

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

Two Level ACDF
Two Level ADR
Hybrid Construct



2017 CASTELVLI SPINE


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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?



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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

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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?




2009 SPINE, Volume 34, Number 22, pp E778-E779
©2009, Lippincott Williams & Wilkins

■ **Effect of Two-Level Total Disc Replacement on Cervical Spine Kinematics**

Frank M. Phillips, MD,* Michael N. Tzermiadianos, MD,† Leonard I. Voronov, MD, PhD,‡§
Robert M. Havey, BS,† Gerard Carandang, MS,† Andrew Dooris, PhD,§
and Avinash G. Patwardhan, PhD,||

- **Conclusion: 2-level cervical TDR produced near-normal mobility at both levels**
 - Did not destabilize operated segments
 - Did not affect motion at adjacent segments



Spine 2011 SPINE Volume 36, Number 23, pp 1912-1919 ©2011, Lippincott Williams & Wilkins

BIOMECHANICS

Disc Replacement Adjacent to Cervical Fusion

A Biomechanical Comparison of Hybrid Construct Versus Two-Level Fusion

Michael J. Lee, MD,* Mark Dumonski, MD,† Frank M. Phillips, MD,‡ Leonard I. Voronov, MD,§§ Susan M. Renner, PhD,¶ Gerard Carandang, MS,† Robert M. Havey, BS,§§ and Avirush G. Patwardhan, PhD,§§

- **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**

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2012 Clinical Biomechanics 27 (2012) 126–130

Contents lists available at ScienceDirect

Clinical Biomechanics

ELSEVIER journal homepage: www.elsevier.com/locate/clinbiomech

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

Ahmad Faizan ^a, Vijay K. Goel ^{a,*}, Ashok Biyani ^a, Steven R. Garfin ^b, Christopher M. Bonn ^c

- **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**

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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

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II. Clinical Outcomes of Surgical Treatment for Two Level Cervical Disc Disease

A. Two Level ACDF Data

Spine 2016 SPINE Volume 41, Number 6, pp 863-869 © 2016 Wolters Kluwer Health, Inc. All rights reserved.
CERVICAL SPINE

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

Jack E. Zigler, MD,* Roger Warren Rogers, DO,† and Donna D. Chonnesi, DrMed†




Two Level ACDF (vs 1 Level)

Zigler et al
Spine 2016

Five year follow-up:



	# Pts	%fu	%Fusion	%ASD sup	%ACDF inf	%Reop
1 level ACDF	81	74	93.3	54.7	44.7	11.1
2 level ACDF	105	75	86.1	70.8	55.0	16.2

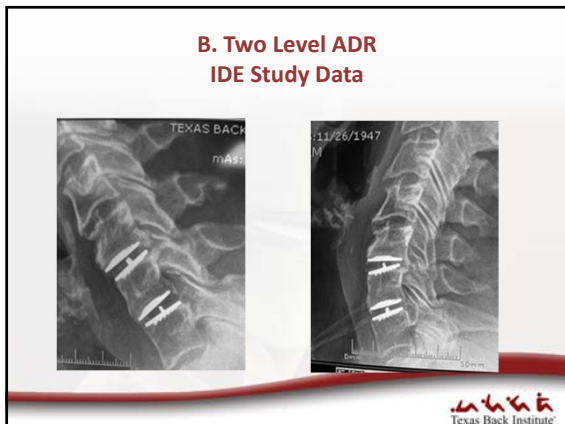
all trends NS



CONCLUSION

- A two level ACDF is not “the same” as a single level ACDF
 - Lower fusion rate
 - Higher ASD
 - Higher re-op rate



JNS SPINE Four Year Follow-Up CLINICAL ARTICLE
J Neurosurg Spine 12:15-25, 2015

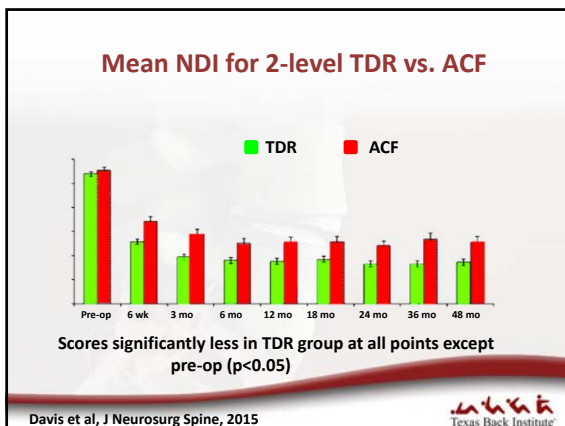
2015

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 J. Davis, MD,¹ Pierce Dalton Nunley, MD,¹ Kee D. Kim, MD,¹ Michael S. Hisey, MD,¹ Robert J. Jackson, MD,¹ Hyun W. Bae, MD,¹ Gregory A. Hoffman, MD,¹ Steven E. Gaede, MD,¹ Guy O. Danielson III, MD,¹ Charles Gordon, MD,¹ and Marcus B. Stone, PhD¹

- 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

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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



JNS SPINE CLINICAL ARTICLE

Five Year Follow-Up


2016

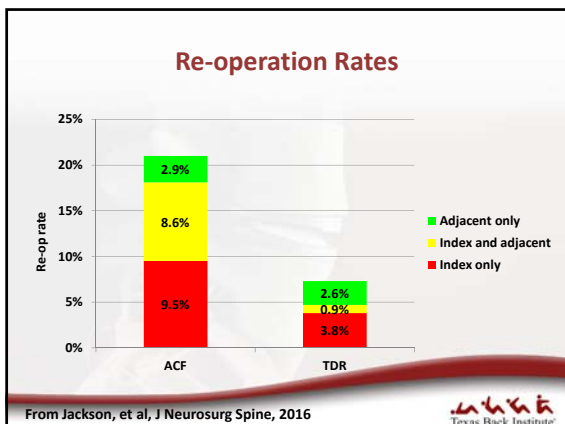
J Neurosurg Spine 24:734-740, 2016

Subsequent surgery rates after cervical total disc replacement using a Mobi-C Cervical Disc Prosthesis versus anterior cervical discectomy and fusion: a prospective randomized clinical trial with 5-year follow-up

Robert J. Jackson, MD,¹ Reginald J. Davis, MD,² Gregory A. Hoffman, MD,³ Hyun W. Bae, MD,⁴ Michael S. Haasy, MD,⁵ Kee D. Kim, MD,⁶ Steven E. Gaede, MD,⁷ and Pierce Dalton Nuntley, MD⁸


- 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)

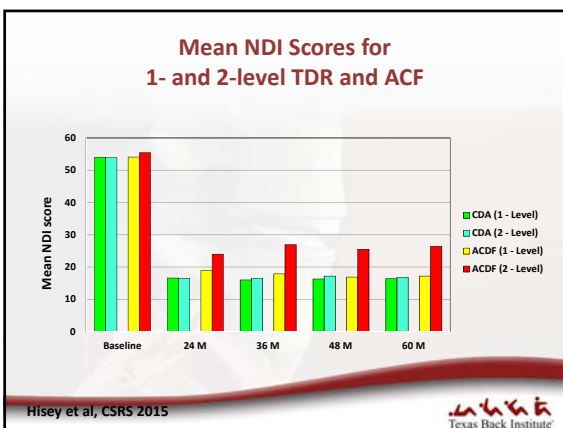




**1- and 2-level TDR and ACF:
Pooled Data from FDA IDE Trial**
Hisey et al, CSRS, 2015


- 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





**1- and 2-level TDR and ACF:
Data from FDA IDE Trial**


- **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?



Eur Spine J (2014) 23:1619–1632
DOI 10.1007/s00586-014-3309-8


2014

REVIEW ARTICLE

Hybrid surgery for multilevel cervical degenerative disc diseases: a systematic review of biomechanical and clinical evidence

Zhiwei Jia · Zhongjun Mo · Fan Ding · Qing He · Yubo Fan · Dike Ruan

- 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




ORIGINAL ARTICLE

Clin Spine Surg, 2016 2016

Artificial Disk Replacement Combined With Fusion Versus 2-Level Fusion in Cervical 2-Level Disk Disease With a 5-Year Follow-up


Gyu Yeul Ji, MD† Chang Hyun Oh, MD,† Dong Ah Shin, MD, PhD,* Yoon Ho, MD, PhD,* Seong Yi, MD, PhD,* Keung Nyun Kim, MD, PhD,* Hyun Cheol Shin, MD, PhD,‡ and Do Heum Yoon, MD, PhD**

- 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

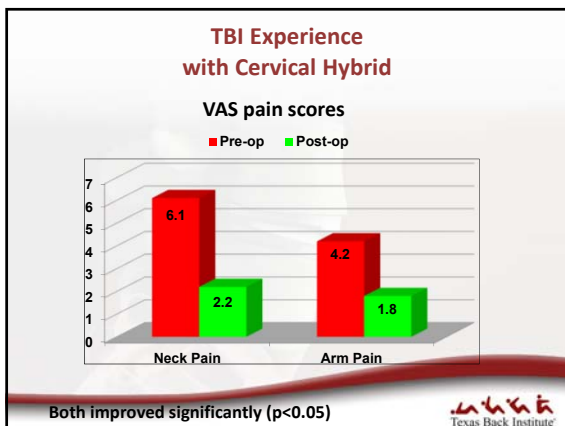
- Retrospective review of our first 80 pts treated with cervical hybrid procedure
- Mean follow-up was 13.6 mo
- 2 re-ops (2.5%):
 - 1 for TDR anterior migration
 - 1 for TDR subsidence
- In both cases, TDR removed and ACDF performed



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





III. Costs

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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

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NEUROSURGERY In press 2016 SPECIAL ARTICLE

Jared D. Ament, MD, MPH*
Zhuo Yang, MS*
Pierce Nuntley, MD†
Marvin B. Stone, PhD‡
Dustin Lee, MD, PhD*
Ken D. Kim, MD*

Cost Utility Analysis of the Cervical Artificial Disc vs Fusion for the Treatment of 2-Level Symptomatic Degenerative Disc Disease: 5-Year Follow-up

- 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

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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)

Ament et al, Neurosurg

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2-level Cervical TDR Cost

- **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

Ament et al, Neurosurg, in press

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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
