Slide 1

Artificial Disc Replacement
Pasquale X. Montesano, M.D.

Slide 2

Also known as...
Total Disc Replacement (TDR)
or
Total Disc Arthroplasty (TDA)

Slide 3

Outline
- Historical perspective
- Lumbar – currently approved implants
- Cervical – currently approved implants
  - The evidence
    - What can we learn from the major trials?
      - Lots of data – can we distill this down to some global conclusions?
    - Safety
    - Adjacent-segment disease
    - Hybrids
- The future?
Slide 4

**History**

- High rate of subsidence.

Slide 5

**Dr. John Charnley (1911-1982)**

"Arthroplasty is the wave of the future. I predict that hip fusions will be reserved for only desperate cases…"

Father of modern hip arthroplasty.

Slide 6

**Dr. Robert Sculco**

"Fusion is the gold standard with excellent long-term follow-up. Arthroplasty is unproven and unnecessary because my patients don't need the motion. I predict that arthroplasty is a passing fad...

We are more likely to see a woman or minority become the President of the United States than see arthroplasty become the dominant operation."
Slide 7

**History**

Fassio – first clinically implanted elastic disc replacement – silastic central ball surrounded by a horseshoe shaped device to prevent subsidence.

Implanted in 4 patients; at 4 yrs follow up all had subsided.


---

Slide 8

**History**

Kostuik (1997) – performed well during in vitro testing but failed in animal studies

---

Slide 9

**History**

Lee et al developed an elastomeric disc replacement with hydroxyapatite coating that also did well in vitro testing but had problems with core migration in canines. It has undergone several modifications but no reports of human implantation.

History

Charité disc was initially developed in Germany in 1984 by orthopaedic surgeon and Olympic gold medalist gymnast Karin Buttner-Janz and engineer Kurt Schellnack.

Charité – Universitätsmedizin Berlin

- Large teaching hospital in Berlin, established 1710
- In 1727 was named Charité (Charity in French), by Frederick William I of Prussia
- Over 40 Nobel Laureates

Charité

The disc was modified several times and various pilot implantations were performed prior to the final design that received U.S. FDA Premarket Approval October 25, 2004 for single-level use L4-S1.
The Charité disc was an unconstrained design, which may have contributed to the problems it eventually had, and it was removed from the market in 2012.

Thierry Marnay in France developed the precursor to the ProDisc-L, which he initially implanted into 64 patients.

ProDisc-L US FDA PMA study started in 2001 and received approval on August 14, 2006 for single-level use L3-S1.

Thierry Marnay
In 2006 – at NYU-HJD
Currently FDA Approved

ProDisc-L (Synthes)
August 4, 2006

ActivL (Aesculap)
June 11, 2015

Slide 17

Why ADR?

Slide 18

Spine fusion is non-physiologic
Mean 17 yrs follow-up

Adjacent-segment degeneration

Pre-op 8yr post-op 16yr post-op

Adjacent-segment degeneration

Pre-op 4yr post-op 12yr post-op 16yr post-op Post re-operation
Slide 22

Adjacent-segment degeneration

---

Slide 23

---

Slide 24

---
Slide 25

**Adjacent Segment Degeneration in the Lumbar Spine**

- 215 patients after lumbar posterior fusion
- 13 years mean F/U duration

>Ghiselli et al 2004

Slide 26

**Adjacent segment degeneration**

Increased stiffness at the fused level leads to hypermobility and increased loading at adjacent segments?

Is this just the natural progression?
Slide 28

Risk Factors for Progression of Lumbar Spine Disc Degeneration

The Olmsted Study

G. Harrow, D. J. Huey, S. I. Hauk, D. V. Lyly, T. T. Saperis

- 9 year follow-up prospective study of natural progression in a group of women (n = 796)
- Disc space narrowing and anterior osteophyte progression of 3% per yr and 4% per year were observed
- Risk factors were older age, LBP, hip and knee OA; trend for BMI > 30
- All were white, middle-class women in the U.K., mean baseline age of 54 +/-6 with a mean BMI of 25 +/-4

Slide 29

The natural history of disc degeneration?


Slide 30

Fusion is non-physiologic
Is ADR any better than fusion?
Well that depends...

Gold standard...?

375 patients initially enrolled in Charité IDE study; 277 eligible for 5yr study
• 160 of those completed their 5yr F/U
• 133 of these were initially randomized: 90 Charité ADR pts compared to 43 ALIF (BAK cages) pts
**Slide 34**

**Charité vs. ALIF 5-yr study**

<table>
<thead>
<tr>
<th></th>
<th>Charité group</th>
<th>ALIF group</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Success&quot; (%)</td>
<td>58</td>
<td>51</td>
</tr>
<tr>
<td>Change in ODI score</td>
<td>-24</td>
<td>-27.5</td>
</tr>
<tr>
<td>Change in VAS</td>
<td>-38</td>
<td>-40</td>
</tr>
<tr>
<td>Physical Function</td>
<td>12.6</td>
<td>12.3</td>
</tr>
<tr>
<td>Employment</td>
<td>69.6%</td>
<td>69.1%</td>
</tr>
<tr>
<td>Long-term disability</td>
<td>8%</td>
<td>29.9%</td>
</tr>
<tr>
<td>Index level ROM</td>
<td>6 degrees</td>
<td>1 degree</td>
</tr>
</tbody>
</table>

**Slide 35**

106 pts out of 108 patients initially implanted, mean F/U 13 yrs

**Slide 36**

**Thierry 2007**

<table>
<thead>
<tr>
<th></th>
<th>Charité group</th>
<th>Comparison group</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Success&quot; (%)</td>
<td>87</td>
<td></td>
</tr>
<tr>
<td>Fusion at adjacent segment</td>
<td>5.8%</td>
<td></td>
</tr>
<tr>
<td>Core subluxation</td>
<td>1.9% (gamma sterilized in air)</td>
<td>1.9% (gamma sterilized in air)</td>
</tr>
<tr>
<td>Index level ROM</td>
<td>10.1 degrees</td>
<td></td>
</tr>
</tbody>
</table>
Lu et al 2015
Charité ADR group
N = 35
No comparison group
Completed Follow-up 32 (91%)
"Success" (FDA criteria) 28 (87.5%)
Reoperation for adjacent segment dz 1 (3%)
Reoperation for pedicle fracture 1 (3%)
Change in VAS 8.5 +/- 0.2 to 1.5 +/- 0.3
Improvement in ODI 41.4 +/- 1.9 to 13.2 +/- 2.4
Pt would have operation again?
25 (78%) “certainly yes”
5 (16%) “probably yes”

Prospective, RCT trial of 152 patients (ADR = 80, PLIF or PLF = 72)
ADR group randomized to Charité, ProDisc or Maverick implant
99% F/U at 5yrs
**Slide 40**

<table>
<thead>
<tr>
<th></th>
<th>Skold et al 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>ADR group</strong></td>
</tr>
<tr>
<td></td>
<td>(n = 80)</td>
</tr>
<tr>
<td>Completed 5yr Follow-up</td>
<td>151 (99%)</td>
</tr>
<tr>
<td>&quot;Totally pain-free&quot;</td>
<td>38%</td>
</tr>
<tr>
<td>VAS Back</td>
<td>23 ± 29</td>
</tr>
<tr>
<td>Change in VAS back</td>
<td>40 ± 32</td>
</tr>
<tr>
<td>ODI (high is bad)</td>
<td>19 ± 17</td>
</tr>
<tr>
<td>Improvement in ODI</td>
<td>56 ± 14</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>&gt;75%</td>
</tr>
<tr>
<td>Reoperations at index level</td>
<td>3/80 (3.8%)</td>
</tr>
<tr>
<td>Adjacent-segment operation</td>
<td>6/80 (7.5%)</td>
</tr>
</tbody>
</table>

**Slide 41**

- Prospective IDE FDA trial, single level from L4-S1, 31 sites
- 577 patients randomized (2:1) to Maverick ADR (n=405) or stand-alone ALIF using LT cage and BMP-2 (n=172)
- >70% at L5-S1 level
- Maverick will not be used in the U.S. due to a patent problem

**Slide 42**

<table>
<thead>
<tr>
<th></th>
<th>Skold et al 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Maverick ADR group</strong></td>
</tr>
<tr>
<td></td>
<td>(n = 405)</td>
</tr>
<tr>
<td>Completed 5yr Follow-up</td>
<td>402 (99%)</td>
</tr>
<tr>
<td>Level</td>
<td></td>
</tr>
<tr>
<td>L4</td>
<td>104 (26%)</td>
</tr>
<tr>
<td>L5</td>
<td>36 (21%)</td>
</tr>
<tr>
<td>Overall Success (FDA)</td>
<td>73.5%</td>
</tr>
<tr>
<td>ODI (high is bad)</td>
<td>19 ± 20</td>
</tr>
<tr>
<td>Improvement in ODI</td>
<td>33 ± 21</td>
</tr>
<tr>
<td>Patient working pre-op</td>
<td>61%</td>
</tr>
<tr>
<td>Patient working at 2 yrs</td>
<td>56%</td>
</tr>
<tr>
<td>Reoperations to remove implant</td>
<td>2 (0.5%)</td>
</tr>
<tr>
<td>– allergic reaction, epidural abscess</td>
<td></td>
</tr>
<tr>
<td>Reoperation at index level</td>
<td>22 (5.5%)</td>
</tr>
<tr>
<td>Angular motion at index level</td>
<td>9.5 degrees</td>
</tr>
<tr>
<td>Angular motion at sub-level</td>
<td></td>
</tr>
</tbody>
</table>
Slide 43

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

Clinical article:

- 236 patients treated at 17 sites, 5yr F/U
- Randomized to ProDisc L or anterior-posterior fusion w/FRA + ICBG

Slide 44

<table>
<thead>
<tr>
<th></th>
<th>ADR group (n=161)</th>
<th>A/P Fusion group (n=75)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed 5yr Follow-up</td>
<td>137 (85%)</td>
<td>56 (75%)</td>
</tr>
<tr>
<td>Level:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L3</td>
<td>54 (33%)</td>
<td>22 (29%)</td>
</tr>
<tr>
<td>L4</td>
<td>104 (65%)</td>
<td>50 (67%)</td>
</tr>
<tr>
<td>L5</td>
<td>3 (1.9%)</td>
<td>3 (4%)</td>
</tr>
<tr>
<td>L5-S1</td>
<td>3 (1.9%)</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Overall success (FDA)</td>
<td>53%</td>
<td>47%</td>
</tr>
<tr>
<td>Device success</td>
<td>93.2%</td>
<td>93.3%</td>
</tr>
<tr>
<td>Fusion rate</td>
<td>NA</td>
<td>95.8%</td>
</tr>
<tr>
<td>ODI (high is bad)</td>
<td>34+/-24</td>
<td>36+/-26</td>
</tr>
<tr>
<td>Improvement in ODI</td>
<td>48+/-35</td>
<td>44+/-37</td>
</tr>
<tr>
<td>Reoperations for implant failure</td>
<td>6 (3.7%)</td>
<td>3 (6.7%)</td>
</tr>
<tr>
<td>Reoperation at index level</td>
<td>13 (8%)</td>
<td>9 (12%)</td>
</tr>
<tr>
<td>Angular motion at index level</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

Slide 45

Device failures

2 poly-ethylene extrusions:
- 1 in a 33yr old power-lifter; lifting 700lb weights
- 2nd in a 41yr old M involved in MVA

(Failure photos above from Leary et al, Spine 2007)
Cochrane review of 7 RCTs (up to December 2011) with 2 year follow-up
- Included 1301 patients that were used to compare ADR to fusion

Back Pain
ODI Improvement
Patient satisfaction

Five-year adjacent-level degenerative changes in patients with single-segment disease treated using lumbar total disc replacement with ProDisc-L versus circumferential fusion

Clinical article:

• Evaluate the 5-year data from ProDisc's IDE study to evaluate for adjacent segment disease
• 166 patients with complete F/U at 5yrs. ADR (n=123) compared to A-P Fusion (n=43)
• For patients with no adjacent-level degeneration at time of index surgery:
  • New Adjacent-level degeneration at 5 yrs:
    • 6.7% after ADR vs. 23.8% after A-P Fusion
    • But: Only 3 had adjacent level surgery in ADR group (1.9%) vs. 3 in fusion group (4%)

Back Pain
ODI Improvement
Patient satisfaction

Back Pain
ODI Improvement
Patient satisfaction
Evaluated pre- and 1 year post-ADR (Maverick implant) in 18 women and 17 males

- Observed maintenance of pre-op sagittal parameters at 1-yr post-ADR
- This is in contrast to multiple studies of lumbar fusion showing loss of lordosis and decreased ST

54 patients followed out to 10 years, 84% follow-up rate from earlier analyses
- 10 single-level ADR and 15 two-level ADR
- One level ADRs: L3-4 (n=3), L4-5 (n=20), L5-S1 (n=14)
- Two-level ADRs: L3-5 (n=2), L4-5 (n=13)
- 67% satisfied FDA criteria for clinical "success"
Range of motion maintained...

Lumbar lordosis maintained...

Reoperations...

<table>
<thead>
<tr>
<th>No.</th>
<th>Index</th>
<th>Full name</th>
<th>Date of operation</th>
<th>Time from index surgery</th>
<th>Causes of reoperation</th>
<th>Reoperation actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>L3-5</td>
<td>M</td>
<td>6.9</td>
<td>1.5</td>
<td>SI, L5S-5</td>
<td>SI, L5S-5</td>
</tr>
<tr>
<td>2</td>
<td>L4-5</td>
<td>F</td>
<td>8.3</td>
<td>1.5</td>
<td>SI, L5S-5</td>
<td>SI, L5S-5</td>
</tr>
<tr>
<td>3</td>
<td>L4-5</td>
<td>F</td>
<td>4.7</td>
<td>1.5</td>
<td>SI, L5S-5</td>
<td>SI, L5S-5</td>
</tr>
<tr>
<td>4</td>
<td>L3-4</td>
<td>M</td>
<td>4.3</td>
<td>1.5</td>
<td>SI, L5S-5</td>
<td>SI, L5S-5</td>
</tr>
<tr>
<td>5</td>
<td>L1-4</td>
<td>F</td>
<td>0.9</td>
<td>1.5</td>
<td>SI, L5S-5</td>
<td>SI, L5S-5</td>
</tr>
</tbody>
</table>

Slide 55

**Physical capability outcomes after trial-disc replacement with ProDisc-L**

- 28 patients, single ADR at L4-5(n=6) or L5-S1(n=9) or two-level ADR at L4-S1(n=3)
- Evaluated a simple series of practical, physical challenge consistent with ADLs

---

Slide 56

**Sullivan et al 2012**

- Significant improvements for all tasks
- No difference L4-5 vs L5-S1 except forward bend (L5-S1 pts could forward-bend longer)

---

Slide 57

**Lumbar Total Disc Replacement for Discogenic Low Back Pain: Two-year Outcomes of the active Multicenter Randomized Controlled IDE Clinical Trial**

- RCT of active ADR(n=218) vs ADR with ProDisc-L (n=106; "control")
- ProDisc-L device is a 3.5 mm high-constraint device with high-density cobalt chromium endplates and an ultra-high molecular weight polyethylene insert
- Non-inferiority FDA IDE trial
Slide 61

Yue et al 2016

![Graph showing adverse event type with bars for different groups: An AdHoc group, an AdHoc Disc group, and a Control group.]

Adverse event type

Self difference was statistically significant.

Slide 62

Yue et al 2016

![Graph showing back pain severity (%) over years for two groups: ProDisc-L and AdHoc Disc.]

Back pain severity (%)

Years

ProDisc-L

AdHoc Disc

Final

Slide 63

Yue et al 2016

![Graph showing trend lines for back pain severity over years for different groups.]

ProDisc-L

AdHoc Disc

Artificial Disc
Retrospective review of 64 patients
lumbar ALIF vs ALIF/ADR hybrid
Not randomized

Chen et al 2016
ALIF group (N = 31)
Hybrid group (N = 33)

1-level ALIF + 1-level ADR
2-level ALIF + 1-level ADR
1-level ALIF + 2-level ADR

Pre-op ODI
Post-op ODI (5 yrs)
Improvement
58+/-6
43+/-8
50%

Pre-op VAS
Post-op VAS
Improvement
6.7+/-2.3
3.2+/-2.2
52%

Failures requiring reoperation
7(23%)
5(15%)
Multi-level ADR

Clinical outcomes after treatment with disc prostheses in three lumbar segments compared to one- or two segments.

Compared 30 patients 1-2 yr after 3-level lumbar ADR to group of 700 patients that underwent 1 or 2 level ADR.

Berg et al 2015

Group A = 3-level ADR; Group B = 1 or 2-level ADR

No significant differences

Cervical Artificial Disc Replacement

Group A = 3 level ADR, Group B = 1 or 3 level ADR

No significant differences
Cervical ADR history

- Ulf Fernstrom – implanted his stainless steel balls in both lumbar and cervical in 1966
- Reitz and Joubert looked at 75 cervical disc arthroplasties performed with the Fernstrom Ball in 32 patients and reported that at the one year point they had not detected either neurological complications or subluxations of the Balls.
- In two cases they did find intrusion into adjacent bone, but the clinical results remained excellent in both cases.


---

Cervical ADR history

- Cummins-Bristol disc designed at the Frenchay hospital in Bristol, UK, in 1989
- Initial clinical results in the 18pts implanted were not promising – 3 cases of anterior screw pull-out, 1 screw breakage, 1 subluxed joint. All had persistent dysphagia.
- The implant was redesigned and reintroduced as the Frenchay cervical disc. Pilot study in 2002 had more favorable results.
- Acquired by Medtronic, it was renamed the Prestige Disc

---

Cervical ADR history

First randomized clinical trial in the U.S. was performed in 2007 to evaluate the Prestige disc compared to fusion.
Prestige ST

• 2 year trial
• 541 patients
• Motion maintained at 2 yrs, quicker return to work with TDR compared to ACDF

Currently FDA Approved

• Single level:
  – Prestige ST (Medtronic)
  – ProDisc (Depuy-Synthes)
  – Porous-coated motion (PCM, NuVasive)
  – Bryan (Medtronic)
  – Secure-C (Sklar)

• One and two levels:
  – Prestige LP (Medtronic)
  – Mobi-C (LDR)
### Slide 82

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Manufacturer</th>
<th>Classification</th>
<th>Biomaterials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prestige ST</td>
<td>Medtronic</td>
<td>Unconstrained</td>
<td>Metal-on-metal</td>
</tr>
<tr>
<td>Bryan</td>
<td>Medtronic</td>
<td>Unconstrained</td>
<td>Titanium alloy</td>
</tr>
<tr>
<td>ProDisc-C</td>
<td>Synthes</td>
<td>Semiconstrained</td>
<td>UHMWPE inlay</td>
</tr>
<tr>
<td>PCM</td>
<td>NuVasive</td>
<td>Semiconstrained</td>
<td>UHMWPE inlay</td>
</tr>
<tr>
<td>Secure-C</td>
<td>Simageon</td>
<td>Semiconstrained</td>
<td>UHMWPE inlay</td>
</tr>
<tr>
<td>SafeC-C</td>
<td>Spineology</td>
<td>Semiconstrained</td>
<td>UHMWPE inlay</td>
</tr>
<tr>
<td>Mobi-C</td>
<td>LDR</td>
<td>Semiconstrained</td>
<td>UHMWPE inlay</td>
</tr>
</tbody>
</table>

### Slide 83

5-yr FDA IDE study of 209 patients treated with single-level ADR with ProDisc-C (n=103) or ACDF (n=106).

### Slide 84

Zigler et al 2013

- At 5 years, re-operation rate was 2.9% in ProDisc-C group compared to 11.3% in ACDF group.
- ProDisc-C group had significantly less neck pain intensity and frequency.
- Otherwise similar outcomes in both groups.
- Motion maintained in ProDisc-C levels.
A 2-year study of 280 patients treated with single-level ADR using Prestige LP compared to 265 ACDF patients in the original Prestige ST study.

Gornet et al. 2015

Essentially identical outcomes at 2yrs except ROM.

5-year data from original IDE trial comparing single-level ADR with PCM (n=163) to single-level ACDF (n=130).
Phillips et al 2015

- Excellent outcomes in both groups
- Significantly better neck disability index (NDI) scores in ADR group
- Significantly better patient satisfaction scores in ADR group
- Significantly higher overall health scores in ADR group
- Significantly less adjacent-level degeneration in the ADR group (33%) compared to ACDF group (51%)

---

3-year RCT comparing single-level ACDF (n=42) vs ADR (n=41)

---

Not statistically significant
4-yrs RCT comparing 2-level ADR (n=202) to 2-level ACDF (n=89)

---

**Davis et al 2015**

Overall success: ADR is superior

---

**Davis et al 2015**

NDI: ADR is superior
4-yr outcomes comparing one-level ADR (n=164) compared to 2-level ADR (n=225)

Bae et al 2015
Secure-C (Globus)

Vaccaro et al 2013

- 2-yr study of 380 patients, 18 study sites
- ADR superior to ACDF for overall success and for post-op improvements in NDI, VAS and SF-36
- Re-operation rate at index level significantly less in ADR group (2.5%) than ACDF group (9.7%)
Long-Term Clinical and Radiographic Outcomes of the Artificial Cervical Disc Replacement at Two Levels: Results from a Level 1 Prospective Randomized Controlled Clinical Trial 7 YEAR FOLLOW-UP

Todd Lanman, MD1, Ken Burkus, MD2, Randall Dryer, MD3, Matthew Gornet, MD4, Jeffrey McConnell, MD5, Scott D. Hodges, DO6

1Cedars-Sinai Medical Center, 2Hughhston Clinic, 3Central Texas Spine Institute, 4The Orthopedic Center of St. Louis, 5OAA Orthopaedic Specialists, 6Center for Sports Medicine & Orthopaedics

DISCLOSURES

• MEDTRONIC – Consulting and Royalty
• STRYKER – Consulting and Royalty
• NUVASIVE – Consulting and Royalty
• CHOICE SPINE – Consulting and Royalty

7-yr RCT comparing two-level ADR (n=209) vs. ACDF (n=188) at two adjacent levels (C3 – C7)

Lanman et al, unpublished
Neurological Success: ADR superior
Lanman et al, unpublished

NDI: ADR superior
Lanman et al, unpublished

Overall success: ADR superior
(Neurologic Success, NDI, Secondary Surgeries, and Adverse Events)
Lanman et al, unpublished
Secondary Surgery at the index level:
ADR group had significantly fewer secondary surgical procedures (4.2%) than the fusion group (14.7%)
Adjacent Level Surgery, ADR is superior:
12.5% for the fusion group and 6.5% for the 2 level PRESTIGE LP group

Results provide Level 1 clinical evidence that demonstrates cervical disc arthroplasty at two adjacent levels is superior in Overall Success to a two level ACDF.

Because re-revision revision surgeries are more than 3 x greater for ACDF group at 7 years, cervical arthroplasty is likely to be a more cost effective treatment.

Patients treated with cervical arthroplasty at 2 levels undergo fewer adjacent level surgeries and this is trending toward significance.

This is the longest prospective 2 level cervical arthroplasty Level I data available in the US.

Cervical ADR vs fusion?
Slide 115

Single-level ACDF vs single-level ADR

Vs.

___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
___________________________________
______________________________
Analysis of load-sharing on uncovertebral and facet joints at the C3-4 level with implantation of the Bryan, Prestige LP, or Prodisc-C cervical disc prosthesis, an in vivo image-based finite element study

Clinical significance??

Load-sharing variance

Clinical significance??
Slide 121

Safety

Adverse Events Reporting and Reversing in Clinical Trials of Cervical Transforaminal Disk Replacement

Prospective multicenter RCT of 151 TDR patients compared to 100 control patients

• 42% had dysphagia at 6wks-3 months after TDR compared to 65% after ACDF
• 6% of patients had long-term dysphagia after TDR compared to 17% after ACDF

Slide 122

No difference between ACDF and TDR

Prospective multicenter RCT of 151 TDR patients compared to 100 control patients

• 42% had dysphagia at 6wks-3 months after TDR compared to 65% after ACDF
• 6% of patients had long-term dysphagia after TDR compared to 17% after ACDF
Longest follow-up reported

Yang et al 2014 – 30yr outcomes!

Yang et al 2014

- 21 patients completed 30yr follow-up
- Motion preserved in 19/26 (73%) of segments
- 19/21 had HO, none were symptomatic
- All had adjacent segment degeneration radiographically, but none of the patients had adjacent-segment disease requiring operation

Best ADR ever!? Made in China
Slide 127

Does ADR slow adjacent-segment disease?

Slide 128

Effect of Fusion on Adjacent Spinal Motion Segments

Adjacent segment disease
– 2.9% per year incidence requiring surgery
– 25% predicted at 10 years

Slide 129

• “Adjacent-segment degeneration” (radiographic) vs.
  • “Adjacent segment disease” (clinically symptomatic)
  • What is natural history of aging vs. iatrogenic?

Data from the 7-year 2-level Prestige LP study provide the most convincing evidence:
12.5% for the fusion group and 6.5% for the 2 level ADR
Jia et al. 2014

- Significantly greater adjacent-segment ROM after ACDF compared to hybrid but controversial amongst some studies
- Generally safe with no additional complications
- Concluded that better quality studies are needed to make any real conclusions when comparing hybrid to multilevel ACDF or ADR
Ongoing FDA IND Trials or pending FDA approval

- M6-L (Spinal Kinetics)
- eXtreme Lateral Total Disc Replacement (Xl TDR; NuVasive) – phase 3 study completed July 2015 →???
Is ADR from a lateral approach the future???