Rebuttal: All Cervical Arthroplasty Devices Are The Same

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Selby Spine
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TDR VS ACDF

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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,[1] Reginald J. Davis, MD,[2] Michael S. Hisey, MD,[3] Pierce D. Nunley, MD,[4] Gregory A. Hoffman, MD,[5] Robert J. Jackson, MD,[6] Hyun W. Bae, MD,[7] Todd Albert, MD,[8] and Dom Coric, MD[9]
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- Comprehensive, long-term evaluation of TDR with Mobi-C Cervical Disc.
- A continuation of a prospective, US FDA IDE clinical trial comparing cervical TDR with Mobi-C Cervical Disc versus ACDF through a 7 year follow up.

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

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RESULTS

At 7 years post-op, composite success analysis demonstrates:

- 95% of patients from both groups who underwent TDR and 88% of ACDF patients reported being VERY SATISFIED
- Differences in clinical effectiveness of TDR vs ACDF becomes more apparent as treatment increases from one to two levels, indicating a significant benefit for TDR over ACDF for two-level procedures

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Currently Approved and Distributed Artificial Discs in the United States

- Over the last decade **7** arthroplasty devices have gained US (FDA) approval:

(All devices approved for single level arthroplasty)

- **Prestige ST** Cervical Disc (Medtronic Sofamor Danek)
- **Bryan** Cervical Disc (Medtronic Sofamor Danek USA Inc.)
- **ProDisc-C** Total Disc Replacement Device (Synthes Spine)
- **Secure-C** Cervical Artificial Disc (Globus Medical Inc.)
- **PCM** Cervical Disc (NuVasive Inc.)
- **Mobi-C** Cervical Disc (LDR Spine USA Inc.) – Approval for use at 2 levels
- **Prestige LP** Cervical Disc (Medtronic Sofamor Danek) – Approval for use at 2 levels

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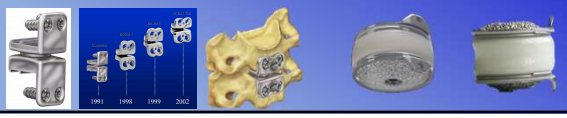
United States FDA Approved Devices

PRESTIGE ST (2007)

- **OLD Cummins/Bristol Disc from England**
- Metal on Metal
- Flexion/Extension +/- 10 degrees
- Lateral Bending +/- 10 degrees
- Unconstrained Axial Rotation
- AP Translation +/- 2mm

BRYAN (2009)

- Metal on Poly
- Lateral Bending +/- 11deg
- Flexion/Extension +/- 11deg
- AP Translation +/- 1mm
- Axial Rotation +/- 7deg



United States FDA Approved Devices

PRODISC-C (2007)

- Metal on Poly
- Flexion/Extension +/- 10 degrees
- Lateral Bending +/- 10 degrees
- Unconstrained axial rotation

SECURE-C (2012)

- Metal on Poly
- Flexion/Extension +/- 15 degrees
- Lateral Bending +/- 10 degrees
- Unconstrained axial rotation
- Translation in the sagittal plane +/- 1.25mm

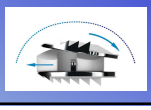
United States FDA Approved Devices

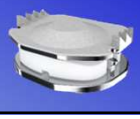
PCM (2012)

- Metal on Poly
- Flexion/Extension 6.5 +/- 3.25 degrees
- Lateral Bending 3.5 +/- 1.75 degrees
- Axial Rotation 2.3 +/- 1.17 degrees
  - Anatomically constrained motion

MOBI-C (2013)

- Metal on Poly
- Flexion/Extension +/- 10 degrees
- Lateral Bending +/- 10 degrees
- Axial Rotation- unconstrained
- Lateral Translation
- Antero-posterior Translation





United States FDA Approved Devices

PRESTIGE LP (2014)

- Ceramic on Ceramic
- Variable center of rotation
- Flexion/Extension +/- 10 degrees
- Lateral Bending +/- 10 degrees
- Unlimited axial rotation constrained by ligaments and posterior elements
- Translation +/- 2mm

Prosthesis Comparison (Overview)

PROSTHESIS	Classification	FIXATION/BEARING DESIGN	Motion
Prestige ST	Metal on Metal	FIXED	Semi-Contrained ball and socket
Bryan	Metal on Poly	MOBILE	Semi-Constrained ball and socket
ProDisc -C	Metal on Poly	FIXED	Semi-Constrained ball and socket
Secure-C	Metal on Poly	MOBILE	Semi-Constrained Ball and socket
PCM	Metal on Poly	FIXED	Minimally constrained large ball & socket
Mobi-C	Metal on Poly	MOBILE	Semi-constrained ball and socket with 5 degrees of freedom
Prestige LP	Ceramic on Ceramic	FIXED	Semi-constrained ball & socket reversed

What Does The Literature Say?

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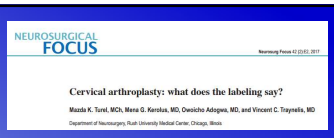

NEUROSURGICAL FOCUS

Cervical arthroplasty: what does the labeling say?

Mazda K. Turel, MCh, Mena G. Kerolus, MD, Owoicho Adogwa, MD, and Vincent C. Traynelis, MD

Department of Neurosurgery, Rush University Medical Center, Chicago, Illinois

- Comparing the labeling of 7 FDA-approved cervical discs for a single level.
- Primary hypothesis - each was a noninferiority hypothesis
  - overall success rate of the investigational group was statistically non-inferior to the rate in the control (ADCF) group.
- Overall Success defined as:
  - Improvement in patient **NDI score** by ≥ 20% or 15 points over baseline
  - **Neurological parameters and reflexes** were maintained or improved
  - No removals, revisions, reoperations, or additional fixations were required to modify any implant
  - No adverse events related to treatment, artificial disc or its implantation

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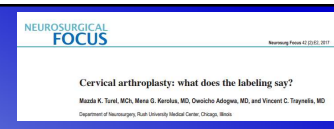

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TABLE 1. Comparison of labeling characteristics of the 7 FDA-approved artificial discs for a single level

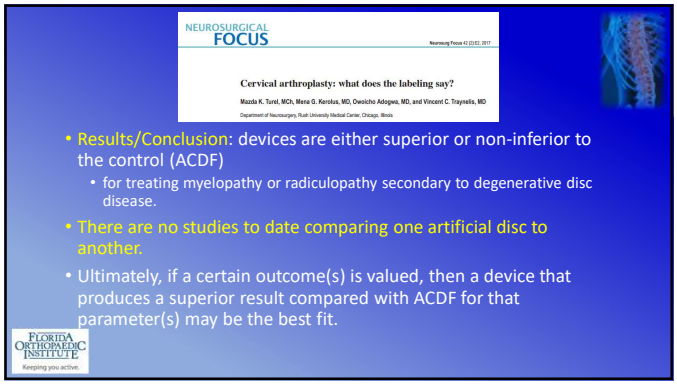
Disc (approval date)	Company	Study Design	Statistical Analysis	NDI	Neurological Success	Secondary Surgery	Overall Success
Prestige ST (2007)	Medtronic	RCT	Bayesian	Noninferior	Superior	Superior	Superior
ProDisc-C (2007)	Synthes	RCT	Frequentist	Noninferior	Noninferior	Superior	Noninferior
Bryan (2009)	Medtronic	RCT	Bayesian	Superior	Noninferior	Noninferior	Superior
Secure-C (2012)	Globus	RCT	Bayesian	Noninferior	Noninferior	Superior	Superior
PCM (2012)	NuVasive	RCT	Frequentist	Noninferior	Noninferior	Noninferior	Noninferior
Mobi-C (2013)	LDR	RCT	Frequentist	Noninferior	Noninferior	Noninferior	Noninferior
Prestige LP (2014)	Medtronic	Non-RCT (I = 280, C = 265)	Bayesian	Noninferior	Superior	Noninferior	Superior (w/o FSU)

C = control; I = intervention; RCT = randomized controlled trial.

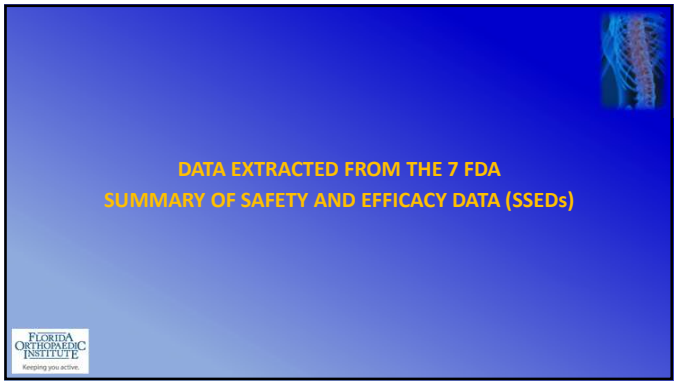
RESULTS In the single-level group, 4 of the 7 artificial discs—Prestige LP, Prestige ST, Bryan, and Secure-C—showed superiority in overall success. Prestige ST showed superiority in 3 of 4 outcome measures (neurological success, revision surgery, and overall success), while the other aforementioned discs showed superiority in 2 or fewer measures (Prestige LP, neurological and overall success; Bryan, Neck Disability Index [NDI] and overall success; Secure-C, revision surgery and overall success; Pro-Disc C, revision surgery). The PCM and Mobi-C discs demonstrated noninferiority across all outcome measures. In the 2-level group, Prestige LP and Mobi-C demonstrated superiority in 3 outcome measures (NDI, secondary surgery, and overall success) but not neurological success.

RESULTS

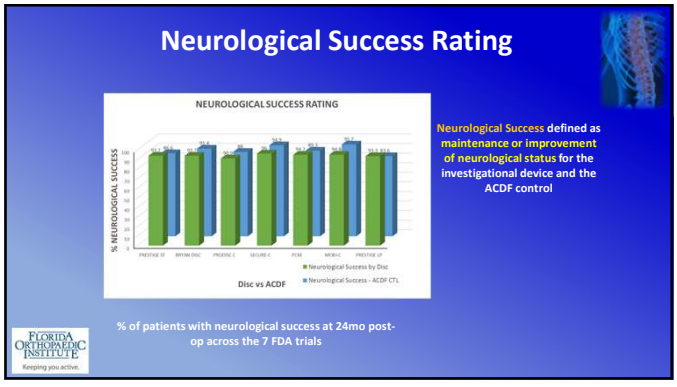
- 4/7 artificial discs (Prestige LP, Prestige ST, Bryan, and Secure-C) showed Superiority in Overall Success
- 3/7 artificial discs (ProDisc-C, PCM, and Mobi-C) showed Noninferiority in Overall Success



- Results/Conclusion: devices are either superior or non-inferior to the control (ACDF)
  - for treating myelopathy or radiculopathy secondary to degenerative disc disease.
- There are no studies to date comparing one artificial disc to another.
- Ultimately, if a certain outcome(s) is valued, then a device that produces a superior result compared with ACDF for that parameter(s) may be the best fit.



DATA EXTRACTED FROM THE 7 FDA SUMMARY OF SAFETY AND EFFICACY DATA (SSEDs)

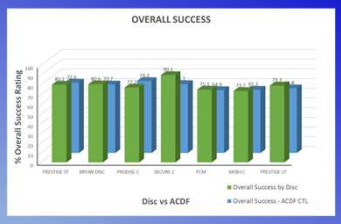


Neurological Success Rating

Neurological Success defined as maintenance or improvement of neurological status for the investigational device and the ACDF control

% of patients with neurological success at 24mo post-op across the 7 FDA trials

Overall Success



% of patients with overall success at 24mo post-op across the 7 FDA trials

Overall Success is defined by :

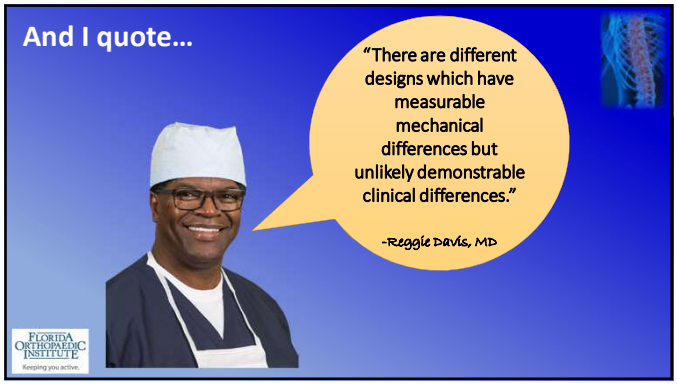
- Improvement in NDI score by > 20% or 15 points over baseline
- Neurological parameters and reflexes were maintained or improved
- No removals, revisions, reoperations, or additional fixations were required to modify any implant
- No adverse events related to treatment, artificial disc or its implantation

NDI Clinical Success Rating

Data reflects % patients with protocol-defined NDI Success at 24mo post-op across the 7 FDA trials

NDI Success defined as ≥ 15 points or ≥ 20% improvement in NDI Score relative to baseline

What the Experts Say


And I quote…
"There are different designs which have measurable mechanical differences but unlikely demonstrable clinical differences."
-Reggie Davis, MD
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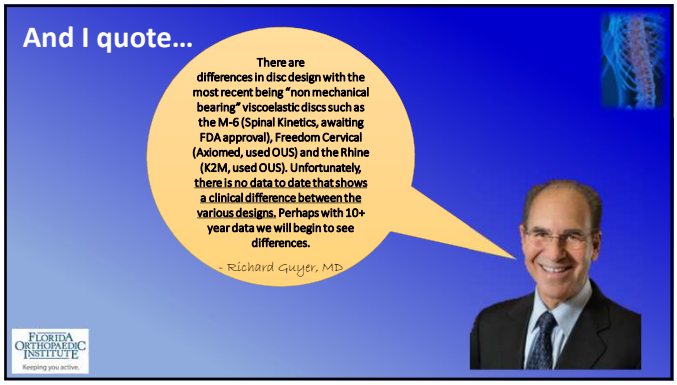
And I quote…
There are differences in disc design with the most recent being "non mechanical bearing" viscoelastic discs such as the M-6 (Spinal Kinetics, awaiting FDA approval), Freedom Cervical (Axiomed, used OUS) and the Rhine (K2M, used OUS). Unfortunately, there is no data to date that shows a clinical difference between the various designs. Perhaps with 10+ year data we will begin to see differences.
- Richard Guyer, MD
Florida Orthopaedic Institute
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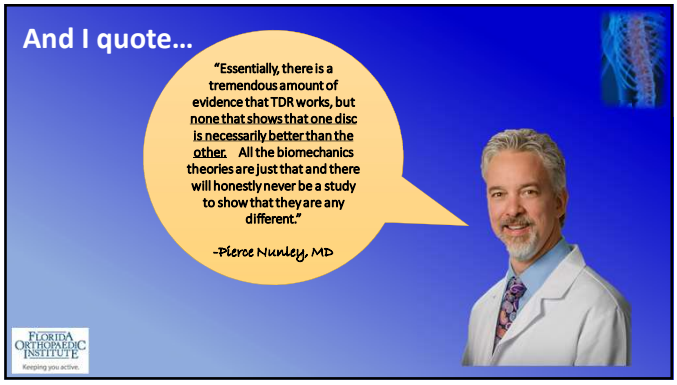
And I quote…
"Essentially, there is a tremendous amount of evidence that TDR works, but none that shows that one disc is necessarily better than the other. All the biomechanics theories are just that and there will honestly never be a study to show that they are any different."
-Pierce Nunley, MD
Florida Orthopaedic Institute
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Score card

- Small- 4
- Hisey- 1

All Arthroplasty Devices ARE THE SAME

- No studies comparing cervical disc replacement devices
- Subtle variations in the discs exist (design, indication, etc.)
- Studies ultimately show that the performance of these discs are uniform