The Artificial Cervical Disc: 2016 update

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Disclosures

Woven Therapeutics
Vertera Spine
• Share Holder

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• Consultant
• Honoraria

• Acknowledgement: John K. Houten M.D.
The Artificial Cervical Disc: 2016 update
Introduction

• The first artificial cervical prosthesis was implanted by Ulf Fernstrom, who described the placement of stainless steel spheres into the intervertebral space in 1966.
• Because of the unacceptable complication rates from these initial endeavors, cervical arthrodesis remained the mainstay for reconstruction of the cervical spine after anterior decompression.
• In 1989, the Cummins- Bristol disc was developed by B.H. Cummins at the Frenchay Hospital in Bristol, United Kingdom.
  • Between 1991 and 1996, 22 of these 2-piece stainless steel joints were implanted into 20 patients
  • Eighteen of these individuals were studied in 1996, all but 2 of the prostheses were mobile
  • No implant failed
• Patients with radiculopathy improved, and those with myelopathy either improved or stabilized.
• This 2-piece metal-on-metal stainless steel device was redesigned and introduced as the Frenchay cervical disc.
• These pioneering efforts were followed by the development of several devices designed to serve as total cervical disc replacements.
Introduction

- Currently, 11 cervical arthroplasty devices have been approved by the FDA for single-level anterior cervical disc procedures: Prestige ST (Medtronic), ProDisc-C (Synthes), Bryan (Medtronic), Kineflex-C (SpinalMotion), Mobi-C (LDR Spine), and Secure-C Artificial Cervical Disc (Globus Medical).
- Designs include one-piece implants, implants with single- or double-gliding articulations with either metal-on-metal or metal-on-polymer bearing surfaces.
# Introduction

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<th>Bryan®</th>
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<td>Metal-on-poly; chrome cobalt, UHMWPE</td>
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<td>Variable; inferior to disc space</td>
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### Introduction

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<td>Fixed</td>
<td>Ball and socket</td>
<td>Porous titanium</td>
<td>Spikes</td>
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</tbody>
</table>

CoCr, cobalt–chrome alloy; COR, center of rotation; PCU, polycarbonate–polyurethane; PEEK, polyetheretherketone; UHMWPE, ultrahigh-molecular-weight polyethylene.

Introduction

• The **cardinal goals** of cervical arthroplasty are to:
  • Preserve normal physiological kinematics and mobility
    • Potential beneficial effect upon level of patient comfort
    • Potential preservation of patient abilities in work/recreation
  • Maintaining stability and alignment across a single cervical motion segment.
• Cervical arthroplasty should also:
  • Allow faster return to work and full activity
  • Elimination of need for bone graft material
    • Iliac crest Autograft can be very painful
    • Allograft with risk of pseudoarthrosis and theoretical potential for disease transmission
• Numerous biomechanical studies have examined the axes of rotation, range of motion, load sharing between anterior and posterior elements at the implanted levels, and stresses in the intervertebral disc at the adjacent levels.
• Proponents of cervical disc replacement claim that maintenance of motion at the operated level will reduce the incidence of adjacent level degeneration and improve long-term clinical outcomes when compared with ACDF.
Introduction

INDICATIONS

• Cervical arthroplasty may be considered for patients with normal cervical spinal alignment and mobility who present with radiculopathy caused by disc herniation (soft or hard), foraminal osteophytes, myelopathy due to a soft central disc herniation, or any combination of the above mentioned entities.

• Auerbach et al. summarized the indications and contraindications listed in the trials of cervical arthroplasty and concluded that approximately 40% of patients with symptomatic cervical degenerative disc disease may be candidates for arthroplasty.

Auerbach et al. Spine J. 2008;8(5):711-716
Introduction

CONTRAINDICATIONS

- Instability with greater than 4 mm of translation.
- Greater than 11 degrees of kyphosis.
- Severe disc degeneration (>50% loss of disc height).
- Severe osteoporosis.
- History of cervical spine infection.
- Severe facet arthrosis.
- Ankylosis.
- Allergy to components of the prosthesis.
- Congenital spinal stenosis.
- Prior laminectomy or excessive removal of the facet joints.
  - Presence of functional or intact posterior elements is essential to stability with a cervical disc prosthesis
- Relative contraindications include
  - Rheumatoid arthritis
  - Renal failure
  - Cancer
  - Preoperative corticosteroids.
Does motion preservation lead to better clinical outcomes?
Cervical Fusion Eliminates Motion

• Patients have good neurologic results from ACDF and relief of arm pain and myelopathy.
• Patients can have discomfort and disability from loss of range of motion.
Cervical Arthroplasty Preserves Motion

Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial

Praveen V. Mummameni, M.D., J. Kenneth Burkus, M.D., Regis W. Haid, M.D., Vincent C. Traynellis, M.D., and Thomas A. Zdeblick, M.D.
Improved Outcome

- Prospective evaluation of 380 patients randomized to SECURE-C artificial disc and ACDF.
- Minimum 24 month follow up.
- Arthroplasty group statistically superior (albeit narrow difference) in outcome measures including NDI, VAS, and SF-36.
- Patient report of “treatment satisfaction” 95.7% in SECURE-C and 85.2% in ACDF.
Equivocal

• Zechmeister reviewed of 95 English and German publications published comparing disc arthroplasty with ACDF.
• Measured single patient relevant endpoints such as pain, disability or quality of life improvements in both groups.
• No statistically significant differences between magnitude of clinical improvement.

Eur Spine J (2011) 20:177–184
DOI 10.1007/s00586-010-1583-7

Artificial total disc replacement versus fusion for the cervical spine: a systematic review

Ingrid Zechmeister · Roman Winkler · Philipp Mad
Effect of Fusion on Adjacent Spinal Motion Segments
Adjacent Level Disease

- Cervical decompression and fusion (ACDF) has been used successfully in the treatment of symptomatic radiculopathy and/or myelopathy.
- Biomechanical studies have reported the deleterious effects of cervical fusion on adjacent level kinematics.
- Adjacent-level degeneration has been defined as pathologic changes next to a previously fused spinal segment, which makes this a radiographic diagnosis, whereas adjacent-level disease is characterized by the development of symptoms of radiculopathy and/or myelopathy.
- Symptomatic adjacent disease is widely considered to occur in a smaller percentage of patients compared with adjacent-level degeneration after ACDF.
- In a widely quoted study of 374 patients, Hilibrand et al. reported a 2.9% incidence of symptomatic ASD per year during 10-year follow-up after ACDF.
- In a separate study, Hilibrand and Robbins estimated the prevalence of adjacent-level disease after ACDF at 9% to 17%, with an annual ASD incidence requiring surgery of 1.5% to 4%.
Adjacent Level Disease

• Goffin et al. studied 180 patients treated with ACDF for either degenerative disc disease (mean age, 48.8 years) or trauma (mean age, 31.6 years), with a minimum 5 years of follow-up.
• 92% demonstrated radiographic changes at adjacent levels to the segment fused, with no difference between the trauma and degenerative cohorts.
• Matsumoto et al. performed a 10-year follow-up MRI study comparing 64 patients treated with ACDF with 201 healthy control patients who did not undergo surgery.
  • The authors reported both ACDF and control patients demonstrated progression of disc degeneration.
  • Fusion was associated with a higher incidence of progression of disc degeneration at adjacent levels.
  • Significant differences in ASD were not established in this study.
• Biomechanical studies have suggested that cervical fusion leads to hypermobility, increases in intradiscal pressure, and stress in the adjacent segments after single and multiple cervical level fusion procedures.
• Furthermore, cadaveric fusion models have demonstrated an increase in adjacent segment motion from 40% to 60% after anterior fixation.
• Consequently, both in vivo and in vitro studies have demonstrated that artificial cervical disc devices maintain index-level sagittal motion, translation, and coupled motion in lateral bending compared with preoperative or intact states.
Adjacent Level Disease

- Dmitriev et al. used cadaveric cervical specimens to compare intradiscal pressures at adjacent motion segments after arthroplasty, allograft dowel, or allograft dowel and anterior instrumentation. The authors demonstrated a 50% increase in intradiscal pressure with fusion compared with intact specimens, an effect mitigated by arthroplasty ($P < 0.05$).
- Proponents of cervical disc replacement claim that maintenance of motion at the operated level will reduce the incidence of adjacent level degeneration and improve long-term clinical outcomes when compared with ACDF.
Five-Year Reoperation Rates, Cervical Total Disc Replacement Versus Fusion, Results of a Prospective Randomized Clinical Trial

Rick B. Delamarter, MD,* and Jack Zigler, MD†

• 209 patients: TDR (prodisc-C) 103 and ACDF 106
• 5 year reoperation rates of 2.9% TDA and 15% ACDF (p=0.0079)
  • TDA 1 reop for index level, 2 for adjacent segment
  • ACDF 8 reop for index level, 8 for adjacent segment

Conclusion: the study demonstrated “a significant sparing effect of TDR on the adjacent level”
Rate of Adjacent Segment Disease in Cervical Disc Arthroplasty Versus Single-Level Fusion

Meta-analysis of Prospective Studies

Kushagra Verma, MD, MS,* Sapan D. Gandhi, BS,† Mitchell Maltenfort, PhD,* Todd J. Albert, MD,* Alan S. Hilibrand, MD,* Alexander R. Vaccaro, MD, PhD,* and Kristin E. Radcliff, MD*

- Pooled data from 6 prospective studies, 1586 patients (ACDF = 777, TDA = 809).
- Follow up ranged from 2-5 years.
- Adjacent level reoperation rate: ACDF 6.9%, TDA 5.1% (not statistically significant).
Adjacent Level Disease

- Theoretical the reduction of ASD remains a primary rationale for the use of CDA, literature reporting the long-term incidence of ASD after arthroplasty is limited.
- Nunley et al. 31 conducted a prospective randomized controlled trial to investigate the incidence of ASD after CDA in 271 patients, with follow-up of 4 years in 167 of those patients.
- Patients with symptomatic cervical radiculopathy after arthroplasty were clinically examined, and diagnostic and imaging studies, including MRI scans, were obtained. At a median follow-up of 51 months.
- 15.2% of patients (26 of 167) met clinical and radiographic criteria of ASD.
  - 3.1% annual incidence regardless of the patient's age, sex, smoking habits, and arthroplasty device design
- Authors reported a significant increase in the risk of developing ASD with presence of osteopenia and lumbar degenerative disease. (Natural history)
- Future investigations incorporating MRI studies with long-term follow-up are needed to understand the impact on the incidence of ASD after arthroplasty.
Adjacent Level Disease

56 yo m cervical myelopathy with large C4/5 HNP
Adjacent Level Disease

Did well for 5 years after C4/5 TDA. Now severe right arm pain and triceps weakness
Adjacent Level Disease

C5/6

C6/7

Myelogram: right sided hnp C5/6, smaller one on right C6/7
Adjacent Level Disease

Treatment: 2-level adjacent interbody fusion
Sagittal Cervical Alignment After Cervical Disc Arthroplasty and ACDF
Sagittal Cervical Alignment

• As range of motion is an essential component of the biomechanical profile of a cervical TDR prosthesis, the presence, maintenance, and/or restoration of cervical sagittal balance after spinal procedures has been recognized as an increasingly important parameter to assess risk for subsequent degeneration at adjacent levels.

• Several recent publications have demonstrated a correlation between cervical kyphosis and axial neck pain or new-onset neurologic symptoms.

• While the long-term clinical consequences of device-level and total cervical kyphosis remain unknown, there is a growing interest in the sagittal performance profile of cervical TDR prostheses.
Sagittal Cervical Alignment

• Okechukwu et al. evaluated the effect on device-level lordosis, cranial and caudal adjacent level lordosis, and overall cervical sagittal alignment (C2–C6) after TDR-C (ProDisc-C) or ACDF.
• Radiographic data were obtained from the randomized group of a multicenter, randomized, prospective, controlled study comparing TDR-C with ACDF in the treatment of 1-level cervical disc disease.
• Complete radiographic data were available for 89 TDR-C patients (average age: 42.2 years) and 91 ACDF patients (average age: 41.7 years).
• Cervical lordosis at the device level, cranial and caudal adjacent levels, and total cervical lordosis (C2–C6) were independently measured before surgery and 2 years after surgery using custom image stabilization software (Quantitative Motion Analysis, Medical Metrics, Inc, Houston, TX).
Sagittal Cervical Alignment

• At 2 years after surgery, the TDR-C group experienced statistically significant changes in lordosis of 3.0° ($P < 0.001$), 0.90° ($P = 0.006$), and -1.9° ($P < 0.001$) at the operative, cranial, and caudal adjacent levels, respectively. ACDF experienced changes in lordosis of 4.2° ($P < 0.001$), 1.0° ($P = 0.001$), and -1.5° ($P = 0.001$), respectively. The between-group differences were significant at the operative level ($P = 0.03$) and the caudal adjacent level ($P = 0.05$). Total cervical lordosis increased in both TDR-C and ACDF by 3.1° and 3.8°, respectively ($P = 0.49$).

• In both TDR-C and ACDF, lordosis increased at the device-level, cranial adjacent level, and in total cervical lordosis, while lordosis decreased at the caudal adjacent level. Although ACDF facilitated a greater increase in device level lordosis (+1.25°) and less loss of lordosis at the caudal adjacent level compared with TDR-C (-0.39°), the clinical relevance of the small differences remain unknown.

<table>
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<th>Table 3. Preoperative and 24-Month Postoperative Cervical Sagittal Alignment: TDR Versus ACDF (n = 180)*</th>
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<td><strong>No. (%)</strong></td>
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<tr>
<td><strong>Level</strong></td>
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<tr>
<td>Superior adjacent</td>
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<tr>
<td>Operative</td>
</tr>
<tr>
<td>Inferior adjacent</td>
</tr>
<tr>
<td>Overall 2C-6</td>
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</tbody>
</table>

*Plusminus values are means ± SD.
†P represents significance of between-subjects effect of TDR/ACDF grouping as calculated by repeated measures ANOVA.
TDR indicates total disc replacement; ACDF, anterior cervical disectomy and fusion.
Why hasn’t CDA become the standard of care for cervical disc disease in 2016.....
CONTRAINDICATIONS

• Instability with greater than 4 mm of translation.
• Greater than 11 degrees of kyphosis.
• Severe disc degeneration (>50% loss of disc height).
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• Relative contraindications include
  • Rheumatoid arthritis
  • Renal failure
  • Cancer
  • Preoperative corticosteroids.
POSITION STATEMENT

Artificial Disc Replacement in the lumbar and cervical spine is considered experimental and investigational.

CODING

Non-Covered CPT® Codes

22856  Cervical - Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation includes osteophytectomy for nerve root or spinal cord decompression and microdissection, single interspace
Post-operative Imaging Issues
Post-operative Imaging Issues

- Devices fabricated with stainless steel or cobalt chrome.
  - MRI will not adequately image operative and adjacent levels
- CT Myelogram is study of choice
Post-operative Imaging Issues

- Devices fabricated with titanium
  - Some artifact, still possible to see operative level and certainly the adjacent levels
  - Examples Prestige® LP, Discover® cervical disc
Post-operative Imaging Issues

IF YOU WANT TO GET AN MRI…do not use the 3T magnet. The higher the strength magnet, the more artifact. Try the 0.8-1.2T machines

Magnetic resonance imaging evaluation of adjacent segments after cervical disc arthroplasty: magnet strength and its effect on image quality

Clinical article

CPT IVAN J. ANTOSH, M.D., LTC JOHN G. DEVINE, M.D., CLYDE T. CARPENTER, M.D., MAJ BRIAN J. WOEBKENBERG, M.D., and COL STEPHEN M. YOEST, M.D.

Madigan Army Medical Center, Department of Orthopaedic Surgery, Ft. Lewis; Olympia Orthopaedic Associates, Olympia, Washington; and Bayne-Jones Army Community Hospital, Department of Orthopaedic Surgery, Ft. Polk, Louisiana

Magnetic resonance imaging evaluation after implantation of a titanium cervical disc prosthesis: a comparison of 1.5 and 3 Tesla magnet strength.

Sundseth J, Jacobsen EA, Kolstad F, Nygaard OP, Zwart JA, Hol PK.
Future Applications
Disease Adjacent to a Fusion

- Compression above the fusion.
- Patient has already lost some range of motion - an additional fusion will certainly affect range of motion in a highly active individual.
Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results

Reginald J. Davis, MD,¹ Pierce Dalton Nunley, MD,² Kee D. Kim, MD,³ Michael S. Hisey, MD,⁴ Robert J. Jackson, MD,⁵ Hyun W. Bae, MD,⁶ Gregory A. Hoffman, MD,⁷ Steven E. Gaede, MD,⁸ Guy O. Danielson III, MD,⁹ Charles Gordon, MD,⁹ and Marcus B. Stone, PhD²

“ACDF patients experienced higher subsequent surgery rates and displayed a higher rate of adjacent-segment degeneration as seen on radiographs.”
2-level Disc Arthroplasty
Conclusions
Conclusions

• Cervical disc replacement after anterior cervical decompression is an innovative technology that is a promising alternative to an instrumented fusion.
  • Preserves motion at the instrumented level(s)
  • Potentially improves load transfer to the adjacent levels compared with fusion
• Several high-quality studies have shown excellent outcomes in patients treated with cervical disc arthroplasty.
  • Consistently shown to be safe and effective
  • Sporadically shown to be superior to ACDF
• A clearer role for the place of cervical disc replacement in the spine surgeon’s armamentarium continues to emerge as our experience with cervical disc arthroplasty broadens.
• Similar to the treatment of all spinal conditions, patient selection and meticulous surgical technique are the keys to a successful outcome.