


Chronic Low Back Pain



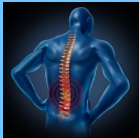
What are the Treatment Options and Supporting Clinical Evidence?

Objectives

- Identify prevalence of low back pain (LBP)
- Discuss relevant anatomy of lumbar spine and intervertebral discs
- Explain clinical implications of degenerative disc disease (DDD)
- Differentiate conservative versus surgical treatment options for patients with LBP
- Discuss clinical considerations of lumbar arthrodesis and lumbar arthroplasty for patients with DDD
- Describe clinical evidence for lumbar arthrodesis and lumbar arthroplasty


Introduction

- LBP affects up to 80% of people at some point in life
- Very common reason to see PCP
- Progresses to chronic in only ~ 5% of patients
 - ✓ Most attributable to degenerative disc disease (DDD)
- 1-2% adults become disabled due to chronic LBP (leading cause of disability worldwide)



Lumbar Spine Characteristics

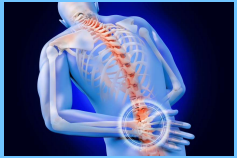
- L1-L5: largest unfused vertebrae
 - ✓ Support weight of torso
- L4-L5 and L5-S1: lowest spinal segments
 - ✓ **Bear most weight**
 - ✓ Prone to injury and degeneration
- L5-S1: lumbosacral joint
 - ✓ Rotation
 - ✓ Enables pelvis and hips to swing



Degenerative Disc Disease (DDD)

What is DDD?

- Describes the symptoms of axial back pain and possible radiating pain and/or weakness/numbness resulting from a degenerated disc(s) in the spine



Causes of DDD

- Primarily related to natural, age-related changes in the discs:

- May also be initiated or exacerbated by injury, cigarette smoking, genes

DDD Overview

Normal aging of the spine:

7 years	30 years	70 years

DDD Overview

- Disc no longer functions normally
- Can lead to:
 - Arthritis, disc herniation, spinal stenosis
- Pressure on spinal cord & nerve roots

Degenerative Cascade

Loss of Disc Height
 Loss of Motion
 Change in Spinal Balance
 Formation of Osteophytes
 Increased Load on the Facets/Ligaments
 Impingement on Spinal Cord or Nerves


Diagnosing and Treating Lumbar DDD

Diagnosing Lumbar DDD

- History and Physical
- Plain Radiographs
- MRI
- CT / Myelography
- Diagnostic Spinal Injections
- Discography

Treating with Conservative Care

- Acute LBP tends to resolve within weeks to months
- Goals are to decrease pain and spasms, provide conditioning for back, and manage other issues associated with back pain





Conservative Care Options

- Education
- Heat / ice
- Physical therapy
- Chiropractic care



Conservative Care Options (cont.)

- Medications
 - ✓ Analgesics (incl. opioids)
 - ✓ NSAIDS
- Nerve blocks
- Epidural steroid injections
 - ✓ No more than 2-4 annually

Surgical Treatment Criteria

Small percentage of patients unresponsive to conservative treatment:

- Extended period of pain, despite conservative treatment
- Unsatisfactory function in daily activities
- Diagnostic tests indicate structural changes
- Lumbar herniation and nerve root compression
- Cauda Equina Syndrome (emergent)

Surgical Treatment Options

Lumbar Arthrodesis (Fusion)

- Removing disc and fusing vertebrae
- Standard for LBP surgery

-or-


Lumbar Arthroplasty (also known as Total Disc Replacement or TDR)

- Removing disc and replacing it with an artificial one
- Alternative to fusion for subset of patients
- No bone graft or other instrumentation needed

Overview of Lumbar Fusion


Eliminates motion at one or more vertebral segments to relieve pain and correct instability, with goals to:

- ✓ Decompress spinal nerves to eliminate pain
- ✓ Restore disc height/appropriate space between vertebrae
- ✓ Eliminate mobility of affected vertebra by fusing it with grafts/implants



Risks with Lumbar Fusion

- Permanent changes in back mechanics/balance
- Irreversible
- Adjacent segment disease seen in up to 80% of patients
- Reoperation of **10-30% within 5 years**



Lumbar Arthroplasty/Total Disc Replacement (TDR)

Overview of Lumbar TDR

- “New” alternative to fusion – available in Europe for 30+ years, US since 2004
- Symptomatic disc removed and replaced with artificial disc (reconstruction vs. fusion)
- Restores height and movement between vertebrae
- Replacing disc maintains more normal motion
 - ✓ Reduction of adjacent level degeneration

Overview of Lumbar TDR (cont.)


- 5 FDA IDE trials with 5-year follow-up
 - 3 compared to fusion
 - 2 compared to other discs
- Multiple studies with 5- to 10-year and ≥10-year follow-up
- Show less wear than hip/knee replacements

3 Generations of Lumbar Discs

Charité	ProDisc-L	activL
First Generation Unconstrained Core <ul style="list-style-type: none"> • Clinical trials begin in 2000, launched 2004 • Unconstrained motion – 5 degrees of freedom • Multiple step insertion • 5 endplate sizes • No longer on the US market (2011) 	Second Generation Constrained Core <ul style="list-style-type: none"> • 2nd generation launched 2006 • Constrained core – 3 degrees of freedom • Multiple step insertion • 2 endplate sizes 	Third Generation Controlled Mobile Core <ul style="list-style-type: none"> • Large gap in development, 3rd generation launched 2015 • Controlled mobile core – 4 degrees of freedom • Single step insertion • 4 endplate sizes

TDR Implant


- Cobalt chromium endplates
- Polyethylene inlay core
- Affix to vertebrae with bone-sparing spikes or keel



FDA Indications for Lumbar TDR


Alternative to lumbar fusion for patients with discogenic LBP:

- 18 to 60 years of age
- Advanced, single-level degeneration of lumbar spine at L3-4, L4-5 & L5-S1
- No more than Grade 1 spondylolisthesis
- Symptoms ≥ 6 months, not responding to conservative treatment
- Primarily back pain



Contraindications for Lumbar TDR

- <18 or >60 years
- Advanced, multi-level disease
- Spinal stenosis, spondylolisthesis, or scoliosis
- Previous major spine surgery
- Neurologic symptoms
- Disease above L3
- Significant facet arthropathy at operative level
- Infection or tumor
- Significant psychiatric disorder



Clinical Evidence for Lumbar TDR

Guyer, et al, 2009:

- No statistical differences in clinical outcomes
- Higher rate of part- and full-time employment
- Lower rate of long-term disability

Gornet, et al, 2010:

- TDR patients returned to work 21 days sooner
- 87% would have surgery again
- Superior to fusion in terms of improved physical function, patient satisfaction, and pain

Clinical Evidence for Lumbar TDR

Zigler, et al, 2012: 5-Yr FU Lumbar TDR versus Fusion

- Follow up rate of 82% on 236 patients out to 5 years
- Both groups improved significantly on VAS (pain) and ODI (function) at 24 months, then maintained changes out through 5 years
- Most importantly, at 5 years, **observed adjacent segment disease in 29% of fusion patients vs 9% of TDR patients = 3:1 ratio (p = .004)**

Clinical Evidence for Lumbar TDR

Zigler, et al, 2018: 5-Yr FU Lumbar TDR ASD Rates:

- Adjacent segment disease in 9% of active patients, which continues to prove out the theory behind artificial discs over time

Clinical Evidence for Lumbar TDR

Zigler, et al, 2017: Meta-Analysis of 5-Year Outcomes from Randomized Trials (fusion vs. disc only):

Studies	ODI	Back Pain	Reoperation	Patient Satisfaction
Guyer 2009	✓		✓✓	✓✓
Gornet 2010	✓✓	✓	✓✓	✓✓
Zigler 2012	✓		✓	✓✓
Skold 2013	✓✓	✓	✓✓	✓✓
5-Year Meta-Analysis	✓✓	✓	✓✓	✓✓

Legend: ✓✓ = TDR significantly better than fusion on one or more outcomes. ✓ = TDR numerically better than fusion on one or more outcomes. Blank cells = No outcomes show TDR as numerically better than fusion.

Return to Work with Lumbar TDR

Garcia, et al, 2015, 2-YR Follow-Up:



Return to Work with Lumbar TDR

Mattei, et al., 2017, Retrospective Analysis:

- Retrospective, controlled study of patients with lumbar DDD who had lumbar TDR or ALIF at a single hospital from 2007-2010 followed out for one year
- Patients who had lumbar TDR had **significantly lower VAS pain and ODI disability scores** out through one year
- Lumbar TDR patients also **returned to work on average 65 days sooner** than ALIF patients

Summary of TDR Results

TDR patients, when compared to fusion:

- ✓ Are more satisfied
- ✓ Have less pain / improved function
- ✓ Return to work more quickly and return to full duty more often
- ✓ Require fewer reoperations / have a lower incidence of adjacent segment disease over the medium- and long-term

Questions?

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