

Disc Arthroplasty vs Fusion: What's the best option?



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Disclosures

Evan M. Packer, M.D., symposium director for this educational activity, is a consultant for SI- Bone, SeaSpine, and Baxter Pharmaceuticals. He has indicated that the presentation or discussion will not include off-label or unapproved product usage. All of the relevant financial relationships listed for this individual have been mitigated.

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Low Back Pain

According to researchers, 15% - 20% of adults have back pain during a single year and 50% - 80% will experience back pain in their lifetime¹

Back pain is one of the most common reasons for missed work.²

Most often caused by muscle strain

Only a small percentage of cases ultimately require surgery

1. Rubin DL. Epidemiology and Risk Factors for Spine Pain. *Neurol Clin.* 2007; May;25(2):353-71.
2. Vallfors B. Acute, Subacute and Chronic Low Back Pain: Clinical Symptoms, Absenteeism and Working Environment. *Scan J Rehab Med Suppl.* 1985; 11: 1-98.

Treating Patients with Lumbar Degenerative Disc Disease (DDD) **3**

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Degenerative Disc Disease (DDD)

DDD is part of our natural aging process or may be initiated by an acute injury

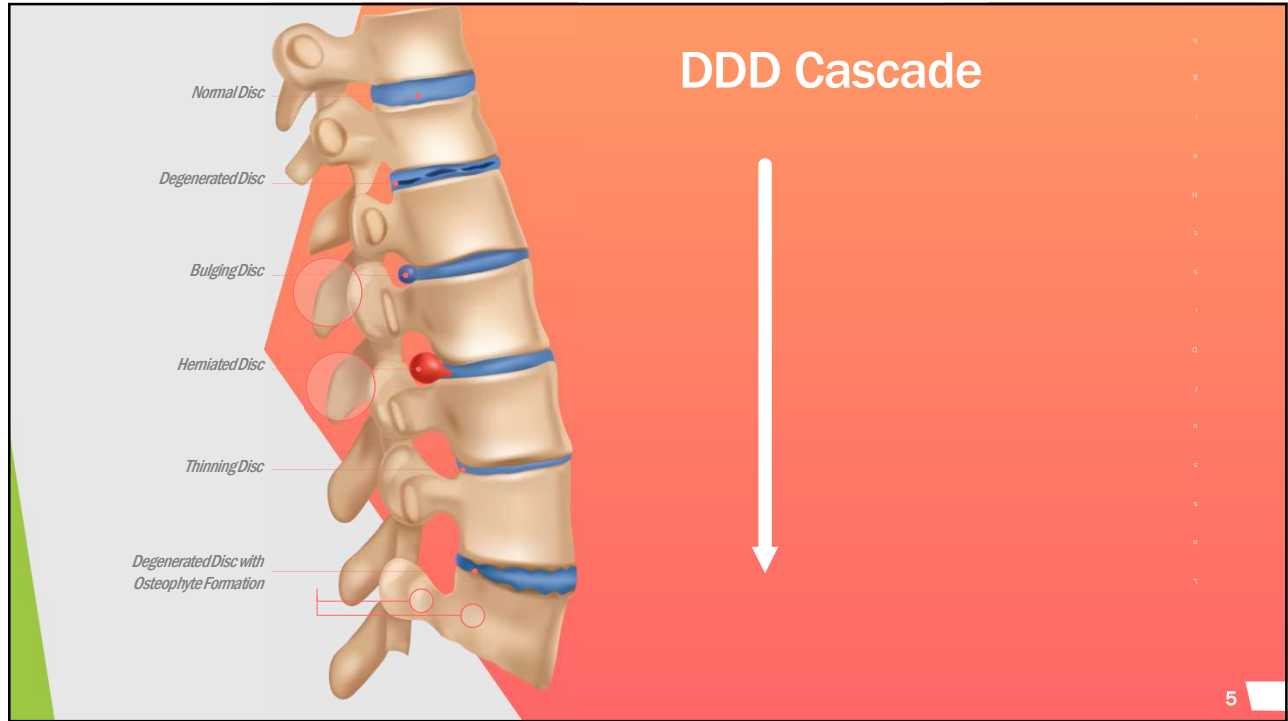
Degenerated discs lose structural integrity and ability to provide cushioning

DDD may result in low back pain and/or nerve pain as the degenerative cascade progresses



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Surgical Intervention: Fusion

Involves removing the patient's diseased disc and inserting a device that allows bone to grow between the vertebrae. The bone growth fuses the vertebrae together—providing stability by eliminating motion.

Goals:

- Remove pain generator
- Neural decompression
- Restore disc height
- Immobilize motion segment

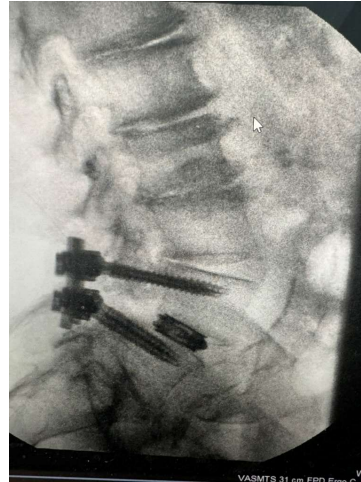
Examples:

- TLIF
- PLIF
- LLIF
- ALIF
- OLIF

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Examples of interbody surgeries



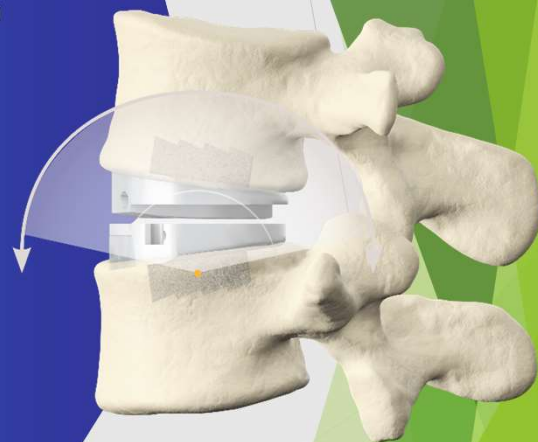
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Surgical Intervention: Total Disc Replacement(LDR)

Involves removing the patient's diseased disc and inserting a device that enables motion at the treated level.

Goals:

- Remove pain generator
- Neural decompression
- Restore disc height
- Stabilize motion segment
- Enable motion

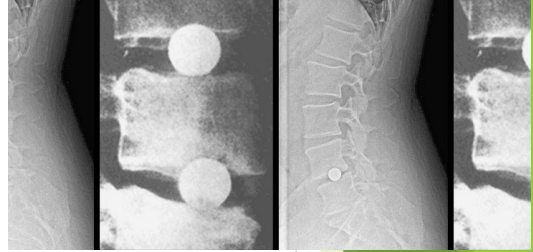


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Treating Patients with Lumbar Degenerative Disc Disease (DDD)

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A Brief History of Lumbar Disc Arthroplasty



- ▶ Origins began in the 1960's with Fernstrom ball
 - ▶ 191 lumbar, 13 cervical with clinical outcomes similar to fusion
 - ▶ Problems with subsidence and extrusion
- ▶ 1980's: Buettner-Janzen and Schnellack published experience with Charite disc
- ▶ Final version of Charite was the SB Charite III (DePuy Spine)
- ▶ Cleared for use in 2004
- ▶ Next generation devices approved: ProDisc-L (2006) and activL (2015)

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A Brief History of Lumbar Disc Arthroplasty (continued)

- ▶ Multiple other devices have completed trials, are undergoing trials, or trials have been discontinued or withdrawn without FDA approval
- ▶ Laterally based disc arthroplasty investigational
- ▶ Following FDA approval of Charite, there was a large rise in use from 2004-2005
- ▶ Issues with adverse events, negative determination by Medicare in 2006
- ▶ Thus, a significant decrease in implants with increase in revision surgeries
- ▶ By 2012, Charite no longer sold in the US
- ▶ Since activL introduction in 2015, interest in lumbar arthroplasty has steadily increased

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Device Design

- ▶ Metal on Metal vs Polyethylene Core
- ▶ Core can be mobile (unconstrained-Charite) or fixed to one of the endplate (semi constrained-Prodisc/ActivL)
- ▶ No advantage for either construct
- ▶ Unconstrained devices have higher ROM for axial rotation and lateral bending, lower ROM in flexion and extension
- ▶ ? About load with constrained devices
- ▶ Seminconstrained activL shows diminished facet loads compared to baseline cadaveric spines



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Us Artificial Disc Market Launch History



Josh Ruth

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Us Artificial Disc Market Launch History



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Lumbar TDR Rationale

The diagram shows a side view of a lumbar vertebra with a Total Disc Replacement (TDR) implant. Two arrows point to the implant, indicating its position relative to the vertebrae.

1. Remove disc/pain generators
2. Restore disc height & mechanical stability following discectomy
3. Maintain motion and spinal balance
4. Reduce potential for adjacent level degeneration

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Surgical Intervention Advancements: TDR Benefits

- Vertebrae are not fused together
- Provides ability to maintain motion
- Slows adjacent level degeneration⁵
- Faster return to activities of daily living and return to work⁶
- Restores sagittal balance and alignment

Maximal Extension Maximal Flexion
Bending Left Bending Right

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⁵Zigler JE, et al, J Neurosurg Spine 17:504-511, 2012 ⁶Tymiak L, et al Neurosurg Focus 2013; 26(2):E18

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Surgical Intervention Advancements: TDR Benefits

Adjacent Level Effects

- TDR constructs show smaller adjacent level effects compared to fusion⁷

Allows for motion to be maintained

- 7.2° of motion maintained at 5 years⁸

FLEXION-EXTENSION RANGE OF MOTION RESULTS¹

Level	Intact	prodisc L at L5-S1	2 Level Disc at L5-S1	Hybrid Disc at L4-L5 Fusion at L5-S1	Fusion at L5-S1	2 Level Fusion at L4-S1
T12-L1	5.56	5.69	6.13	6.87	6.59	8.48
L1-L2	7.93	7.46	8.67	9.25	8.89	10.58
L2-L3	8.14	8.71	8.31	8.86	8.93	10.34
L3-L4	9.51	10.37	11.06	11.65	11.3	10.34
L4-L5	12.8	12.2	9.61	11.65	13.15	13.29
L5-S1	8.07	7.78	7.84	2.02	1.79	1.78
Total ROM	52.01	52.21	51.62	49.58	50.65	46.56

KEY TAKEAWAYS

- Relatively similar lumbar spine ROM across all therapies⁷
- Fusing level(s) has a significant impact on ROM for adjacent levels⁷

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⁷Phillips et al, Spine 2007; May 20 ⁸Zigler et al, J Neurosurg Spine 17, 483-501, 2012

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Surgical Intervention Advancements: TDR Benefits

Adjacent Level Degeneration (ALD)

- Nearly 4x reduction in ALD compared to 360° fusion⁹
- Similar results between patients with and without radiographic evaluation of DDD¹⁰

Pre-Op ALD Status	prodisc L Patients with ALD	prodisc L Patients without ALD	Fusion Patients with ALD	Fusion Patients without ALD
With Pre-Op ALD	~10%	~8%	~28%	~22%
Without Pre-Op ALD	~10%	~8%	~28%	~22%

KEY TAKEAWAY

NEARLY 4x LESS LIKELY

For prodisc L patients to experience change in ALDs than 360° fusion patients⁹

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⁹Zigler JE, et al, J Neurosurg Spine 17:504-511, 2012 ¹⁰Zigler et al, J Neurosurg Spine 17, 483-501, 2012

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Benefits Comparison

	TDR	Stand-Alone ALIF / Integrated Lateral*	PLIF/TLIF
Remove Pain Generators	✓	✓	✓
Neural Decompression	✓	✓	✓
Restore Disc Height	✓	✓	✓
Stabilize Motion Segment	✓	✓	✓
Restores Lordosis	✓	✓	✓
Restores Sagittal Balance	✓	✓	✗
Zero Profile	✓	✓	✗
Retains Posterior Elements	✓	✓	✗
Allows for Motion	✓	✗	✗
Slow the Rate of Adjacent-Level Disease ²¹	✓	✗	✗

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* No devices are currently indicated for 'Stand-Alone' Lateral approach and require supplemental instrumentation.
²¹ Zigler JE, et al, J Neurosurg Spine 17:504-511, 2012

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Two-Year Results: LDR v. Fusion Control

- ▶ LDR patients had greater improvement in ODI
- ▶ LDR patients had significant improvement in VAS Pain (over baseline)
- ▶ LDR had neurological success rate higher than fusion
- ▶ LDR patients were **more satisfied** than fusion patients

- ▶ LDR was shown to **maintain motion**
 - ▶ average segmental motion at 2 years = 7.7°

- ▶ LDR was found by FDA to have “a statistically significant difference in Overall Success rates”** over Fusion control

DJ285

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Five-Year Results

Five-Year Results of the ProDisc-L Multicenter, Prospective, Randomized, Controlled Trial Comparing ProDisc-L With Circumferential Spinal Fusion for Single-Level Disabling Degenerative Disk Disease

Jack E. Zigler, M.D.,¹ Rick B. Delamarter, M.D.²

Texas Back Institute, Plano, Texas; Cedars-Sinai Spine Center, Los Angeles, California

Published in: *J Neurosurgery Spine* 17:493-503, 2012

- ▶ In general, the results were stable from the 2- to 5-year follow-up periods.
 - ▶ Both groups remained significantly improved from baseline, with noninferiority of the **prodisc-L** compared with fusion being maintained.
 - ▶ At 5-year follow-up, the range of motion of the levels treated with **prodisc-L** was 7.2°.
 - ▶ Over 80% of patients experienced improvements in recreational status that were maintained 5 years after the index surgery.
 - ▶ The percentage of TDR patients utilizing narcotics as the 5-year follow-up visit was 38.4%, less than half the percentage of patients who had used narcotics as part of failed conservative treatments.

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Five-year Adjacent-level Data

Five-year adjacent-level degenerative changes in patients with single-level disease treated using lumbar total disc replacement with ProDisc-L versus circumferential fusion

Authors:

Jack E. Zigler, M.D.,¹ Jamieson Glenn, M.D.,² and Rick B. Delamarter, M.D.³

Affiliations: ¹Texas Back Institute, Plano, Texas; ²Core Orthopaedic Medical Center, Encinitas; and ³Cedars-Sinai Spine Center, Los Angeles, California

Published in:

J Neurosurg Spine 17:504-511, 2012

Study Objective:

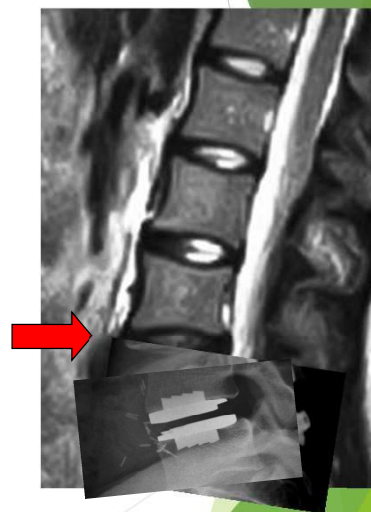
- ▶ Demonstrate adjacent-level degenerative changes from a prospective multicenter study in which patients were randomized to either prodisc-L or circumferential fusion for single-level lumbar DDD at 5 years.

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RESULTS: In All Patients

- Δ ALD was observed 5 years later in:
 - ▶ 28.6% of the patients randomized to Fusion
 - ▶ 9.2% of the patients randomized to ADR

> 3 : 1 Difference



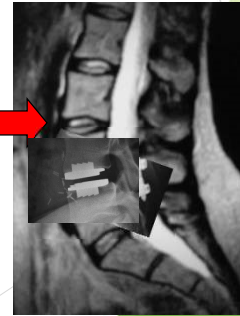
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RESULTS: in Patients with no PreOp ALD (i.e. with a pristine adjacent level)

- ▶ New findings of Adjacent Level Degeneration at 5 years were found in baseline normal levels in:
 - **23.8%** of patients randomized to Fusion
 - **6.7%** of patients randomized to ADR

3 : 1 Difference

p=0.008



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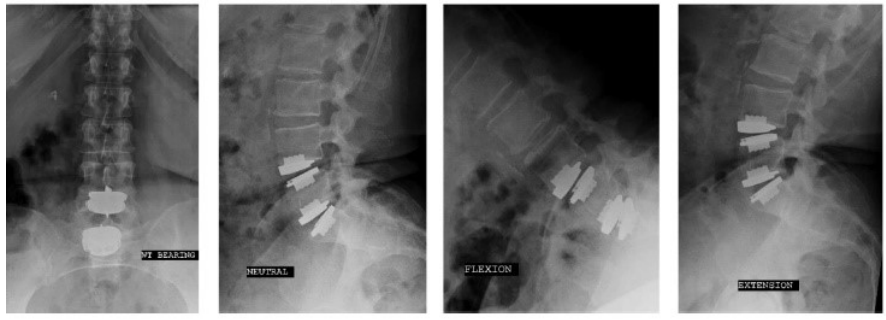
Two-Level prodisc L



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Two-Level prodisc L

- ▶ 33 peer-reviewed journal articles published on two-level LDR



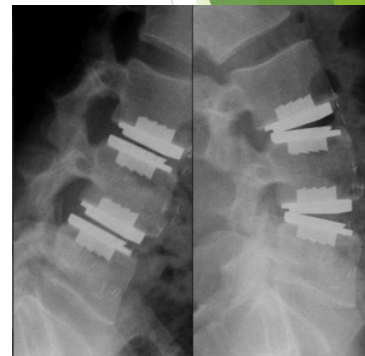
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Summary of 2 Level IDE Findings

prodisc L Total Disc Replacement is a safe and effective treatment for 2-level discogenic back pain between L3-S1.

ODI Improvement	LDR statistically superior	*
SF-36 PCS	LDR statistically superior	*
Re-ops	LDR statistically superior	*
Narcotic Usage	LDR statistically superior	*
Satisfaction	LDR statistically superior	*
Motion	LDR maintains motion: potential to decelerate ALD	

* p < 0.05

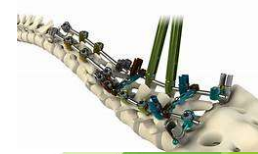


38 yo M @ 24 mo.

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Conclusion

- ▶ Spine Arthroplasty Devices are **the most highly studied implants** we place in the human body. No other device has produced the level of science achieved by TDR PRCT's and meta-analyses over multiple years.
- ▶ Better data than:
 - ▶ Total hips and knees
 - ▶ Plates and screws
 - ▶ Rods and hooks
 - ▶ Intraocular lenses
 - ▶ Pacemakers, etc.



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activL

- ▶ Current device released in 2015
- ▶ Semiconstrained with a mobile core
- ▶ Endplates with a spike or central keel
- ▶ IDE compared it to Charite and ProDisc-L
- ▶ activL had higher rates of success and less adverse events
- ▶ Freedom from reoperation 99% at 5 years
- ▶ Majority of implants 8.5mm vs smallest ProDisc 10mm



Keeled Version

Spiked Version

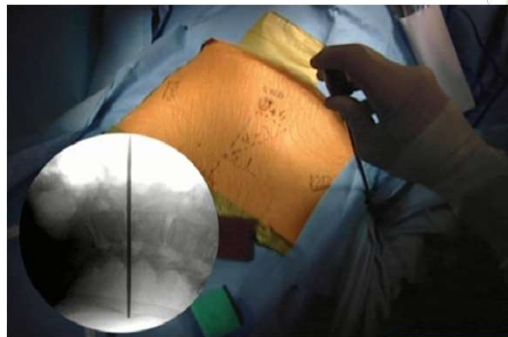
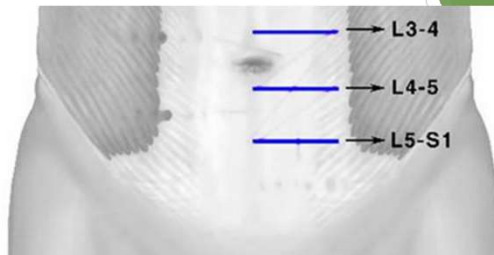


Combination Spike and Keel

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Approach

- ▶ Retroperitoneal approach
- ▶ Transverse or vertical incision
 - ▶ Transverse an option for single level approach vs vertical
 - ▶ Vertical (extensile) for 2 levels



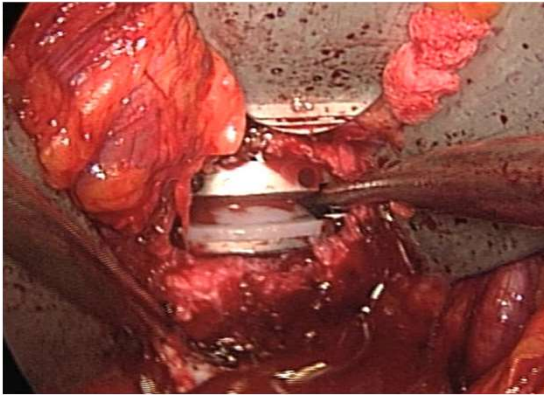
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Surgical Technique



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Final Position



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Things to remember...

- ▶ Choose your patients wisely
 - ▶ Avoid osteopenia (t-score <1.0)
 - ▶ Avoid facet disease
 - ▶ Avoid secondary gain
- ▶ Good carpentry is the key to mobility
 - ▶ Thorough disc excision
 - ▶ Release the posteriolateral corners
 - ▶ Curved curettes and Kerrisons
 - ▶ Resect the PLL
 - ▶ You must place the implant perfectly
 - ▶ Midline
 - ▶ Endplate coverage

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Indications for LDR

- ▶ Ideal candidate early on the Kirkaldy-Willis degenerative timeline than a typical fusion patient
- ▶ Failure 6 mo conservative therapy
- ▶ Skeletally mature
- ▶ Symptomatic DDD
- ▶ No more than a grade I spondylolisthesis
- ▶ Prior microdiscectomy
- ▶ Prior fusion with adjacent segment degeneration
- ▶ ? Below a long scoliosis construct

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Contraindications for LDR

- ▶ Significant spondylolysis or spondylolisthesis
- ▶ Significant facet joint arthropathy, previous facet joint removal
- ▶ Non-mobile segment
- ▶ Osteoporosis
- ▶ Infection
- ▶ ? Obesity, psychiatric issues
- ▶ Geisler looked at Charite failures, and these patients did not improve with revision: Patient Selection!

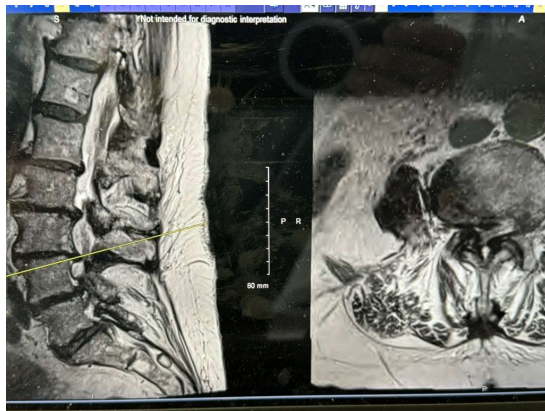
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Cases



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Interbody Fusion Cases



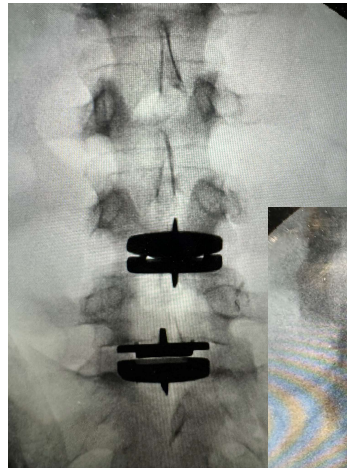
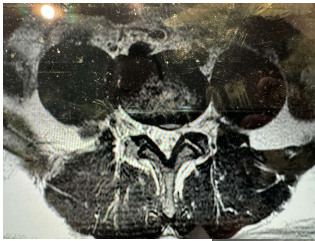
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Interbody Fusion Cases



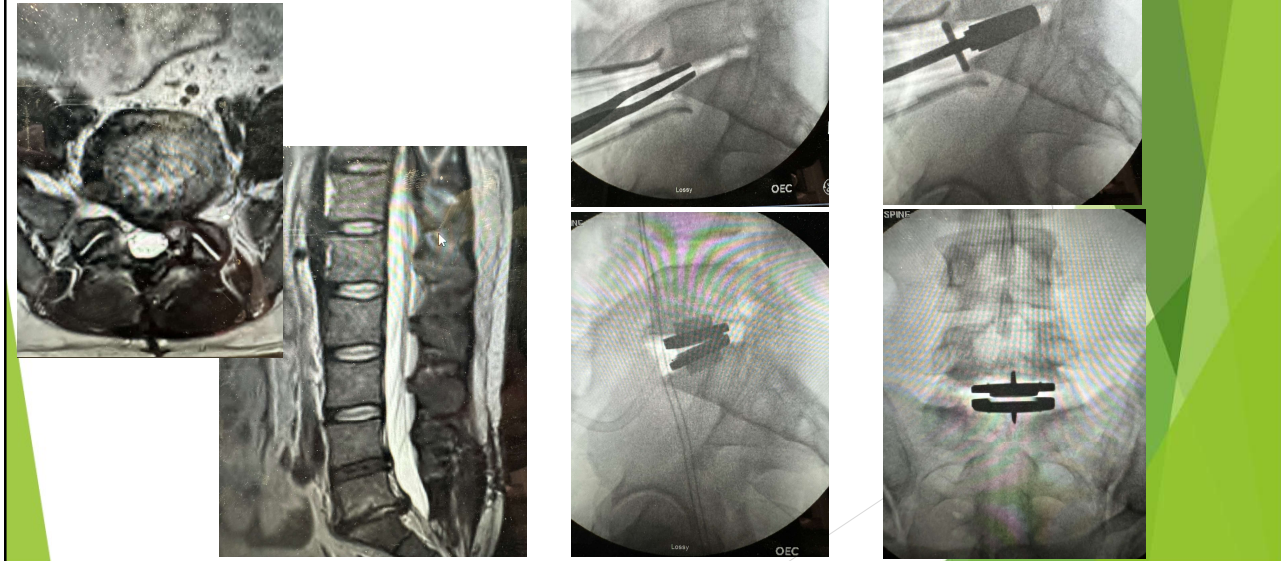
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LDR Cases



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LDR Cases



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Conclusions

- ▶ Both fusion and LDR are accepted as standard of care for lumbar DDD
- ▶ All meta analyses show that LDR improves disability, pain, and patient satisfaction in contrast to fusion
- ▶ Multiple studies preserved clinical and safety benefits at 5 years and beyond
- ▶ Diminished reoperation rates and higher patient satisfaction with arthroplasty over arthrodesis
- ▶ Constant advancements
- ▶ Questions regarding lifelong durability and consequences of the devices

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