What is the Data Supporting The Surgical Treatment of Two Level Cervical Disc Disease?

Two Level ACDF
Two Level ADR
Hybrid Construct

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Jack E. Zigler MD
Medical Director
Texas Back Institute

Introduction

- Painful cervical disc disease at 2 levels is a common problem
- Treatment options:
  - 2 level ACF
  - 2 level TDR
  - Hybrid of TDR and ACF
- Which is optimal?
  - For which patients?

Introduction

- Single-level TDR is gaining increasing acceptance as an alternative to ACDF using allograft and an anterior plate or stand-alone anterior implants
- Two-level TDR data is not as common, primarily due to fewer FDA IDE trials
- Hybrids are less common, but are commonly being performed as an alternative to 2-level ACF
Two Level Alternatives

- Evaluation of 2-level surgical treatment options based on:
  - Biomechanics
  - Clinical outcomes
  - Cost

I. Biomechanics

- One concern with fusion is the potential to increase load on adjacent segments, possibly accelerating degeneration
- Can 2 level TDR or a Hybrid reduce this potential biomechanical problem?

Conclusion: 2-level cervical TDR produced near-normal mobility at both levels
- Did not destabilize operated segments
- Did not affect motion at adjacent segments
Disc Replacement Adjacent to Cervical Fusion

A Biomechanical Comparison of Hybrid Cervical Vertebra Two-level Fusion

- 2-level ACF significantly increased motion at adjacent segments compared with hybrid
- Hybrid had significant biomechanical advantages over 2-level ACF by reducing adjacent-level hypermobility and loads required to achieve a predetermined ROM

2011

2012

Clinical Biomechanics

Adjacent level effects of bi level disc replacement, bi level fusion and disc replacement plus fusion in cervical spine- a finite element based study

- Kinematics are altered significantly by fusion
- Hybrid had less biomechanical effects on adjacent levels compared with fusion
- TDR produced kinematics similar to intact spine with no aggressively degenerating mechanical effects on adjacent levels

2011

Meta Analysis Summary-2014

- Review of biomechanical studies on cervical hybrid surgery
- 8 studies identified
- All found hybrid surgery:
  - Allowed motion at the TDR level
  - Resulted in less adverse effect on adjacent segments compared with 2-level fusion

Jia et al, Eur Spine J, 2014
II. Clinical Outcomes of Surgical Treatment for Two Level Cervical Disc Disease

A. Two Level ACDF Data

Comparison of 1-Level Versus 2-Level Anterior Cervical Discectomy and Fusion: Clinical and Radiographic Follow-Up at 60 Months

Zigler et al
Spine 2016

CONCLUSION

• A two level ACDF is not “the same” as a single level ACDF
  – Lower fusion rate
  – Higher ASD
  – Higher re-op rate
B. Two Level ADR IDE Study Data

- 105 TDR and 225 ACDF patients, FDA IDE trial
- TDR patients had statistically significantly greater improvement than ACDF on NDI, SF-12 PCS, satisfaction, and overall composite success

Four Year Follow-Up

2015

Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4 year follow-up results

Reginald L. Gates, MD; Marco Zeller-Rosen, MD; Youn S. Kim, MD; Michael S. Henry, MD; Robert J. Jackson, MD; Ryan W. Bar, MD; Gregory A. Hoffman, MD; Steven C. Gates, MD

Guy C. Gordon B, MD; Charles Gordon, MD; and Karen E. Stone, PhD

- 105 TDR and 225 ACDF patients, FDA IDE trial
- TDR patients had statistically significantly greater improvement than ACDF on NDI, SF-12 PCS, satisfaction, and overall composite success

Mean NDI for 2-level TDR vs. ACF

Scores significantly less in TDR group at all points except pre-op (<p0.05)

Davis et al, J Neurosurg Spine, 2015
Mobi-C 2-level TDR vs. ACDF at 4 Years Post-Surgery
Davis et al, J Neurosurg Spine, 2015

- Compared to ACDF, TDR patients experienced significantly lower rates of:
  - Subsequent surgery:
    - 4.0% (9 / 225) vs. 15.2% (16 / 105)
  - Adjacent-segment degeneration:
    - 41.5% TDR vs. 85.9% ACDF
  - p<0.01

At 60 mo follow-up, subsequent surgery in 2-level cases was significantly less in TDR: (p<0.01)
- ACDF: 20.9% (22 / 105)
- TDR: 7.3% (17 / 234)

Five Year Follow-Up

Re-operation Rates

![Re-operation Rates Chart]

1- and 2-level TDR and ACF: Pooled Data from FDA IDE Trial
Hisey et al, CSRS, 2015

• Data from 1- and 2-level arms of Mobi-C TDR vs. ACDF in the FDA pivotal trials
  – Prospective, randomized, multicenter studies
  – 1-level: 164 TDR and 81 ACDF pts
  – 2-level: 225 TDR and 105 ACDF pts
  – 5 yr follow-up

Mean NDI Scores for 1- and 2-level TDR and ACF

• Conclusion: at 5 yrs, 1-and 2-level TDR patients showed no significant differences in clinical outcomes
• 2-level ACDF patients had less improvement on NDI, SF-12 PCS, and NDI success than 1-level ACDF patients
• Results suggest TDR has potential benefit over ACDF, particularly for 2-level procedures
Prestige LP 2 Level Study 7 Year Results

Todd Lanman MD
JNS Spine April 2017

- 397 patients (209 LP 2L vs 188 2L ACDF)
- 84 month follow-up
- Prestige LP better with
  - Overall success 78.6% vs 62.7%
  - Neuro success 91.6% vs 82.1%
  - NDI success 87.0% vs 75.6%
  - 2nd index level surgery 4.2% vs 14.7%

C. Data on Cervical Hybrid Constructs

- 1 level has indications or insurance approval for TDR; the other does not
- Conflicting goals at the 2 levels...
  - TDR motion
  - ACF stabilization
- What about the outcomes?

Reviewed 7 clinical hybrid studies
- All studies found improvement in validated outcome measures
- Segmental motion and immobilization were seen at TDR and ACF levels respectively
- Post-op assessments and complication rates were similar or in favor of hybrid compared with TDR or ACF
• 35 patients followed for 5 years
• Hybrid had significantly better outcomes on some parameters up to 3 yr follow-up
  – At 5 yrs, no difference
  – At no time did hybrid have less favorable outcome than ACF

TBI Cx Hybrid Experience-2016

• Retrospective review of our first 80 pts treated with cervical hybrid procedure
• Mean follow-up was 13.6 mo
• 2 re-ops (2.5%):
  – 1 for TDR anterior migration
  – 1 for TDR subsidence
• In both cases, TDR removed and ACDF performed

Our Clinic’s Experience with Cervical Hybrid

• Mean NDI scores improved significantly
  – Pre-op: 43.4
  – Post-op: 22.7 \( p<0.05 \)

• 73.2% of pts improved ≥15 points on the NDI from pre- to post-op
Both improved significantly (p<0.05)

III. Costs

Cost of 2-level TDR

- In addition to safety and clinical outcome, it is important to consider the cost of spine surgery procedures
- This can be challenging due to:
  - Difficulty collecting all cost data on patient during long-term follow-up
  - Differences between billed charges and actual payments based on specific insurance contracts
Data collected based on 330 RCT patients
SF-12 scores used
Costs calculated by extracting dx group codes and applying 2014 Medicare rates
Markov model evaluated QALYs and univariate and multivariate sensitivity analyses applied

2-level Cervical TDR Costs
- TDR cost $1,687 more than ACF over 5 years
- TDR had:
  - $34,377 less productivity loss
  - Significantly greater return-to-work rate (81.6% vs. 65.4%; p<0.03)
- ICER for TDR below US willingness-to-pay threshold of $50,000 per QALY in all scenarios (range -$225,816 per QALY to $22,071 per QALY)

CONCLUSION: First study to report comparative cost-effectiveness of TDR vs. ACF for 2-level DDD at 5 years
The authors concluded that because of the negative ICER, TDR is the dominant modality compared with ACF
Discussion

- 2-level TDR:
  - produces clinical results similar or superior to ACDF
  - has a lower rate of adjacent segment degeneration
  - Has lower re-operation rate than 2L ACDF
  - more cost effective than ACF through 5 yr follow-up

Conclusion

- The clinical outcomes for two level TDR are better than for two level ACDF
- 2L Cx TDR is more cost effective than two level ACDF
- Hybrid constructs appear to be a reasonable compromise with clinical outcomes similar to 2L TDR, no worse or better than 2L ACDF

Thank You