

**Cervical Arthroplasty vs ACDF for
Cervical Radiculopathy:
Which for which patient?
Innovasis Spine Symposium
Deer Valley 2018**



Michael S Hisey, M.D.

President, Texas Back Institute

Chairman, Board of Managers

Texas Health Presbyterian Hospital,

Flower Mound

Disclosures

- **Mobi-C Investigator and speaker**

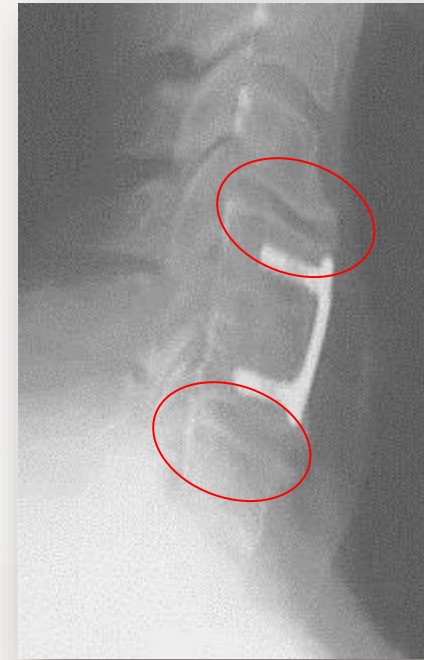
Introduction

- **ACF has long been considered “gold standard” for symptoms related to disc degeneration**
- **Multiple RCTs and other studies, have consistently found cervical TDR similar or superior to ACF**

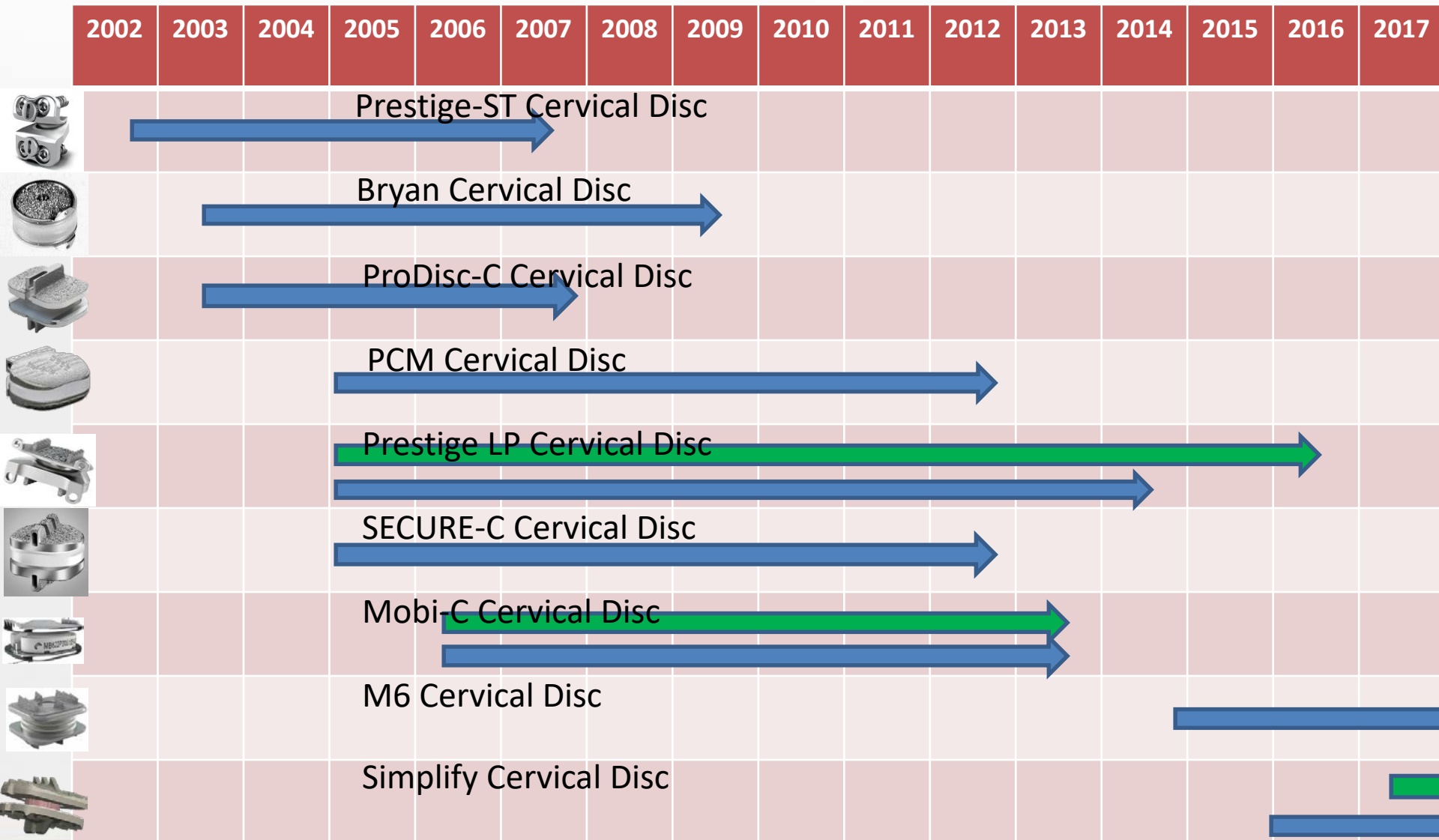
Should you be considering TDR for your patients with cervical HNP?

Disadvantage of ACDF: Adjacent Segment Degeneration

- 25.9% of ACDF pts predicted to have 2nd surgery <10 yrs (Hilibrand, 1999)
- Why?
 - Plate and screws may impact adjacent levels
 - 23.7% of ACDF pts develop moderate to severe ossification at adjacent level (Park, 2005)
 - Adjacent level compensates lost ROM at ACDF level
 - Extra motion fatigues adjacent disc and accelerates degeneration (Schwab, 2006)
- Genetic factors?



Timeline of IDE Approval



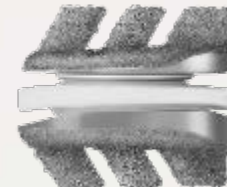
FDA IDE Trials

- **There are 7 completed FDA IDE trials for cervical TDR with data available in public domain**
- **These are all prospective, randomized trials comparing TDR to ACF**

FDA Approved in US

- **Approved**

- **Prestige-ST (2007)**
- **ProDisc-C (2007)**
- **Bryan (2009)**
- **PCM (2012)**
- **SeCure-C (2012)**
- **Mobi-C (1 and 2-level; 2013)**
- **Prestige-LP (1-level 2014, 2-level 2016)**



Current FDA Status in US

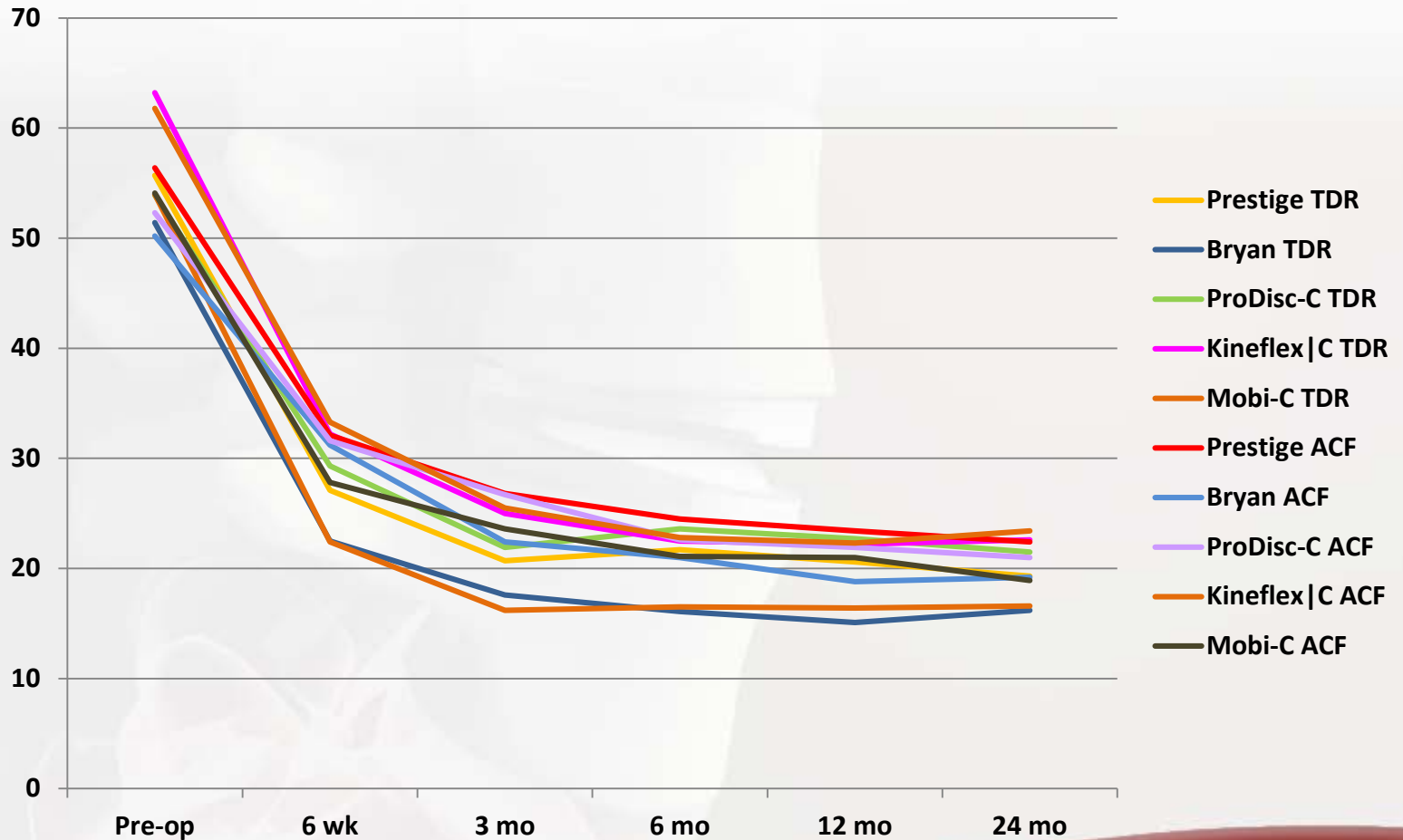
- **Trials ongoing**
 - **M6**
 - **258 Patients Enrolled**
 - **In follow-up**
 - **Simplify 1 level**
 - **150 Patients Enrolling**
 - **Simplify 2 level**
 - **200 Patients Enrolling**



FDA IDE Trials

- **All single level trials found TDR to be non-inferior to ACF**
 - **Superior on some measures**
- **Good results maintained for ≥ 5 yrs in studies with long-term follow-up available**

Mean NDI Scores for TDR and ACF in Various FDA IDE Trials



Mean NDI Scores for TDR and ACF in Various FDA IDE Trials

- **As seen in the graph, data is extremely reproducible across multiple devices**
 - **All represent multicenter trials**
 - **Most conducted at different centers**
 - **Supports generalizability of outcomes**

From Other Countries

- Often relatively small numbers of pts
- Good results for cervical TDR, no indication of less favorable outcomes compared with ACF

Spine

SPINE Volume 37, Number 6, pp 433-438
©2012, Lippincott Williams & Wilkins

RANDOMIZED TRIAL

Randomized, Controlled, Multicenter, Clinical Trial Comparing BRYAN Cervical Disc Arthroplasty With Anterior Cervical Decompression and Fusion in China

Xuesong Zhang, MD,* Xuelian Zhang, PhD,† Chao Chen, PhD,‡ Yonggang Zhang, MD,* Zheng Wang, MD,* Bin Wang, MD,* Wangjun Yan, MD,§ Ming Li, MD,† Wen Yuan, MD,§ and Yan Wang, MD*

Clinical Article

Comparative Analysis of Cervical Arthroplasty Using Mobi-C® and Anterior Cervical Discectomy and Fusion Using the Solis® -Cage

(2010) 19:297-306

/s00586-009-1194-3

CLINICAL ARTICLE

Comparison of outcomes of cervical disc arthroplasty and fusion in everyday clinical practice: surgical and methodological aspects

David Grob · Francois Porchet · Frank S. Kleinstück · Friederike Lattig · Dezsoe Jeszenszky · Andrea Luca · Urs Mutter · Anne F. Mannion

Meta-analysis: TDR vs. ACF

- **No significant differences in NDI, SF-36, or pain scores**
- **TDR had significantly:**
 - **Lower re-op rate**
 - **Greater neurological success rate**
 - **Lower re-op rate for adjacent-level when analyzed using fixed effects model, but not significant using random effects model**

Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial

Clinical article

REGINALD J. DAVIS, M.D.,¹ KEE D. KIM, M.D.,² MICHAEL S. HISEY, M.D.,³
GREGORY A. HOFFMAN, M.D.,⁴ HYUN W. BAE, M.D.,⁵ STEVEN E. GAEDE, M.D.,⁶
RALPH F. RASHBAUM, M.D.,³ PIERCE DALTON NUNLEY, M.D.,⁷ DANIEL L. PETERSON, M.D.,⁸
AND JOHN K. STOKES, M.D.⁹

- **First TDR FDA approved for 2-level**
- **225 TDR, 105 ACF**
- **24 mo follow-up submitted to FDA leading to approval**
- **7 year data available and consistent**

2-level TDR

- TDR superior to ACF on overall success rate (69.7% vs. 37.4%, $p < 0.01$)
- TDR re-op rate (revision, removal, supplemental fixation) significantly less (3.1% vs. 11.4%)
 - 75% of re-op in ACF related to pseudo

LITERATURE REVIEW

Comparing Nonrandomized Observational Studies With Randomized Controlled Trials in Cervical Disc Arthroplasty

A Meta-analysis

Young Min Jee, BS, MBiotech, John Seongweon Bak, BS, MA, Eric Weinlander, BA,
and Paul A. Anderson, MD

- **Baseline pt characteristics differed between prospective observational studies and RCTs**
 - RCTs had younger pts with worse symptoms
- **No difference found in treatment effects between observational studies and RCTs**

TDR ROM

- In addition to pain reduction, a primary goal of TDR is to allow motion at the operated segment
- Does TDR achieve this goal?

Range of Motion Maintained: Data from FDA IDE Trials

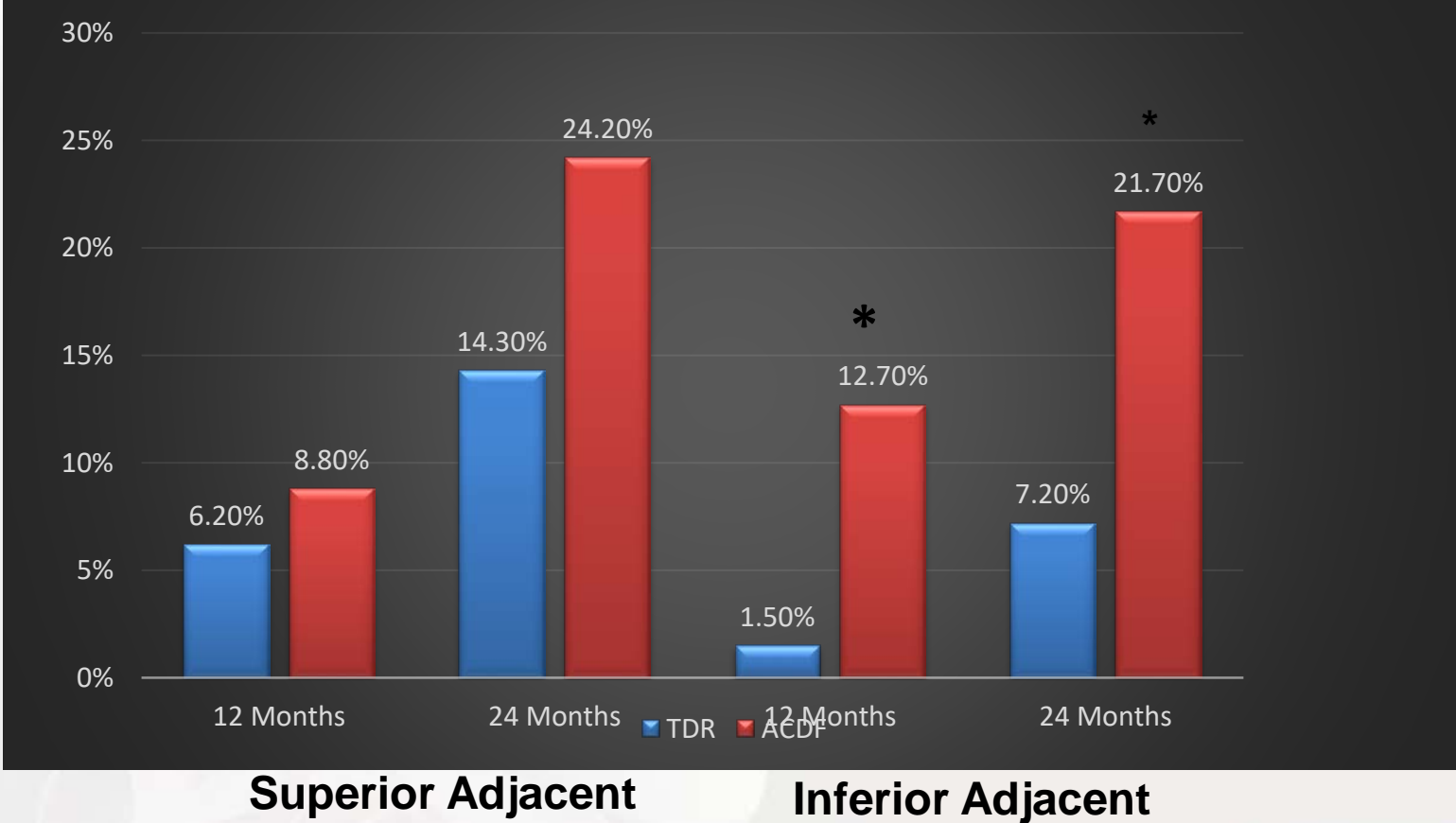
Device	Pre-op	2 yr	4-5 yr
Bryan	6.5°	8.1°	8.5°
Prestige	7.5°	7.6°	6.5°
ProDisc-C	8.5°	9.4°	8.1°
Kineflex C	8.2°	9.8°	NA
Secure-C	8.5°	10.2°	NA
PCM	7.9°	5.7°	NA
Mobi-C	8.2°	10.6°	10.2°

Sasso et al, JBJS 2011; Mummaneni et al, J Neurosurg Spine, 2007; Zigler et al, Spine, 2013;
Secure-C FDA SSED; Coric et al, J Neurosurg Spine, 2011;
Hissey, ISASS 2011; PCM FDA SSED

Adjacent Segment Degeneration

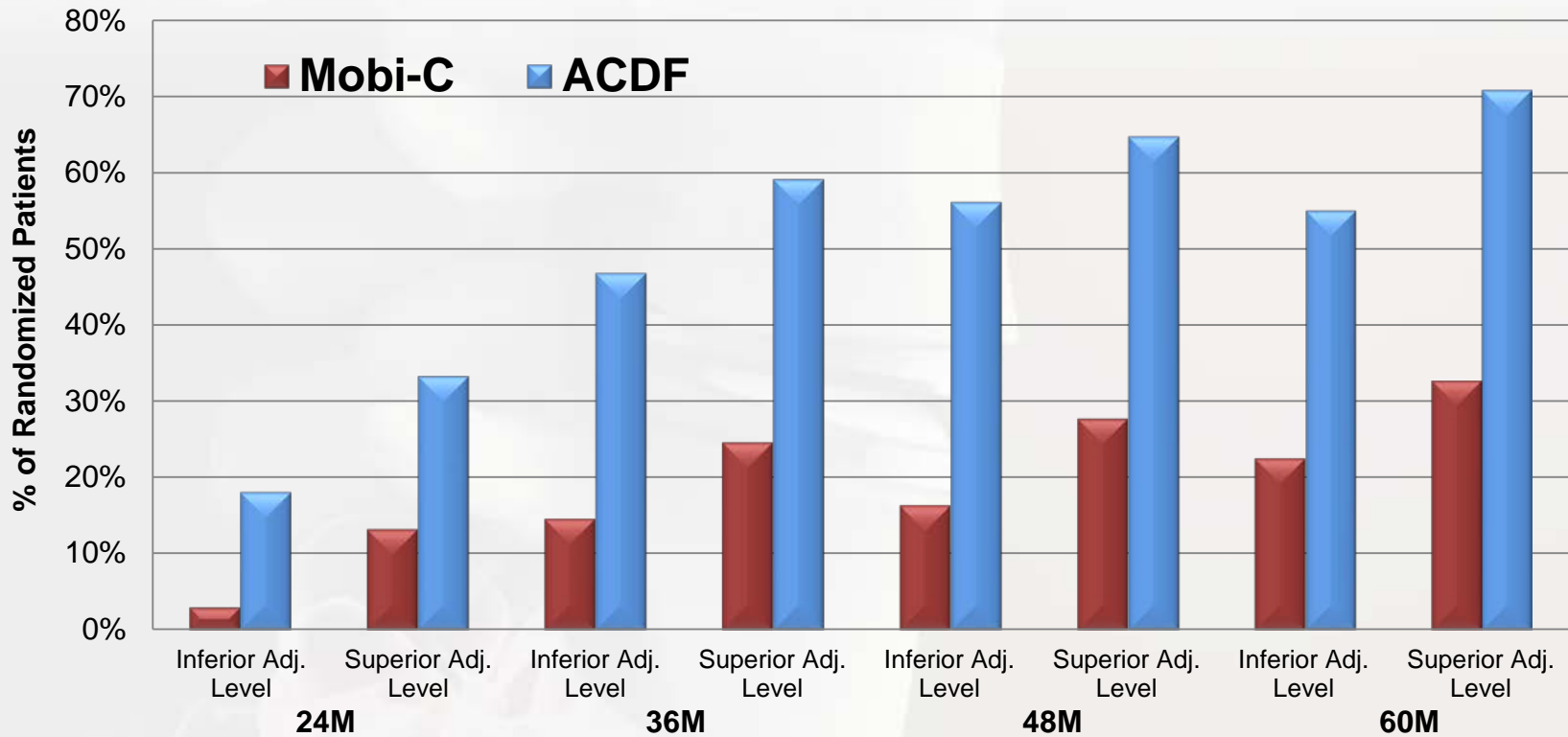
- **One potential benefit of cervical TDR vs. ACF is reducing the acceleration of ASD**
- **Literature generally supports this, though there have been studies that did not**

Mobi-C: Adjacent Segment Degeneration (Kellgren-Lawrence Scale)

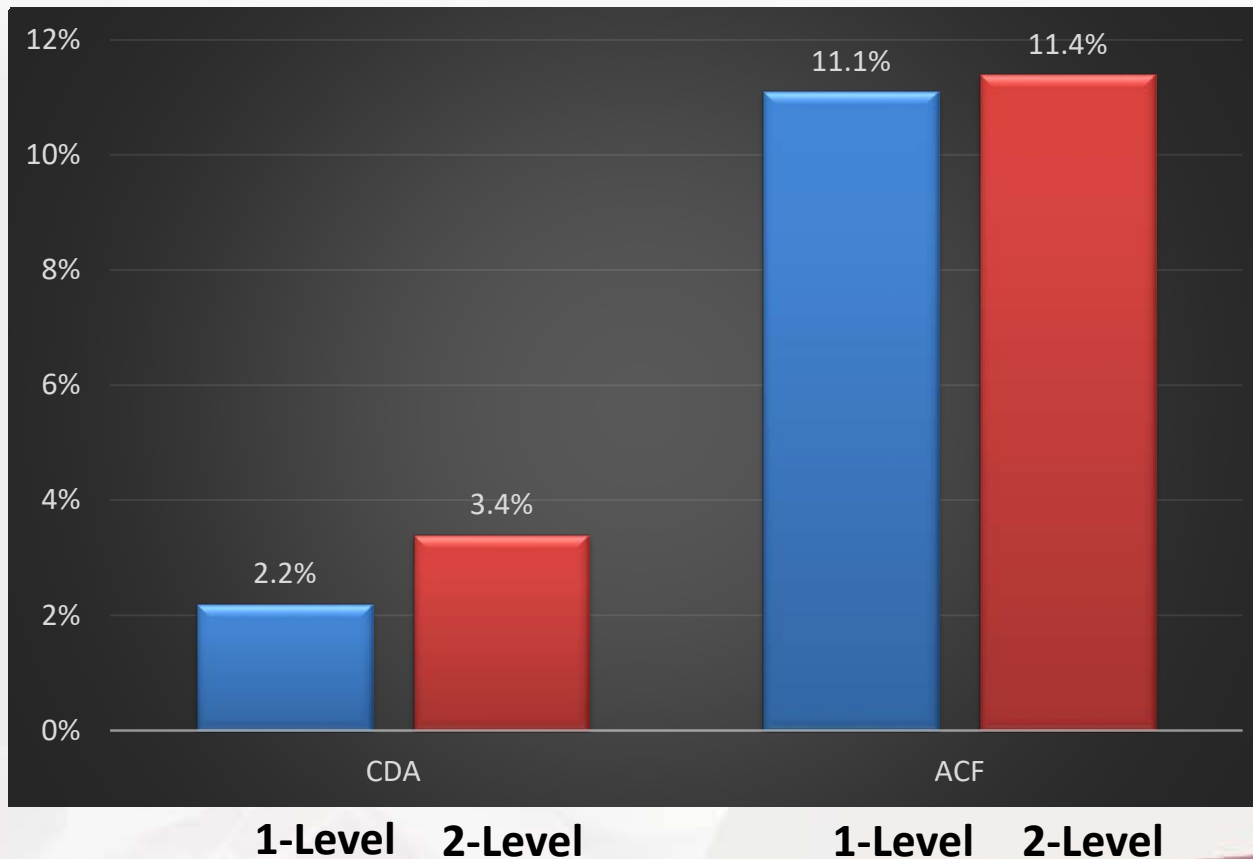


* Adjacent segment degeneration significant (p<0.05)

Inferior and Superior ASD at 60 mos in 2-level Study (Kellgren-Lawrence Scale)



Adjacent Level Subsequent Surgery Rates through 60 Months



Re-operations

- **Re-operations is an important assessment that may reflect safety, device failure, and outcomes**
- **Re-ops can also greatly effect cost and related cost-effectiveness of a procedure in the long-term**

CERVICAL SPINE

Reoperations in Cervical Total Disc Replacement Compared With Anterior Cervical Fusion

Results Compiled From Multiple Prospective Food and Drug Administration Investigational Device Exemption Trials Conducted at a Single Site

Scott L. Blumenthal, MD,* Donna D. Ohnmeiss, Dr. Med,† Richard D. Guyer, MD,* and Jack E. Zigler, MD*

- **Based on patients enrolled in 6 prospective, randomized FDA IDE trials**
- **84 TDR, 52 ACF**
- **Mean follow-up 55.1 mo (range 24–98 mo)**

Re-operations

	TDR	ACF	Significance
Total re-op rate	8.3%	21.2%	p<0.05
Adjacent segment re-op	4.8%	13.5%	0.05 < p < 0.07
Mean time from index surgery to re-op (mo)	54.6	31.1	p<0.01

Re-operations

- **Other studies report similar or significantly lower re-op rate with TDR vs. ACF**
 - **None indicate higher re-op rate with TDR**

Cost

- **Tendency to assume new technology is more costly than current treatment**
- **Is this true for cervical TDR?**

Is there a down side to TDR?

- **Primary short-coming of cervical TDR may be heterotopic ossification, which has no more clinical deficit than fusion resulting in reduced motion at operated segment**

Summary

- Evidence from variety of countries supporting cervical TDR should be new gold standard for treating symptoms related to cervical disc herniation

- It provides

Cervical HNP – Should cervical TDR be the new gold standard?
The evidence say: YES!

What about patients who wouldn't qualify for a Study?

- Sweet spot (?) is the FDA indications
- It is clear that there are benefits of TDR vs ACF in these patients
- Depending on the practice, often represent less than 50% of patients presenting with cervical radiculopathy.

Patient Selection

- **Ideal Patient**
 - One or two level soft disc
 - Contiguous levels
 - Minimal Height loss
 - Arm pain
 - Can be acute or have neuro deficits
- **Also ok, but technically more challenging**
 - Collapsed discs
 - Kyphotic?
 - Osteophytes
 - Myelopathy?



Technical Details

- **Slightly more fussy than an ACDF**
 - **Implant position**
 - **Decompression**
 - **Two level**
- **Every brand of disc has sizing limits**
 - **4.5 mm?**
 - **Endplate sizing?**
 - **So, get good at a couple**
- **Positioning is key**
 - **And varies by implant brand**

Reimbursement

- Perhaps the biggest challenge
 - Hard to get approved, but getting better
 - Appeals turned down because “investigational” or not “On Label”
 - Payment rates significantly lower than the comparable ACDF
 - BCBS is 5/8 of a fusion
 - Patients do demand arthroplasty
 - Faster return to activities
 - Lower adjacent segment disease
 - Arthroplasty is cost effective for the insurers
 - Cheaper at index surgery
 - Less expensive follow-up care

Expanded Indications

(How I think about Cervical
Disc Degeneration)

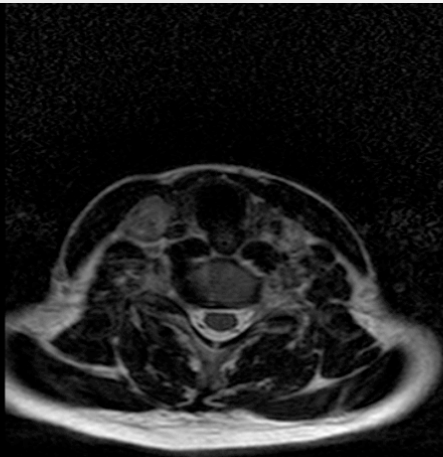
- **1. Is the patient a candidate for surgery?**
 - Symptoms bad enough or Neuro compromise
 - Failed appropriate non-surgical care
- **2. Are each level a candidate for arthroplasty**
 - Radiculopathy or Myeloradiculopathy
 - Very selective about axial pain only
 - No significant deformity
 - No significant facet degeneration
 - No contraindication (osteoporosis, infection...)
- **3. Can I save levels by offering arthroplasty?**

High Risk for Failure

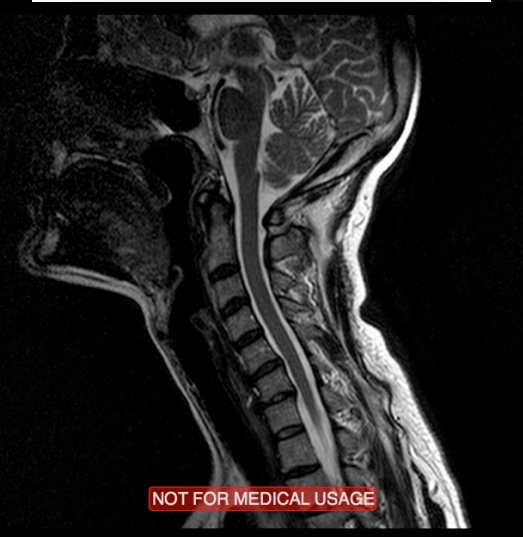


Saving levels with arthroplasty?

- Multi level disease, but one clearly symptomatic
- Fusing only the symptomatic level has a high rate of accelerating adjacent segment disease



NOT FOR MEDICAL USAGE



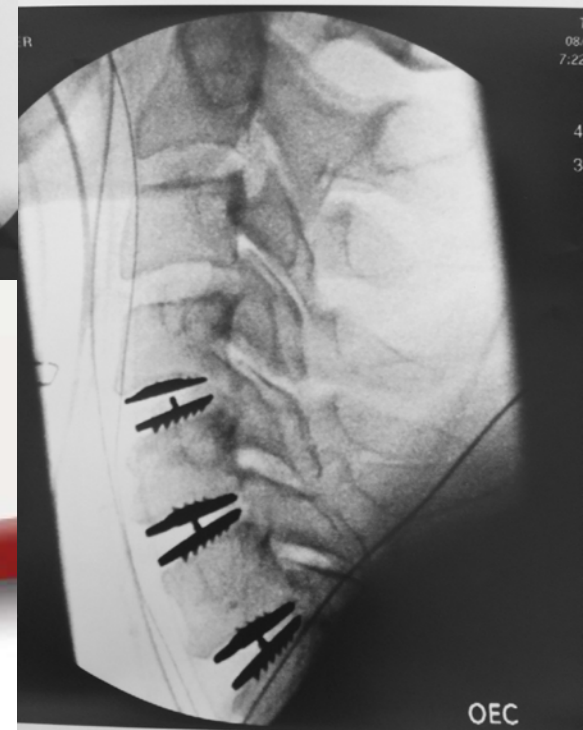
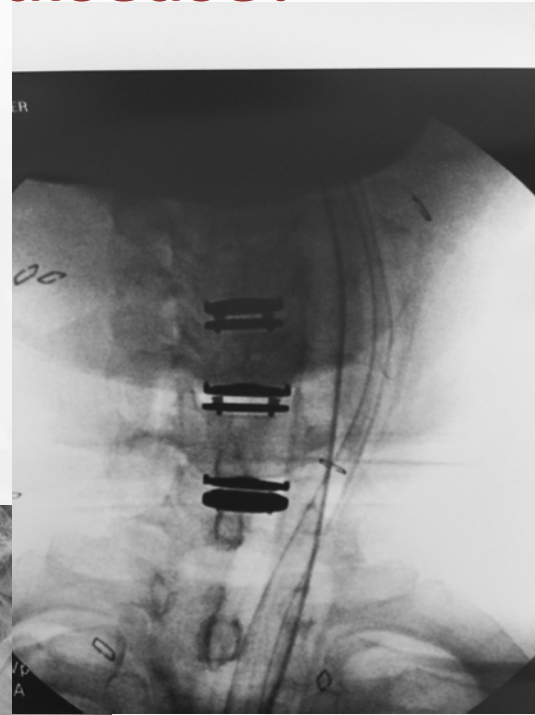
NOT FOR MEDICAL USAGE



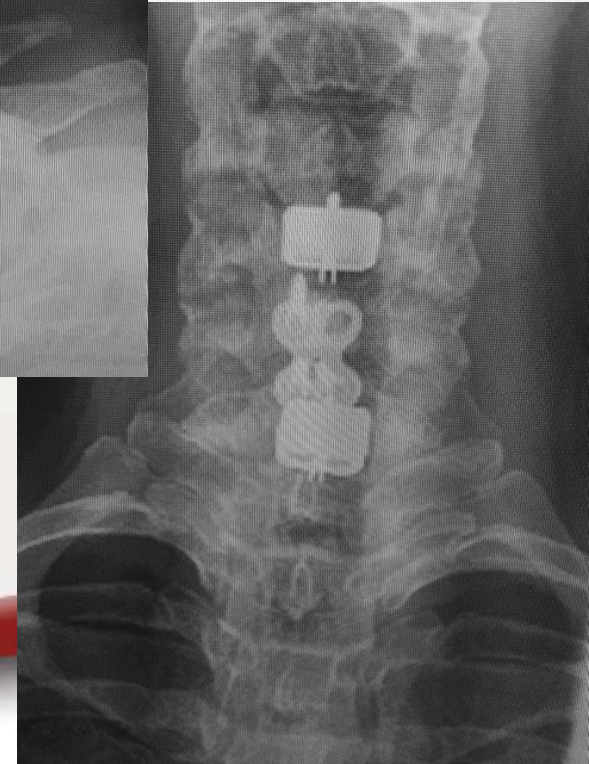
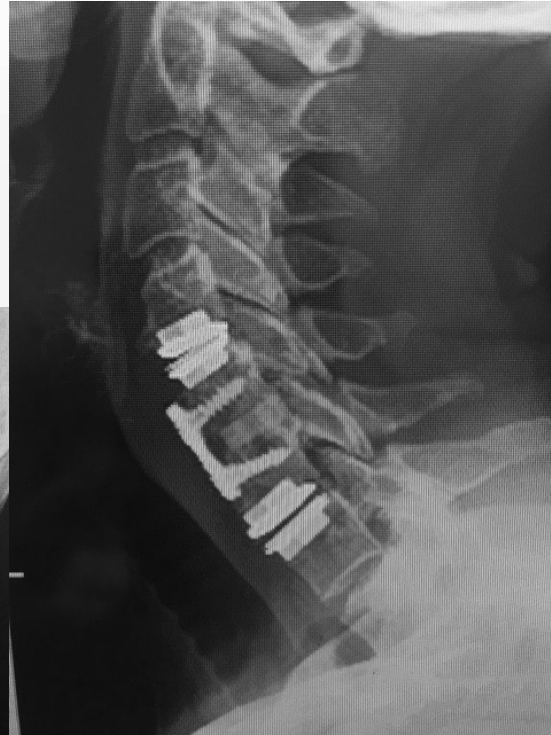
NOT FOR MEDICAL USAGE



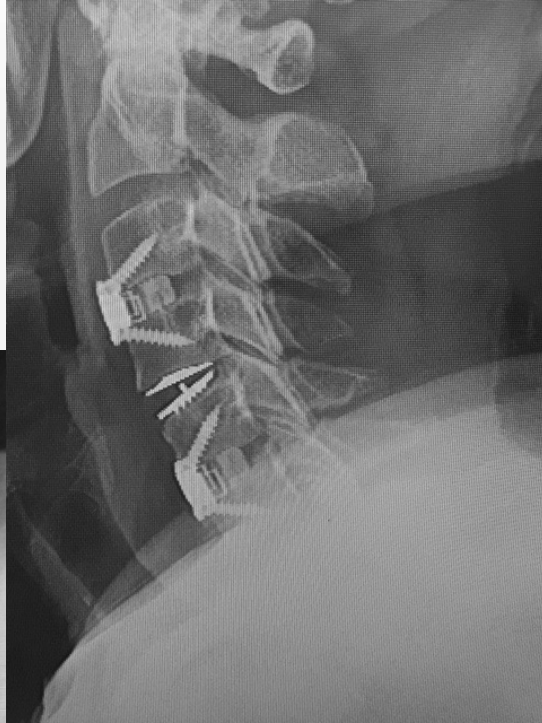
What about patients with more than two level disease?



New HNP(s) next to a fusion?



Some level a candidates for a fusion, the others not?

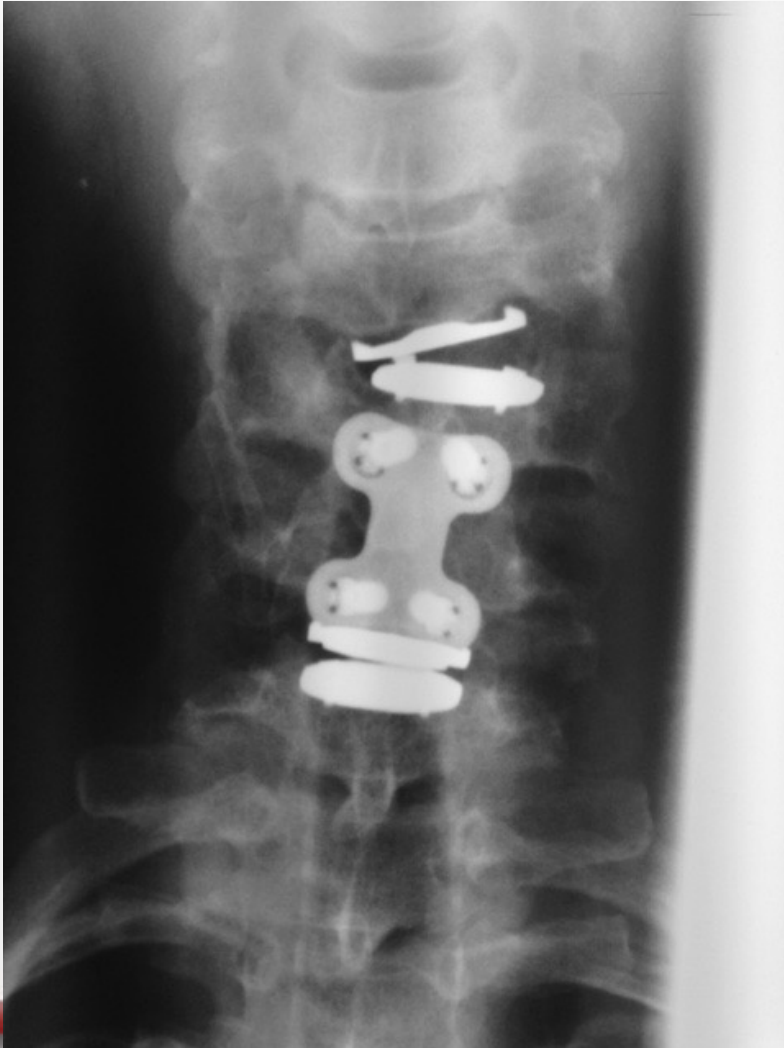


Positioning Becomes More Critical with Multiple Levels

- **Stone Stacking...**
 - **Easy with one, harder with more**



It's not a panacea...



Bottom Line

- **If the individual disc levels and overall alignment are candidates for TDR, that will be the best option**
- **Otherwise, Fusion for levels that aren't candidates or or if the overall alignment requires fusion to correct.**



Texas Back Institute

Thank You

FILE LANE NO PARKING

