What's New in Cervical Spine Surgery: Total Disc Arthroplasty

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Disclosures

- I have a potential conflict with this presentation due to:
  - (a) None related directly to this talk
  - (b) Consulting/Royalty/Speaker's Bureau payments for unrelated products from: Alphatec, Biomet, DiFusion, Seaspine, Spineart, Stryker

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One Level Cervical Radiculopathy/Myelopathy

- Historical gold standard surgical treatment: ACDF
- Excellent fusion rates and clinical results
- Good long term data

Why Look for an Alternative

- ACDF "Problems"
  - Pseudarthrosis
  - Adjacent segment disease (ASD)
    - ? Natural history vs post-operative affect
  - Loss of motion
    - ? Increased adjacent segment stress

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Can We Decrease ASD?

- Goal is to maintain disc space motion following anterior cervical discectomy
  - Cervical total disc replacement (cTDR)
- Theoretically it may decrease ASD
- May allow retained motion
  - Is it even clinically relevant?
  - Is the motion “normal” biomechanically?

cTDR: Clinical Interest

- Almost all published after 2001

Increased Business Interest

- Becoming a billion dollar business

NUVASIVE®
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May 13, 2004

CORPORATE INFORMATION

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- Corporate Governance
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- Event Calendar

Press Release

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NuVasive Announces Acquisition of Cervical Total Disc Replacement Device

The initial payment for purchase of Cervitech will be approximately $47 million, with an additional contingent payment of $33 million upon FDA approval of the device. At NuVasive's discretion, all

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The New York Times

Technology

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2nd Medtronic Neck Disk Wins Panel Approval

By BARNABY J. FEDER
Published: July 18, 2007

Medtronic, which late Monday became the first medical device maker cleared to sell an artificial neck disk in the United States, may also become the first company to sell a device that would compete with it.

An independent panel of orthopedics experts recommended late yesterday by a 7-1 vote that the Food and Drug Administration approve the second device, the Bryan cervical disk, a newer design. The company says the Bryan more closely resembles a natural spinal disk than the Prestige ST disk that the F.D.A. cleared for sale a day earlier.

Cervical TDR: History

Surgical experience with an implanted artificial cervical joint

BRIAN H. CUMMINS, F.R.C.S., JAMES T. ROBERTSON, M.D., AND STEVEN S. GILL, F.R.C.S.

Department of Neurosurgery, Frenchay Hospital, Bristol, United Kingdom; and Department of Neurosurgery, University of Tennessee Health Science Center, Memphis, Tennessee

- First clinical report of CDR
  - Bristol-Cummins
- 22 implanted for myelopathy in endstage cervical disease
- Evolved into Prestige I, II, and ST (Medtronic)

J Neurosurg 88:943–948, 1998

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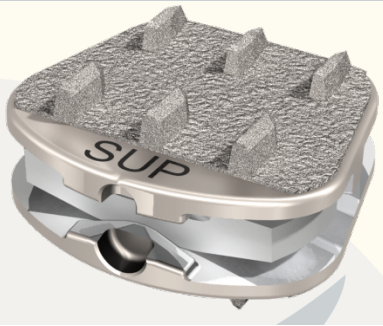
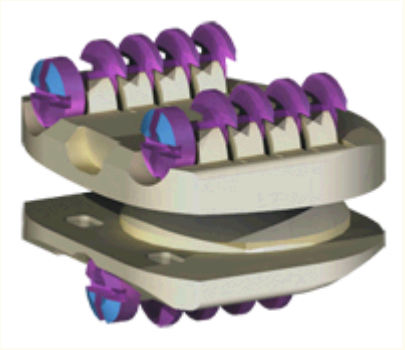
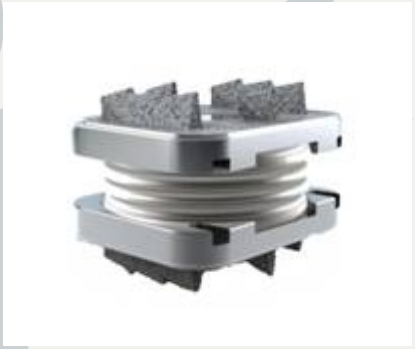
Today: Many Choices . . .







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Cervical TDR - Materials and Fixation

Prosthesis	Materials	Fixation	Motion	Comments
Prestige LT (Medtronic)	Metal-on Metal 316 stainless steel Endplates grit-blasted to allow for bony ingrowth	Screw fixation	Semi-constrained	
Prodisc-C (Synthes)	Cobalt-Chrome UHMWPE	Keel Fixation. Endplates sprayed with Titanium	Semi-constrained	
Acroflex Disc	Rubber Core bonded to two titanium plates Second Generation: Acroflex-100 consists of an HP-100 silicone elastomer core bonded to two titanium endplate	Fixation spikes	Semi-constrained	Only 6 patients were implanted before the clinical trial was stopped due to a report that 2-mercaptobenzothiazole, a chemical used in the vulcanization process of the rubber core, was possibly carcinogenic in rats
Bryan (Medtronic)	Polyurethane Center with titanium endlplates Flexible membrane that surrounds the inner portion of the disc	One piece device	Unconstrained Motion	Europe N=73 - 52 with excellent to good outcome
PCM (Cervitech)	Cobalt chrome with UHMWPE	Titanium/calcium phosphate coating on a serrated surface. Second generation PCM-V has a keel	Semi-constrained	
Cervicore (Stryker)	Cobalt Chrome Metal on Metal	Titanium spray + 3 spikes for bony fixation. Screws to promote primary fixation	Semi-constrained	
Mobi-C (LDR)	Metal base plates with UHMWPE insert	Mobile bearing technology	Semi-constrained	

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Cervical TDR - Materials and Fixation

Prosthesis	Materials	Fixation	Motion	Comments
Secure-C (Globus)	Two metal endplates with plastic core	Keel Fixation		
Kineflex-C (Spinal Motion)	Two cobalt chrome-Mo end plates and CCM core		Retention ring	
Discover (Depuy)	Cobalt-Chrome UHMWPE	Spike Fixation Grit blasted for Fixation	Semiconstrained	
NeoDisc (Nuvasive)	1) solid silicone core, containing no silicone gel, that acts like a cushion similar to a normal intervertebral disc. 2) An encapsulating jacket formed from a polyester textile Standard titanium alloy bone fixation screws	Standard titanium alloy bone fixation screws	Semiconstrained	Unique design.
NuNec (Pioneer)	PEEK on PEEK prosthesis Hydroxyapatite coating for additional fixation	CAM locking mechanism	Semiconstrained	
M6(Spinal Kinetics)	Titanium endplates Viscoeleastic polymer core UHMWPE annulus	Tri-keel fixation	Semiconstrained	Replication of native disk
Discocerv (Scient' x /Alphatec)	Ceramic	Groove fixation	Semicostrained	
Synergy Disc	Cobalt-Chrome UHMWPE	Spike Fixation Grit blasted for Fixation	Semiconstrained	

cTDR: Does It Work

- Much of the data is based upon IDE RCT's
- Review of initial cTDR studies:
  - Prestige, Bryan, ProDisc

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Initial IDE Studies

- Controls: ACDF with allograft and plate
- 2 year follow up
- Radiculopathy or myelopathy from single-level disease
  - One cTDR now with 2 level approval
- Exclusion criteria
  - Marked spondylosis/Facet joint arthrosis
  - <2 º motion at index segment
  - >50% disc space collapse
  - Segmental instability (>3 mm translation)
  - Cervical kyphosis

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Prestige ST IDE

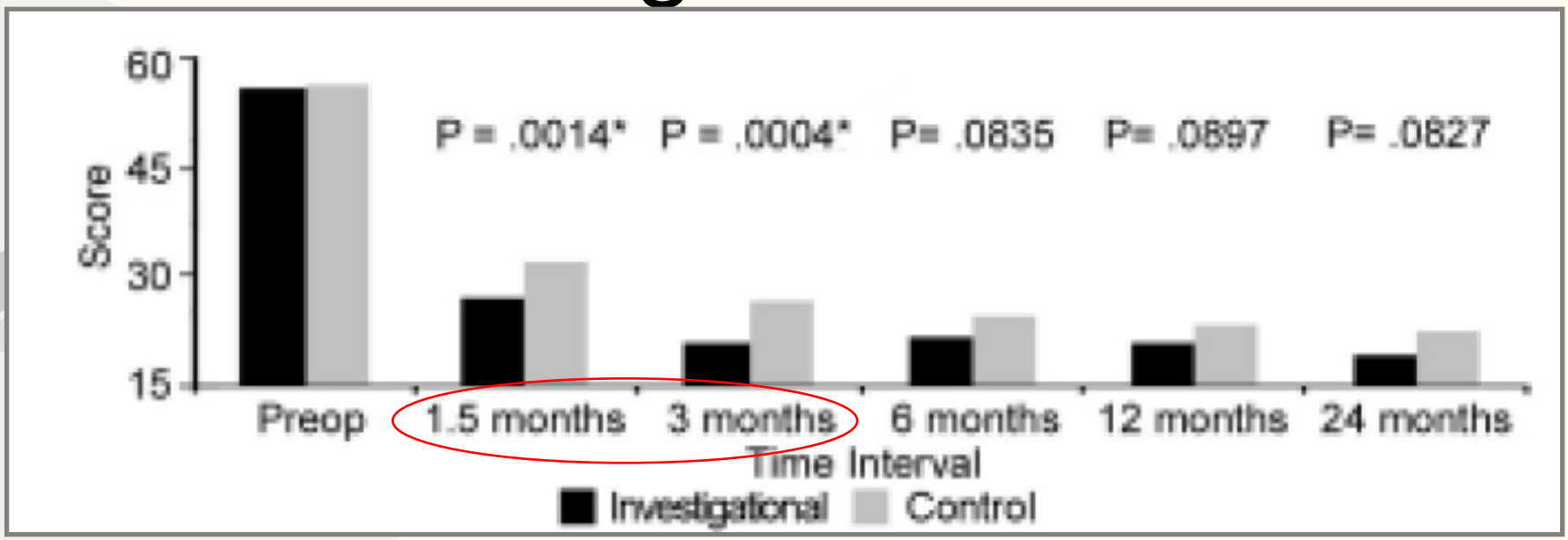
Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial

PRAVEEN V. MUMMANENI, M.D.,[1] J. KENNETH BURKUS, M.D.,[2] REGIS W. HAID, M.D.,[3] VINCENT C. TRAYNELIS, M.D.,[4] AND THOMAS A. ZDEBLICK, M.D.[5]

- Prestige ST stainless steel metal on metal ball and trough articulation
- CDR (276 pts) vs. ACDF (265 pts) for single level disease

J Neurosurg Spine 6:198–209, 2007

Prestige ST IDE



- NDI better in CDR group up to 3 mo only
  - Collar use?
- No difference in SF 36, neck or arm pain, or return to work status
- In 2007 became first CDR FDA approved

J Neurosurg Spine 6:198–209, 2007

Bryan IDE

Comparison of BRYAN Cervical Disc Arthroplasty With Anterior Cervical Decompression and Fusion

Clinical and Radiographic Results of a Randomized, Controlled, Clinical Trial

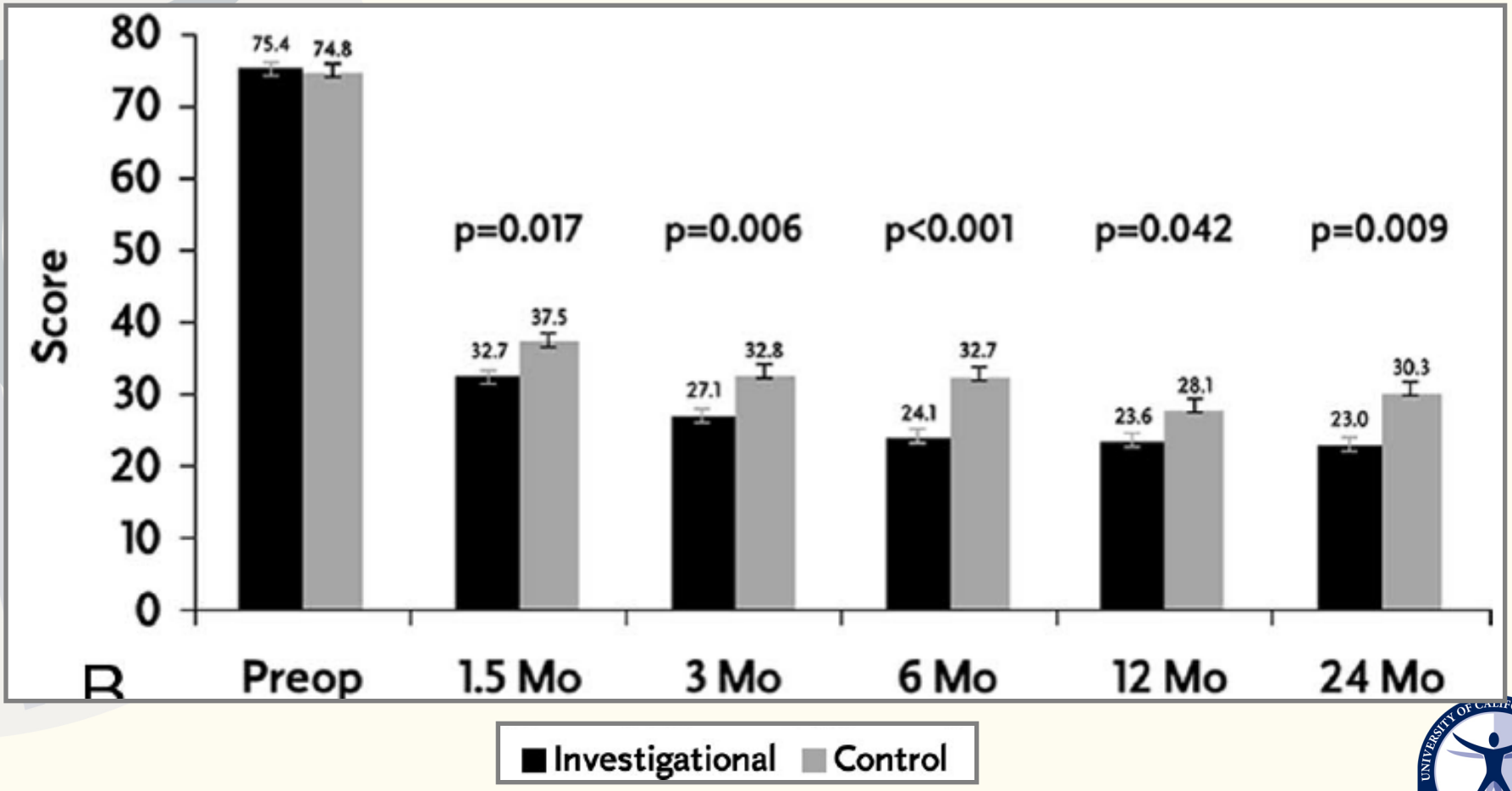
John G. Heller, MD,* Rick C. Sasso, MD,† Stephen M. Papadopoulos, MD,‡
Paul A. Anderson, MD,§ Richard G. Fessler, MD, PhD,¶ Robert J. Hacker, MD,‖
Domagoj Coric, MD,** Joseph C. Cauthen, MD,†† and Daniel K. Riew, MD‡‡

- Polyurethane nucleus between titanium shell
- CDR (242 pts) vs. ACDF (221 pts)
- Better SF-36 score and arm pain relief at 1 yr for CDR
  - Not significant at 2 yrs

Spine • Volume 34 • Number 2 • 2009

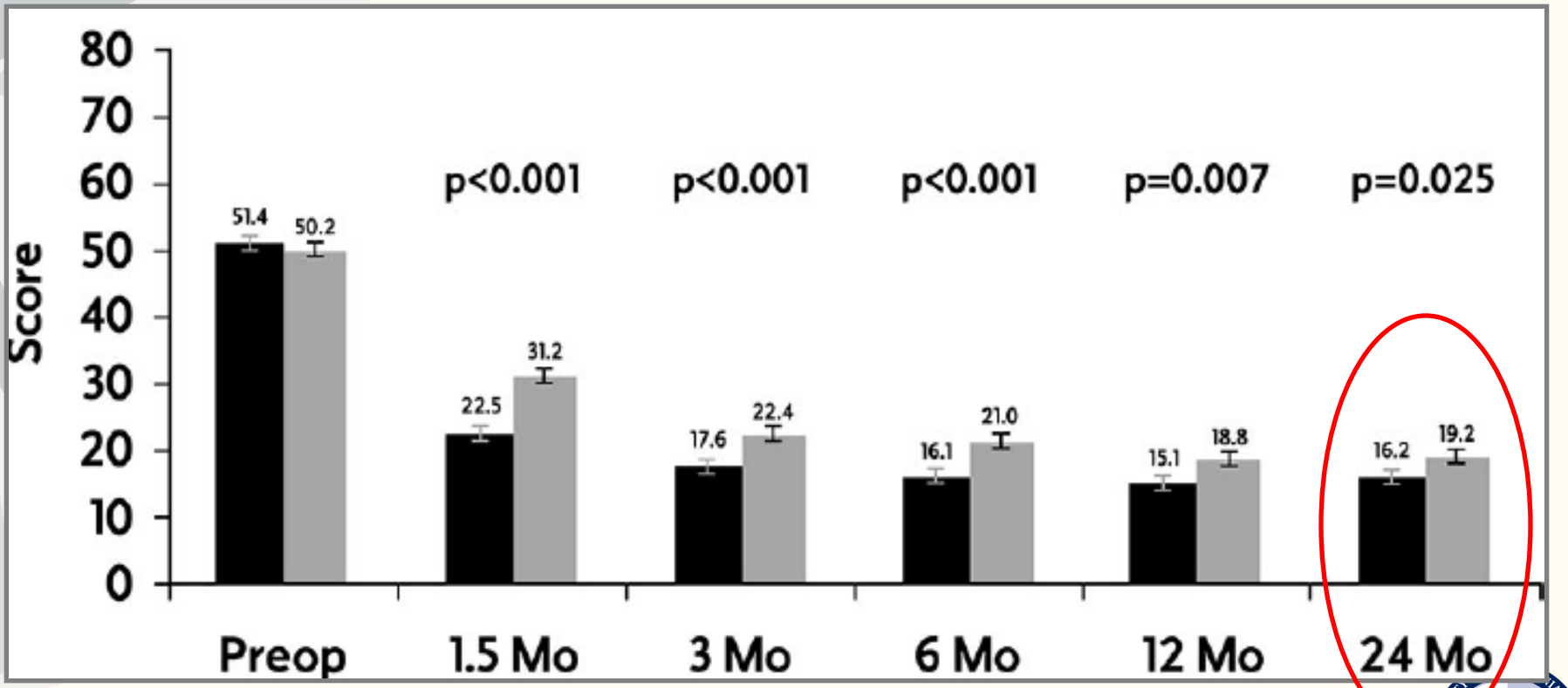
Bryan IDE

- Lower neck pain score for CDR at all time points



Bryan IDE

- Lower NDI score for CDR at all time points
  - Difference may not be clinically significant



Spine • Volume 34 • Number 2 • 2009

Bryan IDE

- 13 day earlier RTW in CDR group
  - ? Due to collar use in ACDF group

Letters

To the Editor:

Re: Comparison of Bryan cervical disc arthroplasty with anterior cervical decompression and fusion. Clinical and radiographic results of a randomized, controlled clinical trial.

Ronald H.M.A. Bartels, MD, PhD
Department of Neurosurgery
Radboud University Nijmegen Medical Centre
Nijmegen, The Netherlands

SPINE Volume 34, Number 16, pp 1740–1741

During a meeting in Orlando, FL, the results of this study were presented. When asked for, the presenter admitted that a collar was prescribed if the patients who underwent a cervical anterior discectomy with fusion.[2] The study was also presented during Eurospine in Geneva in 2008. The presentation even included a slide showing this difference that also was statistically different.[3]

I can imagine that patients wearing a collar are not allowed to drive or to perform certain activities. Therefore, the prescription of a collar is a major confounding factor. In other words, the faster return-to-work is not related to the effects of an arthroplasty, but to wearing a collar. To evaluate this properly, either the results are

ProDisc-C IDE

Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease

Daniel Murrey, MD[a,*], Michael Janssen, DO[b], Rick Delamarter, MD[c], Jeffrey Goldstein, MD[d], Jack Zigler, MD[e], Bobby Tay, MD[f], Bruce Darden, MD[a]

- Metal on UHMWPE with CoCrMo alloy and midline keel
- CDR (103 pts) vs. ACDF (106 pts)
- No differences in any clinical outcome measures at 1 or 2 yrs

The Spine Journal 9 (2009) 275–286

IDE ProDisc-C

- Significant differences at 2 yrs in favor of CDR
  - Secondary surgeries
    - 9% ACDF vs 2% cTDR
      - Why such a “high” reoperation rate on ACDF’s within 2 years?
  - More patients on narcotics
    - 19% ACDF vs 10% cTDR
- Unblinded surgeon discretion used to prescribe further treatments

The Spine Journal 9 (2009) 275–286

Issues with cTDR Studies

- Short and mid-term data only
- Bias
  - Study design: Highly selective of patients
  - Conflict of interest
  - Enrollment bias (patient desire for cTDR)
- Have the goals (ROM and ASD) been achieved?
  - Most studies show non-inferiority

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Conflict of Interest

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

The authors have received or will receive benefits for personal and/or professional use from Medtronic Sofamor Danek in relation to products named in this article.

Comparison of BRYAN Cervical Disc Arthroplasty With Anterior Cervical Decompression and Fusion

Clinical and Radiographic Results of a Randomized, Controlled, Clinical Trial

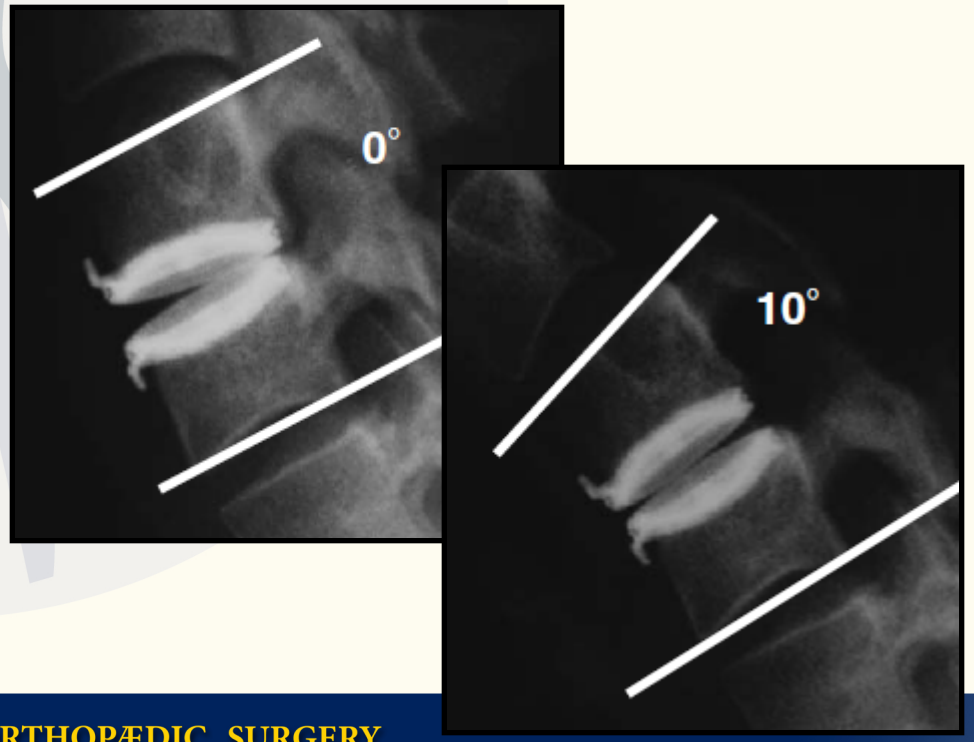
One or more author(s) has/have received or will receive benefits or professional use from a commercial party related directly or indirectly to this manuscript: *e.g.*, honoraria, gifts, consultancies, royalties, stocks, stock options, decision making position.

Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level

The authors MJ and RD acknowledge a financial relationship (consultants, lecturers, and speakers for Synthes Spine) that may indirectly relate to the subject of this research.

ROM

- Preserving ROM ↓ adjacent IDP/facet forces?
- 3 IDE studies with ≈ 7º ROM at treated segment
  - ≈ 15% of patients with ↓ ROM or ankylosis



Adjacent Level Disease

- Prevention of ALD is main focus of CDR
- Hilibrand, et at, 1999 is repeatedly cited

23. Hilibrand AS, Carlson GD, Palumbo M, Jones PK, Bohlman HH: Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. **J Bone Joint Surg Am 81:**519–528, 1999

2. Hilibrand AS, Carlson GD, Palumbo MA, et al. Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. *J Bone Joint Surg Am* 1999;81:519–28.

14. Hilibrand A, Carlson G, Palumbo M, et al. Radiculopathy and myelopathy at segments adjacent to the site of previous anterior cervical arthrodesis. *J Bone Joint Surg Am* 1999;81:519–28.

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Adjacent Level Disease

Radiculopathy and Myelopathy at Segments Adjacent to the Site of a Previous Anterior Cervical Arthrodesis*

BY ALAN S. HILIBRAND, M.D.†, GREGORY D. CARLSON, M.D.‡, MARK A. PALUMBO, M.D.§, PAUL K. JONES, PH.D.‡, AND HENRY H. BOHLMAN, M.D.‡, CLEVELAND, OHIO

Investigation performed at the Department of Orthopaedic Surgery, University Hospitals Spine Institute, Case Western Reserve University School of Medicine, Cleveland

- 2.9% per yr symptomatic adjacent level disease

of the arthrodesis or its extent. Therefore, we believe that symptomatic adjacent-segment disease is the result of progressive cervical spondylosis at adjacent levels and is not caused by the arthrodesis itself.

- In agreement with progression in non-fusion procedures (Henderson, 1983, Neurosurg)

J Bone Joint Surg Am. 1999;81:519-28

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Adjacent Level Disease

Assessment of adjacent-segment disease in patients treated with cervical fusion or arthroplasty: a prospective 2-year study

JAMES T. ROBERTSON, M.D., STEPHEN M. PAPADOPOULOS, M.D., AND VINCENT C. TRAYNELIS, M.D.

- Bryan vs. Affinity cage
- 2 yr FU
- Patients from separate RCT trials
- Cohort of patients 6 yrs apart

J Neurosurg Spine 3:417–423, 2005

Adjacent Level Disease

Summary of radiological findings obtained 24 months after surgery

Variable	Treatment Group (%)		p Value*
	Affinity Cage	Bryan Disc	
new osteophyte formation	28 (17.9)	8 (10.8)	0.175
osteophyte enlargement	14 (8.9)	0	0.006
DDD			
increase	6 (3.8)	3 (4.0)	1
new	3 (1.9)	1 (1.3)	1
ALL calcification increase	3 (1.9)	1 (1.3)	1
total of new x-ray changes	54 (34.6)	13 (17.5)	0.009

- 7% symptomatic in fusion group vs 0% in CDR
- Radiographs not blinded
- Posterior osteophytes not included

J Neurosurg Spine 3:417–423, 2005

But, Hold On . . .

- Nunley, et al. Spine 2011
  - 170 patients
  - Three randomized trials TDA = 113, ACDF = 57
  - Persistent symptoms → CT/MRI cervical spine
- Median f/u 42 months
- Rates of symptomatic ASD higher in TDA:
  - 14.3% ACDF
  - 16.8% TDA
- Associated Risk factors: osteopenia & concurrent lumbar disease

Nunley PD, Jawahar A, Kerr EJ 3rd, Gordon CJ et al. **Factors Affecting the Incidence of Symptomatic Adjacent Level Disease in Cervical Spine after Total Disc Arthroplasty: 2 - 4 Years Follow-Up of 3 Prospective Randomized Trials.** Spine (Phila Pa 1976). 2011 May 14

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Other Issues with cTDR: Imaging

- MRI imaging may be impossible in some devices
  - Sekhon, et al. Spine 32: 2007
  - Non-titanium devices make MRI imaging impossible due to artifact
    - PCM, Prodisc C
  - Could not visualize either the operated upon nor adjacent levels
  - With titanium devices, imaging was more feasible

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Other Issues with cTDR

- Will individual implant designs effect outcomes?
- Future revisions due to wear?

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So, Does cTDR Work?

- cTDR is likely non-inferior to ACDF in the short and mid-term
  - But long term results unknown
- Has not yet been proven to be “better”
  - ROM is maintained in some patients
    - May not be clinically relevant
    - Some cTDR develop ankylosis
  - ASD
    - Inconsistent data regarding effect of cTDR
    - Natural history of disc degeneration vs effect of fusion

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Summary

- Multiple cTDR options available and more coming
- Surgeon must know the indication/exclusion criteria
  - Critical for patient outcomes
- Long term clinical impact remains unclear

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Thank You!