Complications Cervical Total Disc Replacement

UCSF Spine Symposium
June 1, 2013
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Disclosures

Depuy/Synthes Spine    honoraria
Stryker Spine consultant, honoraria
Fellowship support: OREF, AOSpine, Nuvasive, Globus

Cervical disc arthroplasty is approved in the U.S. for only single level use from C3-C7
CTDR RCT Enrollment

<table>
<thead>
<tr>
<th></th>
<th>ACDF</th>
<th>CTDR</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mummaneni et. al</td>
<td>265</td>
<td>276</td>
<td>541</td>
</tr>
<tr>
<td>Sassco et. al</td>
<td>221</td>
<td>242</td>
<td>463</td>
</tr>
<tr>
<td>Murrey et. al</td>
<td>103</td>
<td>106</td>
<td>209</td>
</tr>
<tr>
<td>Hisey et. al</td>
<td>164</td>
<td>81</td>
<td>245</td>
</tr>
</tbody>
</table>

Cervical TDR RCT NDI

Secondary Procedures @ Index Level ProDisc C (Delamarter et. al SASJ 2010)

<table>
<thead>
<tr>
<th>ProDisc C</th>
<th>24 months</th>
<th>48 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACDF</td>
<td>8.5% (9 patients total)</td>
<td>11.3% (12 patients total)</td>
</tr>
<tr>
<td>ProDisc C</td>
<td>1.9% (2 patients total)</td>
<td>2.9% (3 patients total)</td>
</tr>
</tbody>
</table>

- 3 supplemental posterior fixation for neck pain/pseudo
- 5 revisions for neck pain/pseudo
- 1 revision for plate subsidence
- 1 plate removal due to plate lift-off
- 1 laminectomy/foraminotomy for foraminal stenosis
- 1 adjacent level fusion @ 24 months plate removed @ index level
- 3 converted to fusion for pain
- Revisions performed by non-IDE study surgeons
Secondary Procedures @ Index Level Prestige at 5 years
(Mummaneni and Burkus JNS Spine 2010)

Table 3: Secondary surgeries and interventions at the index level. (Summary based on the IDE protocol definitions.)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational Group</th>
<th>Control Group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N = 276)</td>
<td>(N = 265)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No. (%) of patients</td>
<td>No. (%) of patients</td>
<td></td>
</tr>
<tr>
<td>Revision</td>
<td>0 (0.0)</td>
<td>5 (1.9)</td>
<td>0.023</td>
</tr>
<tr>
<td>Supplemental fixation</td>
<td>0 (0.0)</td>
<td>12 (4.6)</td>
<td>0.002</td>
</tr>
<tr>
<td>BGS (including BGS)</td>
<td>0 (0.0)</td>
<td>7 (2.7)</td>
<td>0.007</td>
</tr>
<tr>
<td>Removal</td>
<td>7 (2.5)</td>
<td>13 (4.9)</td>
<td>0.174</td>
</tr>
<tr>
<td>Elective removal</td>
<td>0 (0.0)</td>
<td>5 (1.9)</td>
<td>0.028</td>
</tr>
<tr>
<td>Reoperation</td>
<td>4 (1.4)</td>
<td>2 (0.7)</td>
<td>0.696</td>
</tr>
</tbody>
</table>

*Some surgeries involved both index and adjacent levels.

Complications of cTDR

- Poor preoperative planning
  - Patient Selection

- Intraoperative
  - Problems with technique
  - Visualization

- Post-operative problems
  - Early
  - Intermediate

Contraindications to cTDR

- Cervical instability (translation >3 mm and/or >11° rotational difference to that or either adjacent level)
- Known allergy to implant materials (titanium, polyethylene, cobalt, chromium, and molybdenum)
- Posttraumatic vertebral body deficiency/defority
- Facet joint degeneration
- Neck or arm pain of unknown etiology
- Normal neck pain on the cervical spine that is not alleviated by pain-relieving medications
- Severe spondylitis (worsening osteopeny, disc height loss >50%, and decrease of motion >5°)
- Osteopenia/osteoporosis
- Prior surgery at the level to be treated
- Active malignancy; any patient with history of invasive malignancy, unless treated and asymptomatic for at least 5 years
- Presently on medications that can interfere with bone/soft tissue healing (ie, steroids)
- Autoimmune spondyloarthropathies (rheumatoid arthritis)
- Active local/systemic infection
- Autoimmune spondyloarthropathies (rheumatoid)
- Pregnant
- Other metabolic bone disease (ie, Paget's and osteomalacia)
- Morbid obesity (BMI>40 or weight>100 lb over ideal body weight)

Adapted from Auerbach, Balderston, Spine Journal 2008
41-year-old reports two years of worsening neck and right shoulder complaints. The patient also complains of right intermittent pain and numbness in the C7 distribution.
Nickel

- 10%-30% of inexpensive jewelry release nickel
- 20% mobile phones in Danish market release nickel >0.5 ug/cm²/wk,

Chromium

- Historically due to occupational exposure to cement
  - First case reports form construction workers who built the metro in Paris in 1908 >2ppm
  - Addition of iron sulfate to cement decreased amount of water soluble hexavalent chromium.
  
Delayed Hyper-Reactivity to Metal Ions After Cervical Disc Arthroplasty
A Case Report and Literature Review
David A. Cavanaugh, MD,* Pierce D. Nunley, MD,* Eubulus J. Kerr, III, MD,*
David J. Werner, MD,† and Ajay Jawahar, MD, MS*
Spine 2009

- Cobalt chrome particles induce inflammatory mediator release from macrophages in vitro
- Micro and nano particles induce aneuploidy and cytotoxicity in fibroblasts
- Tissue retrieved from failed metal on metal hip replacements show periarticular lymphocytic reaction

- Chromium exposure is a consumer problem
  - 50% of 850 leather goods contain chromium
  - 17% contains >10mg/kg
**Cobalt**

- Mainly through consumer exposure in trace amounts in jewelry as an impurity found in nickel
- Cosensitization can lead to severe dermatitis
- Dental implants (alloys) also contain cobalt.

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**Intraoperative Complications**

- Suboptimal placement
- Suboptimal decompression
- Overly aggressive bone removal
- Intraoperative vertebral body fracture

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**Inadequate Imaging**
Kyphotic malalignment after anterior cervical fusion is one of the factors promoting the degenerative process in adjacent intervertebral levels.

A. Katsuura, S. Hukuda, Y. Saruhashi, K. Mori
European Spine Journal 2001

Axial symptoms and cervical alignments after cervical anterior spinal fusion for patients with cervical myelopathy.
Kawakami M, Tamaki T, Yoshida M, Hayashi N, Ando M, Yamada H. JSD 1999

- local kyphosis and narrowing of the neural foramen at the fused segment were recognized more often in patients with axial symptoms than in those without
Sears et. al, JSD Tech 2007

Byran Disc experience

<table>
<thead>
<tr>
<th>N</th>
<th>2 M</th>
<th>FSU angular change</th>
<th>C2-C7 angle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johnson 2004</td>
<td>13</td>
<td>-4.7 deg FSU</td>
<td>No Δ</td>
</tr>
<tr>
<td>Pickett 2004</td>
<td>14</td>
<td>-6.0 deg FSU, -3.8 deg Shell</td>
<td>No Δ</td>
</tr>
<tr>
<td>Yoon 2006</td>
<td>46</td>
<td>No Δ</td>
<td>-2.1 deg</td>
</tr>
<tr>
<td>Sears/Sekhon 2007</td>
<td>67</td>
<td>-2.0 deg FSU (-8 to +5), -2.0 deg shell (-15 to +11.5)</td>
<td>-4 deg</td>
</tr>
<tr>
<td>Kim 2008</td>
<td>47</td>
<td>10/28 lordotic, 2/11 kyphotic</td>
<td>86% pres Lordosis, 33% res Kyphosis (1), 33% lordosis (1)</td>
</tr>
</tbody>
</table>

No Δ

∆
Vertebral body split fracture after a single-level cervical total disc replacement: Case report

*Tsung-Hei Tu, M.D.,1,2 Jau-Ching Wu, M.D.,1–3 Li-Yu Fay, M.D.,1,2 Chin-Chu Ko, M.D.,1,2 Wen-Cheng Huang, M.D., Ph.D.,1,2 and Henrich Cheng, M.D., Ph.D.,1–3

Post-operative Complications

- Subsidence
- Heterotopic ossification
- Implant migration/loosening

“I’ll have someone come in and prop you for the fall.”
Prodisc-C Heterotopic Ossification Rates at Adjacent Level at 4 years (Delamarter et al. SASJ 2010)

14 cases at adjacent level(s) in ACDF group (13.2%)
- 10 cases of HO present but not influencing the ROM
- 2 cases of HO possibly affecting the vertebral ROM
- 1 case of HO affecting ROM on F/E or lateral bending
- 1 case of HO causing inadvertent arthrodesis

1 case at adjacent level(s) in ProDisc-C group (1%)
- 1 case of HO possibly affecting the vertebral ROM
Difference in Occurrence of Heterotopic Ossification According to Prosthesis Type in the Cervical Artificial Disc Replacement SPINE 2010
Seong Yi, MD, PhD,* Keung Nyun Kim, MD, PhD,* Moon Sul Yang, MD,* Joong Won Yang, MD,* Hoon Kim, MD,* Yoon Ha, MD, PhD,* Do Heum Yoon, MD, PhD,* and Hyun Chul Shin, MD, PhD†

CLINICAL ARTICLE

Uncovertebral hypertrophy is a significant risk factor for the occurrence of heterotopic ossification after cervical disc replacement: survivorship analysis of Bryan disc for single-level cervical arthroplasty

Sang-Bong Chung; Ionut M. Merzov; Sun-Ho Lee; Whan Eoh; Eun-Sung Kim
An incomplete paraplegia following the dislocation of an artificial cervical total disc replacement
Case report
Lennart Viezens, M.D.,1 Christian Schaefer, M.D.,2 Jörg Beyerlein, M.D.,2
Roland Thietje, Ph.D.,3 and Nils Hansen-Algenstaedt, M.D., Ph.D.2

Cervical Total Disk Replacement: Complications and Avoidance
Orthopedic Clinics of North America, Volume 43, Issue 1, Pages 97-107
Behnam Salari, Paul C. McAfee

Comparative fixation methods of cervical disc arthroplasty
versus conventional methods of anterior cervical arthrodesis:
segregation, teeth, keels, or screws?
Laboratory investigation
BRENN W. CONROY, M.S.,2 NDUBH H., M.D.,1 ANTHONY M. ZIOTI, B.S. ENS.,3
AND P.A. W. MCKEE, M.D.2

Tensile Load at Failure (Newtons)
Conclusion

- Good evidence showing cervical disc arthroplasty is a safe procedure compared to ACDF.
- Complications other than heterotopic ossification have been limited to case reports.
- We will face further challenges as the bearing surfaces wear out.