State of Total Disc Replacement: Past, Present, and Future

Richard D. Guyer, M.D.

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Disclosures

Guyer	(a) Alphatec; (b) Spinal Kinetics, Spinal Ventures, Mimedix; (c) DePuy-Synthes Spine, K2M, Flexuspine, Mimedix, Aescalup; Safe Orthopedics (d) DePuy-Synthes Spine, K2M, Paradigm Spine

Key: (a) royalties; (b) stock/options; (c) consulting/SAB; (d) Speaker/ faculty; (e) Research; (f) Fellowship and related research; (g) other

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Introduction

- Lumbar and cervical TDR
  - Have been the most studied spinal conditions with more than a dozen IDEs
  - Long history in US dating to 2000
    - Strong outcomes
    - Lower than expected adoption for Lumbar but excellent for Cervical
  - Promising future

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TDR Market Overview

- Global market for non-fusion treatments to expand from $521M in 2014 to $749M in 2021
- Growth driven by cervical TDR due to:
  - Increasing availability of clinical efficacy data
  - Improving reimbursement environment
  - Rising prevalence of degenerative spine diseases
  - Industry's aggressive efforts in physician training and DTC marketing
- Market underpenetrated at only 20% of procedures globally, less in the US despite regulatory clearances of devices

Global Data Healthcare. Dec 2015. Spinal Non-Fusion, Global Analysis and Market Forecasts; Markets and Markets report. The Spine Group/LinkedIn

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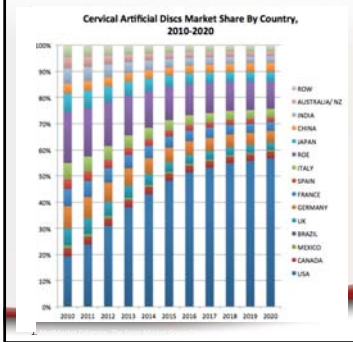
TDR Market Overview



- Europe has been dominant market for C-TDR until ~2013 due to less stringent regulatory approval process
- US is now, and will remain, dominant market for C-TDR through 2020 with increasing number of approved devices, improved reimbursement

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Looking first at Lumbar TDR:

- Lumbar TDR has been used OUS since 1980s
  - We know a lot about the outcomes
  - Multiple studies, from multiple countries show good outcomes at 2, 5, ≥10 yr follow-up
  - Multiple FDA-regulated trials found TDR to be at least as effective as fusion and superior on some measures

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US IDE Studies (Not a Comprehensive List)

- Charité approved 2004, removed from US market 9/2013 by DePuy due to poor sales and purchase of Synthes (ProDisc), not disasters!!!
- ProDisc-L approved 2006
- activL – approved 6/2015
- Maverick – completed, patent issues
- FlexiCore – withdrawn by Stryker
- Kineflex-L – withdrawn by Spinal Motion
- Freedom – 3rd gen, polymer, not submitted
- L TDR – lateral insertion, aborted
- Triumph – posterior insertion aborted

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TDR Design Types

- Ball and Socket
  - Semiconstrained
  - Unconstrained

- Viscoelastic
  - Elastomeric polymer

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FDA Trial Data Published

- Charite vs. ALIF - 5 yr data
- ProDisc-L vs. 360 - 5 yr data
- Maverick vs. ALIF - 5 yr data
- Flexicore vs. 360 - 2 yr data
- Kineflex-L vs. Charité - 5 yr data
- activL vs. Charité or ProDisc-L - 2 yr data
  - 5 yr coming very soon

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What Is Needed for Widespread Use of an Implant?

- Must establish:
  - Safety
  - Efficacy
  - Defined indications
  - Address cost
- Equally Important
  - Reimbursement
  - Surgeon perception

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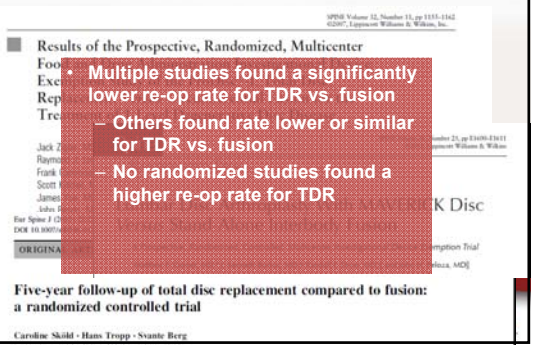
Safety


Results of the Prospective, Randomized, Multicenter

K Disc

Five-year follow-up of total disc replacement compared to fusion: a randomized controlled trial

Caroline Skold · Hans Tropp · Svante Berg

- Multiple studies found a significantly lower re-op rate for TDR vs. fusion
  - Others found rate lower or similar for TDR vs. fusion
  - No randomized studies found a higher re-op rate for TDR

TBI Re-operation Experience

- Consecutive series beginning with 1st TDR case in 2000 from IDE studies
- Included all TDR pts at least 2 yrs (longest 134 months) post-op and all pts who were fusion controls in randomized FDA IDE TDR trials
  - 1,058 TDR
  - 112 hybrid
  - 67 fusion

ISSLS, 2013

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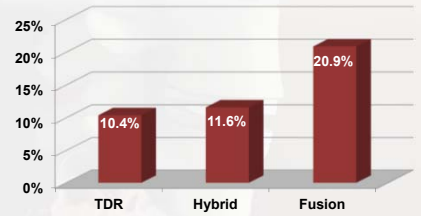
Re-op Rates by Surgery Type



TDR significantly lower than fusion ($p<0.02$); trend for hybrid< fusion ($0.05<p<0.08$)

TBI, ISSLS, 2013

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TDR: Effectiveness

- Lumbar FDA IDE trials:
  - 4 with 5 yr follow-up
  - 2 additional with 2 yr follow-up
- Multiple studies from Europe with ≥10 yr follow-up
- Multiple studies from Asia with 2-5 yr follow-up

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TDR: Effectiveness

- All these studies have consistently reported maintained good outcomes throughout longest term follow-up
- FDA IDE trials found significant improvement by 6 wk post-op and maintained through 2 and 5 year follow-up with NO DEGRADATION
- Following are new additional lumbar TDR studies

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Spine
SPINE Volume 41, Number 11, pp 971–977
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OUTCOMES

Long-Term Outcomes Following Lumbar Total Disc Replacement Using ProDisc-II

Average 10-Year Follow-Up at a Single Institute

Se-Jun Park, MD, Chong-Suh Lee, MD, PhD, Sung-Soo Chung, MD, PhD, Keun-Ho Lee, MD, Wan-Seok Kim, MD, and Jun-Young Lee, MD

- DDD group (n=39): Axial LBP from DDD
- DDD+other group (n=15): DDD + ≥1 of the following: previously fused adjacent level, spondy, retrolisthesis, facet joint arthritis, lateral recess stenosis
- Mean follow-up 120.0 mo

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Mean 10-yr Clinical Follow-up

- Significantly better outcomes in DDD vs. DDD+other dx group:
  - Success: 76.9% vs. 40.0%
  - Satisfaction: 87.2% vs. 60.0%
- 5 pts (9.3%) had revision fusion surgeries, all were DDD+other group
- Segmental ROM was well maintained in DDD group, but not in the other group

Park et al, Spine, 2016

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European Journal of Spine Surgery

Comparison of Single-Level and Multiple-Level Outcomes of Total Disc Arthroplasty: 24-Month Results

Christoph Schätz, Dr. med.,[1] Karsten Bitter-Lang, Dr. med.,[1] Lutz Gissel, Dr. med.,[1] Nadine Dreßler, Dr. med.[2]
[1] Orthopädische Klinik Markgröningen gGmbH, Markgröningen, Germany, [2] Spezialpraxis für Wirbelsäulenchirurgie, Potsdam, Germany

- 83 pts receiving M6 lumbar TDR (49 1-level, 43 multi-level)
- Prospective, post-market, multicenter registry study
- Significant improvement in VAS and ODI scores ($p<0.05$; ≥50% improvement)
- No device revisions or removals (no comment on other re-ops)

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Viscoelastic Disc Arthroplasty Provides Superior Back and Leg Pain Relief in Patients with Lumbar Disc Degeneration Compared to Anterior Lumbar Interbody Fusion

- Data from 48 pts with viscoelastic TDR (Freedom Disc) from SWISSspine registry
- Compared with 131 ALIF pts from Spine Tango registry
- Covariates included in the models: age, gender, number of levels treated, level(s) treated, disc herniation as additional dx, pre-op back and leg pain scores, and follow-up interval
- TDR associated with significantly greater back and leg pain relief ($p<0.01$) compared with ALIF

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What's New for Lumbar TDR and Updates

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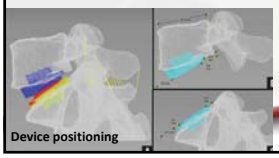
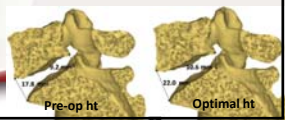
Orthopedics, 2016

Patient-Specific Templating of Lumbar Total Disk Replacement to Restore Normal Anatomy and Function

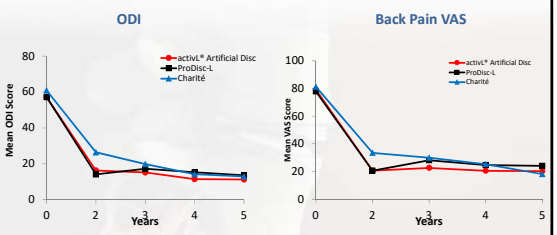
Jill A. Fattor, MS, PA; Justin F. M. Hollenbeck, MS; Peter J. Laz, PhD; Paul J. Rullkoetter, PhD; Evalina L. Burger, MD; Vikas V. Patel, MD; Christopher M. J. Cain, MD

- Used CT and finite element modeling to evaluate interaction of pt anatomy, implant geometry, and implant positioning with goal of maximizing ROM and outcomes

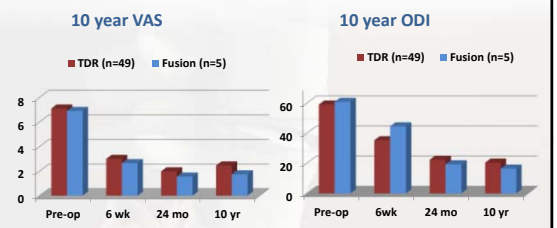




activL Preliminary 5 Year Outcome Data



Preliminary Minimum 10 Year Data for ProDisc-L vs. 360 Fusion FDA Study at TBI



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COCHRANE COLLABORATION

Total Disc Replacement for Chronic Discogenic Low Back Pain

A Cochrane Review

- **TDR had statistically significantly greater improvement in back pain, ODI scores and pt satisfaction**
  - **Conclusions: differences in clinical improvement were not beyond generally accepted boundaries for clinical relevance**

Meta-analysis of RCTs

- Purpose: Compare effectiveness and safety of TDR vs. fusion
- Searched Medline, Embase, Clinical, Ovid, BIOSIS and Cochrane registry of controlled clinical trials
- 7 relevant RCTs with total of 1,584 pts, 2 yr follow-up
- TDR more effective in ODI, VAS, hospital stay duration, greater willingness to choose the same operation again
- Differences not significant for op time, blood loss, complications, re-op rate or RTW rates

Rao, Arch Orthop Trauma Surg, 2014

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Other Clinical Outcome

- One of the major potential clinical benefits of lumbar TDR is reducing the occurrence of adjacent segment degeneration
- Those of us involved in TDR from the beginning have been searching for this evidence as it is what has motivated our research
- But ASD is like old "Natural history vs Increased stress of fusion" or "Genetics vs Environment" arguments

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ASD: ProDisc TDR vs. Fusion
The "Holy Grail" of lessened ASD finally!!!

- Δ ASD observed at 5 years in:
  - 28.6% of fusion patients
  - 9.2% of TDR patients

> 3 : 1 Difference

P<0.01

Zigler et al, J Neurosurg Spine, 2012

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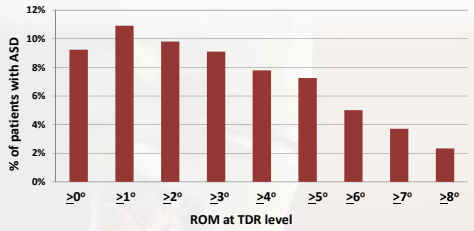
ASD and ROM of TDR Level: 5-yr Follow-up from Activ L



For each additional degree of motion at the TDR level, there was a decline in the rate of ASD (data from activL FDA trial)

Guyer, ISASS, 2017

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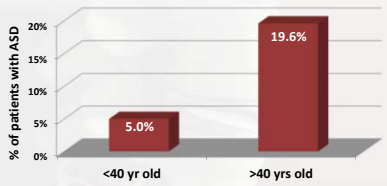
ASD and Age at 5-yr Follow-up



ASD significantly greater in older patient subset, p<0.01 (data from activL FDA trial data)

Guyer, ISASS, 2017

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Lumbar Adjacent Segment Degeneration and Disease After Arthrodesis and Total Disc Arthroplasty

James S. Harrop, MD,* Jim A. Youssef, MD,† Mitch Maltenfort, PhD,* Peggy Vorwald, BS,† Pascal Jabbour, MD,* Christopher M. Bono, MD,‡ Neil Goldfarb, BS,§ Alexander R. Vaccaro, MD,* and Alan S. Hilibrand*

- Reviewed 27 Class I and II fusion and TDR studies
  - 314/926 fusion patients developed AgDD = 31%
  - 31/313 TDR patients developed AgDD = 3%
    - p<0.0001

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What About Cost?

- Assumption: New technology is always more expensive
- But, look at the data!

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Lumbar TDR Costs Studies

- Several studies compared TDR to fusion
  - Methods included economic modeling (Guyer et al, 2007), randomly selected patients and averaged database charges/costs (Patel et al, 2008), IDE trial patients (Leven et al. 2007), and national data registries with unmatched comparison groups (Kurtz et al, 2010)

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Lumbar TDR Costs Studies

- Although the methods used in the studies varied greatly they all found TDR was less expensive than fusion with the one exception of a cost model for ALIF with autograft only which is rarely used today
- Cost advantage vs fusion with various implants, various approaches, various graft materials with little uniformity from surgeon to surgeon

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Cervical TDR
Best data, so briefly…

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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)

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Current FDA Status in US

- Trial completed / withdrawn
  - Kineflex|C
- Trials ongoing
  - M6
  - Simplify (1 and 2 level studies)
- Trials ended
  - Discover
  - Neodisc
  - Cervicore

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FDA IDE Trials

- All 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

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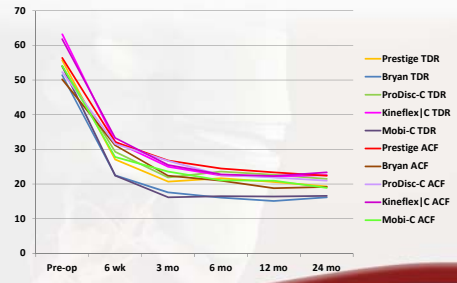
Mean NDI Scores for TDR and ACF in Various FDA IDE Trials showing similar results



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What Happens 7-10 Years Post-TDR?

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Int J Spine Surg, 2016

Cervical Disc Arthroplasty with Prestige LP Disc Versus Anterior Cervical Discectomy and Fusion: Seven-Year Outcomes

Matthew F. Gornet, MD,[1] J. Kenneth Burkus, MD,[2] Mark E. Shaffrey, MD,[3] Hui Nian, PhD,[4] Frank E. Harrell, Jr. PhD[4]
[1]The Orthopaedic Center of St. Louis, St. Louis, Missouri, [2]Wilderness Spine Services, The Hughston Clinic, Columbus, Georgia, [3]Department of Neurosurgery, University of Virginia, Charlottesville, Virginia, [4]Vanderbilt University School of Medicine, Department of Biostatistics, Nashville, Tennessee

- 280 pts, 20 sites, 1 level TDR
- 265 historical control ACDF pts
  - From original Prestige study, same indications and assessments
- TDR maintained significantly improved clinical outcomes and segmental motion
- TDR at least non-inferior to ADF

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Prestige LP: 7 yr Follow-up

	TDR	ACDF
Follow-up rate	75.9%	70.0%
Overall success	74.9%	63.2%
NDI success	86.1%	80.1%
% satisfied	90.9%	85.6%
Re-op (index level)	6.4%	10.9%

Gornet, IJSS 2016

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Mobi-C: 7 yr Follow-up

	TDR	ACDF
Follow-up rate	80.1%	73.5%
Overall success	55.2%	50.0%
NDI success	76.5%	80.8%
% satisfied	90.9%	80.8%
ASD inferior level	43.8%	63.0%
ASD superior level	40.4%	66.7%
Re-op	3.0%	12.3%

Hisey et al, NASS, 2016

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Spine

SPINE Volume 42, Number 4, pp 209–216
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RANDOMIZED TRIAL

Long-term Clinical Outcomes of Cervical Disc Arthroplasty

A Prospective, Randomized, Controlled Trial

Willa R. Sasso,* Joseph D. Smucker, MD,† Maria P. Sasso,* and Rick C. Sasso, MD†

- 10 yr follow-up of 1 center's FDA IDE pts
- 19 TDR, 23 ACDF (follow-up rates 84.6% and 92.0%)
- Re-op rates:
  - TDR 9%
  - ACDF 32%

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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?

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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°	NA
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°	NA

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; Hisey, ISASS 2011; PCM FDA SSED

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Adjacent Segment Degeneration

- One potential benefit of cervical TDR vs. ACF is reducing the acceleration of ASD
- Literature mixed on whether this benefit has been recognized

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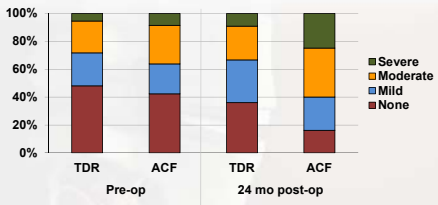
Kineflex|C Adjacent Segment Disc Degeneration



Pre-op: no difference; Post-op: significant difference ($p<0.01$), indicating more patients in ACF group had greater grades of adjacent segment degeneration

Coric et al, J Neurosurg Spine, 2011

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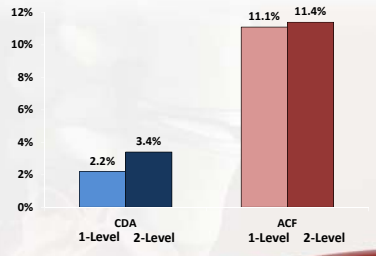
Adjacent Level Subsequent Surgery Rates through 60 Months



Mobi-C FDA IDE trial data

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Imaging

- One potential disadvantage of TDRs with metal components is artifact seen on MRI
- MRI technology continually improving to reduce artifact
- Materials used for TDRs is also changing that will facilitate imaging

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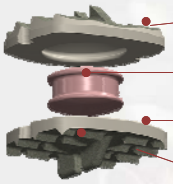
Simplify Disc
Currently enrolling 1 and 2 level IDE study



PEEK superior endplate

Ceramic core

PEEK inferior endplate

Titanium plasma spray (porous)

Semi-constrained design

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Post-TDR Artifact on MRI

PEEK on Ceramic

Metal-on-metal

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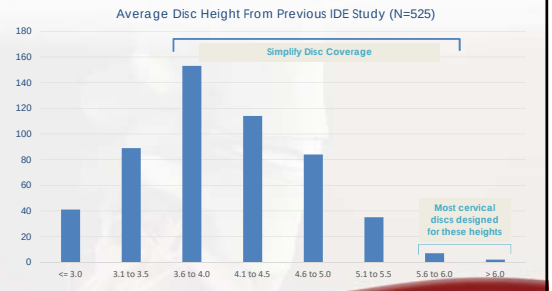
Simplify discs–lower heights match cervical anatomy



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Elastomeric Discs

Motion occurs within polymer, Provides shock absorption, Mimics properties of natural disc (Axis of Rotation, etc)

- Elastomeric Disc
  - All Elastomer
    - CADisc
    - Polymer-Bone abrasion
    - Addition of HA to enhance
    - Nucleus Replacement 'interface' problems
    - Prosthetic-endplate
  - Metal Backed
    - Mobile 'Bumper'
      - Bryan
      - M6
      - C ESP
      - Free motion between metal and polymer
      - Core free to move
      - Polymer-Metal Sliding → Wear
      - Need for Surrounding Envelope
      - More complex
    - Attached Core
      - K2M Rhine
      - Freedom

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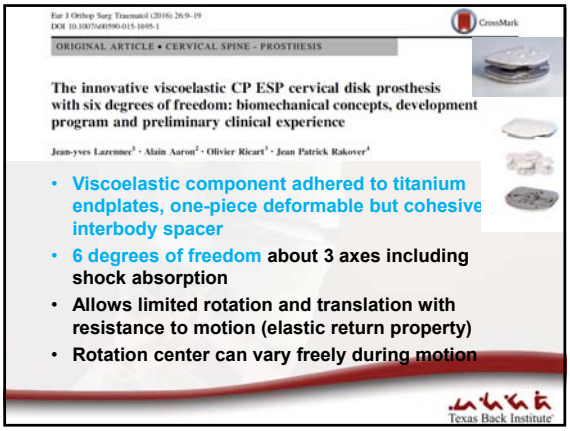
Eur J Orthop Surg Traumatol (2016) 26:9–19
DOI 10.1007/s00590-015-1695-1

ORIGINAL ARTICLE • CERVICAL SPINE - PROSTHESIS

The innovative viscoelastic CP ESP cervical disk prosthesis with six degrees of freedom: biomechanical concepts, development program and preliminary clinical experience

Jean-yves Lazennec[3] · Alain Aaron[2] · Olivier Ricart[1] · Jean Patrick Rakover[4]

- **Viscoelastic component adhered to titanium endplates, one-piece deformable but cohesive interbody spacer**
- **6 degrees of freedom about 3 axes including shock absorption**
- **Allows limited rotation and translation with resistance to motion (elastic return property)**
- **Rotation center can vary freely during motion**

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CP ESP
Gaining wide use OUS

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Freedom Disc

- Viscoelastic polyurethane
- Recently approved in Australia
- No study data
- US cervical IDE never initiated and lumbar IDE never completed

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Rhine Disc - K2M

- CE Mark Jan 2016
- 1st implant Jan , 2016
- Germany, Belgium, Spin, Italy, UK, South Africa
- 300 implanted so far
  - 60% one level
  - 40% 2 level

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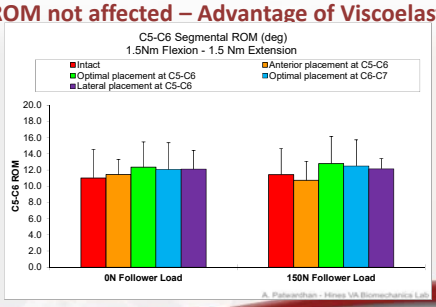
Rhine Disc

K2M "RHINE" TDA C5-C6 ROM Regardless of Anterior or Lateral Positioning ROM not affected – Advantage of Viscoelastic



Available online at www.sciencedirect.com
SciVerse ScienceDirect
ELSEVIER
International Journal of Spine Surgery 6 (2012) 71–77

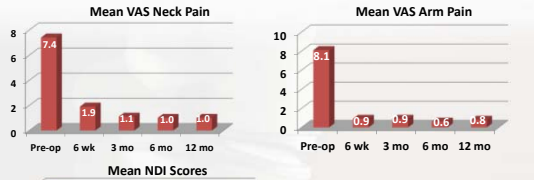
M6

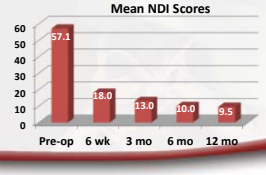
Cervical total disc replacement using a novel compressible prosthesis: Results from a prospective Food and Drug Administration–regulated feasibility study with 24-month follow-up

Carl Lauryssen, MD [a,*], Domagoj Coric, MD [b], Thomas Dimmig, MD [c], David Musante, MD [c], Donna D. Ohnmeiss, PhD [d], Harrison A. Stubbs, PhD [e]

- **30 pts, TDR at 1 or 2 levels**
- **Significant improvements throughout 24 mo in:**
  - **NDI: 67.8 to 20.8**
  - **VAS neck pain: 7.7 to 2.4; right arm pain: 6.0 to 2.1; left 6.3 to 1.6**

M6 FDA IDE
12mo, 2 Centers, 39 patients





Mean VAS neck , VAS arm pain, and NDI scores improved significantly by 6 wk post-op and remained improved through 12 mo follow-up

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Summary

- Strong data to support lumbar and cervical TDR
- Appropriate patient selection is key
  - Indications continue to be refined
- What we are not seeing: publications, even case reports, reporting high numbers of failed TDRs, catastrophic failures, deaths from revisions, etc.
- Ongoing development of surface technology, materials, viscoelastic devices
- Patient specific design like TKA?

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Summary

- Currently, greatest barrier to TDR adoption is insurance reimbursement
  - Is slowly improving
    - Cervical better than lumbar with 85% coverage vs 45% coverage
  - For lumbar, some surgeons may be slow to adopt due to need for access surgeon and/or not familiar with anterior approach
  - Also, the lumbar disc companies are not likely to jeopardize their much larger and profitable fusion business with the exception of Aesculap

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Do Lumbar and Cervical TDR Have ...ure?

- The most st...

So there is NO QUESTION that Lumbar and Cervical TDR

Are the Future !

- ...cost profile
- No rash of reports on device failures

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Center of rotation (COR) with simplify disc

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Viscoelastic Discs

Company	Cervical Devices	Lumbar Devices	Comments
AxioMed	Freedom Cervical	Freedom Lumbar	• Features viscoelastic polymer core to mimic normal human disc characteristics
Spinal Kinetics	M6-C	M6-L	• Features viscoelastic polymer core to simulate native disc and UHMWPE fibers to emulate native annulus
K2M		Physio-L	• Acquired Physio-L PCU disc technology from NexGen Spine

Confidential

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Appropriately Selected Patients

- LBP +/- leg pain of lesser severity
- Failed ≥6 mo non-op care (PT, meds, education, activity modification, etc.)
- MRI and disco correlative with symptoms and physical exam
  - DDD at 1-2 levels
  - No other spine pathology
- No significant psychological problems
- Good bone quality

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Adjacent Segment Disease, Natural History or Biomechanical?? Literature Review

- Biomechanically fusions increase intradiscal pressure, facet loading, and hypermobility above and beyond natural history
- Radiographic 5.2%- 100% at 36-360 mo f/u
- Symptomatic 5.2-18.5% at 44.8-164 mo f/u (higher with pedicle screws, 12.2-18.5%)
- Risk factors = pedicle screws, facet joint violation, sagittal malalignment, and fusion length

Park et al., Spine 2004

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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

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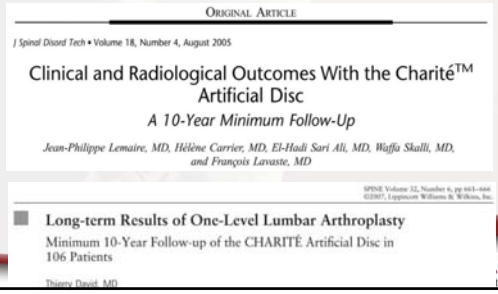
Charité 10-13 Year Follow-up

- Old evaluation methods, but excellent follow up of >90% with 90% "exe-gd"



ORIGINAL ARTICLE

J Spinal Disord Tech • Volume 18, Number 4, August 2005

Clinical and Radiological Outcomes With the Charité™ Artificial Disc

A 10-Year Minimum Follow-Up

Jean-Philippe Lemaire, MD, Hélène Carrier, MD, El-Hadi Sari Ali, MD, Waffa Skalli, MD, and François Lavaste, MD

Long-term Results of One-Level Lumbar Arthroplasty

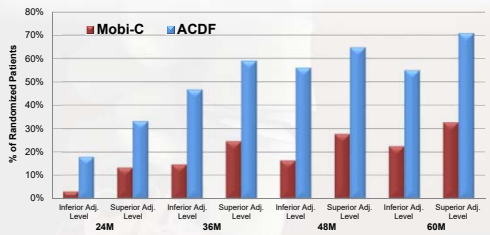
Minimum 10-Year Follow-up of the CHARITÉ Artificial Disc in 106 Patients

Thierry David, MD

CP ESP

- Titanium endplates and hydroxyapatite coating
- Inner and outer core (polycarbonate urethane)
- 6 degrees of freedom restores "natural" mobility

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



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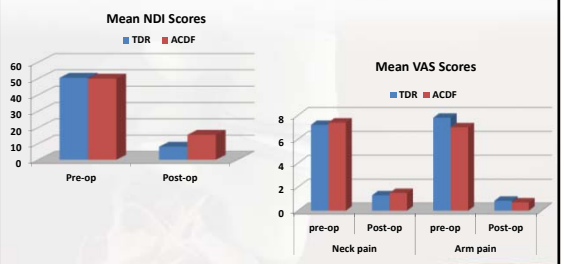
Bryan: 10 yr Follow-up



Sasso et al, Spine, 2017

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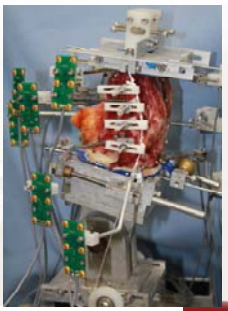
Quality of Motion Study

Experimental protocol:

- Intact
- C5-C6 TDA Anterior placement
- C5-C6 TDA Optimal placement
- C6-C7 TDA Optimal placement
- C5-C6 TDA Lateral placement



Cervical spine set-up showing intact specimen.

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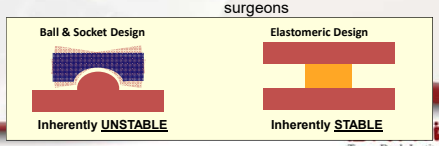
Elastomeric Designs

The human disc provides
- Shock absorption
- Stability
- Controlled motion

Elastomeric Polymers
- Motion occurs within polymer
- Provides shock absorption
- Mimics properties of natural disc
- Attractive & intuitive solution to surgeons



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From Other Countries

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

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

parison of outcomes of cervical disc arthroplasty and fusion yday clinical practice: surgical and methodological aspects

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

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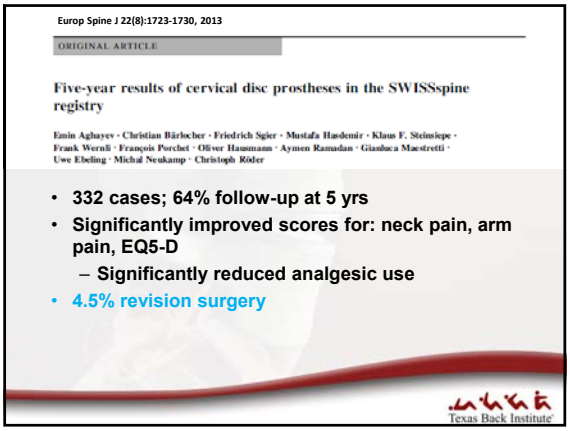

Europ Spine J 22(8):1723-1730, 2013

ORIGINAL ARTICLE

Five-year results of cervical disc prostheses in the SWISSspine registry

Emin Aghayev · Christian Bärlocher · Friedrich Sgier · Mustafa Hasdemir · Klaus F. Steinsiepe · Frank Wernli · François Porchet · Oliver Hausmann · Aymen Ramadan · Gianluca Maestretti · Uwe Ebeling · Michal Neukamp · Christoph Röder

- **332 cases; 64% follow-up at 5 yrs**
- **Significantly improved scores for: neck pain, arm pain, EQ5-D**
  - **Significantly reduced analgesic use**
- **4.5% revision surgery**

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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

Upadhyaya et al, J Neurosurg Spine, 2012

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What about the Cost of Cervical TDR?

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J Neurosurg Spine 19:546–554, 2013
©AANS, 2013

Cost-effectiveness analysis: comparing single-level cervical disc replacement and single-level anterior cervical discectomy and fusion

Clinical article

Sheeraz A. Qureshi, M.D., M.B.A., Steven McAnany, M.D., Vaddi Goz, B.A., Steven M. Koehler, M.D., and Andrew C. Hecht, M.D.

- Used outcome literature, NIS, and Medicare reimbursement data to create decision tree model for cost-effectiveness analysis
- Cost model designed for period of 20 yrs
- TDR was more beneficial and less expensive than ACF

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Cost

Eur Spine J (2009) 18:232–237
DOI 10.1007/s00586-008-0866-8

ORIGINAL ARTICLE

Only construct less expensive than TDR was Brantigan cage w no graft – not standard of care

Single-level cervical radiculopathy: clinical outcome and cost-effectiveness of four techniques of anterior cervical discectomy and fusion and disc arthroplasty

Arup K. Bhadra · A. S. Raman · Adrian T. H. Casey · R. J. Crawford

Other cost studies also favor TDR

Surg Neurol Int. 2010; 1: 77.
Published online 2010 December 13. doi: 10.4103/2152-7806.73803

PMCID: PMC3011106

Safety and cost-effectiveness of outpatient cervical disc arthroplasty

Richard Wohns

TDR less expensive than ACF

Spine

SPINE Volume 40, Number 8, pp 521-529
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Costs of Cervical Disc Replacement *Versus* Anterior Cervical Discectomy and Fusion for Treatment of Single-Level Cervical Disc Disease

An Analysis of the Blue Health Intelligence Database for Acute and Long-term Costs and Complications

Kris Radcliff, MD* Jeff Zigler, JD† and Jack Zigler, MD†

- Insurance industry data generally unavailable
- Blue Health spun off as a for-profit venture by "the Blues", allowing access to payment database
- **Allowed authors to "work backwards" from payments to clinical events (post-op, peri-op, and pre-op) by CPT and ICD-9 codes**

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Total Costs: TDR ~ 12% Lower

	TDR	ACDF
Index event	$20,722	$22,379
Index event + 90 day global post-op period	$22,761	$25,029
Discharge to 6 wks	$791	$1,236
6 wks to 3 mos	$1,216	$1,497
3 to 6 mos	$2,147	$2,631
6 to 12 mos	$4,127	$4,566
12 to 18 mos	$3,106	$3,914
18 to 24 mos	$2,862	$3,596
24 to 36 mos	$3,753	$4,806
36 to 48 mos	$1,040	$1,526
TOTAL	**$34,979**	**$39,820**

Radcliff et al., Spine 2015

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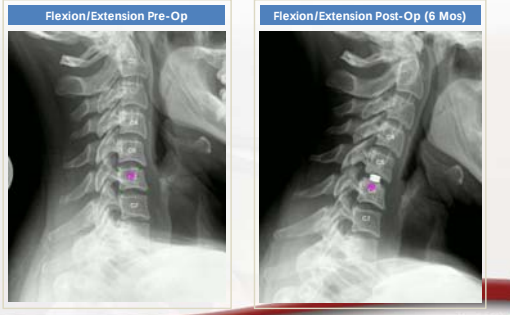
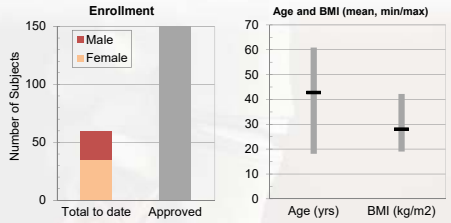
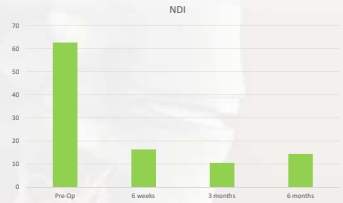
Center of rotation (COR) with simplify disc



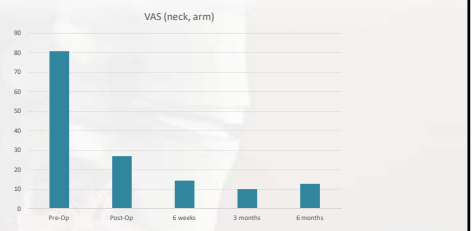
Single level IDE study - demographics



Single level IDE study - ndI



Single level IDE study – VAS (Neck and Arm)



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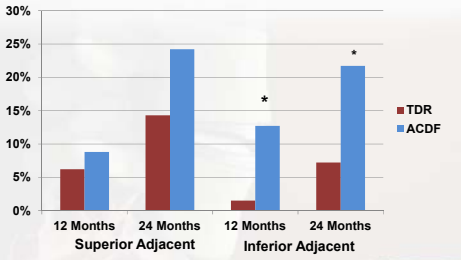
Mobi-C: Adjacent Segment Degeneration (Kellgren-Lawrence Scale)



* Adjacent segment degeneration significant (p<0.05)

Hisey et al

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Mobi-C: 7 yr Follow-up

- Improvement in NDI, VAS neck pain, and SF-12 scores similar between groups
- TDR group maintained segmental ROM at every time point through 84 mo
- No significant difference in rates of AEs or major complications

Hisey et al, NASS, 2016

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