Cervical Disc Arthroplasty (CDA) vs ACDF: 2-Level Comparison

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Disclosures

• Consultant: DePuy Spine
• Other Financial Support (royalty):
  – DePuy Spine
  – Thieme Publishing
  – Quality Medical Publishers
  – Taylor and Francis Publishers
• Honoraria: AO Spine
• Stock: Spinicity/ISD
CASE 1.
49F with radicular pain in b/l upper extremities, hyperreflexia and gait instability.
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49F with radicular pain in b/l upper extremities, hyperreflexia and gait instability.
CASE 2.

39F with right shoulder pain and radicular pain radiating down right arm. No myelopathy or gait instability.
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Five-year clinical results of cervical total disc replacement compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial

Kris Radcliff, MD,¹ Domagoj Coric, MD,² and Todd Albert, MD³

Long-term follow-up: Two-level

- Five year follow-up Mobi-C, two-level cTDR: Level I data, prospective, randomized IDE study.
- ACDF=105 (f/u=87%); Mobi-C=225 (f/u=91%)

TDR vs ACDF:
Greater improvement in Neck Disability Index at all time points

Radcliff K, Coric D, Albert T,
TDR vs ACDF:
Greater improvement in SF-12 Physical Component Summary at all time points

Radcliff K, Coric D, Albert T,
TDR vs ACDF:
Greater reoperation rates at index levels AND adjacent levels for ACDF group

Index level reoperation:
- ACDF = 16.2%
- cTDR = 4.3%

Adjacent level reoperation:
- ACDF = 11.4% (2.3%/yr)
- cTDR = 3.1% (0.6%/yr)

Mean reoperation-free survivorship:
cTDR demonstrate lower probability for secondary surgical intervention through 5 years

TDR vs ACDF:
Overall success rate at 5 years for cTDR meets superiority and non-inferiority criteria (FDA composite outcome measure)

Superiority of cTDR over ACDF at 5 year
\((p<0.025)\)

Long-Term Clinical and Radiographic Outcomes of the an Artificial Cervical Disc Replacement at Two Levels: Results from a Level 1 Prospective Randomized Controlled Clinical Trial

Todd Lanman, MD¹, Ken Burkus, MD², Randall Dryer, MD³, Matthew Gornet, MD⁴, Jeffrey McConnell, MD⁵, Scott D. Hodges, DO⁶

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Presented at CNS and EuroSpine, 2016
• **Design**
  - Compare safety and efficacy of PRESTIGE LP vs. ACDF at two adjacent levels (C3 – C7) at 84 months follow up.
  - 397 subjects randomized
    - 209 Investigational cervical disc
    - 188 Control ACDF

• **Prestige LP Cervical Disc**
  - FDA approved 2014 based on 1-level study
  - Titanium ceramic composite
  - 2-piece, low profile with ball and trough articulation
  - Primary and secondary fixation features
At 7 years, the investigational disc demonstrated statistical superiority over fusion on overall success, observed rate (78.6 % vs 62.7%, respectively; posterior probability of superiority=99.8%)
Secondary Surgeries Involved with Adjacent Levels

Comparison of Time to Secondary Surgeries Involved with Adjacent Levels

% Patients Who Had Secondary Surgeries at Adjacent Levels

Treatment Group: Investigational, Control

PPS = 94.2%

Months from Index Surgery to Secondary Surgery
TDR vs ACDF: Summary
Lanman et al., 2016

• *Long-term follow-up: 2-level*
  • Prestige-LP: 2-level, 7-year IDE follow-up.
  • cTDR had statistically significantly higher rate of neurological success for cTDR (92% v 82%).
  • cTDR had statistically significantly fewer secondary surgery at index level (4.2% v 14.7%).

• Adjacent level reoperation:
  • ACDF= 12.5% (1.7%/yr)
  • cTDR= 6.5% (.93%/yr)  \( PPS=94.2\% \) (nonsig)
Long-term evaluation of cervical disc arthroplasty with the Mobi-C cervical disc: a prospective, randomized multicenter clinical trial with seven year follow-up

- **Long-term follow-up: 1- and 2-level**
  - Seven year follow-up Mobi-C, 1-and 2-level cTDR: Level I data, prospective, randomized IDE study.
  - Adjacent level reoperation:
    - Both 1- and 2-level TDR groups had statistically significantly lower incidence of secondary surgery.
  - Adjacent level reoperation:
    - 1-level: ACDF=13.6% cTDR=3.7% (p=0.007)
    - 2-level: ACDF=11.4% cTDR=4.4% (p=0.03)

Societal Cost: ACDF vs. CDA

- Markov model for economic and decision analysis: theoretical cohort of 45-65 year old patients using Medicare billing data

Factors driving lower cost:
- Lower operative cost (surgeon’s fee) and slightly lower perioperative cost
- Earlier return to work
- Lower reoperation rates that occur further in the future (discounted)
- Even if reoperation rates affected by bias (and rates are equivalent), CDA would be significantly less expensive

Summary

- Superior materials, imaging and profile (in evolution)
  - Several FDA-approved CDA devices for 1- and 2-level
  - May be more effective design characteristics
- Long term results vs. ACDF have demonstrated:
  - Superiority: Neck pain/NDI, Overall success (+/- FSU), Neurological success, and Secondary surgeries depending upon IDE (not consistent)
- Questions STILL not fully answered:
  - Bridging bone/heterotopic ossification (rates ~10%)
  - Metal ion issues (appears safe)
- 1- and 2 level CDA: viable, sustainable and cost-effective alternative to ACDF in selected patients
Credits:
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Dom Coric, MD