

Surgical Solutions for Back Pain

Arthroplasty?

Fusion?

None of the Above?

Brad Duhon, MD, FAANS

***Colorado Pain Society Annual Meeting
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Bio/Disclosure

- ▶ **Brad Duhon, MD, FAANS**
- ▶ University of Colorado-Assistant Professor of Neurosurgery
- ▶ UC Health Highlands Ranch Hospital-Chief of Surgery
- ▶ UC Health Highlands Ranch Hospital-Director of Neurosurgery/Spine

- ▶ **Disclosure:**
 - ▶ Consultant-Boston Scientific
 - ▶ Consultant-Providence Medical
 - ▶ Consultant-SI Bone, Inc

- ▶ *No support for this presentation*
- ▶ *No royalties/grants*

I AM A SURGEON

“A chance to cut, is a chance to cure.”

Background

- ▶ Mechanical Back Pain
 - ▶ Aka Axial Low Back Pain, “Nonspecific” Back Pain
 - ▶ Most common cause of disability between ages 45-65
- ▶ With improved health and health care, people are living longer, and thus degenerative spine disorders are becoming more prevalent
- ▶ Billions of dollars have been spent on surgery for LBP
 - ▶ Thousands of research articles dedicated to the topic
 - ▶ Still no consensus on efficacy
- ▶ Disclaimer:
 - ▶ Vast majority of mechanical low back pain will resolve with time and conservative care
 - ▶ **Focus today: Persistent/Refractory mechanical back pain**
 - ▶ Excluding: Claudication, radiculopathy, instability



Goals

1. Review literature and data on 3 procedures:

1. Lumbar Fusion (LF)

1. DDD
2. Degenerative Scoliosis
3. Adjacent Segment Disease

2. Lumbar Disc Arthroplasty (LDA)

3. MIS SI Joint Fusion

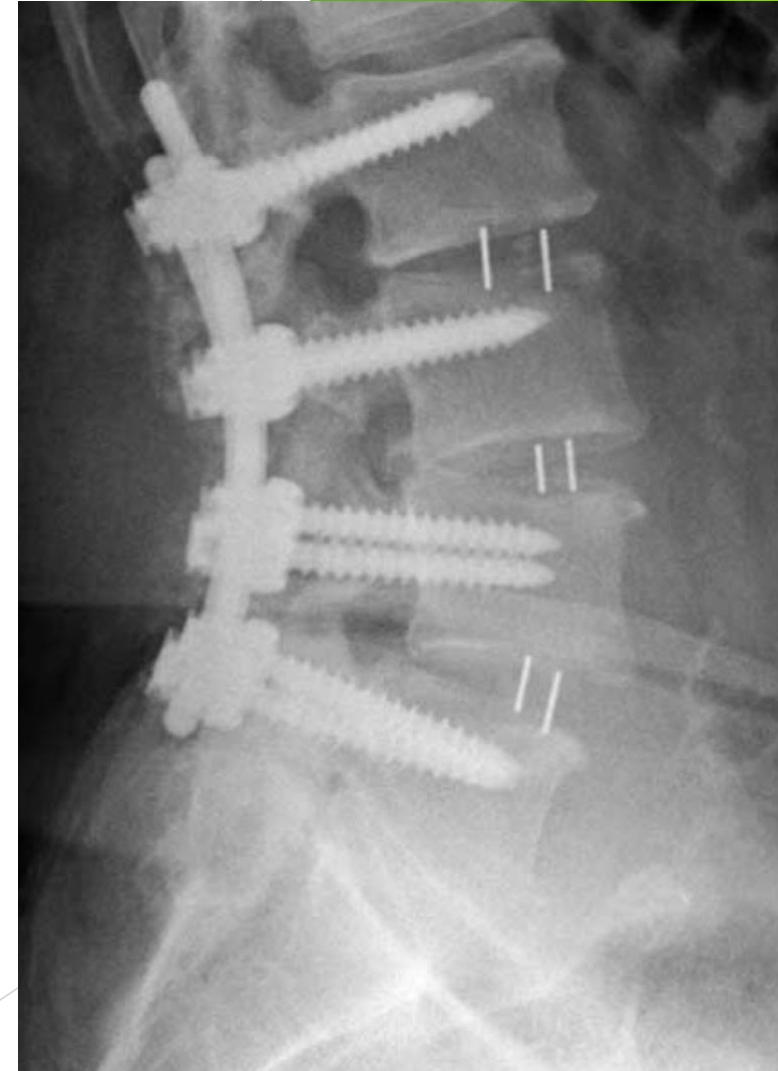
▶ Target Population:

- ▶ *Mechanical Back pain due to degenerative disc disease, lumbar spondylosis **WITHOUT** radiculopathy, claudication, instability, myelopathy*

Lumbar Fusion

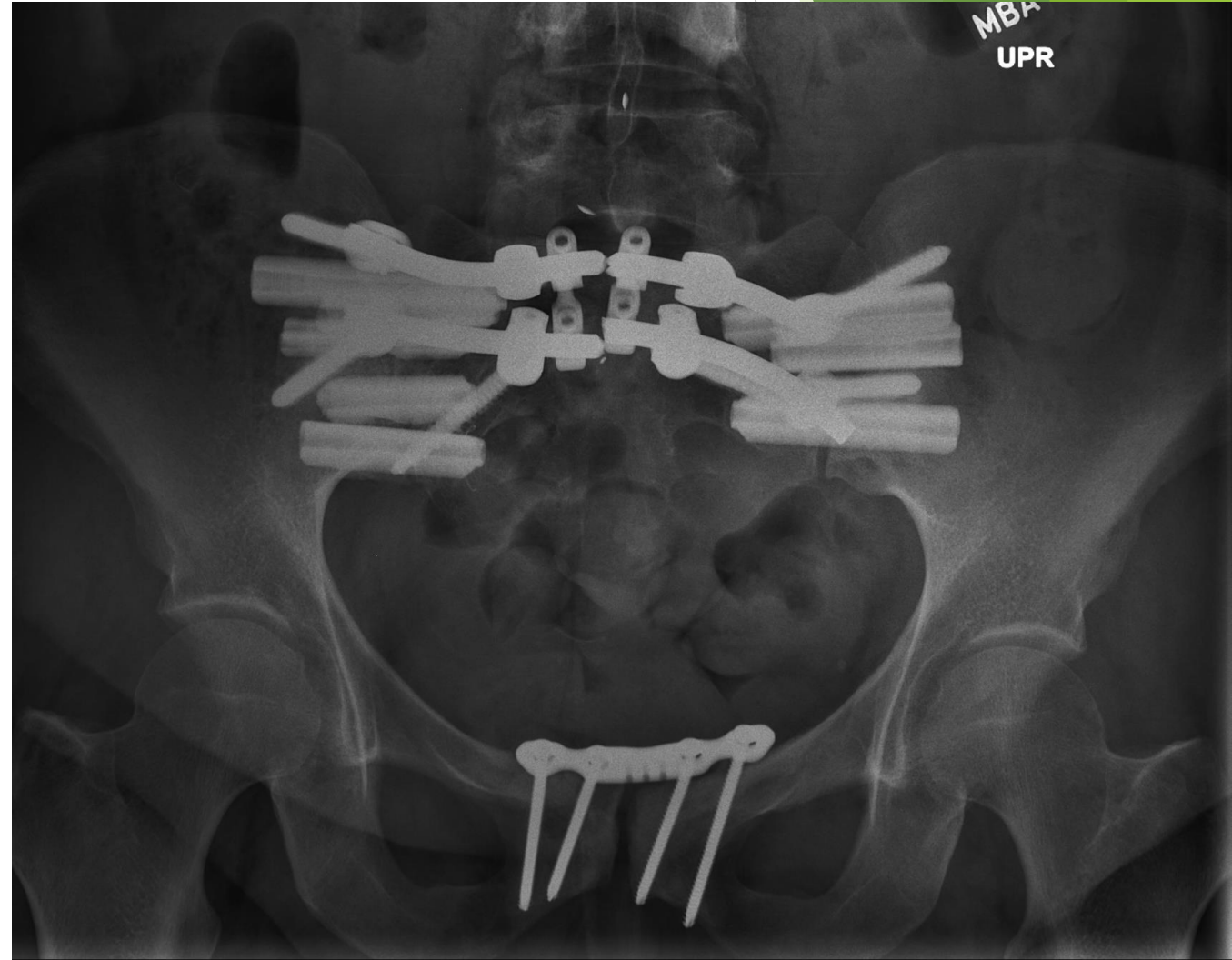
Surgical Solutions-Lumbar Fusion

- ▶ Surgical intervention has been utilized for years for mechanical back pain
 - ▶ Despite its widespread use, it remains controversial
- ▶ Clinical Studies have been flawed and outcomes variable
 - ▶ High Crossover Rates make definitive statements difficult
 - ▶ “Back Pain” is a highly variable disease and impossible to standardize
 - ▶ Follow-up rate is normally quite poor
 - ▶ *British-Norwegian Prospective study =55%*
- ▶ Despite drastic improvements in diagnostic tools
 - ▶ Correlation hasn't been proven
 - ▶ “Just because it doesn't look good, doesn't make it painful.”
- ▶ Multiple Surgical Options
 - ▶ TLIF, PLIF, ALIF, Lateral, Oblique, Open vs MIS



Surgical Solutions-Lumbar Fusion

- ▶ Underlying pathology/indications highly varied
 - ▶ Discogenic Pain
 - ▶ Facetogenic Pain
 - ▶ Degenerative Scoliosis
 - ▶ Spondylolisthesis
 - ▶ Degenerative vs Isthmic
 - ▶ Stable vs Unstable
 - ▶ SI Joint dysfunction
 - ▶ *Many, if not most, are a mixed picture*
- ▶ Fusion Concerns:
 - ▶ Adjacent Segment Degeneration/Disease (ASD)
 - ▶ TLIF-43%/10%
 - ▶ ALIF-44%/18%
 - ▶ PLIF-82%/27%



Clinical Study

The long-term outcome of lumbar fusion in the Swedish lumbar spine study

Rune Hedlund, MD, PhD^{a,*}, Christer Johansson, MSc^a, Olle Hägg, MD, PhD^b,
Peter Fritzell, MD, PhD^c, Tycho Tullberg, MD, PhD^d, Swedish Lumbar Spine Study Group

- ▶ Prospective RCT in Sweden comparing lumbar fusion to PT
- ▶ Inclusion:
 - ▶ Age 25-65
 - ▶ LBP >2yrs without nerve compression
 - ▶ Degenerative facets L4-5 or L5-S1 on XR, CT, or MRI
- ▶ Exclusion:
 - ▶ Previous Surgery (“successful” microdiscectomy ok)
 - ▶ Spondylolysis
 - ▶ Spondylolisthesis
 - ▶ Fracture (new or old)
 - ▶ Infection
 - ▶ Inflammatory process
 - ▶ Neoplasm

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► Demographics

► 294 Patients (144W 150M)

► Mean Age 47

► 3:1 Randomization Surgery:PT

► 3 Fusion Types Allowed (Autograft only)

► Posterolateral Non-instrumented

► Instrumented Posterolateral

► Instrumented Circumferential

► ALIF or PLIF with Instrumentation

► ***No difference identified between surgery***

► Primary Outcome: Global Assessment

► Much Better, Better, Unchanged, Worse

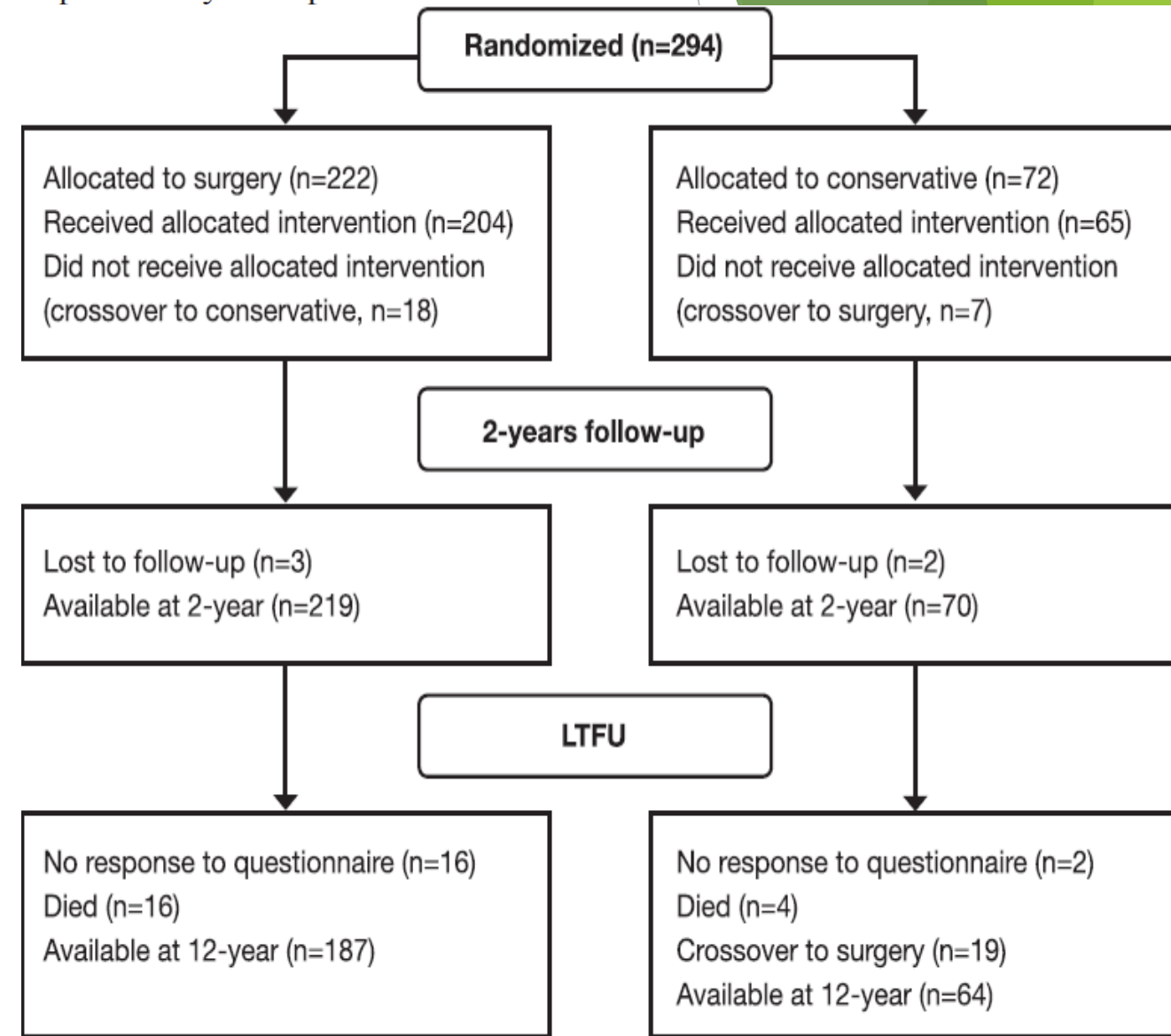
	Surgical group (n=222)	Medical interventional group (n=72)
Age (range)	43 (25–64)	44 (26–63)
Sex (female)	112 (50.5%)	37 (51.4%)
Smoking	40.6%	49.3%
Comorbidity	39.1%	23.5%
Mean pain duration, years (range)	7.8 (2–34)	8.5 (2–40)
Mean time of sick leave, years (range)	3.2 (0.1–18)	2.9 (0.1–8)
Working part or full time	20.9%	23.6%
ODI (0–100)	47.3 (11.4)	48.4 (11.9)
VAS back pain (0–100)	64.2 (14.3)	62.6 (14.3)
VAS leg pain (0–100)	35.3 (25.4)	35.6 (25.2)
Zung depression scale (20–80)	39.1 (13.3)	39.4 (13.9)

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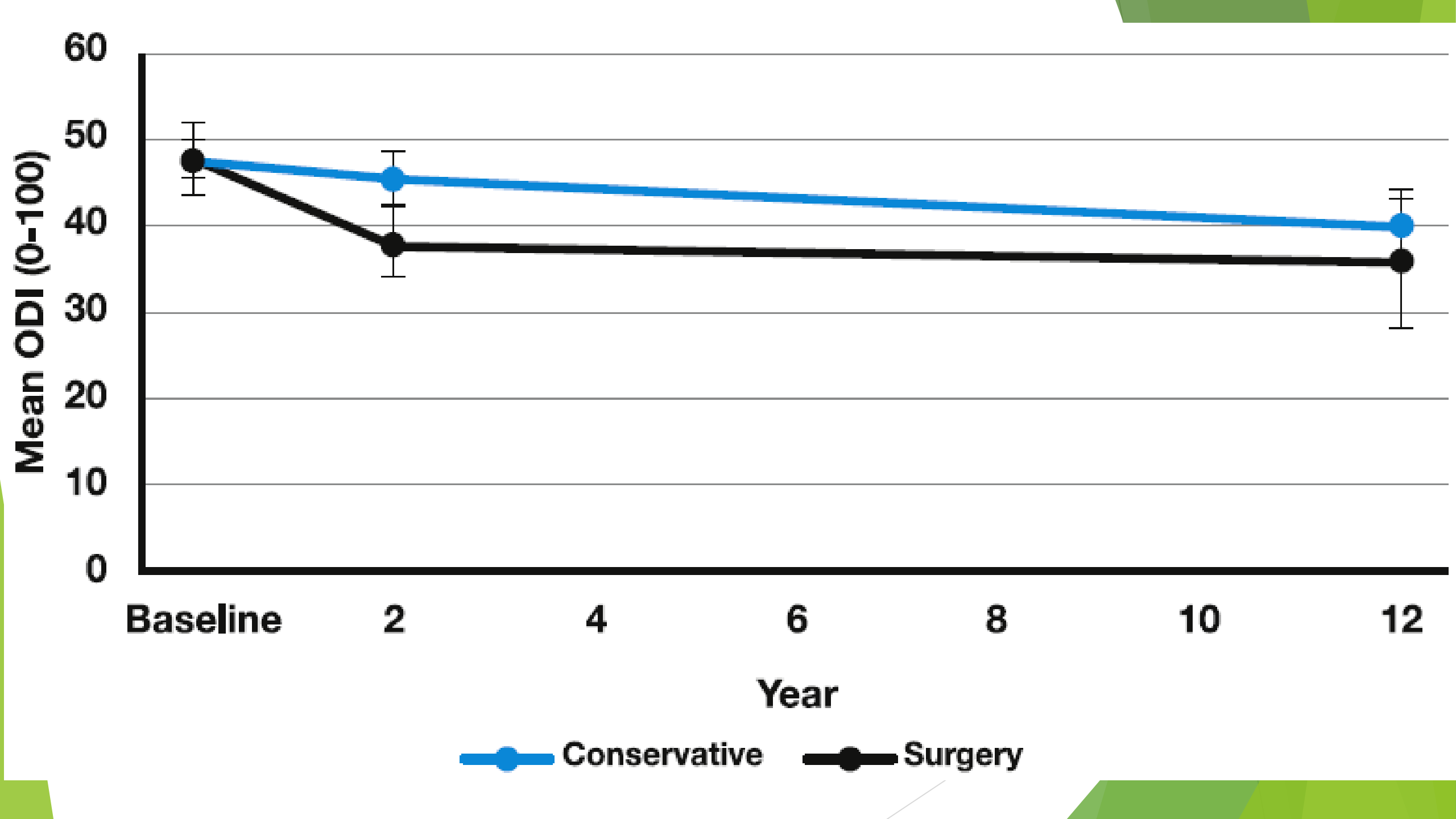
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- ▶ Mean f/u 12.8yrs (9-22)
- ▶ 85% F/U
 - ▶ 20 died (unrelated) → 92% f/u
- ▶ Results:
 - ▶ ITT (Intention to Treat):
 - ▶ No difference (36% Cons → Surg Xover)
 - ▶ AT (As Treated):
 - ▶ Surgery Superior
 - ▶ PP (Per Protocol-Excluded if Xover or lost):
 - ▶ Surgery Superior
 - ▶ GCAC:(Xover pts scored as failure)
 - ▶ Surgery Superior



As-treated analysis (fusion vs. medical interventional treatment) on outcome at LTFU

Outcome measure	Fusion surgery (n=205) Unadjusted mean (SD)	Medical interventional treatment (n=46) Unadjusted mean (SD)	Adjusted LTFU treatment effect: fusion compared with medical interventional (95% CI)*	Adjusted p-value
Primary outcome				
Global Assessment (back pain)				
Much better	28%	9%	−0.51 (−0.85 to −0.17)	.004
Better	38%	22%		
Unchanged	18%	53%		
Worse	16%	16%		
Secondary outcome				
ODI (0–100)				
Baseline	47.4 (11.2)	47.6 (13.0)		
LTFU	35.8 (18.6)	40.1 (17.3)	−4.1 (−10.2 to 1.9)	.182
VAS LBP (0–100)				
Baseline	64.0 (14.2)	62.9 (15.1)		
LTFU	45.6 (23.7)	51.0 (23.5)	−5.5 (−13.5 to 2.5)	.175
VAS LP (0–100)				
Baseline	34.7 (25.4)	35.5 (26.2)		
LTFU	40.6 (43.9)	39.1 (25.3)	1.3 (−12.7 to 15.3)	.859
Pain medication				
Several times a day	27%	20%	−0.14 (−0.51 to 0.22)	.442
Every day	19%	13%		
Occasionally	33%	49%		
Never	21%	18%		
Pain frequency				
Always	43%	42%	0.06 (−0.33 to 0.47)	.736
Daily	23%	31%		
Several times a week	11%	11%		
Occasionally	23%	16%		
Work status				
Full-time/part-time	39%	39%	−0.14 (−0.60 to 0.31)	.529
Not working	61%	61%		
Zung depression scale (20–80)				
Baseline	43.3 (8.2)	43.7 (9.1)		
LTFU	40.7 (10.5)	46.8 (10.7)	−5.8 (−10.1 to −1.7)	.006
<i>Would you go through the same treatment again?</i>	76%	86%	1.65 (0.59 to 4.60)	.341 [†]



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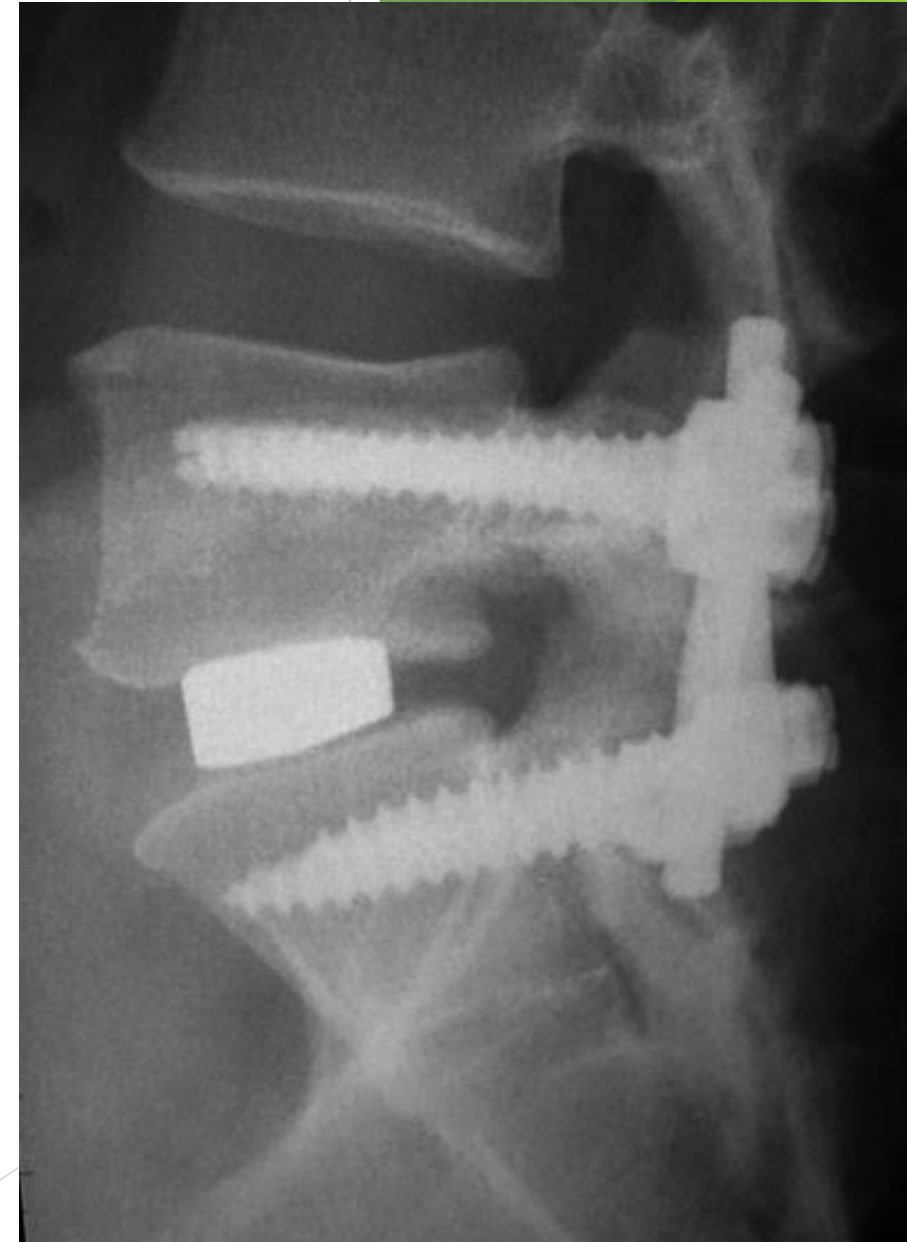
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- ▶ Ultimately surgical arm lead to:
 - ▶ 33% improvement in back pain score
 - ▶ 25% decrease in disability (ODI)
 - ▶ Lower total economic cost
 - ▶ Twice as many returned to work
- ▶ Circumferential Fusion with highest fusion rate
 - ▶ Clinically no difference found
- ▶ *Again, statistically conflicting due to crossover*

Anatomic Surgical Management of Chronic Low Back Pain

Bohdan Chopko, MD, PhD*; **John C. Liu, MD[†]**; **Mohammad K. Khan, DO[†]**

- ▶ Literature review of prospective clinical studies for LBP
 - ▶ Evaluated Lumbar fusion, Lumbar disc arthroplasty, Dynamic stabilization
- ▶ 30 RCT reported outcomes for lumbar fusion for LBP
 - ▶ Majority compared surgical techniques
 - ▶ 3 Studies reported negative effects of surgery
 - ▶ Compared with cognitive-behavioral model or structured rehab
 - ▶ Only one demonstrated clear superiority to conservative care
 - ▶ Only 16% “Excellent” outcomes vs 6% in conservative arm
 - ▶ Confirmed the variability in approach
 - ▶ No real differences reported between surgical techniques
 - ▶ MIS techniques do appear superior short-term, but long-term not validated
 - ▶ Instrumentation does appear preferable for fusion
 - ▶ ASD is apparently higher
 - ▶ Functional and clinical superiority has not been proven



Open vs MIS Lumbar Fusion

- ▶ **MIS Superiority:**
 - ▶ Blood Loss
 - ▶ Muscle Damage/Atrophy
 - ▶ Length of Stay
 - ▶ Narcotic Usage/Dependence
 - ▶ Shorter Return to work
- ▶ **Disadvantages:**
 - ▶ Surgeon Comfort
 - ▶ Length of Surgery*
 - ▶ Posterolateral Fusion
 - ▶ Relevant?
 - ▶ Sagittal Balance
 - ▶ **Long-term Superiority has not been proven**



Lumbar Fusion for DDD

- ▶ More than just a radiographic diagnosis
 - ▶ Zhou & Abdi:
 - ▶ 26.7-59% Sensitivity for predicting DDD on MRI
- ▶ Provocative Discography (Pain reproduction)
 - ▶ Mixed reports, but some data found superior response to fusion
 - ▶ Should be performed by experienced “3rd Party”
 - ▶ Has been found to influence surgical decision making in 71% of cases
 - ▶ ?Iatrogenic Degeneration?



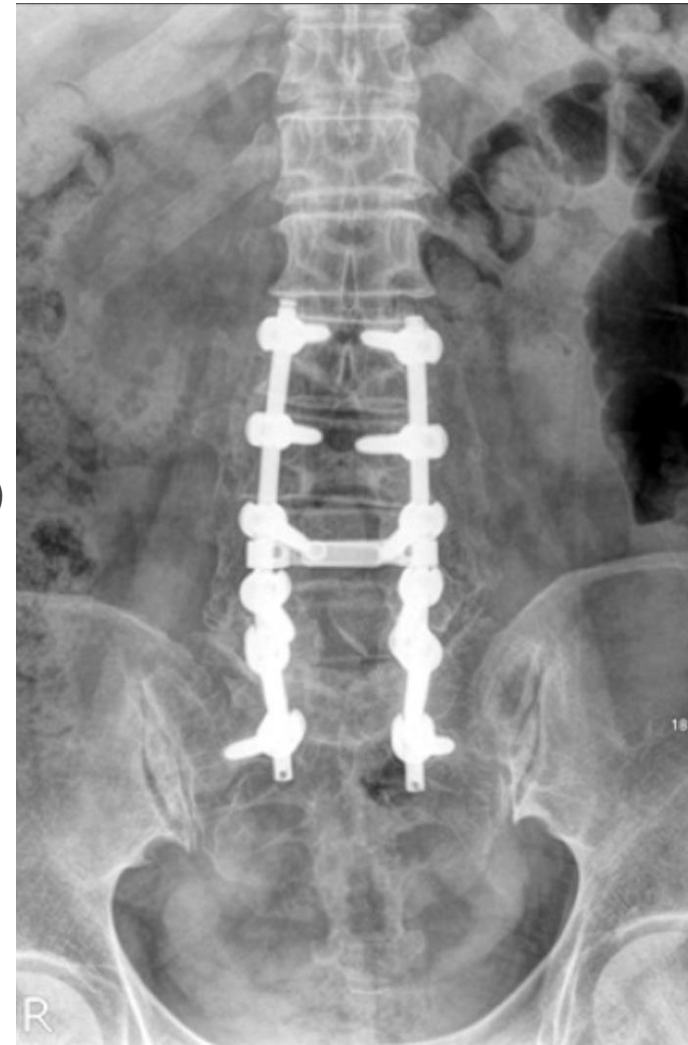
Degenerative Scoliosis

- ▶ Systematic Review for Degen Scoliosis Surgery
- ▶ 59 studies reviewed
 - ▶ All felt to be weak designed or small
- ▶ Conclusions:
 - ▶ Surgical correction “Generally Appropriate”:
 - ▶ At least moderate symptoms
 - ▶ Larger (>30deg) or progressive deformity
 - ▶ Sagittal imbalance
 - ▶ Overutilization (Unindicated correction surgeries)
 - ▶ **Rate as high as 70%**
- ▶ Revision Rates (*Phan et al*):
 - ▶ Short segment (<3 levels): 14%
 - ▶ Long segment (>2 levels): 17%

Surgery for Degenerative Lumbar Scoliosis

The Development of Appropriateness Criteria

Peggy Guey-Chi Chen, MD, MSc, MHS,* Michael D. Daubs, MD,[†] Sigurd Berven, MD,[‡] Laura B. Raaen, MPH,* Ashaunta T. Anderson, MD, MPH, MS,^{*,§} Steven M. Asch, MD, MPH,^{¶,||} and Teryl K. Nuckols, MD MSHS^{*,**}, and the Degenerative Lumbar Scoliosis Appropriateness Group



Degenerative Scoliosis

Problems/Limitations:

- ▶ *What defines a “deformity?”*
- ▶ 1. So much emphasis has been placed on sagittal balance/SVA
 - ▶ Given surgeons permission slip to over-extend constructs
 - ▶ Problem is L4-5, but to “correct alignment,” construct extended L2-Sacrum
- ▶ 2. Goals for alignment appear different based on age
 - ▶ *Grannie didn’t develop a flat back overnight*
 - ▶ Don’t treat for a number. It’s a piece of the equation/global picture
- ▶ 3. How do you know the deformity is the cause of pain?
 - ▶ Many with scoliosis have SI Jt pain, isolated/focal pain



Lumbar Fusion for Adjacent Segment Disease

Adjacent Segment Disease

► Background:

- Fusing mobile spinal segment(s) increases strain on adjacent segments inducing/promoting degeneration
 - *Adjacent intradiscal pressure found to be 45% higher after fusion*
- Incidence highly varied

► Definition:

- Disc degeneration, facet arthropathy, spinal stenosis, instability at a level contiguous with a prior fused segment

► Factors:

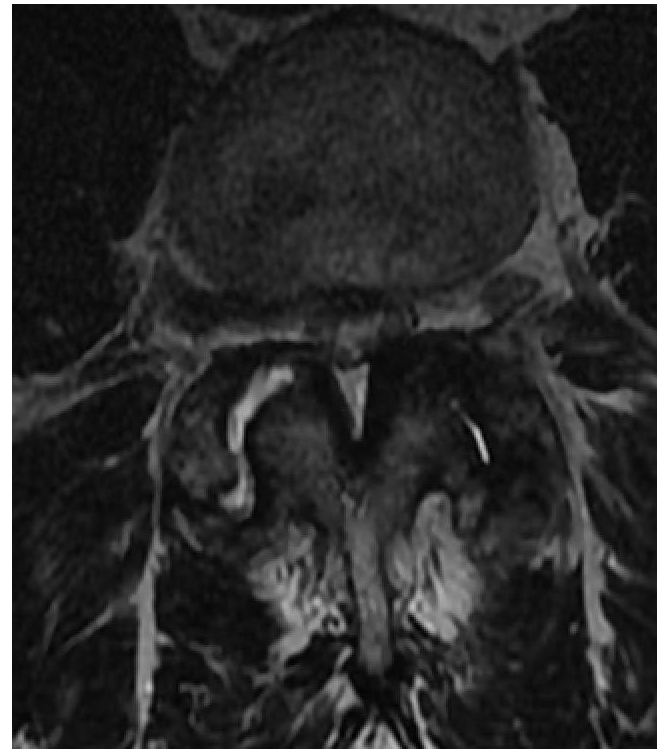
- Age-Dependent degeneration
- Extent of prior decompression
- Screw placement
- Sagittal Alignment

► Presentation:

- Mechanical back pain
 - Discogenic, Facetogenic, Instability
- Stenosis
 - Claudication
 - Radiculopathy

► Incidence

- All over the place
- Radiographic: 5-100%
- Symptomatic: 5-18% (up to 164 months)



Adjacent Segment Disease

- ▶ Literature Review of ASD after Lumbar Fusion
- ▶ 56 Articles identified
- ▶ Timing
 - ▶ Some studies ~25 months
 - ▶ Others 8-11 months
- ▶ Predisposing Factors (*Indeterminate impact*)
 - ▶ Pedicle Screws
 - ▶ Superior screw position?
 - ▶ MIS Limitation?
 - ▶ Pre-existing degeneration
 - ▶ Number of segments fused
 - ▶ Sagittal Alignment
 - ▶ Age >55 (Most validated)
 - ▶ Osteoporosis
- ▶ Presentation
 - ▶ Most asymptomatic
 - ▶ Back pain, radiculopathy, instability, claudication

Adjacent Segment Disease after Lumbar or Lumbosacral Fusion: Review of the Literature

Paul Park, MD, Hugh J. Garton, MD, MHsc, Vishal C. Gala, MD, Julian T. Hoff, MD, and John E. McGillicuddy, MD

- ▶ Treatment
 - ▶ Same conservative algorithms exist as virgin spine
 - ▶ Surgery:
 - ▶ *Very little data*
 - ▶ All studies with different conclusions/recs
 - ▶ Instability? Mechanical Back Pain?
 - ▶ Extend Fusion
 - ▶ Disc herniation/Radiculopathy only?
 - ▶ Decompression can be attempted
 - ▶ Claudication?
 - ▶ Most debated due to amount of decompression needed
 - ▶ *If extension chosen, instrumentation mandatory*
 - ▶ 80% higher risk of pseudoarthrosis
- ▶ Outcomes
 - ▶ Overall published outcomes quite poor
 - ▶ Extension of fusion appears to be superior to decompression
 - ▶ 7/37 in one study with reoperation
 - ▶ Data is very limited
 - ▶ 1 study with 77% very good outcomes @ 5 years
 - ▶ 5/39 needed another operation

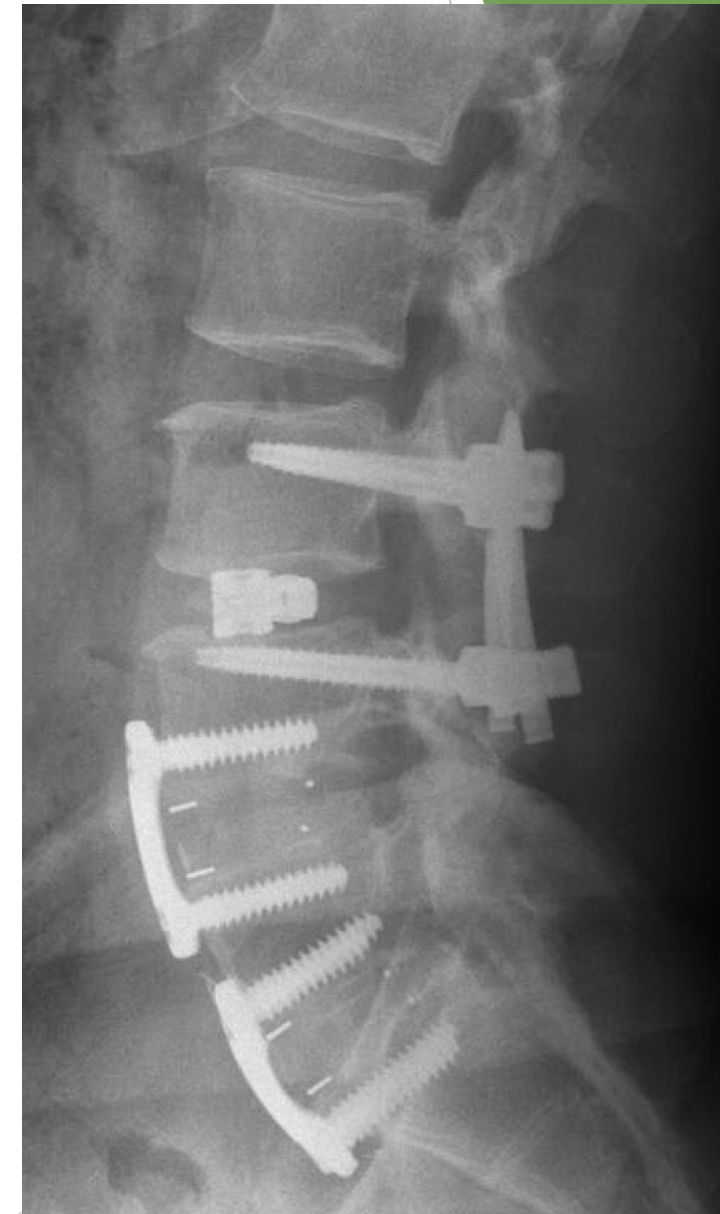
Adjacent Segment Disease

[Orthopedics](#). 2018 Mar 1;41(2):e161-e167. doi: 10.3928/01477447-20170621-02. Epub 2017 Jun 30.

Effectiveness of Reoperations for Adjacent Segment Disease Following Lumbar Spinal Fusion.

[Drysch A](#), [Ajiroye RM](#), [Sharma A](#), [Li J](#), [Reza T](#), [Harley D](#), [Park DY](#), [Pourtaheri S](#).

- ▶ Meta-Analysis of Surgery for ASD
- ▶ 5 studies (All Level IV) included
 - ▶ 118 patients total
- ▶ Extension of Fusion was choice in all studies
- ▶ Results:
 - ▶ Clinical Improvement in 71%
 - ▶ Radiographic Fusion 89%
- ▶ Revision Rates:
 - ▶ 4.5-23%



Conclusion

- ▶ High variability in disease states and techniques confounds data
- ▶ High crossover rates confound data
- ▶ *Data to support lumbar fusion for mechanical back pain is poor at best*
 - ▶ *Problem: Pathology and surgical solutions are so varied*
- ▶ Going back to the well and fusing again seems to be standard for ASD
 - ▶ Outcomes data very limited
 - ▶ *Can decompression be successful?*
- ▶ *National Institute for Health and Care Excellence (NICE)*
 - ▶ 2017 Guideline statement over fusion for non-specific LBP
 - ▶ *“Fusion for non-specific low back pain should only be performed as part of a randomized controlled trial, xxx. Thus, spinal fusion xxx will no longer be routine forms of treatment for patients with low back pain.”*

Lumbar Disc Arthroplasty

aka Lumbar Disc Replacement

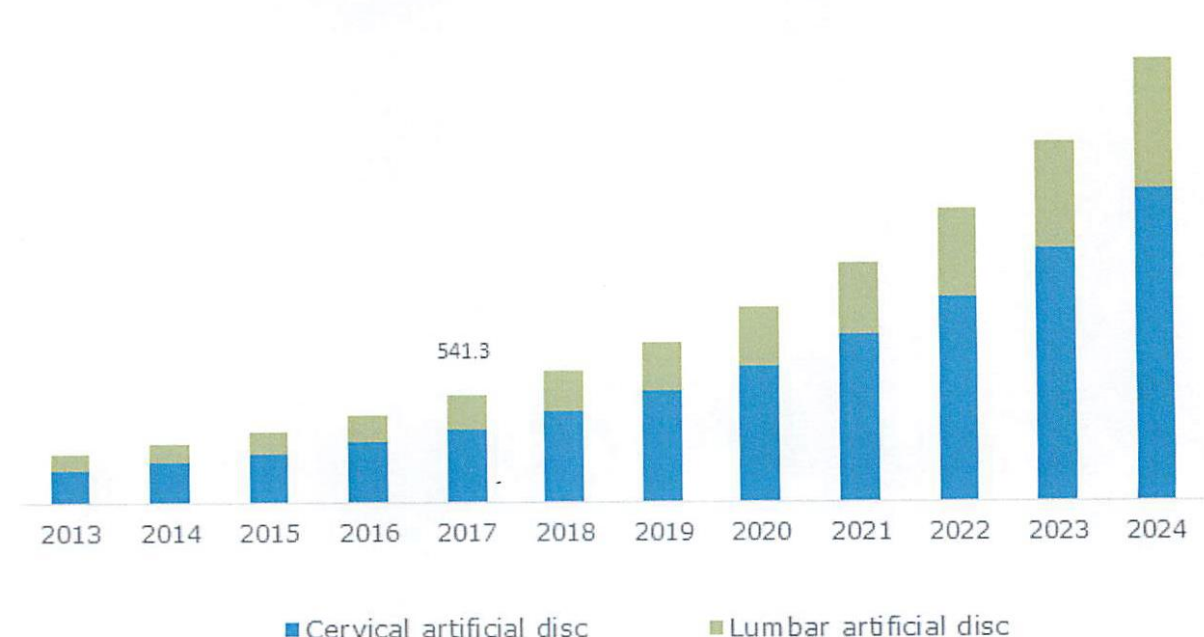
Lumbar Total Disc Arthroplasty (TDA)



Mechanism/Background

- ▶ Indicated for single-level Degenerative Disc Disease
- ▶ 3 FDA-Approved Devices (One no longer manufactured)
 - ▶ Synthes Pro-Disc L
 - ▶ Aesculap Active-L
- ▶ Attempts to mimic natural spinal motion
 - ▶ Theory:
 - ▶ Reduced morbidity of ASD, pseudoarthrosis, donor-site pain
- ▶ Contraindications:
 - ▶ Spondylolisthesis
 - ▶ Spondylolysis/Facetogenic Pain
 - ▶ Stenosis (Foraminal or Central)
 - ▶ Deformity
 - ▶ Osteoporosis
 - ▶ +/- Adjacent to a fusion
- ▶ *Insurance Approval Very Difficult*

U.S. Artificial Disc Market, By Type, 2013 – 2024, (USD Million)



Placement determines the biomechanics



Lumbar Total Disc Arthroplasty (TDA)

- ▶ Huang , et al
 - ▶ 100 Patients with mechanical low back pain
 - ▶ 95% with at least one contraindication
- ▶ 10-year adjacent segment disease:
 - ▶ 2-4.5% for TDA
 - ▶ 14-29% for lumbar fusion
- ▶ Satisfaction rates equivalent (85-95%)
- ▶ Faster patient recovery
 - ▶ Higher return to work rates
 - ▶ Lower long-term employment
- ▶ Lower reoperation rates
- ▶ Disadvantages:
 - ▶ Surgeon experience/comfort
 - ▶ Insurance Approval
 - ▶ Strict inclusion criteria
 - ▶ Early devices with poor outcomes
 - ▶ Complication rates largely related to:
 - ▶ Exposure, improper sizing, surgeon technique



Comparison of artificial total disc replacement versus fusion for lumbar degenerative disc disease: a meta-analysis of randomized controlled trials

Jiangbo Wei • Yueming Song • Lin Sun • Chaoliang Lv

- ▶ Review of 6 RCT evaluation TDR vs Lumbar fusion (2 years)
 - ▶ 1081 Patient-TDR
 - ▶ 522-Lumbar Fusion
- ▶ VAS:
 - ▶ Improved VAS for back pain in both groups, superior for TDR
- ▶ ODI:
 - ▶ Improved ODI for back pain in both groups, superior for TDR
- ▶ Return to work:
 - ▶ No difference between the 2 groups
- ▶ Complications:
 - ▶ Complication rate significantly higher in fusion group than TDR
- ▶ Reoperation rate:
 - ▶ No different between the 2 groups

Lumbar total disc arthroplasty: outdated surgery or here to stay procedure? A systematic review of current literature

Matteo Formica¹ · Stefano Divano¹ · Luca Cavagnaro¹ · Marco Basso¹ ·
Andrea Zanirato¹ · Carlo Formica² · Lamberto Felli¹

► 59 Articles Included

► Findings:

- Majority showed no improvement over fusion (VAS)
 - *Trend toward TDA*
- *All studies did demonstrate significant reduction in LBP*
 - Skol, et al (5yrs): 62 → 22 (VAS)
 - Zigler (5yrs): 75 → 37 (VAS)
- Functional Outcomes:
 - Guyer, et al:
 - Return to work 65% TDA vs 46% fusion
 - Disability 8% TDA vs 21% fusion
- Safety:
 - No difference in complication rates
 - Reoperation rates overall higher in fusion
- Adjacent Segment Disease:
 - Pooled risk:
 - 1.2% TDA vs 7% Fusion



Complications and Revisions

The evidence base further demonstrates similar or lower risk of other types of complications such as reoperations with TDR than with fusion over time

2 years

Meta-analysis	Complications	Reoperations
	TDR vs. Fusion: Odds Ratio (95% CI)	
Nie et al., 2015	0.50 (0.29, 0.84); P = 0.008	0.62 (0.36, 1.06); P = 0.08
Noshchenko 2014	0.60 (0.48, 0.75); P < 0.001	0.83 (0.58, 1.18); P = 0.302
Rao 2014	0.72 (0.45, 1.14); P = 0.16	0.83 (0.39, 1.77); P = 0.63
Ren 2014	---	0.15 (0.04, 0.61); P = 0.0008
Jacobs 2012	---	0.80 (0.51, 1.24); P = 0.31
Wei 2013	0.57 (0.38, 0.84); P = 0.31	0.91 (0.57, 1.46); P = 0.71

5 to 10+ years

5-year RCTs

- Reoperation rates never higher with TDR^{1,2,3,4}
 - 2.3% to 8% for TDR
 - 8.3% to 16.3% for fusion
- Significantly lower SAEs with TDR²
- Very low device migration / subsidence

Long-term Observational

- Reoperation rates typically ≤7% for TDR⁵⁻⁹
- Not seeing studies with high rates of failed TDRs, catastrophic failures, deaths
- Reasonably low rates of overall complications

- Multiple studies found a significantly lower re-op rate for TDR vs. fusion
- Some found rate lower or similar for TDR vs. fusion
- No randomized studies found a higher re-op rate for TDR

RCTs: ¹ Guyer 2009; ² Zigler 2012; ³ Skold 2013; ⁴ Gornall 2016; ⁵ Siegel 2016; ⁶ Tatzsman 2010; ⁷ Aghaiey 2014; ⁸ 51
Observational: ⁹ Lemaire 2005; ⁶

Final Words of Wisdom From Experienced Arthroplasty Surgeons...

- Lumbar TDR is not for every patient
 - Lumbar TDR is not for every surgeon
 - A good TDR is better than a good fusion
 - A good fusion is better than a bad TDR
 - A bad TDR is worse than a bad fusion
- *“FUSION COVERS UP THE SURGEON’S SINS...”*
- ARTHROPLASTY MAGNIFIES THE SURGEON’S SINS...”

Conclusions

- ▶ TDA with comparable (?superior?) Outcomes for LBP with Lumbar Fusion
- ▶ Complication rates not worse than Lumbar Fusion
- ▶ Reoperation Rates appear better than Lumbar Fusion
- ▶ Adjacent segment disease better than fusion
- ▶ **All studies with 5 year f/u with significant reduction in LBP**
- ▶ Problem:
 - ▶ Comparing to “Gold Standard” which isn’t very good.
- ▶ *National Institute for Health and Care Excellence (NICE)*
 - ▶ 2017 Guideline statement over fusion for non-specific LBP
 - ▶ ***“Fusion for non-specific low back pain should only be performed as part of a randomized controlled trial, and that lumbar disc replacement should not be performed. Thus, spinal fusion and disc replacement will no longer be routine forms of treatment for patients with low back pain.”***

SI Joint Fusion

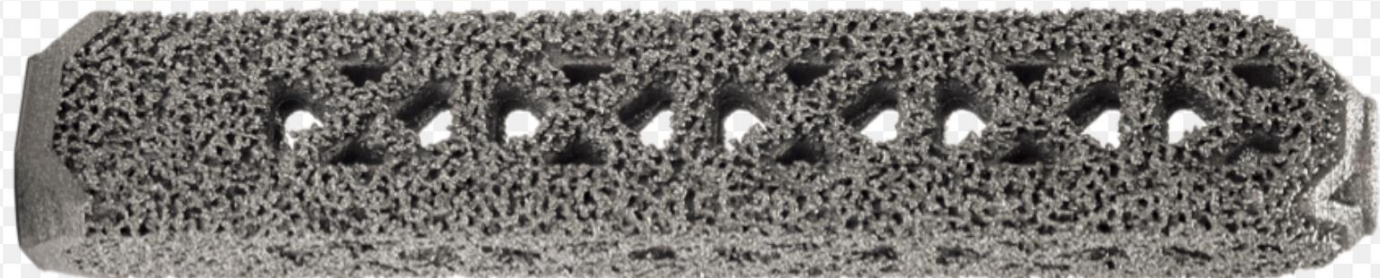
Background

- ▶ SI Joint Fusion has exploded in last decade (*Lorio, et al*)
 - ▶ 251 ('09) vs 1012 ('12)
 - ▶ 37% MIS ('09) vs 87% ('12)
- ▶ Currently >10 MIS SI Jt Fusion devices
 - ▶ *Most data of iFuse procedure*
 - ▶ *Over 60 publications on MIS SI Jt fusion*
- ▶ With technology comes increase interest
- ▶ MIS SI Joint fusion is currently the fastest growing spinal market
 - ▶ Currently 5% of spine market
 - ▶ Expected to reach 20% by 2021

SiFix™
Sacroiliac Intra-articular Fusion Allograft



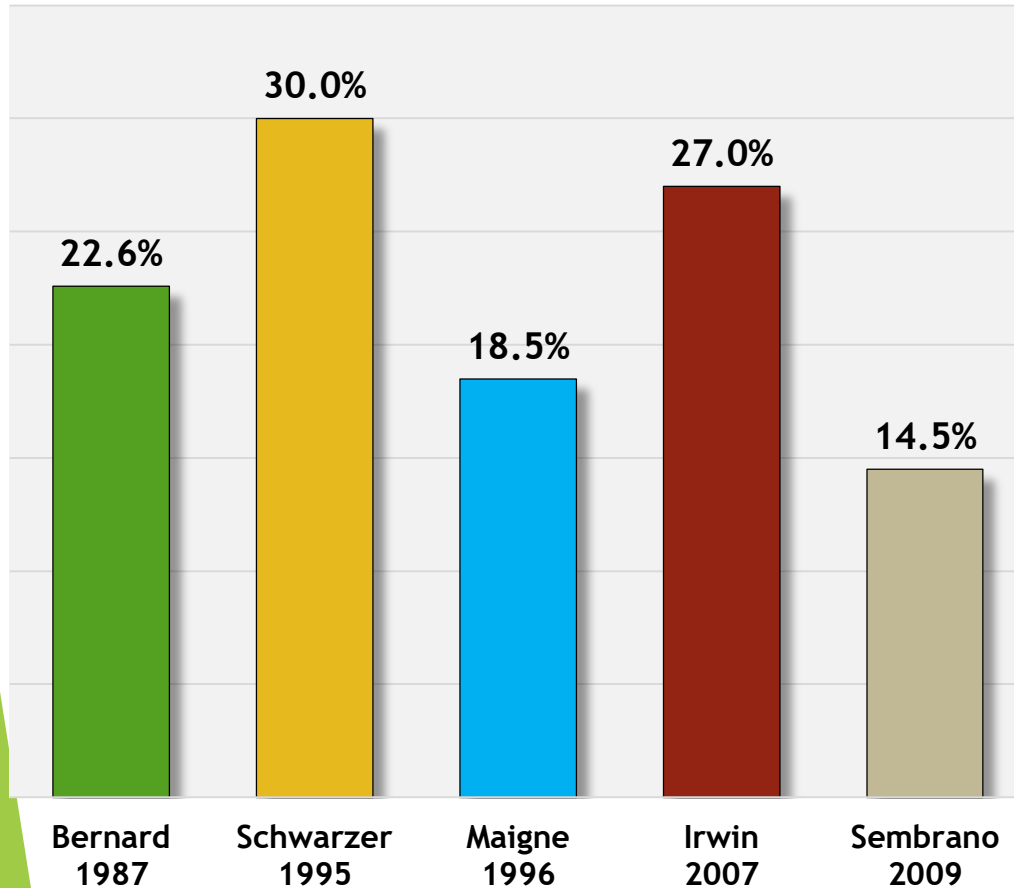
source: NUTECH



Prevalence of SI Joint Pain

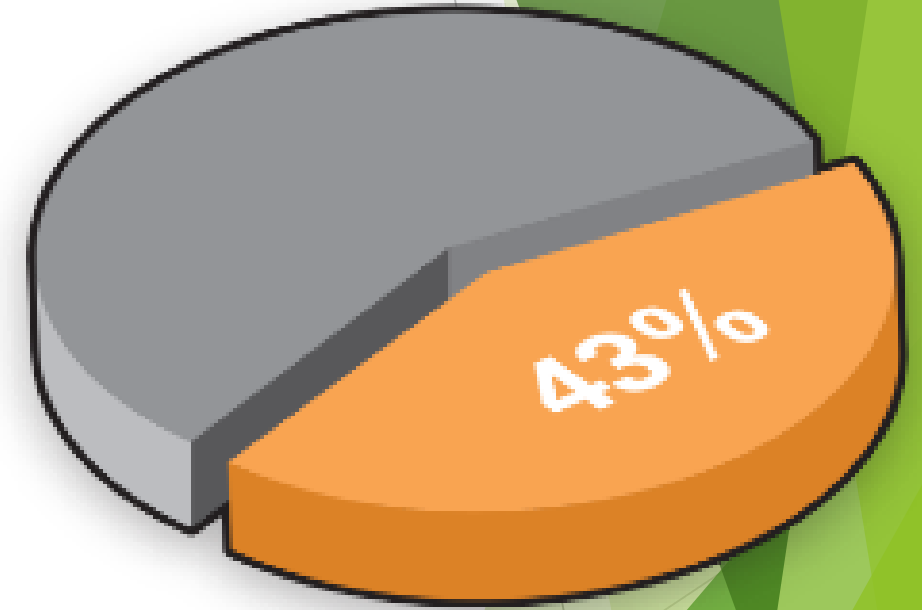
15-30%

Component of chronic LBP



32-43%

Symptomatic Post-Lumbar Fusion



32% Katz 2003

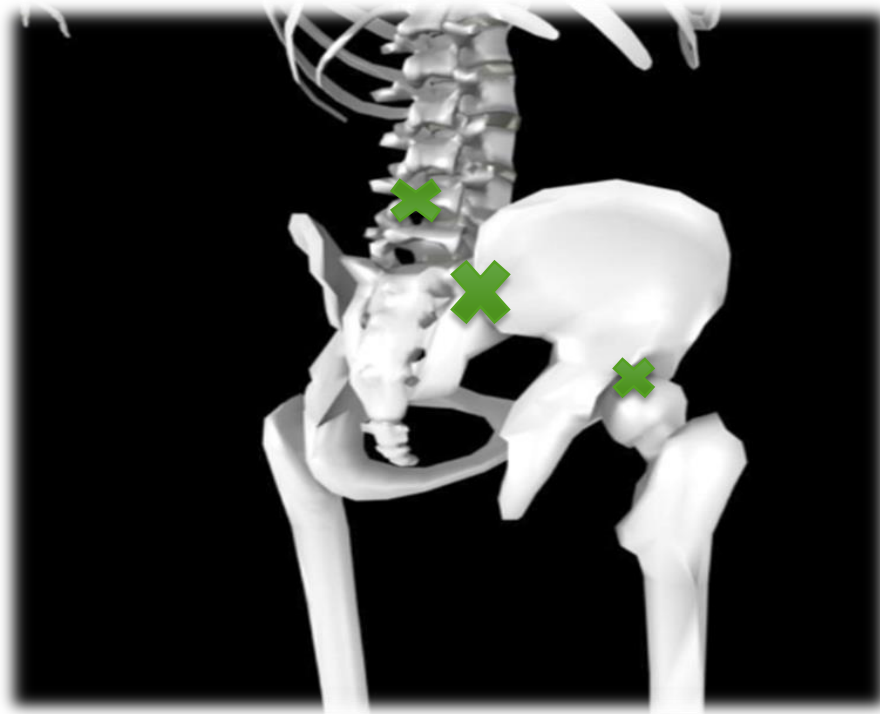
35% Maigne 2005

43% DePalma 2011

40% Liliang 2011

DePalma - *Pain Med* 2011

Adjacent Segment Degeneration^{1,2}



75% of post-lumbar fusion patients showed SI joint degenerative changes on CT scan 5 years after

vs.
only 38% age- and gender-matched controls without prior lumbar fusion

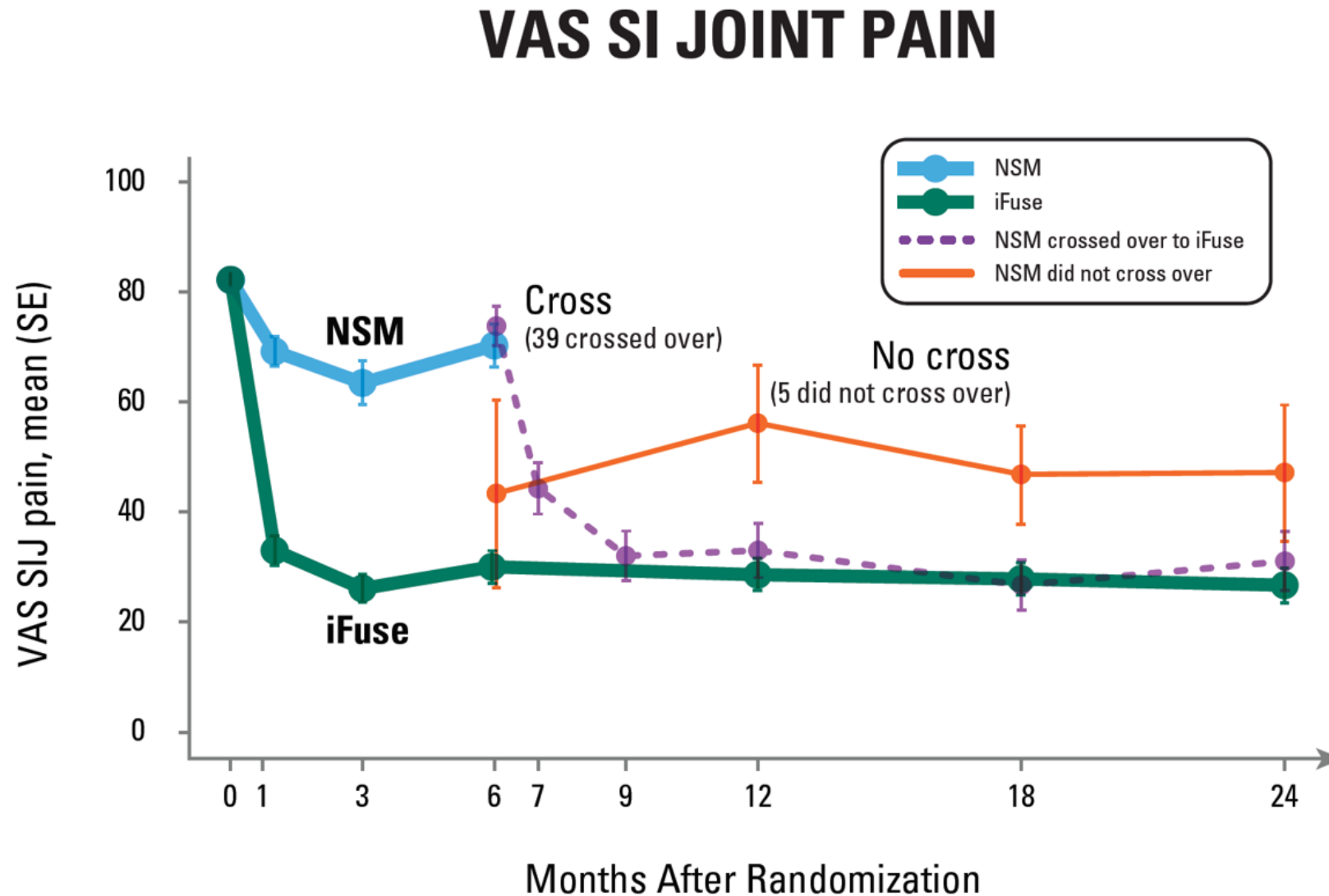
Ha et al. 2008

Lumbar fusion leads to increases in angular motion and joint stress at the SI joint

Ivanov et al. 2009

1. Ha – *Spine* 2008
2. Ivanov – *Spine* 2009

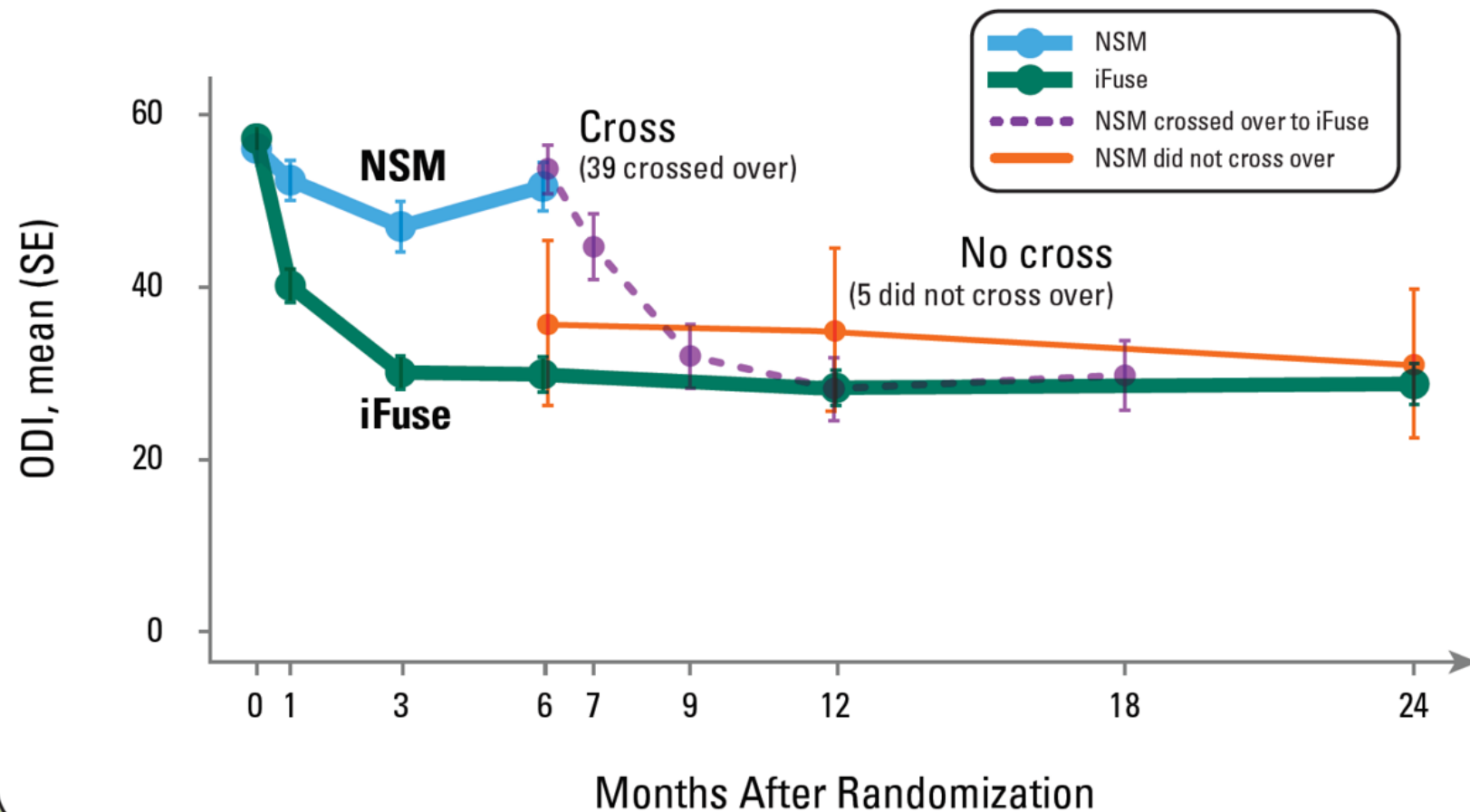
INSITE 2-year Results: VAS SI Joint Pain Improves more after SI joint fusion than NSM



Data from article Fig. 2

INSITE 2-year Results: ODI Improves more after SI joint fusion than NSM

OSWESTRY DISABILITY INDEX



Data from article Fig. 2

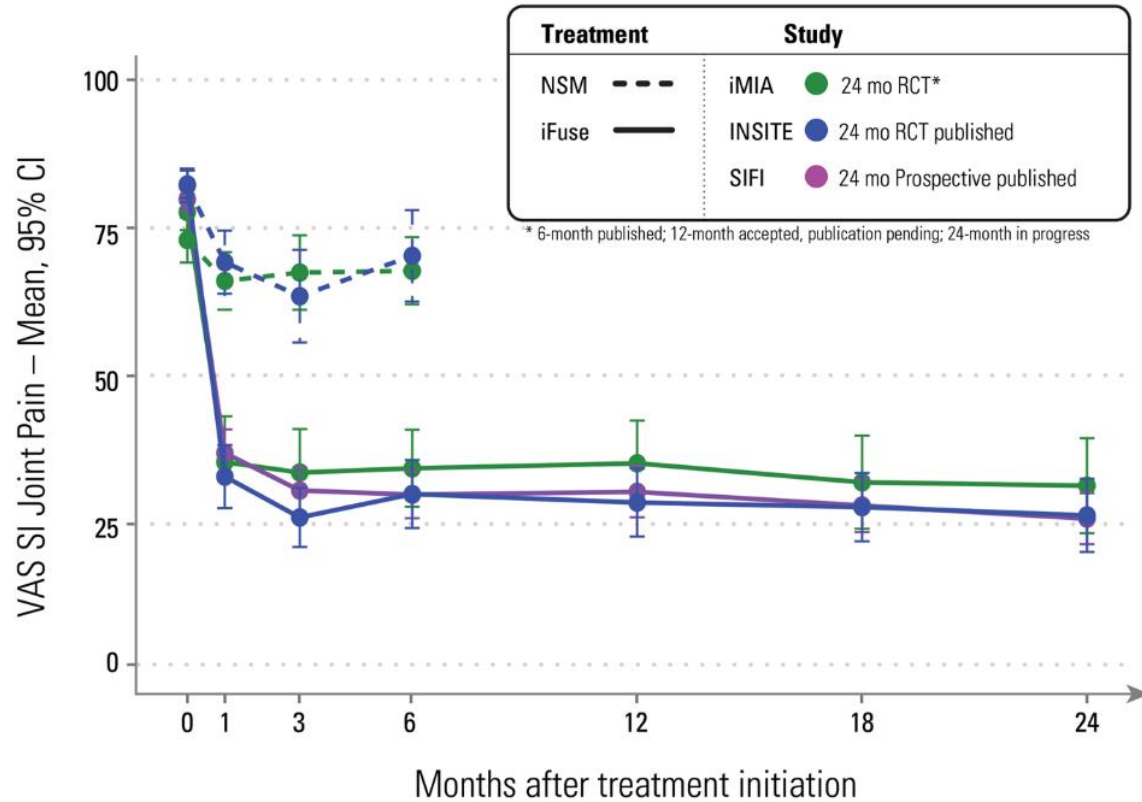
Prospective Study Results

INSITE, iMIA, SIFI



Pooled Analysis of INSITE, iMIA & SIFI
published ahead-of-print in *SPINE* – 2017
March 27

VAS SI Joint Pain

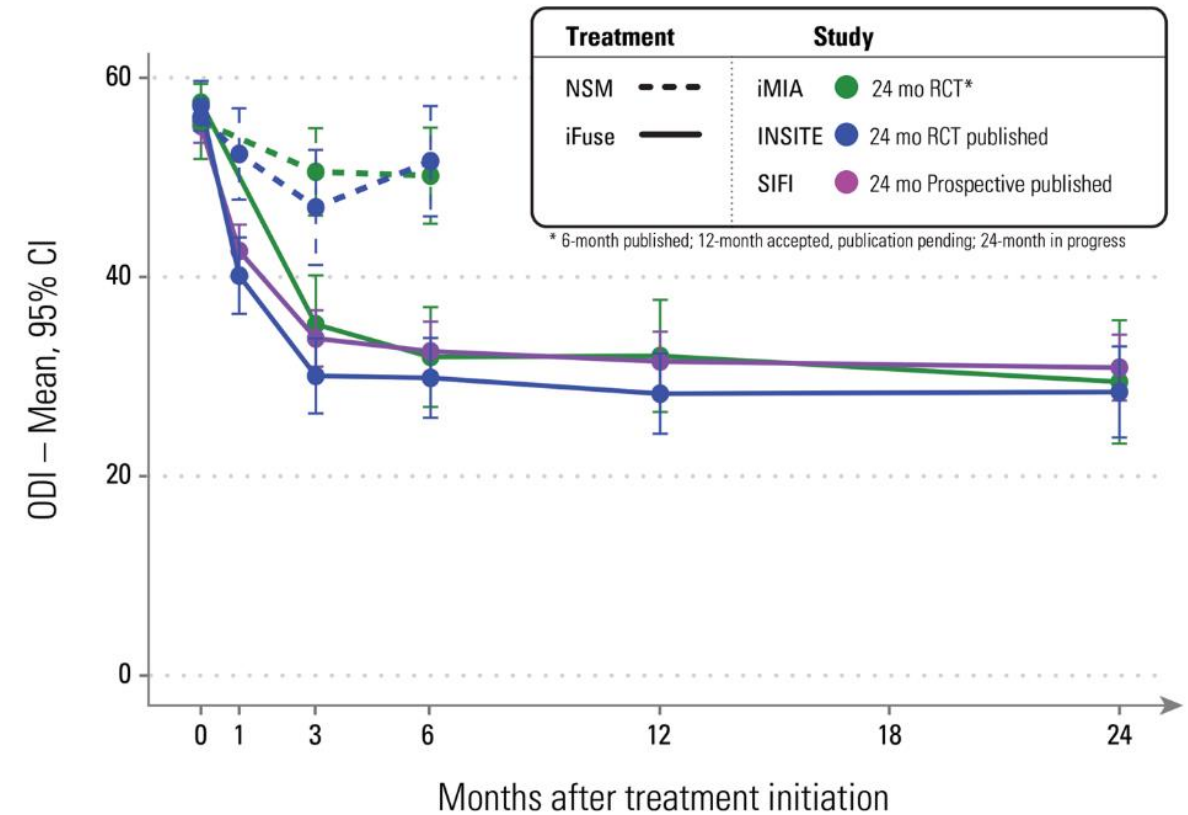


Sturesson – *Eur Spine J* 2016 (iMIA 6mo)

Polly – *Int J Spine Surg* 2016 (INSITE 2yr)

Duhon – *Int J Spine Surg* 2016 (SIFI 2yr)

Oswestry Disability Index



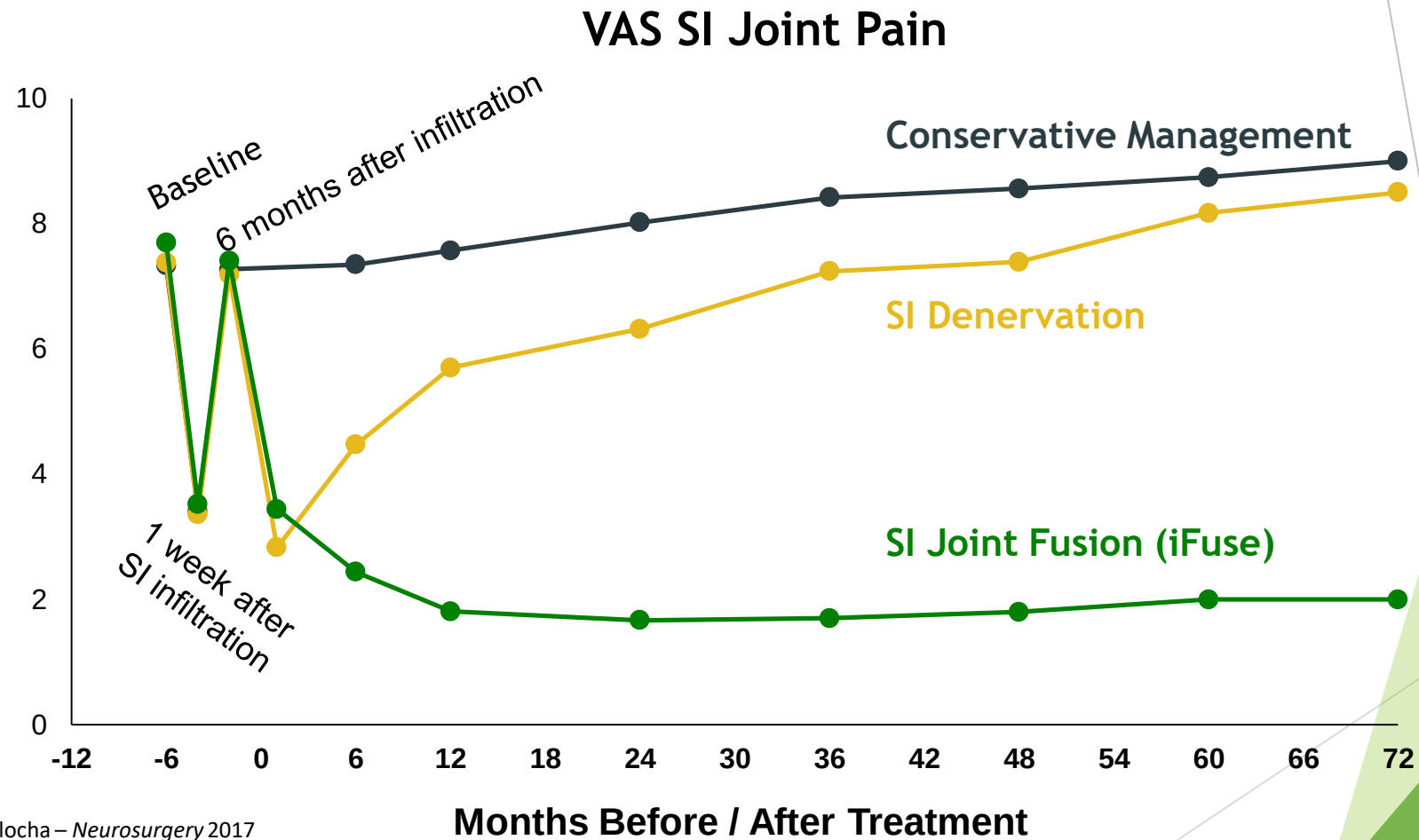
Dengler - *Spine* 2017 Mar 27 (pooled analysis)

6-Year Comparative Cohort Study

CM, RF, SI Joint Fusion (iFuse)

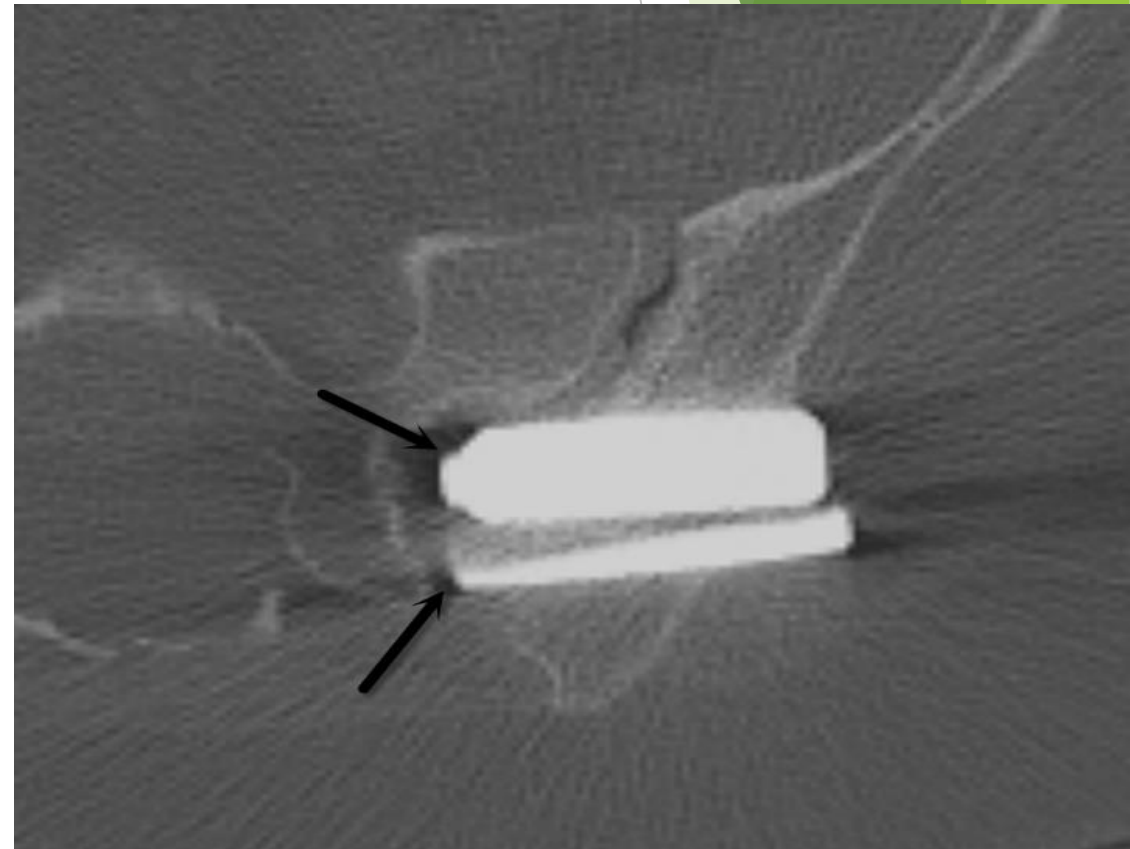


Published: 2017 April 20



Data (ALL Revisions)

- ▶ *Cher, et al.* (iFuse)
 - ▶ Revision Rate
 - ▶ 11,388 patients (4/2009- 8/2014)
 - ▶ 3.5% cumulative revision rate at 4 years
- ▶ *Spain & Holt* (iFuse)
 - ▶ Retrospective comparison iFuse vs Screws (4 years)
 - ▶ 5.7% revision rate (iFuse-274)
 - ▶ 30.8% screws
 - ▶ 80% if followed out to 10 years
- ▶ *SIFI & INSITE* (iFuse)
 - ▶ 1/313 for “lucency” at 2 years
- ▶ My experience (iFuse):
 - ▶ 192 cases (>100 >2yrs)
 - ▶ 4 Delayed Revisions
 - ▶ 3 Pseudoarthrosis
 - ▶ 1 Osteoporosis
 - ▶ 2 Osteopenia
 - ▶ 1 Recurrent pain

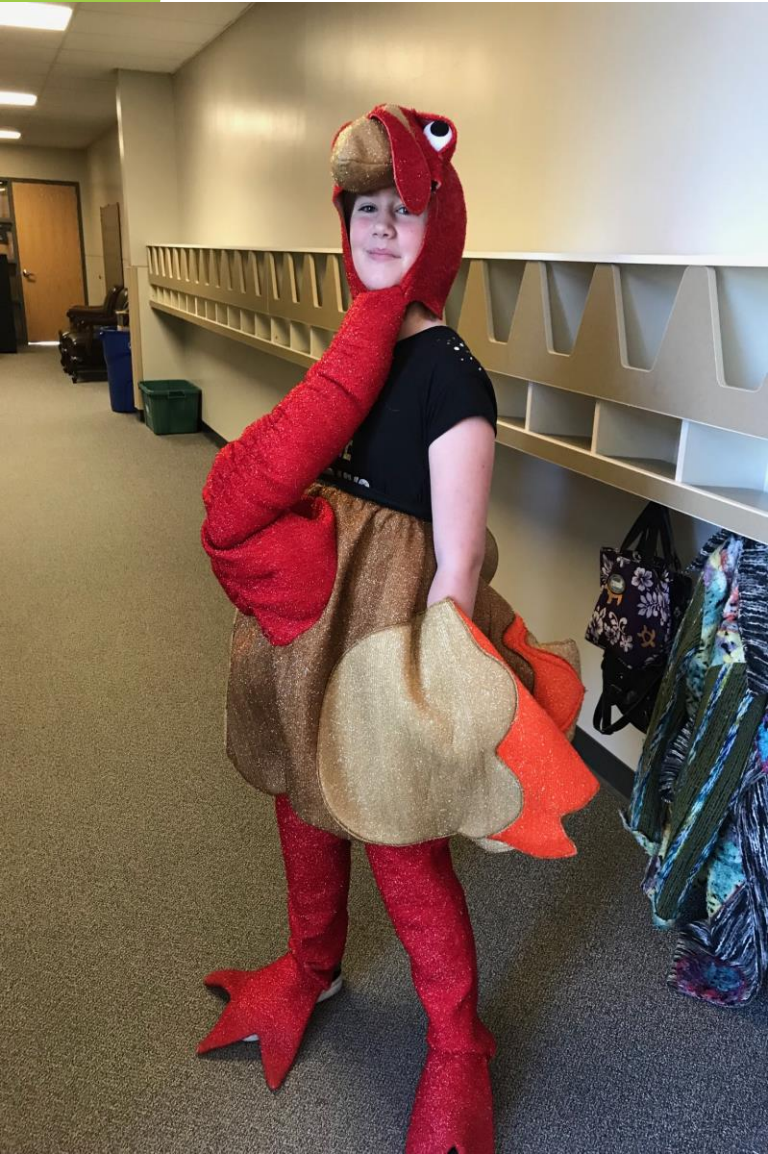


Conclusions

- ▶ When discussing surgical outcomes for mechanical back pain, SI Joint dysfunction should be included
- ▶ Rapidly growing market, but with new technology comes apprehension
- ▶ Multiple prospective publications exist on outcomes
- ▶ Revision rates being evaluated, but incidence still not yet known
- ▶ Does data on one technique carry over to others?
- ▶ Outcomes appear at least on par, if not superior to fusion/arthroplasty

Union Memorial Resident Index: People to not operate on.

- People with hyphenated names
- More allergies to meds than meds
- Allergy to >2 opioids
- Face tattoos
- Adults with stuffed animals
- Copper-colored hair
- Women with hats
- Ethnic attire of different ethnicity
- Sunglasses indoors
- Fibromyalgia
- Hair stylists
- Flight Attendants
- Injuries caused by video games
- “Horse people”
- “High pain tolerance”
- Pain >> 10



Thank you

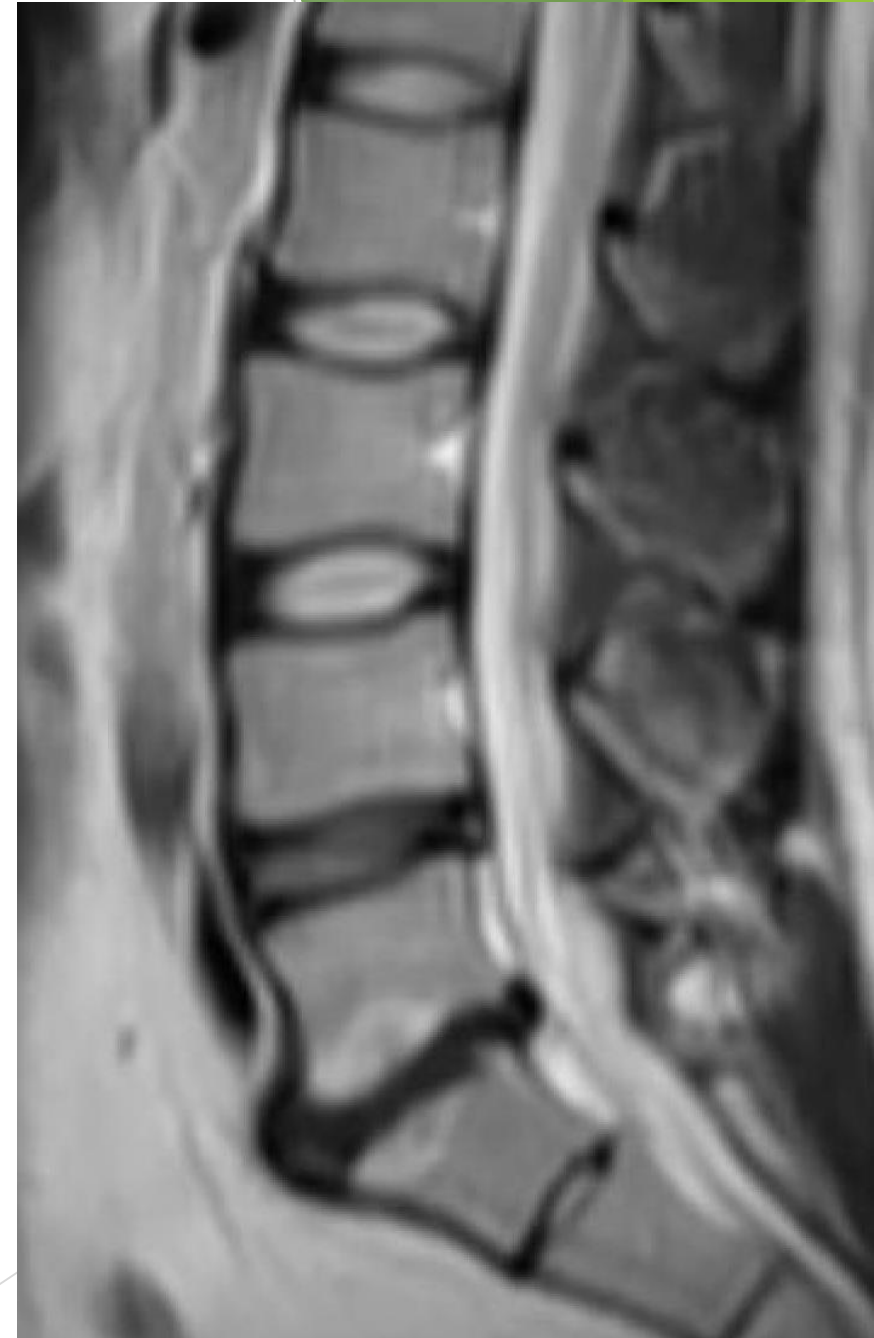
Questions?



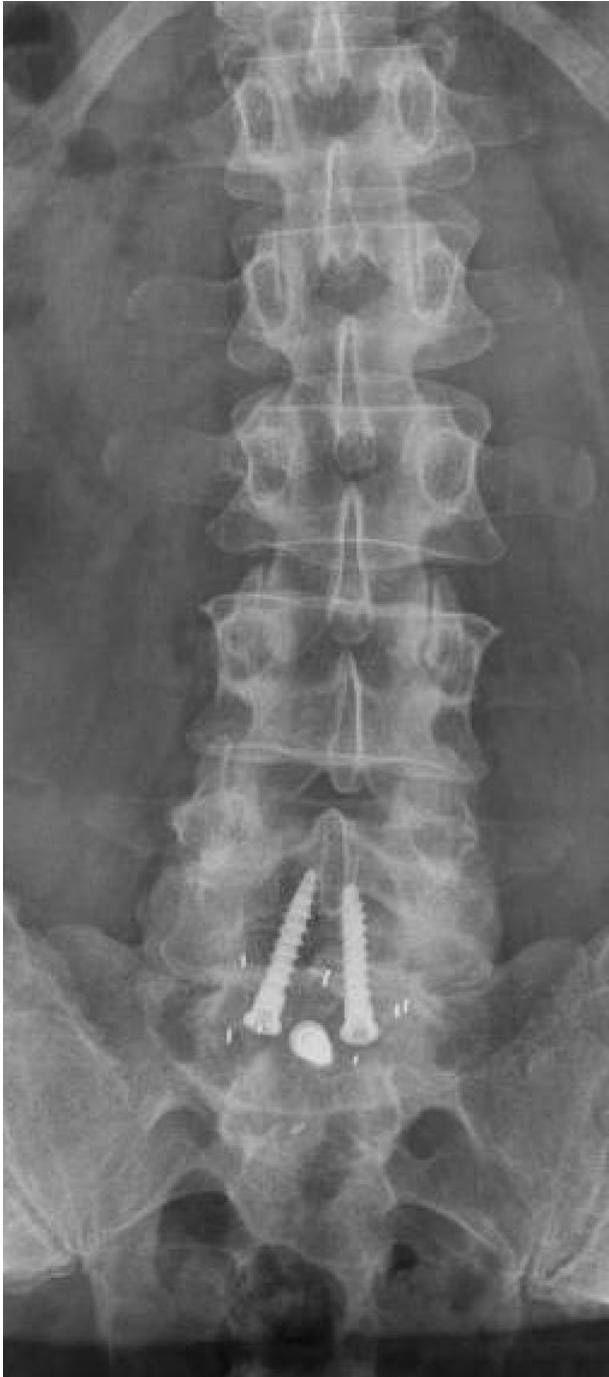
Cases

Patient 1

- ▶ 45 y/o man with mechanical back pain x 15yrs
 - ▶ Worse with sitting and alleviated by activity
 - ▶ *Up to a point*
- ▶ Extensive PT
- ▶ On IBP and Tramadol
- ▶ Exam:
 - ▶ Non-specific
 - ▶ Neuro intact
- ▶ Workup:
 - ▶ ???
- ▶ L5-S1 Facet MBB → Meaningful Relief
- ▶ Disco → Concordant L5-S1 only
- ▶ Surgery?
 - ▶ ***L5-S1 ALIF***

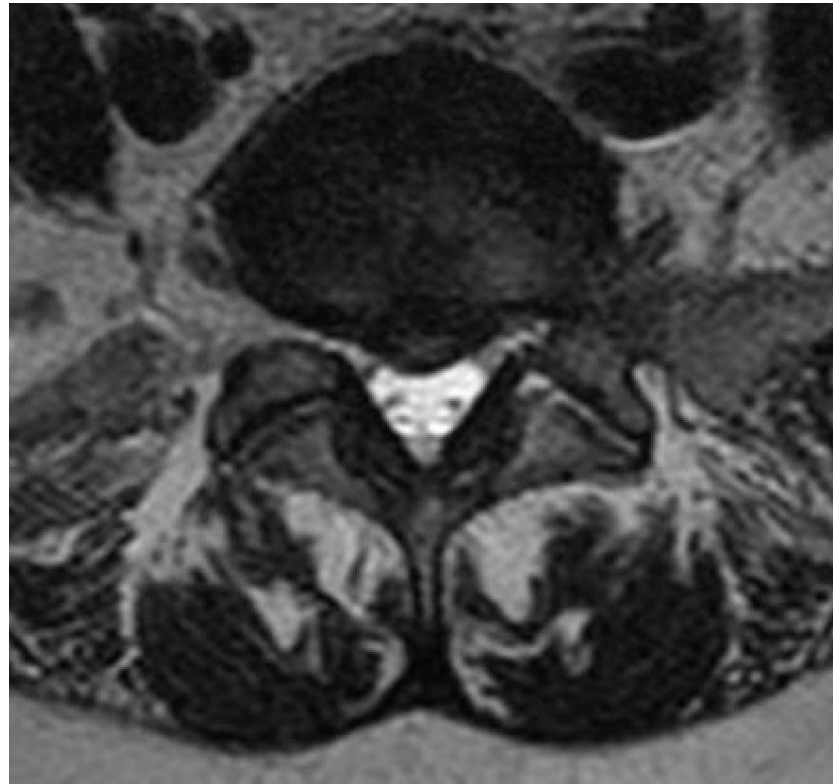


Patient 1



Patient 2

- ▶ 42 y/o woman with ~10 yrs LBP
- ▶ Will radiate down back of legs when pain is severe (S1)
 - ▶ Back pain >>> Leg pain (80:20)
- ▶ Has had extensive PT and some ESI with relief (fading)
- ▶ Works as a massage therapists and can't stand for longer sessions
- ▶ Exam:
 - ▶ Non-focal
 - ▶ Neuro intact
- ▶ Workup?
 - ▶ L4-S1 MBB non-diagnostic
 - ▶ Disco offered: Declined
- ▶ Plan:
 - ▶ L5-S1 Disc Arthroplasty



Patient 2

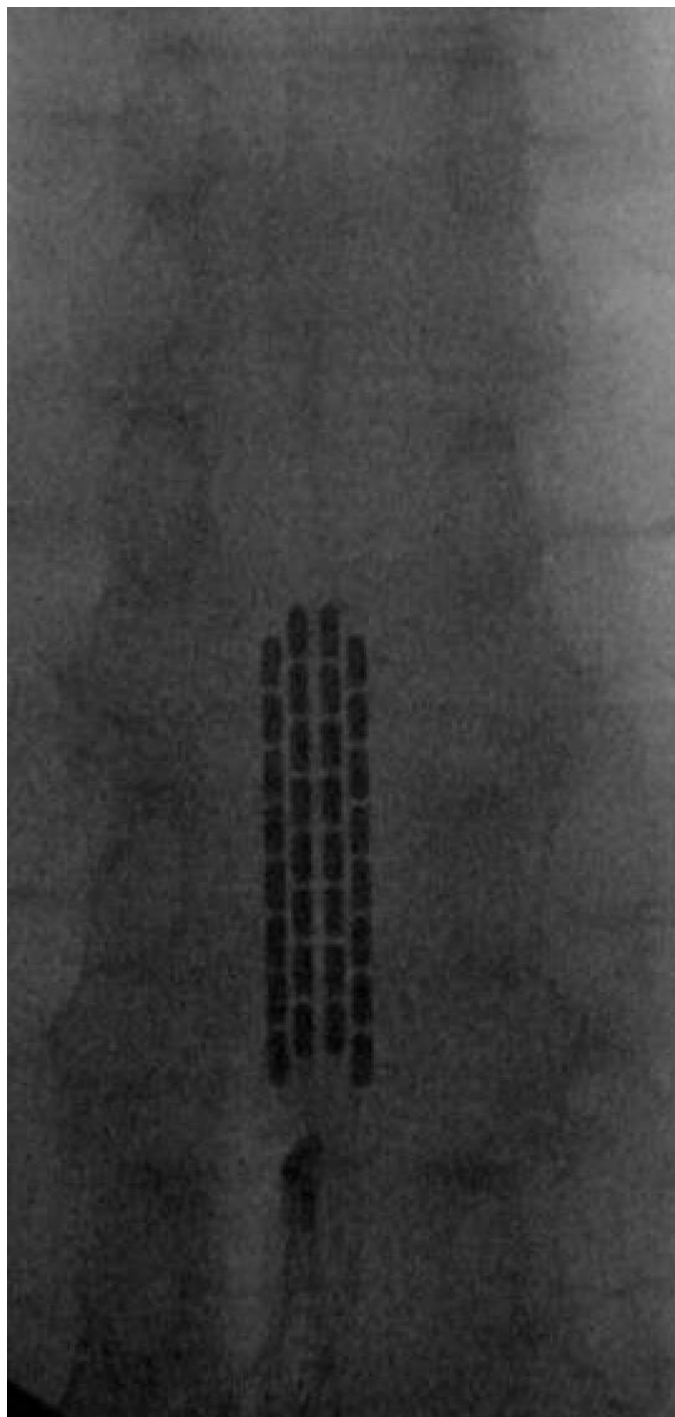


Patient 3

- ▶ 38 y/o man s/p multilevel lumbar decompression with CoFlex
- ▶ Chronic back & leg pain
 - ▶ Back>Leg 60:40
 - ▶ Leg Pain non-descript
- ▶ Exam:
 - ▶ Non-focal
 - ▶ Neuro intact
- ▶ Workup:
 - ▶ Lumbar MBB-No relief
 - ▶ Lumbar ESI-No relief
- ▶ Decision:
 - ▶ SCS Trial → Excellent Coverage and Benefit
 - ▶ Implant placed

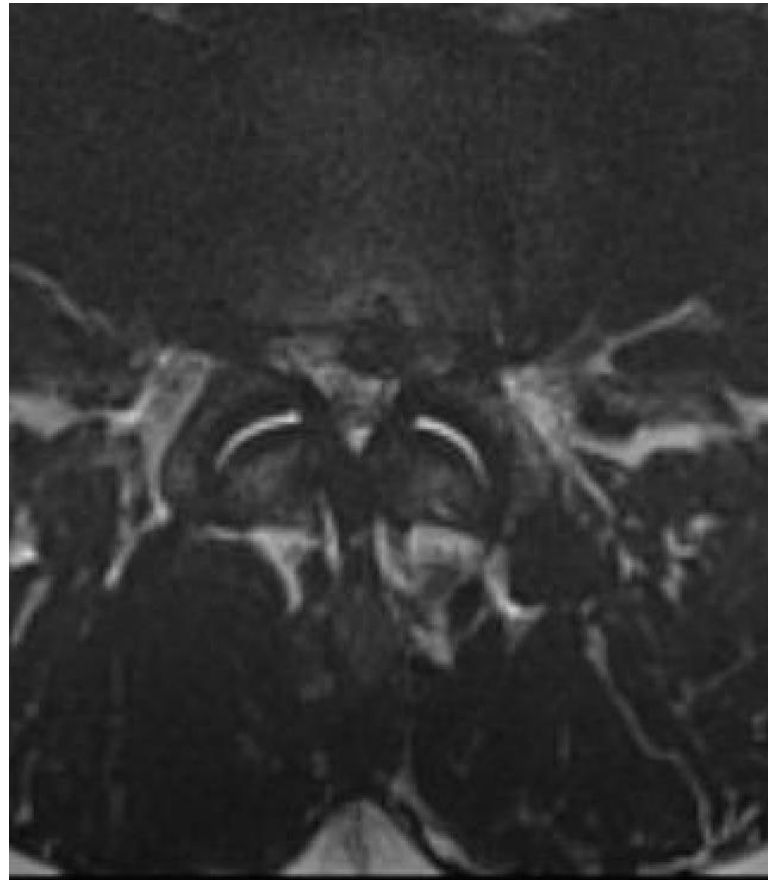


Patient 3



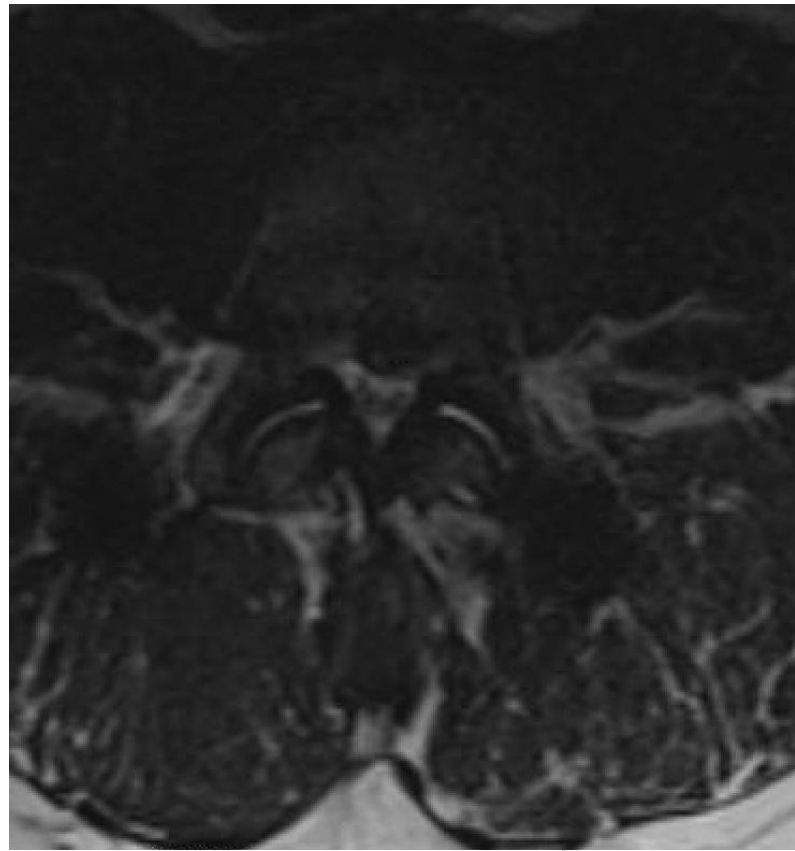
Patient 4

- ▶ 46 y/o man many years s/p L4-S1 fusion
 - ▶ Ant/Post
 - ▶ Returns with acute onset left leg pain (L4)
- ▶ No mechanical back pain
- ▶ Exam:
 - ▶ SLR Left
 - ▶ Motor intact
- ▶ Workup:
 - ▶ PT, meds, ESI all with partial relief
- ▶ Plan?



Patient 4

- ▶ Offered and receive MIS Right L3-4 microdiscectomy
 - ▶ Post-op leg pain resolved
- ▶ Returns ~9 months later with return of symptoms
- ▶ Initially we tried the usual suspects
 - ▶ Lost 75lbs as well
 - ▶ Symptoms much improved and kept at bay
- ▶ Ultimately came back 18 months after discectomy
 - ▶ Return at least as bad as pre-op
 - ▶ 4/5 left quad
- ▶ Plan?



Patient 4

- ▶ Taken back for MIS Left L3-4 TLIF
- ▶ At 9 months, pain free
 - ▶ Back sore at times
 - ▶ Leg function returned



Conclusion

- ▶ Evidence far from definitive for surgery for Low Back Pain
- ▶ Both total disc arthroplasty and lumbar fusion not supported by most payers for pure mechanical back pain
- ▶ NICE with no support for fusion or arthroplasty
- ▶ Degenerative scoliosis over-utilized as a justification for lumbar fusion
 - ▶ Support for the surgery is soft
 - ▶ Revision, complication, and re-operation rates are high given complexity and patient population
- ▶ SCS traditionally without adequate evidence to make a statement
 - ▶ Newer technologies (Burst, HF, Computational modeling) appear encouraging
 - ▶ Long term data lacking
- ▶ My opinion:
 - ▶ Success can be had with any of the above
 - ▶ Requires good clinical judgement
 - ▶ Requires collaborative relationship with interventional pain for localization of pain generator
 - ▶ *Just because it looks bad, doesn't mean it needs surgery*



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