


**Cervical Arthroplasty –  
History, What's Available and What's the Difference?**

**Michael S Hisey, M.D.**  
Past-President, Texas Back Institute  
Chairman, Board of Managers  
Texas Health Presbyterian Hospital,  
Flower Mound



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**Disclosures**

- Training faculty for Mobi-C (now ZimmerBiomet)
- Investigator on multiple cervical and lumbar ADR studies
- Will discuss on and off label indications



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**Cervical Arthroplasty**



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### FDA Approved in US

- **Approved**
  - Prestige-ST (2007)
  - ProDisc-C (2007)
  - Bryan (2009)
  - PCM (2012)
  - SECURE-C (2012)
  - Mobi-C (1 and 2-level; 2013)
  - Prestige-LP (1-level 2014, 2-level 2016)




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### Current FDA Status in US

- **Trials ongoing**
  - M6
    - 258 Patients Enrolled
    - In follow-up
  - Simplify 1 level
    - 150 Patients Enrolling
  - Simplify 2 level
    - 200 Patients Enrolling




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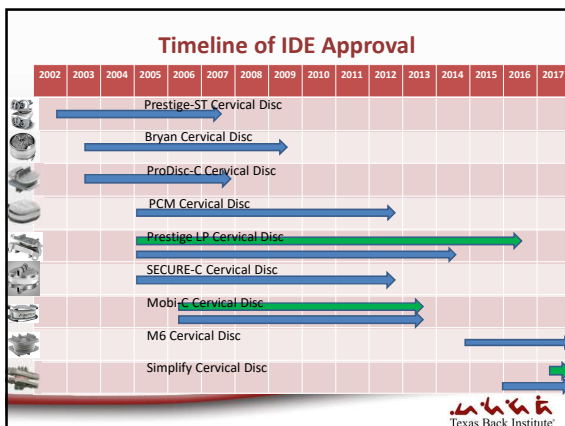
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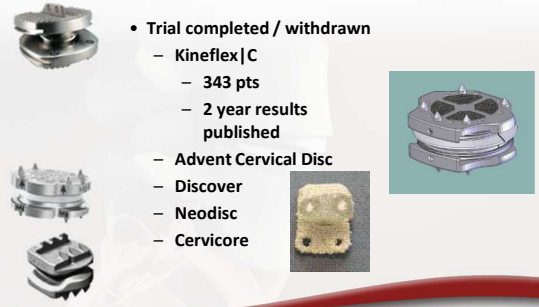
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### Current FDA Status in US

- Trial completed / withdrawn
  - Kineflex|C
    - 343 pts
    - 2 year results published
  - Advent Cervical Disc
  - Discover
  - Neodisc
  - Cervicore



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### Current Investigation Status OUS Registered on ClinicalTrials.gov

- Freedom Cervical Disc (Axiomed)
  - 50 pts, enrolling
- RHINE (K2M)
  - 166 pts, enrollment unknown
- Granvia-C (Medicrea)
  - 70 pts enrolled
- Triadyme-C (Dymicron)
  - 100 pts, 1&2 level, enrolling in Europe
- NuNeck (Pioneer/RTI)
  - 20 pts, UK Limited Trial
- CP-ESP (FH Orthopaedics)
  - 110 pts, enrolling



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### Differences

Focus on Devices Available or Currently under Study

• <b>Materials</b>	• <b>Type/Range of Motion</b>
• <b>Fixation/Technique</b> <ul style="list-style-type: none"><li>– Primary</li></ul>	– Degrees of Freedom
• <b>Articular Surface</b>	– Hard Stops
	• <b>Sizing</b>
	• <b>Indications</b>



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### Materials

- 5 Discs have CoCrMo Endplates
  - 4 with UHMWPE cores
    - Mobi-C
    - SecureC
    - PCM
    - ProDisc C
  - One with polycarbonate core and UHMWPE annulus
    - M6
- All with Ti Plasma Spray
  - Mobi C with Hydroxyapatite Coating
  - PCM with Calcium Phosphate Coating


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### Materials

- 2 Metal on Metal Discs
  - Prestige ST is Stainless Steel
  - Prestige LP is a Titanium/Ceramic Alloy
- One Titanium endplate with polycarbonate polyurethane core
  - Bryan
- One PEEK endplates with Ti Plasma Spray, Ceramic coated AL core
  - Simplify


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### Primary Fixation

- Screws
  - Prestige ST
- Keels
  - SecureC
  - ProDisc C
- Press Fit
  - Bryan
  - PCM
- Ridges/Teeth
  - Mobi-C
  - Prestige LP
  - Simplify
  - M6


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### Bearing Surface

- 4 Discs have CoCrMo Endplate vs UHMWPE
  - Mobi-C – 2 surfaces
  - SecureC - 2 surfaces
  - PCM - one surface
  - ProDisc C - one surface
- 2 Metal on Metal Discs
  - Prestige ST - Stainless Steel vs Stainless Steel
  - Prestige LP - Titanium/Ceramic Alloy



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### Bearing Surface

- 2 Metal Endplate with Polymer Core – Both with ingrowth prevention/debris containment skirts
  - Bryan - Titanium endplate with polycarbonate polyurethane core
  - M6 - CoCrMo Endplates with polycarbonate core
- One PEEK vs Ceramic Core
  - Simplify



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### Type of Motion

- Ball and Socket (Dome with congruent surface), ball convex up
  - F/E, Lateral Bend, Axial Rotation
    - ProDisc C
    - PCM



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### Type of Motion

- Ball and trough, ball convex down
  - F/E, Lateral Bend, Axial Rotation, AP translation
    - Prestige ST
    - Prestige LP





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### Type of Motion

- Multiple articulations -
- Ball and Socket (Dome with congruent surface) superior, ball convex up, flat articulation inferior, limited by tabs
  - F/E, Lateral Bend, Axial Rotation, AP and Lateral Translation
    - Mobi-C





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### Type of Motion

- Multiple articulations
- Ball and Socket (Dome with congruent surface) superior, ball convex up, cylindrical articulation inferior, oriented with axis transverse
  - F/E, Lateral Bend, Axial Rotation, AP Translation
    - Secure C





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### Type of Motion

- Multiple articulations
- Ball and Socket (Dome with congruent surface) superior and inferior, ball convex up superior, down inferior, contained by lips
  - F/E, Lateral Bend, Axial Rotation, AP and Lateral Translation
  - Simplify


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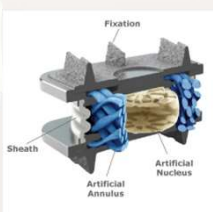

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### Type of Motion

- Metal with Polymer Core
  - 6 degrees of freedom
  - Bryan
  - M6


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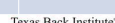
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### Sizing – A significant differentiator

	Height Range	Endplate Footprints/Sizes	Lordosis option?	Total Sizes
Prestige ST	6-7mm (2)	3 depths	Parallel only	4
Prestige LP	5-8mm (4)	4 depths	Parallel only	13
Secure C	7-12mm (6)	4	Parallel and 6 degree	48
Bryan	6mm (1)	5 diameters	Parallel only	5
PCM	6.5-8mm (3)	3	Parallel only	9
Mobi-C	5-7mm (3)	6	Parallel only	18
Prodisc C	5-7mm (3)	6	Parallel only	18
M6	6-7mm (2)	4	Parallel only	8
Simplify	4-6mm (3)	3	Parallel and 5 degree	15




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### Indications

- All labeled for C34-C67
- Prestige LP and Mobi-C are indicated for contiguous 2 levels
- PCM labeling has an option for adjacent to fusion



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### Do They Work?

- Published Results
- Pain Scores
- Re-Operations
  - Same Site
  - Adjacent Levels
- Maintained Motion



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### Published Data From the PRCT's of Cervical Arthroplasty Implants

- 2 year IDE data
  - Bryan, Prestige, ProDisc-C, SecureC, PCM, Mobi-C, Kineflex|C
  - Cervicore (4 sites)
- 5 Year IDE data
  - ProDisc-C
  - Mobi-C 1&2 Levels (7 year accepted for publication)
  - PCM (some AE data at 7 years) Spine 2015
- 7 Year data
  - Prestige-ST J Neurosurg Spine 2014
  - ProDisc-C JBJS 97-A(4) 2015
  - Prestige-LP IJSS 2016
  - Prestige 2L JNS 2017



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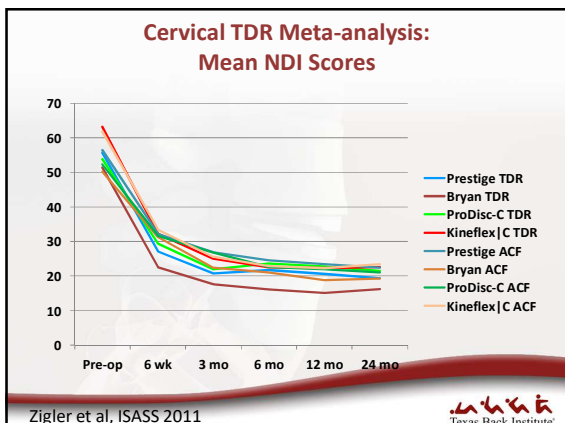
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### Do they work?

**At 5-7 year follow-up of large patient cohorts prospectively randomized to ADR vs. ACDF:**

- There is statistically significantly less radiographic Adjacent Level Degeneration in ADR patients
  - superior adjacent >> inferior adjacent
- Strong trend that motion is protective against any progression of ALD (p=.07)
- Motion is statistically significantly protective against severe ALD (p=.0013)
- Reoperation rates are less with ADR in all studies

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### SUMMARY OF MULTIPLE LEVEL I PUBLISHED STUDIES

- No data suggesting C-ADR inferior to ACF based on clinical outcomes, complications, or re-operations out to 5-7 years
- Strong Level I data shows that cervical ADR:
  - Reduces or delays adjacent segment degeneration compared with ACDF
  - Has a significantly lower re-operation rate than ACDF

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### Recommendations

- Become facile with at least a couple of the cervical devices
- Understand the sizing, positioning, disc prep and other technique differences between devices
- Stay close to the approved indications
- Think arthroplasty first
- Remember – all arthroplasty candidates are ACDF candidates, but not all ACDF candidates are arthroplasty candidates



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