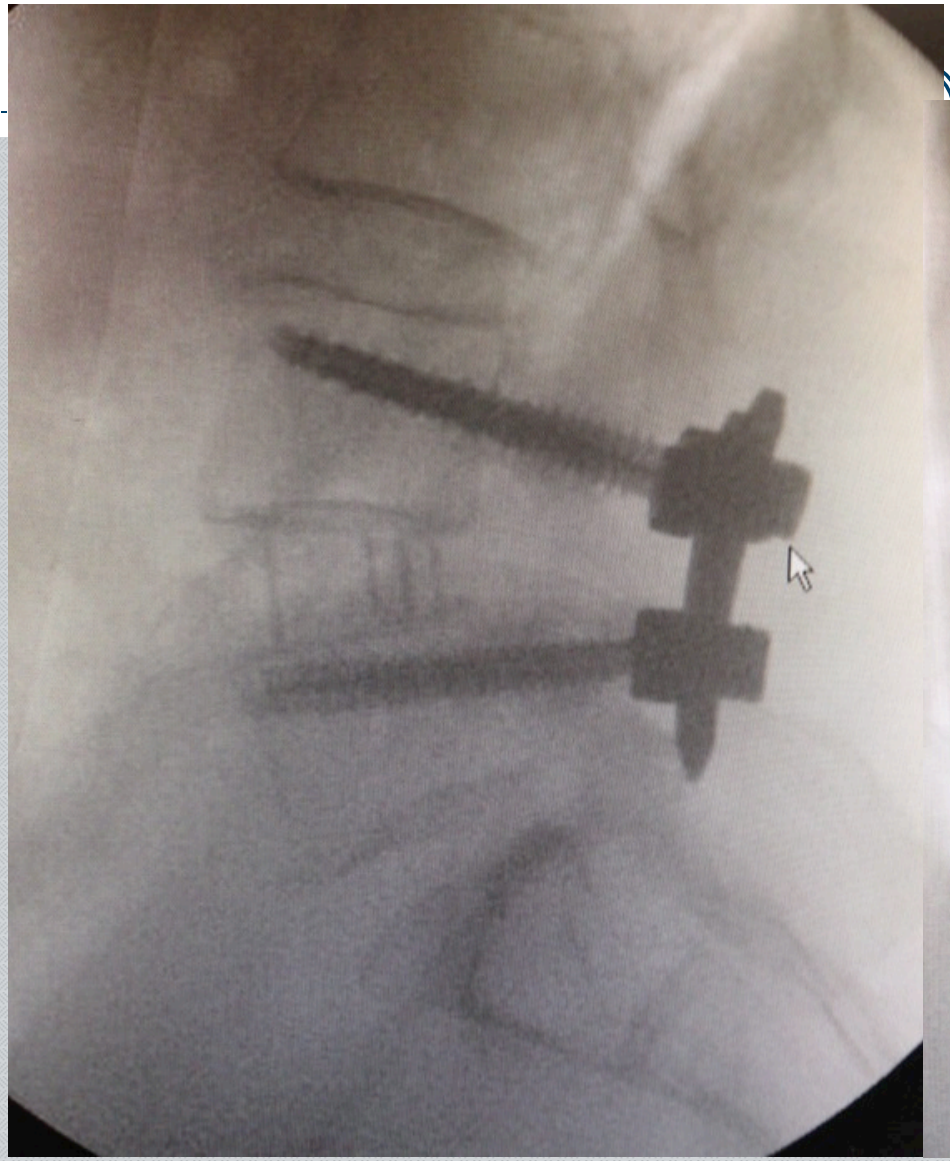
Case Example: Degenerative Spondylolisthesis

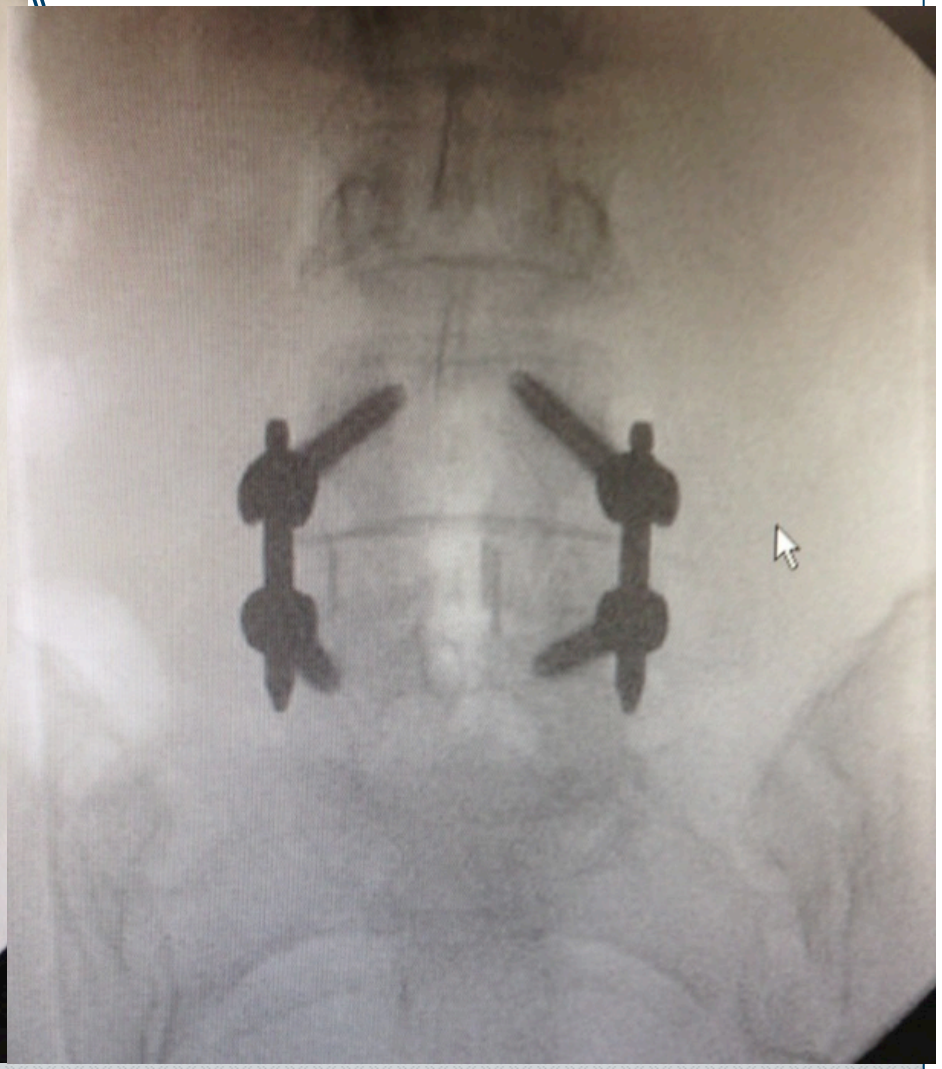
71 yo F years of LBP rad B/L LEs. MRI mod stenosis, lat recess stenosis











Another DS Patient

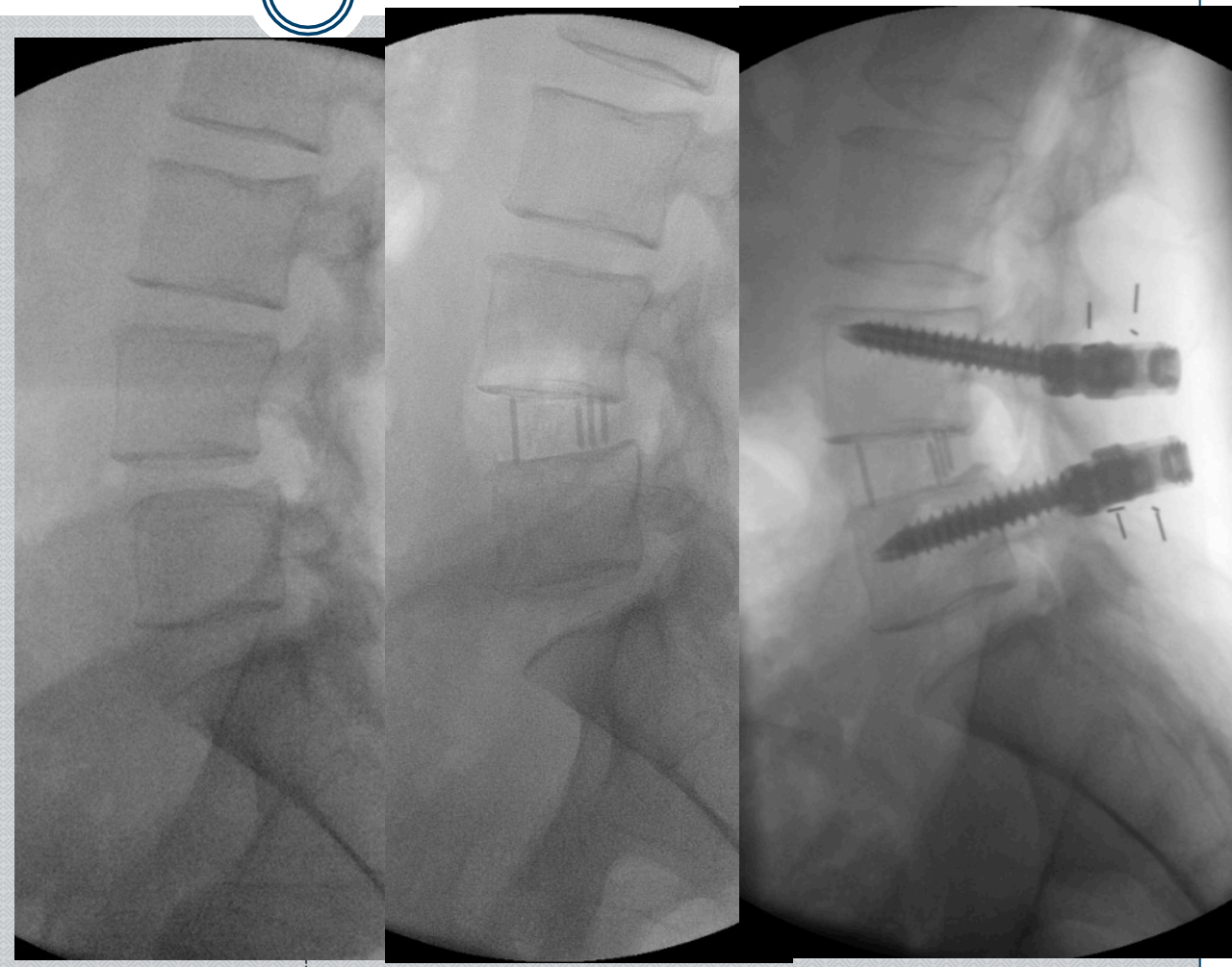
Recent spondy case


LATERA
ERE

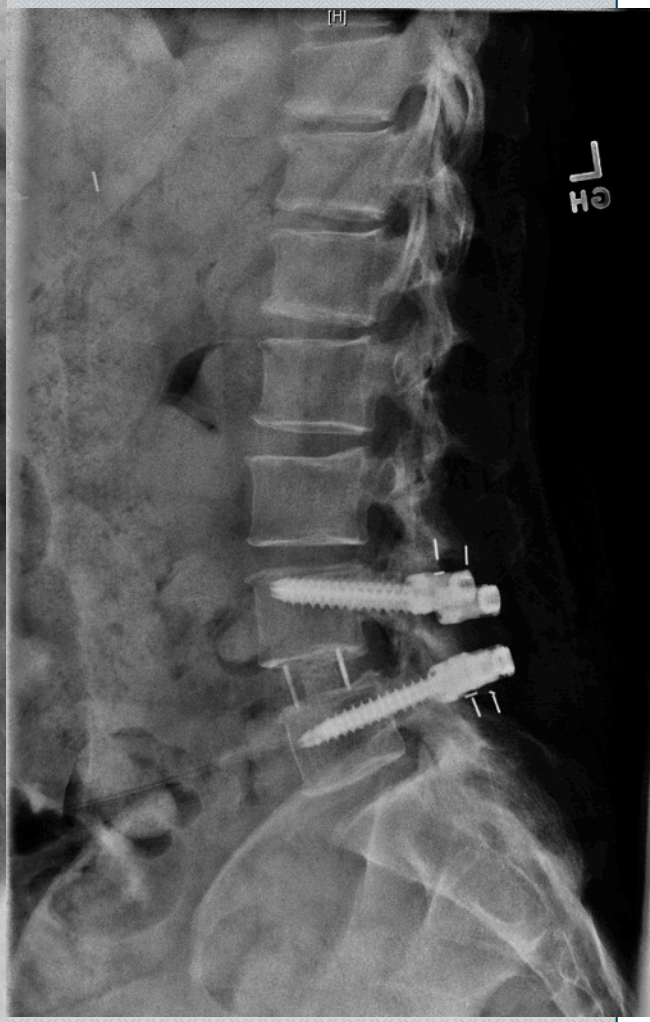
Case Example: Degenerative Spondylolisthesis

- 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

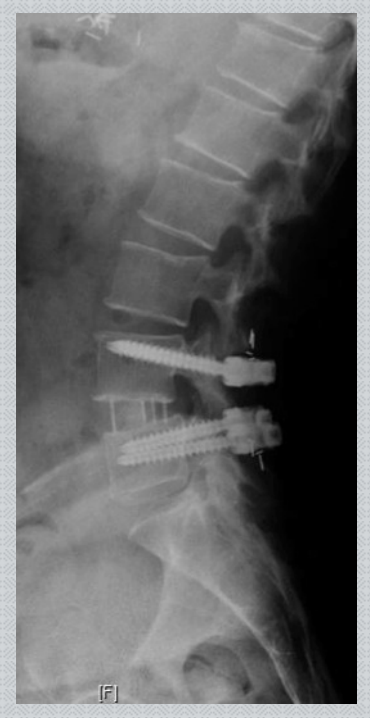
- Procedure
  - L4-5 lateral IBF
  - L4-5 bilateral pedicle screws/rods



- 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



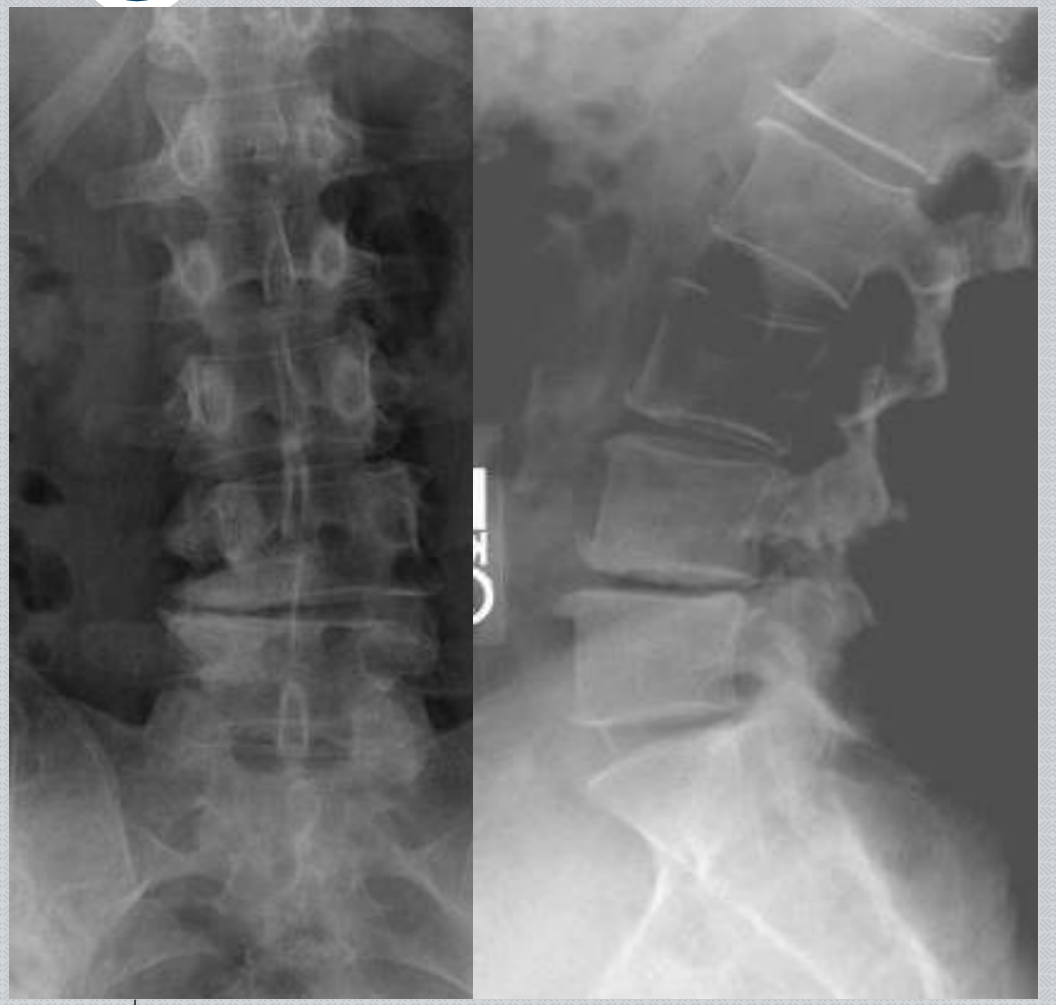
	Pre	Intra	Post	Last
Slip (%)	6.8mm (19.5%)	1.8mm (5.2%)	0.9mm (2.6%)	2.4mm (6.9%)
SL	-17°	-22°	-21°	-22°
DH	8.1mm	---	12.9mm	13.9mm
FH	18.2mm	---	19.6mm	20.9mm
FW	12.0mm	---	11.5mm	12.3mm
FV	198.6	---	236.7	275.3

Case Example: Degenerative Disc Disease

50 yo F BP and right L3 radiculopathy

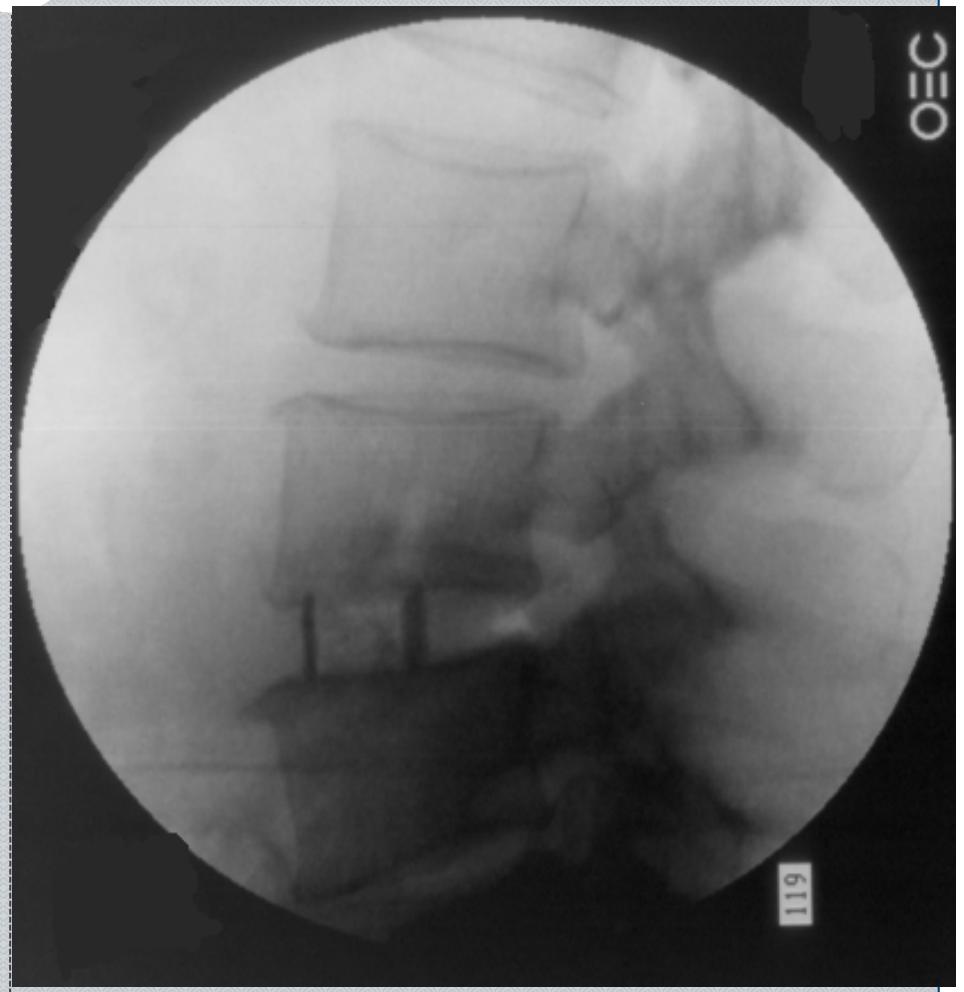
Case Example 3
Degenerative Disc Disease

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



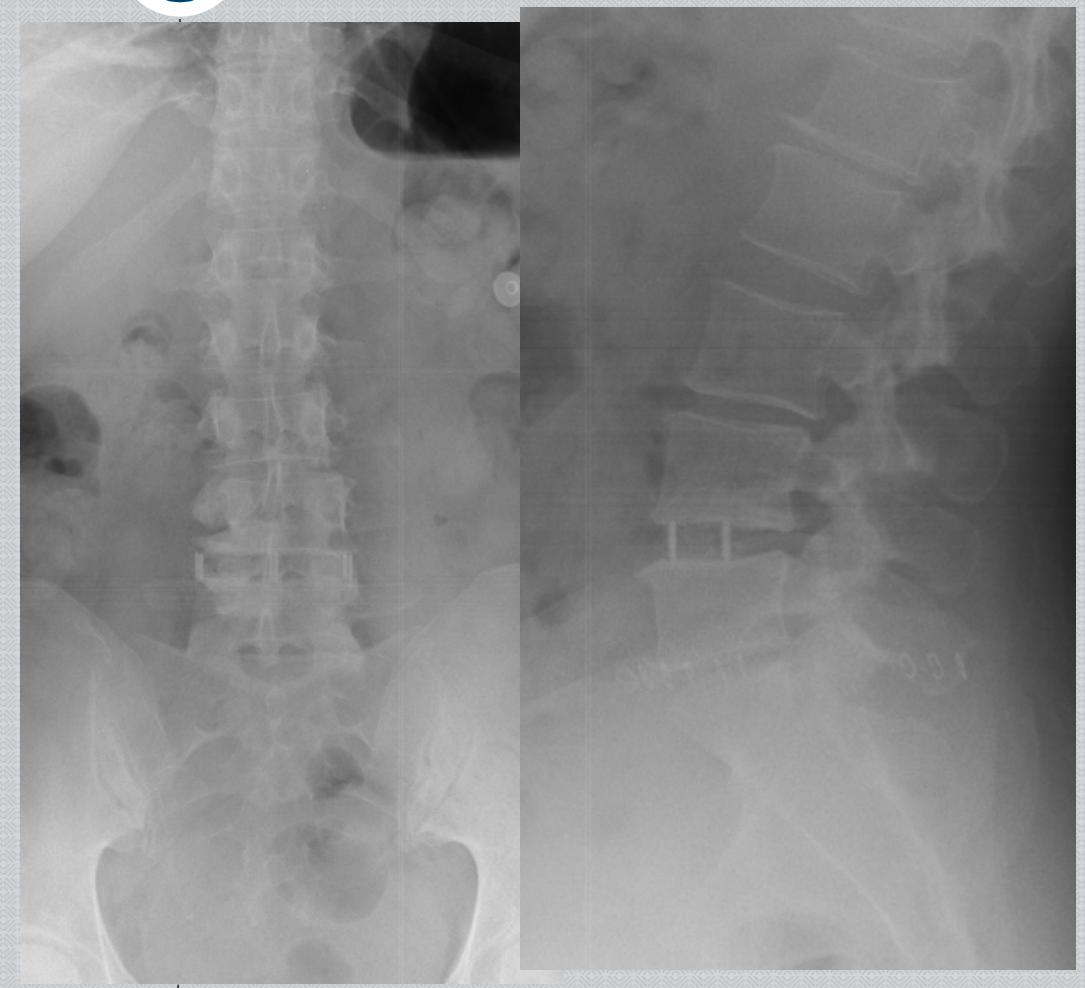
Case Example 3
Degenerative Disc Disease

- Procedure
  - L4-5 lateral IBF
  - Standalone



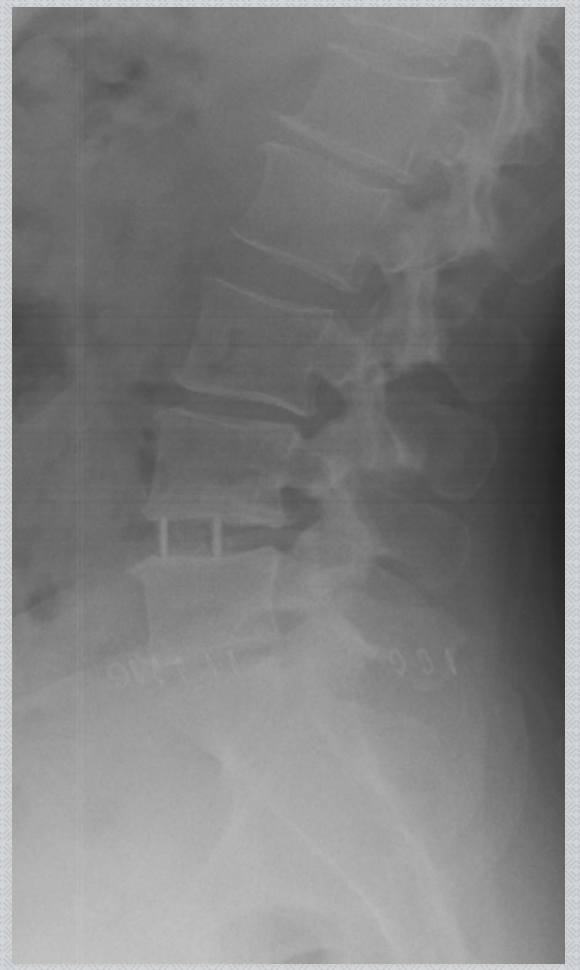
Case Example 3
Degenerative Disc Disease

- Patient was discharged POD #1



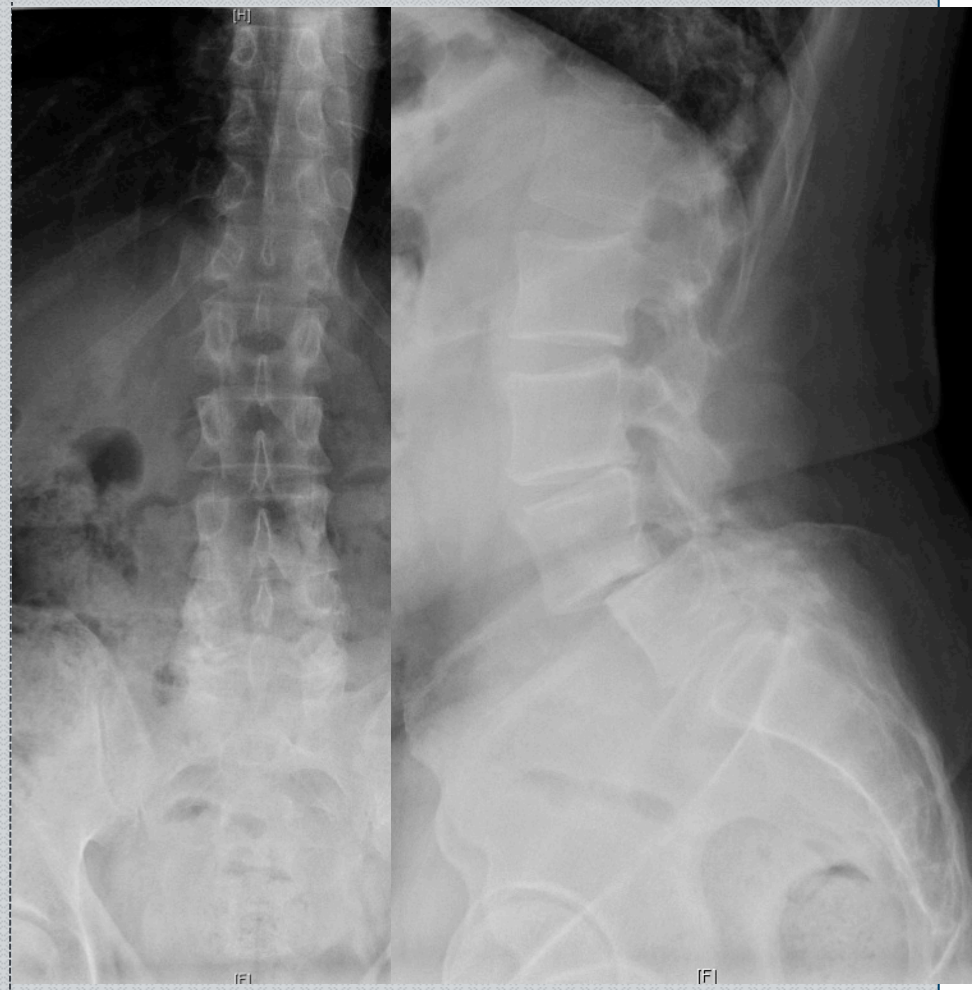
Case Example 3

Degenerative Disc Disease



Case Example: Post Lam syndrome (spondy)

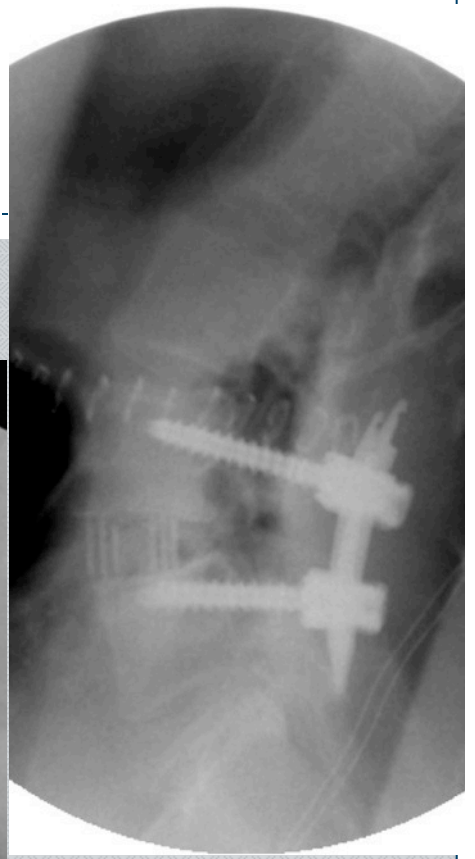
- 58 y/o male
- CC/PMHx:
  - 2007: laminectomy + left facectectomy for LBP + bilat LE pain
  - Left LE improved, right did not
  - Repeat surgeries May + Aug 2008, no relief
- L4-5 PLS
  - Grade II spondylolisthesis
  - Instability on flex/ext



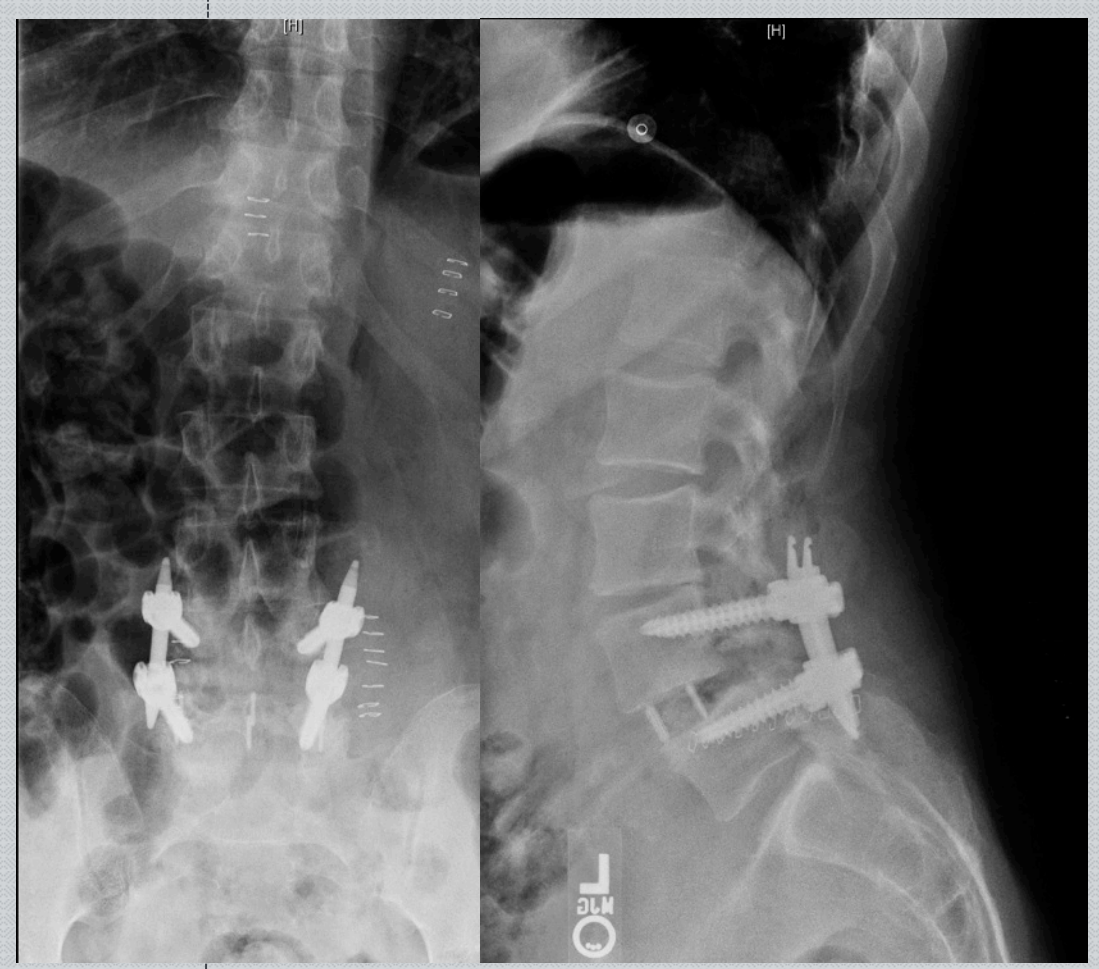
Case Example 6

Post-Laminectomy Syndrome

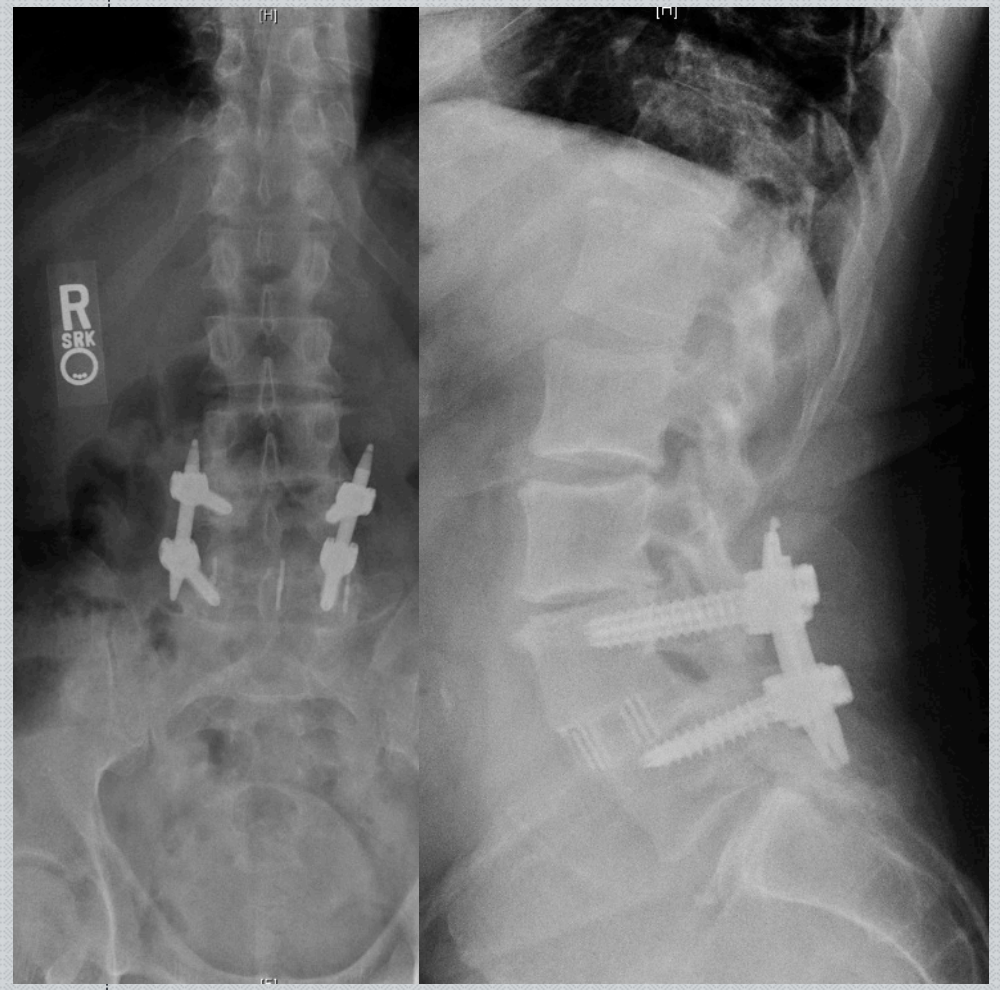
- Procedure
  - L4-5 Lateral IBF
  - L4-5 bilateral pedicle screws/rods



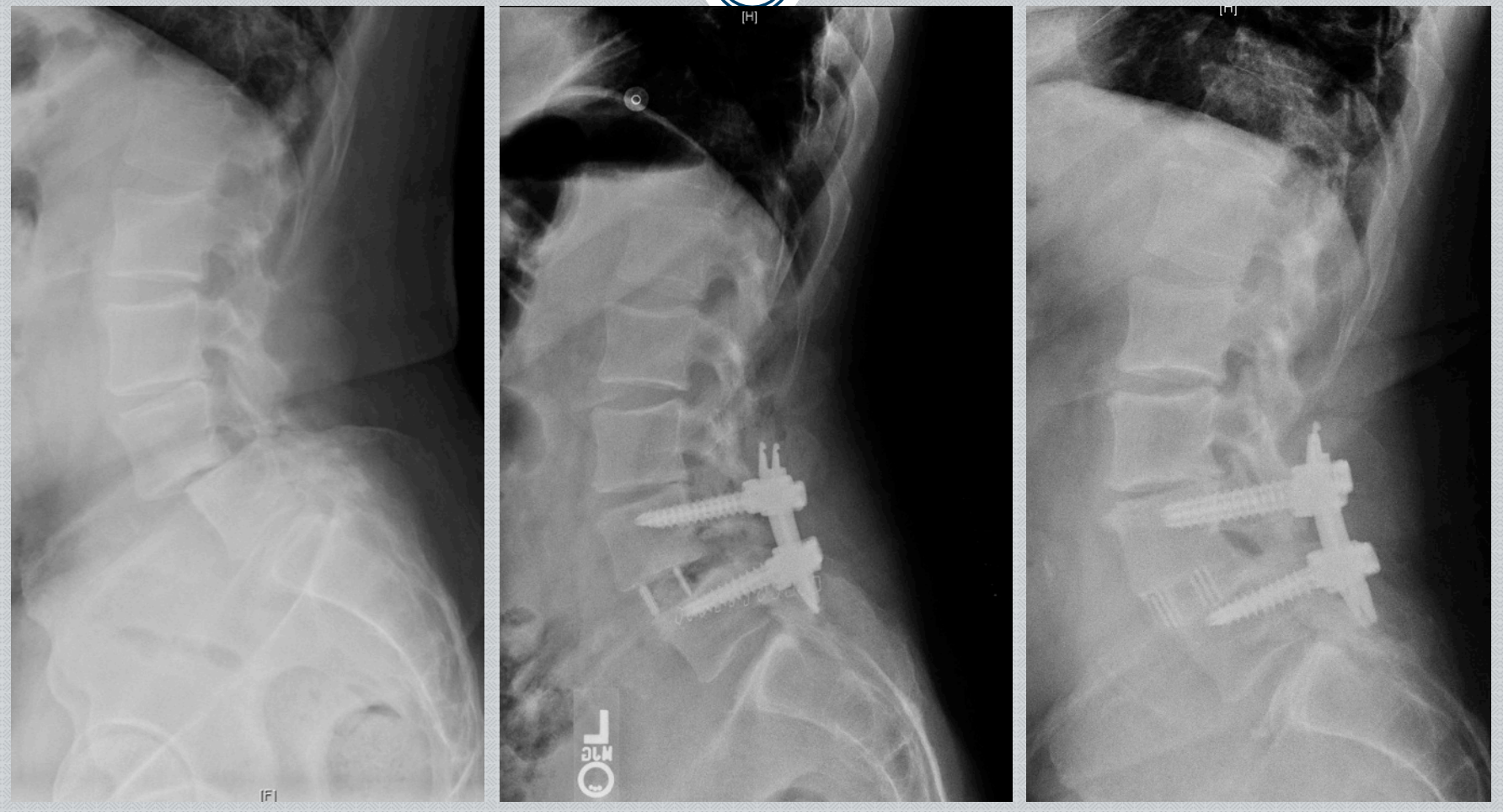
- Patient was discharged POD 1
- No new neurologic deficits or complaints



- 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



Case Example: Post lam syndrome (spondy)



58 yo M, 3 laser surgeries L4-5, worsening L4 radic

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

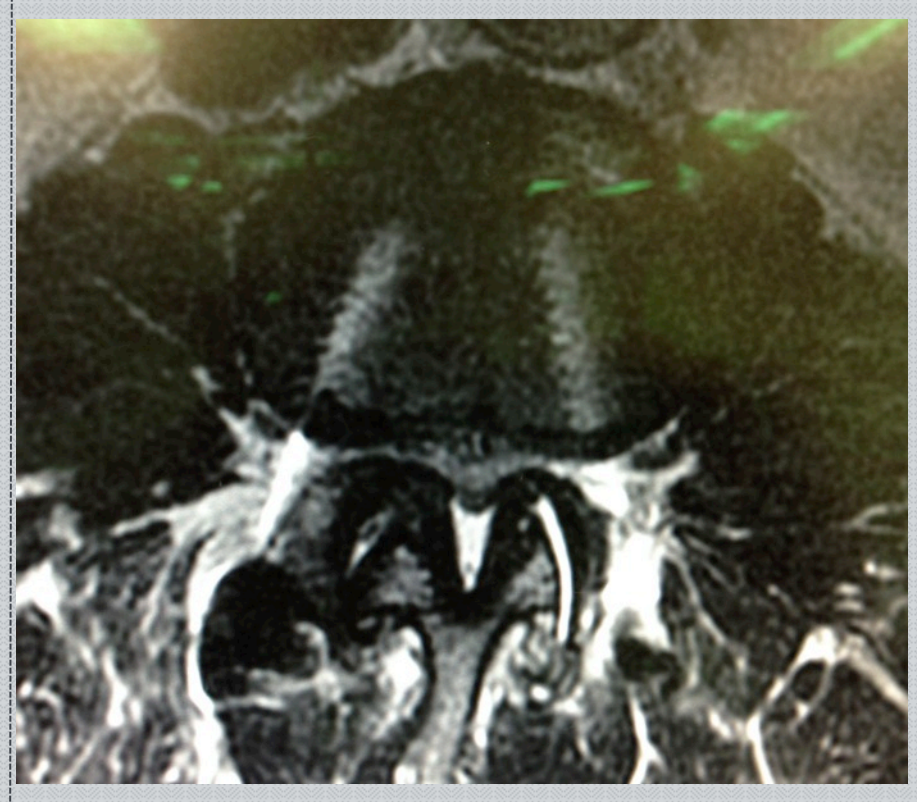
- Patient was discharged POD #1
- No new neurologic deficits or complaints

- 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

Case Example: Adjacent Segment Disease

56 yo s/p L3-S1 fusion, new groin/upper medial thigh pain. Instability on F/E x-rays L2-3

Another example of adjacent segment disease



Discussion: Comparative Studies

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THE SPINE JOURNAL

The Spine Journal 9 (2009) 13–21

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]

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Received 4 January 2008; accepted 5 August 2008

Landmark paper from 1 of the best surgeons in the country using open lumbar fusions. This is the gold standard for open fusions in our opinion.

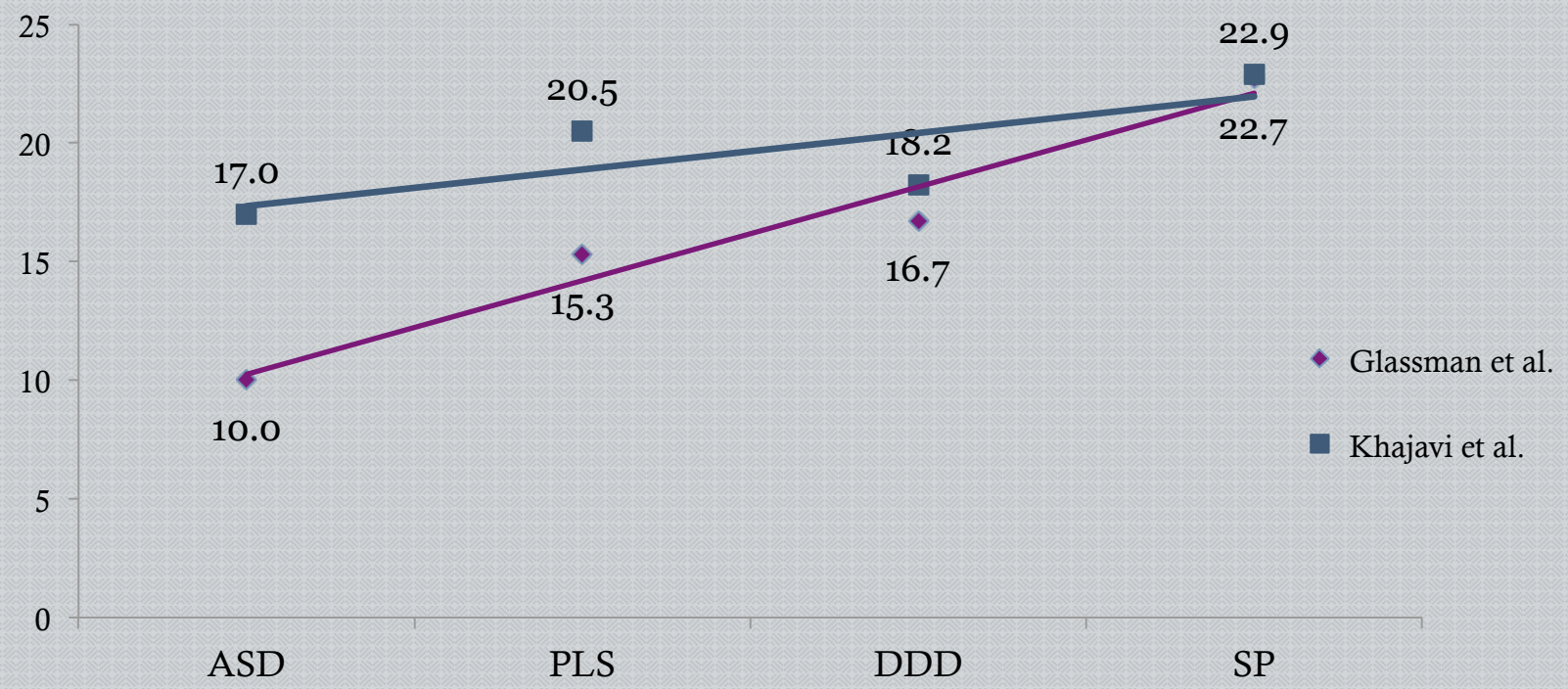
Discussion: Comparative Studies

	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 some isthmic spondylolisthesis pts at L5-S1, who have a better outcome generally

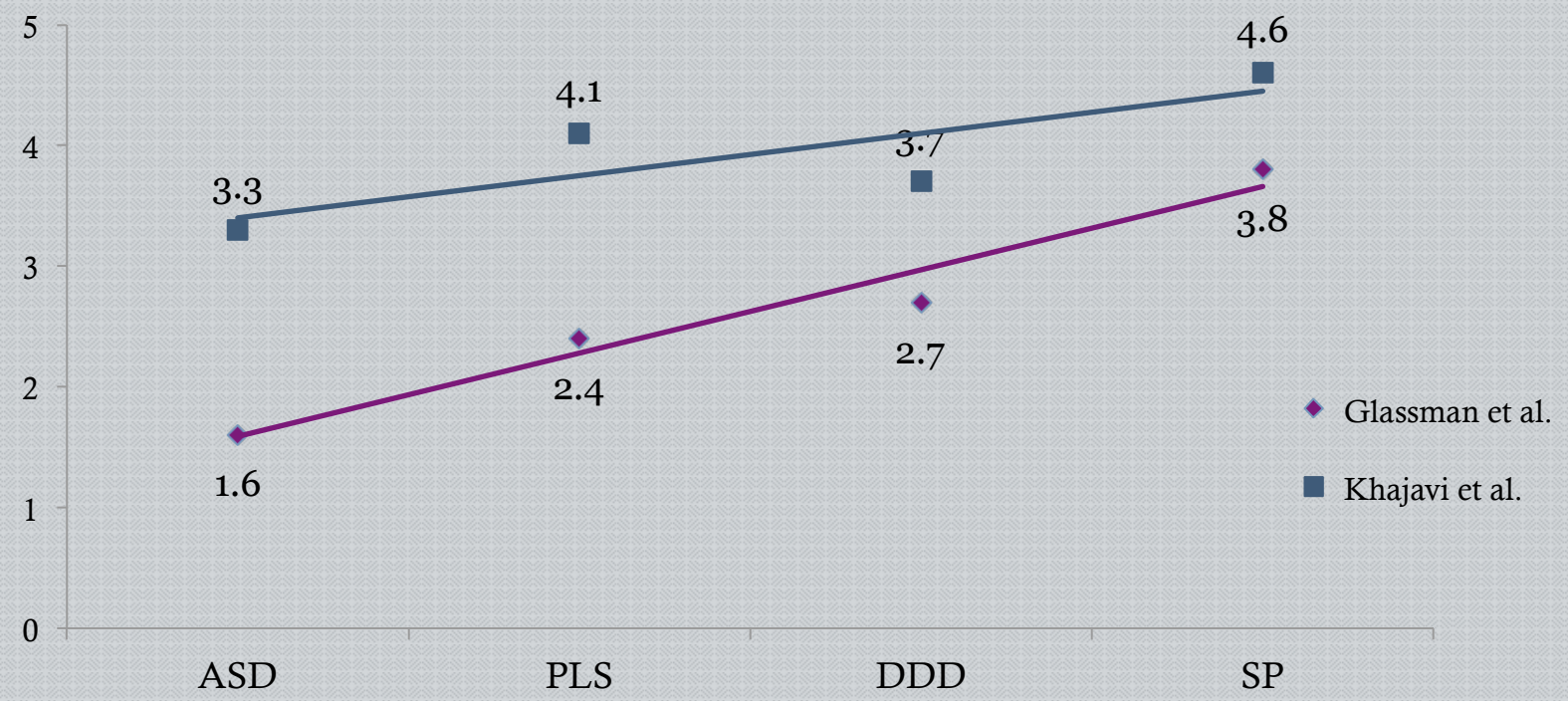
Discussion: Net Improvement: ODI

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



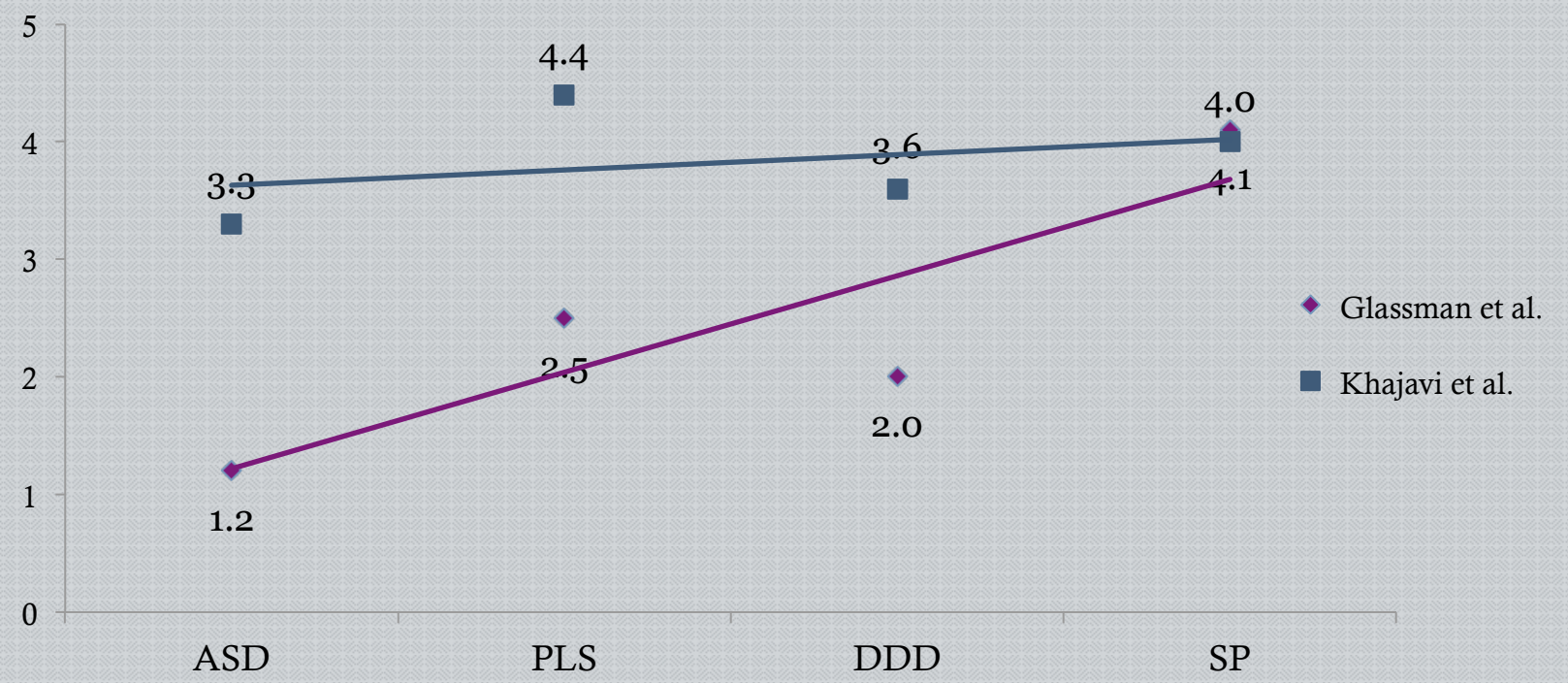
Discussion: Net Improvement: NRS LBP

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



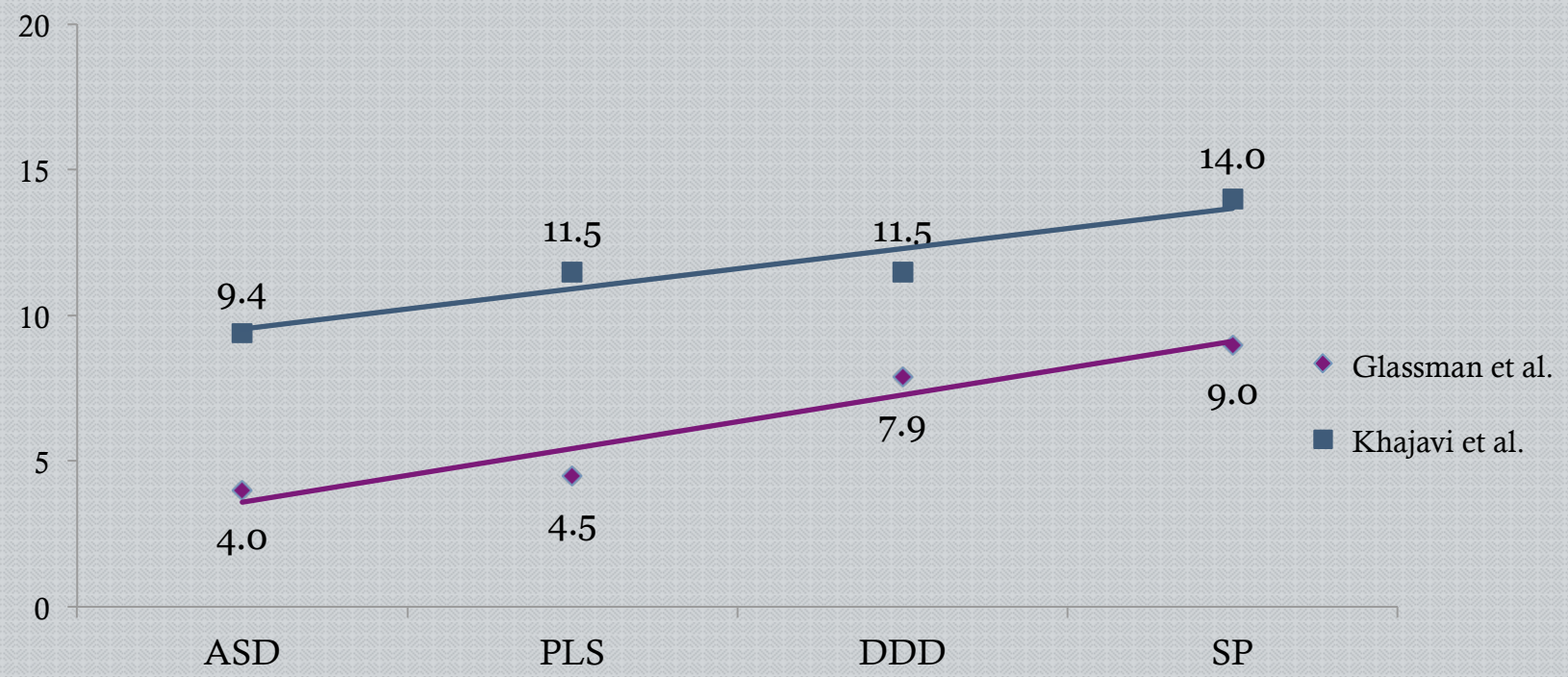
Discussion: Net Improvement: NRS LP

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

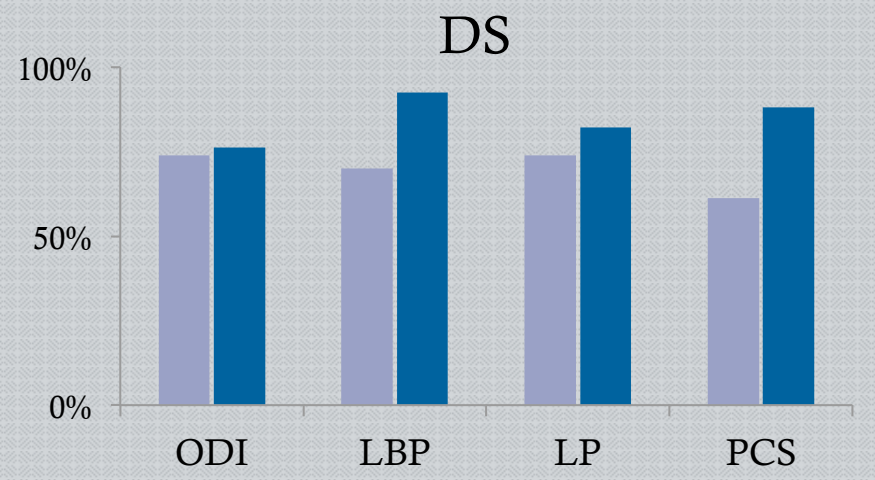
[1]Glassman et al. *J Bone Joint Surg Am*. 2008;90:1839-47.

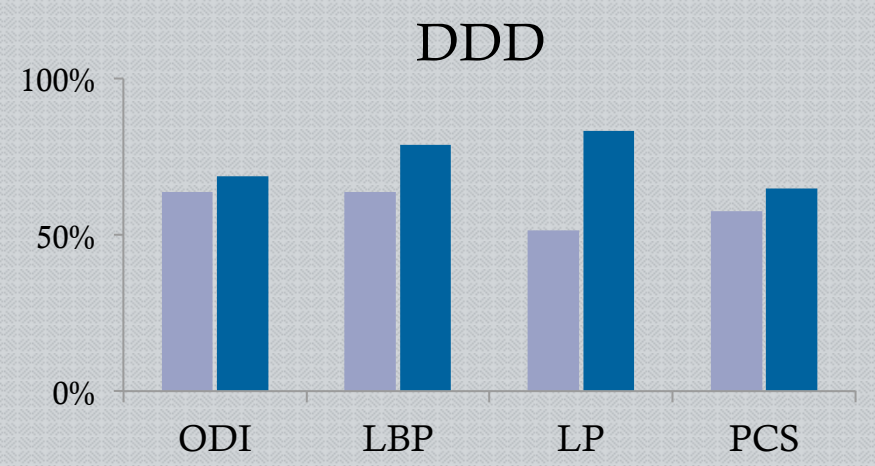
[2]Copay AG, et al. *Spine J*. 2008;8:968-74.

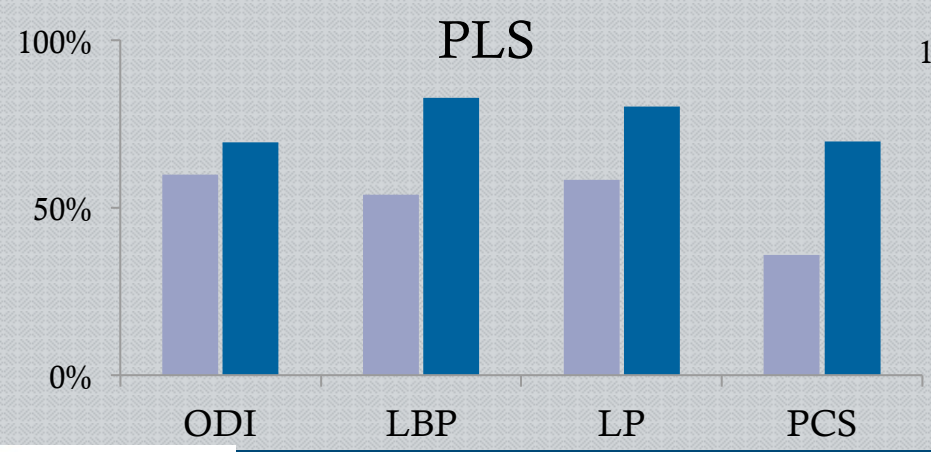
MCID Comparison

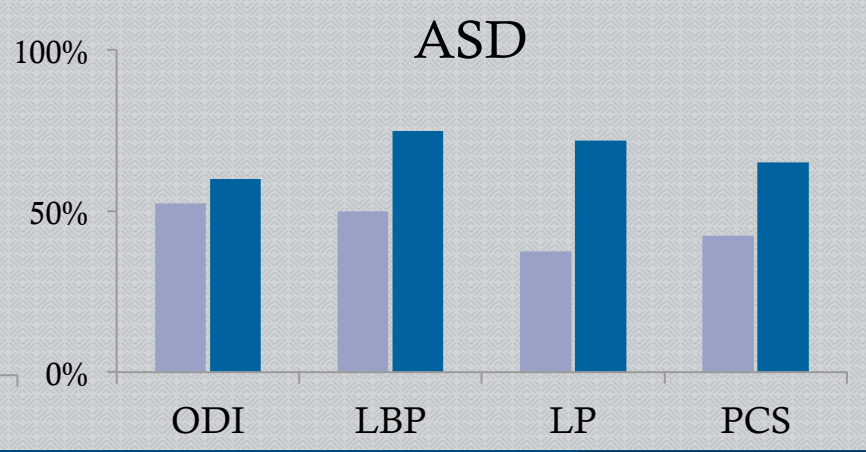
Glassman et al
Khajavi et al

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

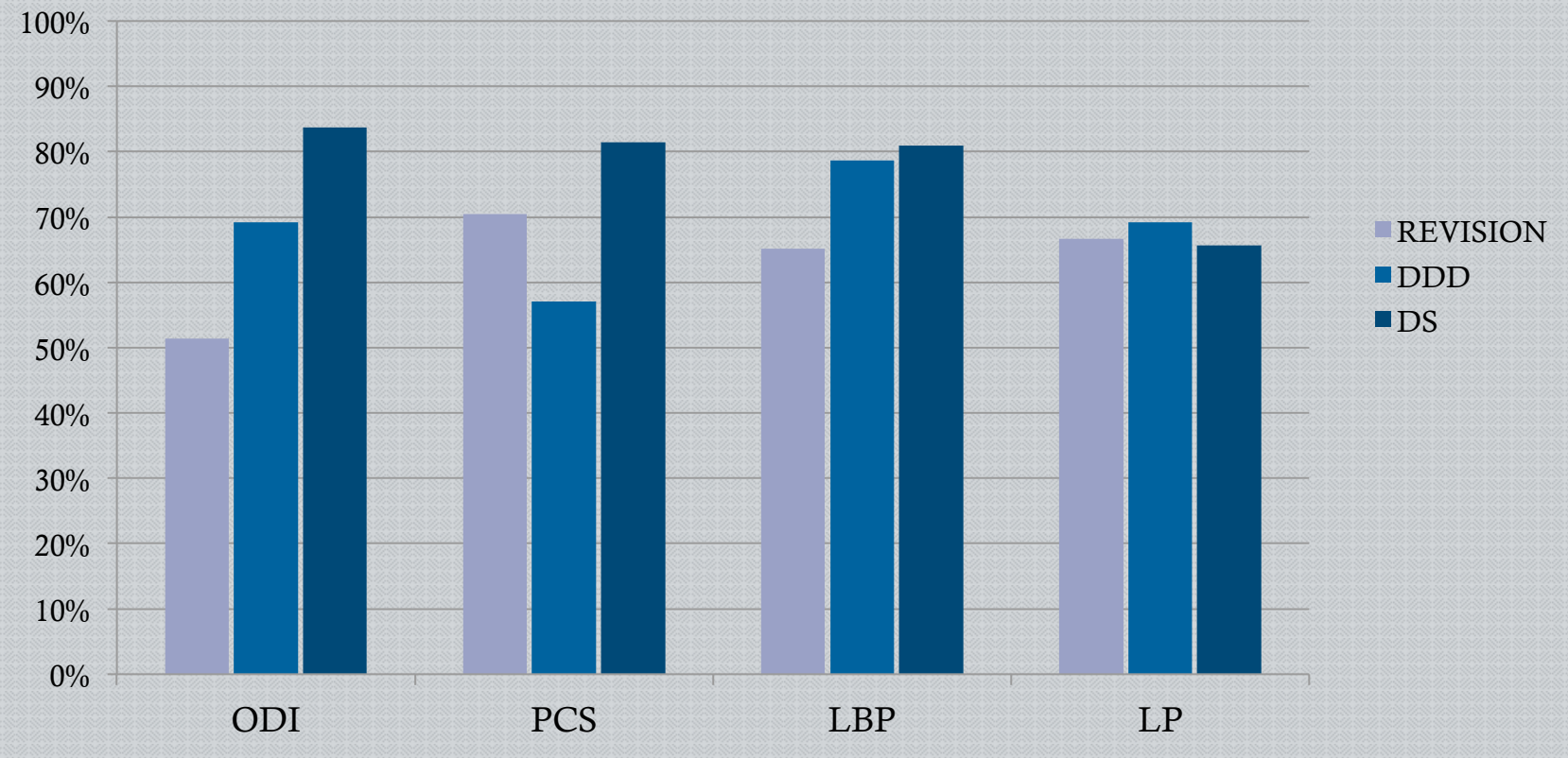








Substantial Clinical Benefit (SCB)



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

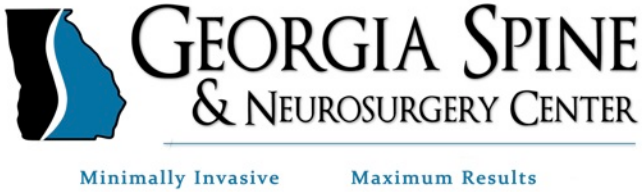
- Strengths
  - All consecutive patients L1-5 included
  - Outcomes all prospectively collected

- 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!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