Is a Lumbar TDR work vs a standalone ALIF?

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Disclosures
Consultant - Aesculap
Royalties - Activ L

The Lies About TDR

- Experimental/Investigational
- No long term data
- High rate of horrible complications
- ALIF is pretty good operation and patients do great

Why Do Surgeons Lie About TDR?

- To Avoid Learning a New Procedure
- To Avoid the Learning Pains
- To Make Patient Selection Easier
- To Make More Money

The Truth: Motion is better than Fusion

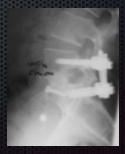
- Shoulder
- Hip
- Knee

The Truth: Motion is better than Fusion

- Cervical spine

The Truth:
ALIF is a great operation for the surgeon but not for the patient

- Ray et al, Spine 1997
  - 96% fusion rate @ 2 yrs for Ray Cage
  - 65% good-to-excellent results
- Kuslich et al, Spine 2000
  - 95% fusion rate @ 4 yrs for BAK cage
  - 63% gainfully employed
- Boden et al, Spine 2000
  - 93% fusion rate @ 2 yrs for LT cage + InFUSE
  - 72% patient satisfaction
- Zigler et al, Spine 2007
  - 97% fusion rate @ 2 years 360 fusion control TDR IDE
  - 67% VAS Satisfaction @ 2 years



Radiographic success ≠ Clinical success

An ALIF is still a Fusion

- You cannot expect the clinical outcomes of ALIF to change regardless of the cage.

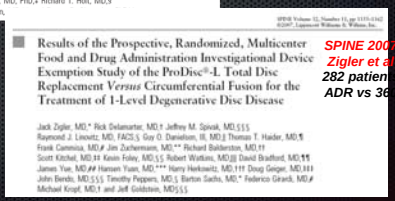
Prospective, Randomized, Controlled Multicenter FDA IDE Trials: 2-Year Data

A Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemptions Study of Lumbar Total Disc Replacement With the CHARITÉ™ Artificial Disc *Versus* Lumbar Fusion

Part I: Evaluation of Clinical Outcomes

Scott Blumenthal, MD,* Paul C. McAfee, MD,† Richard D. Guyer, MD,* Stephen H. Hochschuler, MD,* Fred H. Geisler, MD, PhD,‡ Richard T. Holt, MD,§ Rolando Garcia, Jr., MD, MPH,¶ John J. Regan,

SPINE 2005
Blumenthal et al
304 patients
TDR vs ALIF cages



Results of the Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemption Study of the ProDisc®-L Total Disc Replacement *Versus* Circumferential Fusion for the Treatment of 1-Level Degenerative Disc Disease

Jack Zigler, MD,* Rick Delamarter, MD,† Jeffrey M. Spivak, MD,‡‡§

SPINE 2007
Zigler et al
282 patients
ADR vs 360

Both found TDR at least as safe and effective as fusion, superior on some measures

Lumbar disc arthroplasty with Maverick disc versus stand-alone interbody fusion: a prospective, randomized, controlled, multicenter investigational device exemption trial.

Gornet MF, Burkus JK, Dryer RF, Peloza JH
Spine, 2011 Dec 1;36(25)

- 2:1 randomization
- 577 patients
  - 405 TDR with Maverick
  - 172 ALIF with LT cages and BMP
- The investigational group had statistically superior outcomes ($P < 0.05$) at all postoperative evaluations in:
  - ODI,
  - back pain
  - SF-36
  - Patient satisfaction.
  - Fewer implant or implant/surgical procedure-related adverse events ($P < 0.001$).
- Return-to-work intervals were reduced for investigational patients.
- In the investigational group, overall success **superiority** was found when compared to the control group as defined by the FDA IDE

Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITÉ artificial disc versus lumbar fusion: Five-year follow-up

Richard D. Guyer, MD[a,*], Paul C. McAfee, MD[b], Robert J. Banco, MD[c], Fabian D. Bitan, MD[d],

- 5-yr follow-up: 90 TDR vs. 43 ALIF
- ODI and VAS: no change between years 2-5
- ROM maintained in TDR group
- TDR had significantly greater RTW with fewer patients
  - on long-term disability

Five-year results of the prospective, randomized, multicenter, Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential arthrodesis for the treatment of single-level degenerative disc disease

Clinical article

JACK E. ZIGLER, M.D.,[1] AND RICK B. DELAMARTER, M.D.[2]

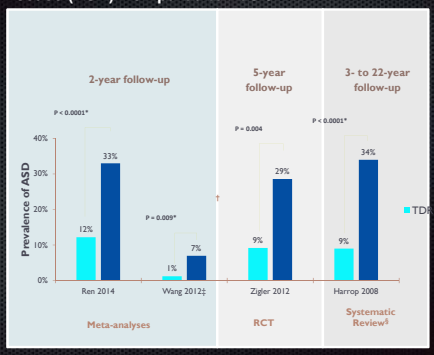
- N = 236 patients (TDR and 360 fusion control)
- Overall follow-up rate - 81.8%
- Both groups improved significantly on VAS and ODI scores at 24 months with no significant changes between the 24- and 60-month follow-up
- At 60 months, successful radiographic ROM in 93.7% of TDR pts, mean 7.2º

Study	Study Design	Follow-up	Region
Guyer 2009	IDE RCT	5 years	US
Gornet 2010	IDE RCT	5 years	US
Zigler 2012	IDE RCT	5 years	US
Guyer 2015	IDE RCT	5 years	US
Garcia 2015	IDE RCT	2 years	US
Skold 2013	RCT	5 years	Sweden
Aghayev 2014	Observational**	Mean, 5.5 years	Sweden
Siepe 2014	Observational**	Mean, 7.4 years	Europe
David 2007	Observational	Mean, 13.2 years	France
Park 2012	Observational	Mean, 6 years	Korea
Lu 2015	Observational	Mean, 11.8 years	China
Lemaire 2005	Observational	Mean, 11.3 years	France
Tropiano 2005	Observational**	Mean, 8.7 years	France

** Prospective study design

- **>13 years** of data from around the world
- **5 FDA IDE** trials, 3 with fusion control, 2 with TDR controls + 1 OUS RCT with fusion as control
- **Multiple studies with 5 to 10-year and ≥10-year follow-up**

5-Year Data: Lumbar TDR With Over 3-Fold Decrease in Adjacent Segment Disease (ASD) Compared to Fusion



* P-value is based on pooled results from meta-analytic analysis. † Rate of adjacent segment degeneration for TDR from 5-year follow-up reported in the Zigler 2012 RCT are similar to those reported in a 5-year prospective single-arm study of TDR (187S) (Aghayev et al., 2014). † Examined adjacent segment pathology, a proposed umbrella term referring to the breadth of clinical and/or radiographical changes at adjacent motion segments that developed subsequent to a previous spinal intervention. ‡ Included 27 prospective single-arm TDR and fusion studies.

Level I(a) Data: 2-Year Meta-Analyses TDR vs Fusion

All meta-analyses reporting on disability, pain, and patient satisfaction demonstrate that TDR significantly improves these outcomes at 2 years in contrast to surgical fusion for the treatment of lumbar DDD

Published Meta-Analyses
Yajun et al., 2010
Jacobs et al., 2012
Wei et al., 2013
Rao et al., 2014
Noshchenko et al., 2014
Nie et al., 2015

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

Results of Meta-Analysis Provide Long-Term that Individual Studies Are Not Powered to Draw

- Meta-Analysis of Long-Term Randomized Controlled Trials considered Level 1(a) evidence
- Four outcomes selected based on what the studies had in common
- 3 of the 4 studies showed statistical favor to TDR at 5 years

Endpoint Evaluated	Outcomes Favor	p-Value
Disability (ODI)	TDR	0.05
Pain (VAS)	TDR	0.25
Reoperation	TDR	0.002
Patient Satisfaction	TDR	0.01

2 years

Meta-analysis	Complications	Reoperations
	TDR vs. Fusion: Odds Ratio (95% CI)	
Nie et al., 2015	0.50 (0.29, 0.84); P = 0.008	0.62 (0.36, 1.06); P = 0.08
Noshchenko 2014	0.60 (0.48, 0.75); P < 0.001	0.83 (0.58, 1.18); P = 0.302
Rao 2014	0.72 (0.45, 1.14); P = 0.16	0.83 (0.39, 1.77); P = 0.63
Ren 2014	—	0.15 (0.04, 0.61); P = 0.0008
Jacobs 2012	—	0.80 (0.51, 1.24); P = 0.31
Wei 2013	0.57 (0.38, 0.84); P = 0.31	0.91 (0.57, 1.46); P = 0.71

5 to 10+ years

5-year RCTs

- Reoperation rates never higher with TDR[1,2,3,4]
  - 2.3% to 8% for TDR
  - 8.3% to 16.3% for fusion
- Significantly lower SAEs with TDR[2]
- Very low device migration / subsidence

Long-Term Observational

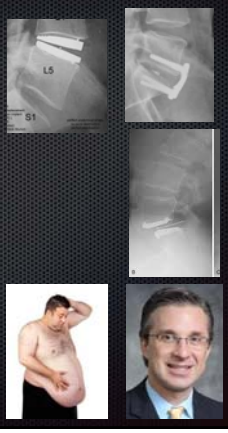
- Reoperation rates typically ≤7% for TDR[5-9]
- Not seeing studies with high rates of failed TDRs, catastrophic failures, deaths
- Reasonably low rates of overall complications
- Per FDA-required, real-world medical device reporting (MDR), explantation rate of 3rd Gen disc 0.006%

CTs: [1] Guyer 2009; [2] Zigler 2013; [3] Skold 2013; [4] Gornet 2010. Observational: [5] Lemaire 2005; [6] Siepe 2006; [7] Katsimihas 2010; [8] Aghayev 2014; [9] Siepe 2014.

The Inconvenient Truth: TDR is better than ALIF

- A fusion hides a surgeon's mistakes
- A disc replacement magnifies a surgeon's mistake

- A good TDR is better than a good fusion
- A good fusion is better than a bad TDR
- A bad fusion is better than a bad TDR
- TDR is not for any patient
- TDR is not for any surgeon



The Truth: Motion is Better than Fusion

- TDR **outcomes** better than fusion, long-term rehab
- TDR **complications** lower than fusion
- TDR **adjacent segment degeneration** less than fusion
- TDR **reoperation rates** lower than fusion
- TDR **direct and indirect costs** lower than fusion

Thank You!