

# Cervical Disc Arthroplasty: Where are we today?

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## Disclosures

Consulting – Aesculap Spine



## Goals for the next 10 minutes:

- Update on the latest publications from the clinical trials
- What are some of the problems and controversies
- How many levels are appropriate
- Future directions

# Neurosurgical Focus 2017

Survey of 383 AOSpine International members

84.3% performed ACDF as standard procedure








47.8% Occasionally performed ADR

7.3% Used ADR as standard

Concerns for adoption

Lack of evidence

Cost

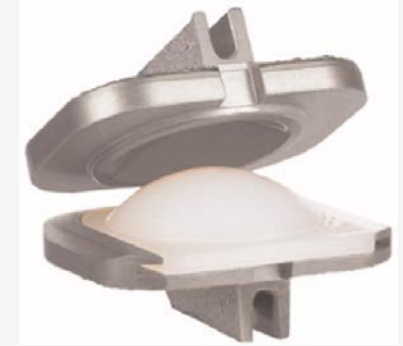
Product/ Sponsor	Level	MoA	Efficacy	Safety
ProDisc-C Centinal Spine (2008) 	1	CoCrMo endplates w/ Ti plasma coating UHMWPE core Ball & socket design	Overall Success: 72.3% NDI: 21.4	SS: 1.8%
BRYAN Medtronic (2009) 	1	Ti Shells & Wires PCU/PE nucleus	Overall Success: 80.4% NDI: 16.2	SS: 2.5%
PCM NuVasive (2012) 	1	CoCrMo endplates UHMWPE spacer	Overall Success: 72.0% NDI: 21.8	SS: 5.2%
SECURE-C Globus (2012) 	1	CoCrMo endplates w/ Ti plasma coating UHMWPE core	Overall Success: 90.1% NDI: ~12	SS: 2.5%
Mobi-C Zimmer (2013) 	2	CoCrMo endplates w/ Ti-hydroxyapatite coating	Overall Success: 73.7% (1-lvl), 69.7% (2-lvl) NDI: ~15 (1-lvl), ~17 (2-lvl)	SS: 1.2% (1-lvl), 3.1% (2-lvl)
Prestige LP Medtronic (2016) 	2	Ti-Ceramic composite w/ plasma spray coating	Overall Success: 79.3% NDI: ~15 (both 1 and 2-lvl)	SS: 5.0% (1-lvl), 2.4% (2-lvl)
M6-C Orthofix (2019) 	1	Ti Alloy endplates PCU/UHMWPE artificial nucleus	Overall Success: 86.8% NDI: 90.5%* (*>15pt improvement)	SS: 1.9%

UHMWPE = Ultra High Molecular Weight Polyethylene, PE = Polyethylene, PCU = Polycarbonate Urethane, NDI = Neck Disability Index, SS = Secondary Surgery

# ProDisc-C Total Disc Replacement Versus Anterior Cervical Discectomy and Fusion for Single-Level Symptomatic Cervical Disc Disease

Seven-Year Follow-up of the Prospective Randomized U.S. Food and Drug Administration Investigational Device Exemption Study

Michael E. Janssen, DO, Jack E. Zigler, MD, Jeffrey M. Spivak, MD, Rick B. Delamarter, MD, Bruce V. Darden II, MD, and Branko Kopjar, MD, MS, PhD



- 97% Follow Up
- 85% Satisfaction Rate
- 88% Neurologic Success
- Reoperation Rate: 7% ADR:18% ACDF
- 11% HO with Loss of Motion

# Long-term Evaluation of Cervical Disc Arthroplasty with the Mobi-C® Cervical Disc: A Randomized, Prospective, Multicenter Clinical Trial with Seven-Year Follow-up

Kris Radcliff, MD,<sup>1</sup> Reginald J. Davis, MD,<sup>2</sup> Michael S. Hisey, MD,<sup>3</sup> Pierce D. Nunley, MD,<sup>4</sup> Gregory A. Hoffman, MD,<sup>5</sup> Robert J. Jackson, MD,<sup>6</sup> Hyun W. Bae, MD,<sup>7</sup> Todd Albert, MD,<sup>8</sup> Dom Coric, MD<sup>9</sup>

<sup>1</sup>Department of Orthopedic Surgery, Rothman Institute, Thomas Jefferson University, Egg Harbor, NJ, <sup>2</sup>Greater Baltimore Neurosurgical Associates, Baltimore, MD, <sup>3</sup>Texas Back Institute, Plano, TX, <sup>4</sup>Spine Institute of Louisiana, Shreveport, LA, <sup>5</sup>Orthopedics Northeast, Fort Wayne, IN, <sup>6</sup>Orange County Neurosurgical Associates, Laguna Hills, CA, <sup>7</sup>Cedars-Sinai Spine Center, Los Angeles, CA, <sup>8</sup>Hospital for Special Surgery, Cornell Medical College, New York, NY, <sup>9</sup>Carolinas Medical Center, Carolina Neurosurgery & Spine Associates, Charlotte, NC



- F/U 84.4% ADR:75% ACDF
- Overall Success:
  - 1-level 55.2% ADR 50% ACDF
  - 2-level **60.8% ADR 34.2% ACDF**
- Bridging Bone:
  - 1-level: **11.1%**
  - 2-level **11.1%**
- Maintenance of motion in both 1- and 2-level
- Decreased ASD in 1- and 2-level
- Reduction in secondary surgeries in ADR groups

2-level group demonstrated superiority to ACDF

# Ten-year Outcomes of Cervical Disc Replacement With the BRYAN Cervical Disc

*Results From a Prospective, Randomized, Controlled Clinical Trial*

William F. Lavelle, MD,\* K. Daniel Riew, MD,<sup>†</sup> Allan D. Levi, MD, PhD,<sup>‡</sup> and Jeffrey E. Florman, MD<sup>§</sup>



- F/U 54% ADR (130/242) 48% ACDF (105/221)
- Overall Success
  - 81.3% ADR
  - 66.3% ACDF
- Maintained Angular Motion
- Decreased ASD



# Two-level cervical disc arthroplasty versus anterior cervical discectomy and fusion: 10-year outcomes of a prospective, randomized investigational device exemption clinical trial

Matthew F. Gornet, MD,<sup>1</sup> Todd H. Lanman, MD,<sup>2</sup> J. Kenneth Burkus, MD,<sup>3</sup> Randall F. Dryer, MD,<sup>4</sup> Jeffrey R. McConnell, MD,<sup>5</sup> Scott D. Hodges, DO,<sup>6</sup> and Francine W. Schranck, BSN<sup>7</sup>

<sup>1</sup>The Orthopedic Center of St. Louis, St. Louis, Missouri; <sup>2</sup>Institute for Spinal Disorders, Cedars-Sinai Medical Center, Los Angeles, California; <sup>3</sup>Wilderness Spine Services, Columbus, Georgia; <sup>4</sup>Central Texas Spine Institute, Austin, Texas; <sup>5</sup>Orthopedic Specialists, Allentown, Pennsylvania; <sup>6</sup>Center for Sports Medicine & Orthopaedics, Chattanooga, Tennessee; and <sup>7</sup>SPIRITT Research, St. Louis, Missouri

- Overall Success: 80.4% ADR    62.2% ACDF
- Secondary Surgeries
  - 9.0% ADR
  - 17.9% ACDF
- Grade III or IV HO 39%



## Cervical disc arthroplasty: 10-year outcomes of the Prestige LP cervical disc at a single level

Matthew F. Gornet MD<sup>1</sup>, J. Kenneth Burkus MD<sup>2</sup>, Mark E. Shaffrey MD<sup>3</sup>, Francine W. Schranck BSN<sup>4</sup> and Anne G. Copay PhD<sup>4</sup>

<https://thejns.org/spine/view/journals/j-neurosurg-spine/31/3/article-p317.xml>

- No significant changes from 7 year data
- Class IV HO
  - 2 yr – 1.2%
  - 7 yr – 4.6%
  - 10 yr – 9.0%

# Long-Term Clinical Experience with Selectively Constrained SECURE-C Cervical Artificial Disc for 1-Level Cervical Disc Disease: Results from Seven-Year Follow-Up of a Prospective, Randomized, Controlled Investigational Device Exemption Clinical Trial

ALEXANDER VACCARO, MD, PHD,<sup>1</sup> WILLIAM BEUTLER, MD,<sup>2</sup> WALTER PEPPELMAN, DO,<sup>2</sup> JOSEPH MARZLUFF, MD,<sup>3</sup> ANDREW MUGGLIN, PHD,<sup>4</sup> PREM S. RAMAKRISHNAN, PHD,<sup>5</sup> JACQUELINE MYER,<sup>5</sup> KELLY J. BAKER, PHD<sup>5</sup>

<sup>1</sup>Rothman Institute, Philadelphia, Pennsylvania, <sup>2</sup>Pennsylvania Spine Institute, Harrisburg, Pennsylvania, <sup>3</sup>Trident Regional Medical Center, Charleston, South Carolina, <sup>4</sup>Paradigm Biostatistics LLC, Anoka, Minnesota, <sup>5</sup>Globus Medical, Audubon, Pennsylvania



- Overall Success: 86.3% ADR    70% ACDF
- Decreased surgery for ASD in ADR group
- Maintained ROM
- HO 7.7%

CLINICAL ARTICLE

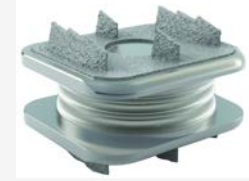
# Comparative Study Between M6-C and Mobi-C Cervical Artificial Disc Replacement: Biomechanical Outcomes and Comparison with Normative Data

My Pham, MD, Kevin Phan, MD, Ian Teng, MD, Ralph J Mobbs, MD

*NeuroSpine Surgery Research Group (NSURG), Prince of Wales Private Hospital, Sydney, New South Wales, Australia*

- 2 year data awaiting publication
- Comparison showed relatively same flexion/extension

Stay Tuned



Literature Review

# Artificial Discs in Cervical Disc Replacement: A Meta-Analysis for Comparison of Long-Term Outcomes

Waseem Wahood <sup>1, 2</sup>, Yagiz Ugur Yolcu <sup>1, 2</sup>, Panagiotis Kerezoudis <sup>1, 2</sup>, Anshit Goyal <sup>1, 2</sup>, Mohammed Ali Alvi <sup>1, 2</sup>, Brett A. Freedman <sup>3</sup>, Mohamad Bydon <sup>1, 2</sup>  

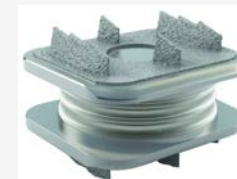
Looked at 65 studies and evaluated HO, ASD, reoperation rate

## Conclusions

The results of the present meta-analysis indicate that surgical and clinical outcomes may differ among different CDR devices. These findings may assist surgeons in tailoring their decision making to specific patient profiles. Future multicenter efforts are needed to validate associations found in this study.

# All Discs aren't the same

- Different Axis of Rotation
- Different Degrees levels of constraint
- Different ROM
- Different Levels of HO
- Sizes
- Shapes
- Methods of Fixation



# Heterotopic Ossification After Cervical Total Disc Replacement at 7 Years—Prevalence, Progression, Clinical Implications, and Risk Factors

PIERCE D. NUNLEY, MD, DAVID A. CAVANAUGH, MD, EUBULUS J. KERR III, MD, PHILLIP ANDREW UTTER, MD, PETER G. CAMPBELL, MD, KELLY A. FRANK, MS, KYLE E. MARSHALL, MS, MARCUS B. STONE, PhD

*Spine Institute of Louisiana, Shreveport, Louisiana*

More research is needed on:

- Clinical significance
- Causes
- Predictive modeling

## Safety and Efficiency of Cervical Disc Arthroplasty in Ambulatory Surgery Centers vs. Hospital Settings

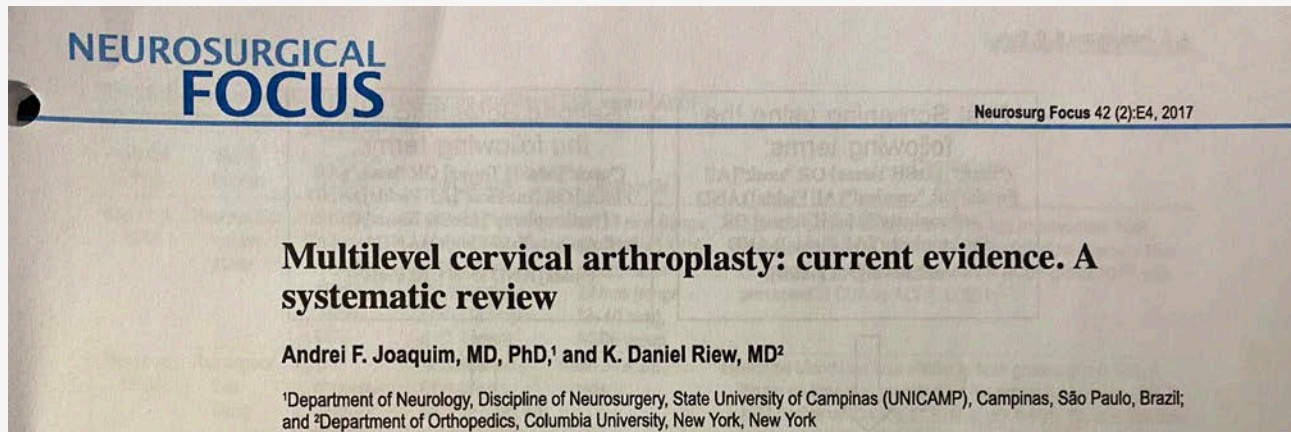
MATTHEW F. GORNET, MD,<sup>1</sup> GLENN R. BUTTERMANN, MD, MS, FAAOS,<sup>2</sup> RICHARD WOHNS MD, JD, MBA,<sup>3</sup> JASON BILLINGHURST, MD,<sup>4</sup> DARRELL C. BRETT, MD,<sup>5</sup> RICHARD KUBE, MD,<sup>6</sup> J. RAFAE SALES, MD,<sup>7</sup> NICHOLAS J. WILLS, MD,<sup>8</sup> ROSS SHERBAN, MD,<sup>9</sup> FRANCINE W. SCHRANCK, BSN,<sup>10</sup> ANNE G. COPAY, PhD<sup>10</sup>

<sup>1</sup>*The Orthopedic Center of St Louis, St Louis, Missouri,* <sup>2</sup>*Midwest Spine & Brain Institute, Stillwater, Minnesota,* <sup>3</sup>*NeoSpine, Puyallup, Washington,* <sup>4</sup>*Orthopedic Center of Palm Beach County, Atlantis, Florida,* <sup>5</sup>*Northwest Spine Surgery, Portland, Oregon,* <sup>6</sup>*Prairie Spine and Pain Institute, Peoria, Illinois,* <sup>7</sup>*Northwest Spine & Laser Center, LLC, Portland, Oregon,* <sup>8</sup>*Summit Orthopedics, Eagan, Minnesota,* <sup>9</sup>*Sherban Spine Institute, Boynton Beach, Florida,* <sup>10</sup>*SPIRITT Research, St Louis, Missouri*

- 145 pts treated in ASC
- Shorter surgery times
- Less Blood Loss
- 1- and 2- level safe in ASC

# Is Multilevel cTDR effective?

Long-term results from multiple RCTs for 2-level  
Can offer equivalent clinical outcomes  
Lower Cost



- 42 articles reviewed
- Higher HO rate in multi-levels, but questionable clinical significance
- More research is needed



# My Advice

Know your Device

Learn how to balance multilevel surgery with that device

Definitely don't make it your first case with a new device



Where will the future take us?

Hybrids

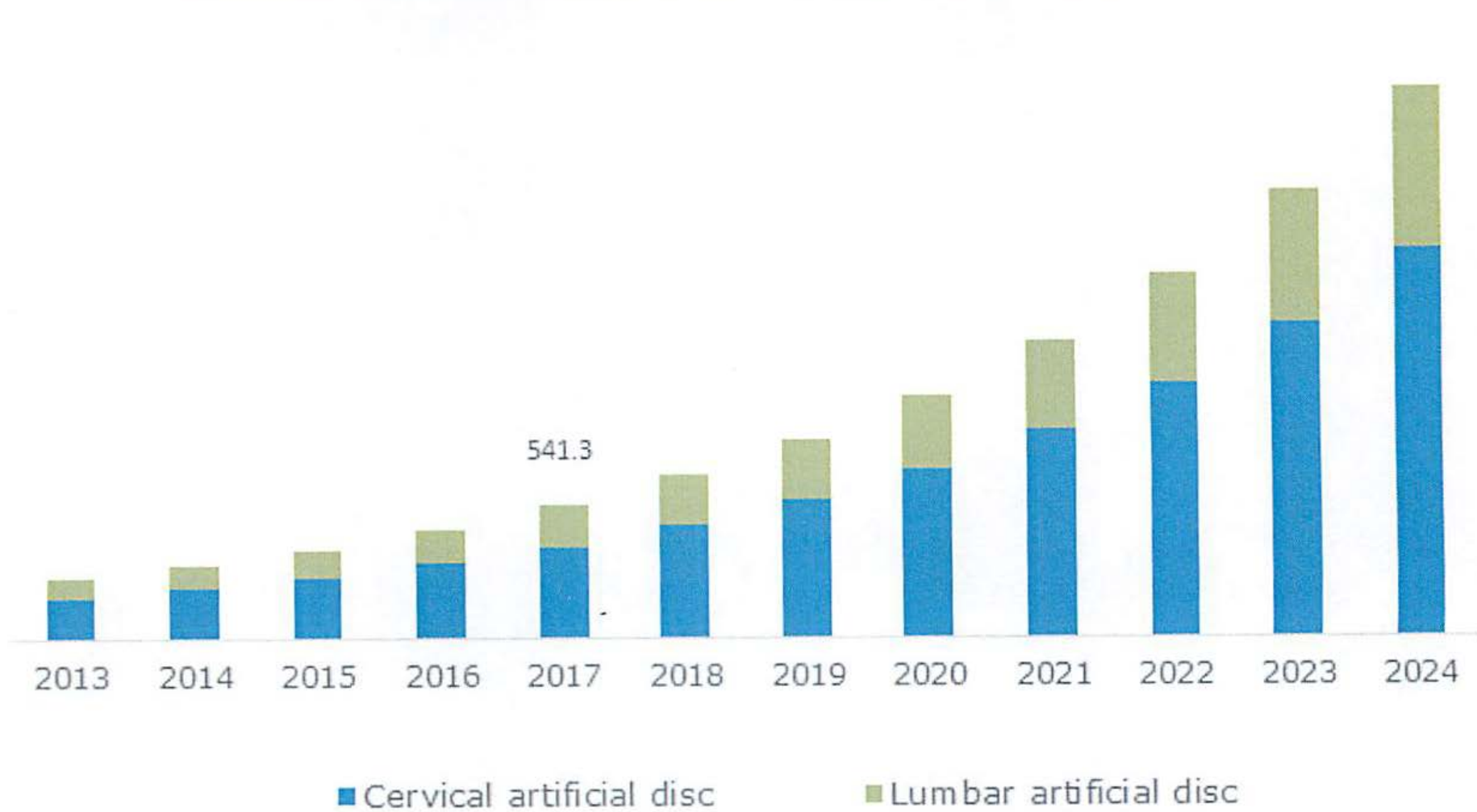
- Initial Surgery
- Adjacent to a prior fusion

Moving away from metal on poly

- M6
- Simplify



U.S. Artificial Disc Market, By Type, 2013 – 2024, (USD Million)



Cervical Total Disc Replacement Device Market Detail Analysis focusing on Application, Types and Regional Outlook

### CERVICAL TOTAL DISC REPLACEMENT DEVICE MARKET DETAIL ANALYSIS FOCUSING ON APPLICATION, TYPES AND REGIONAL OUTLOOK

📅 JANUARY 11, 2020    👤 NEHA@XPLOREMR.COM    📄 CERVICAL TOTAL DISC REPLACEMENT DEVICE  
MARKET, CERVICAL TOTAL DISC REPLACEMENT DEVICE MARKET GROWTH, CERVICAL TOTAL DISC  
REPLACEMENT DEVICE MARKET TRENDS

#### RECENT POSTS

Microgrid Market 2019-2026 –  
Competitive Market analysis, Scope,  
Trend, Stake, Progress, and Forecast

- It's MIS
- Quick recovery
- Short hospital stay
- Low revision rate
- "doctors prefer disc replacement over fusion"
- Surge in acquisitions and mergers have spurred the trends

# Thank You

