# THE CURRENT STATE OF CERVICAL AND LUMBAR SPINAL DISC ARTHROPLASTY

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## TECHNOLOGY CREEP

The growth of spinal implant and orthobiologic technologies over the last several years is increasing in tempo (Figure 1) and fast approaching the US hip and knee markets in annual dollar sales. During this time, a number of start-up and established medical device manufacturers have focused increasing resources on solutions for spinal problems. The role of the orthopaedic and neurosurgeon in these enterprises as inventor, owner, and user has contributed to this march of progress. This exhibit describes a small (<1%), but increasingly visible, aspect of these advancing technologies, that of artificial disc replacement.

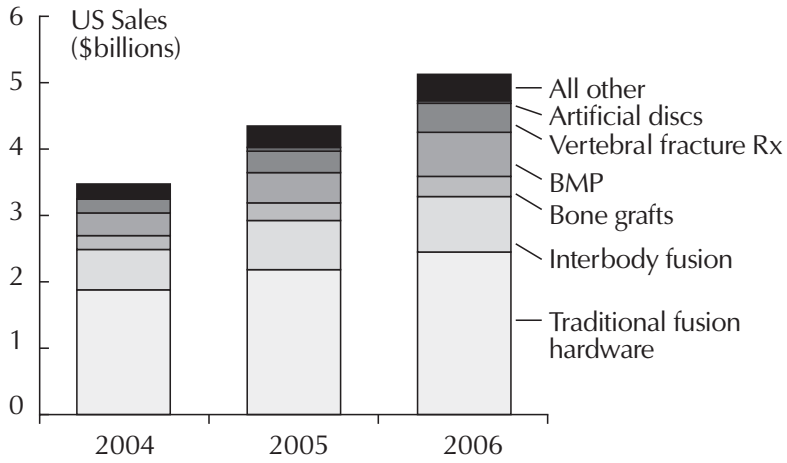


*Figure 1: US spinal device sales*
*Source: Orthopedic Network News*

## THE PROBLEMS THEY SOLVE

The etiology of mechanical back and neck pain is not well understood and is among the more difficult problems encountered by the spine surgeon. Specific pain generators may include the disc as well as the facet joints at any given or multiple level of the spinal column. Treatment goals, not unlike hip and knee reconstruction, seek to eliminate pain, maintain or restore stability, correct height loss, and in the case of disc arthroplasty, offer motion preservation. Fusion is the accepted gold standard of treatment, but lacks the latter prospect of intervertebral mobility. Successful patient outcomes for both lumbar and cervical fusion range from 60-85%, but report complications of adjacent spinal disc disease, incomplete pain relief, and morbidity arising from the surgical approach.[2,4-10,13]

# SPINAL DISC ARTHROPLASTY: A ROAD LESS TRAVELED

The emergence of disc arthroplasty as an alternative to fusion is dependent on careful patient selection. Lumbar disc arthroplasty is suited for discogenic low back pain without the presence of instability (Figure 2); whereas cervical replacements are currently indicated as an alternative to fusion in the absence of instability after discectomy and decompression for radiculopathy/myelopathy or for axial neck pain (Figure 3). These current indications will likely modify as experience with these devices is gained.[1,3,12,14]

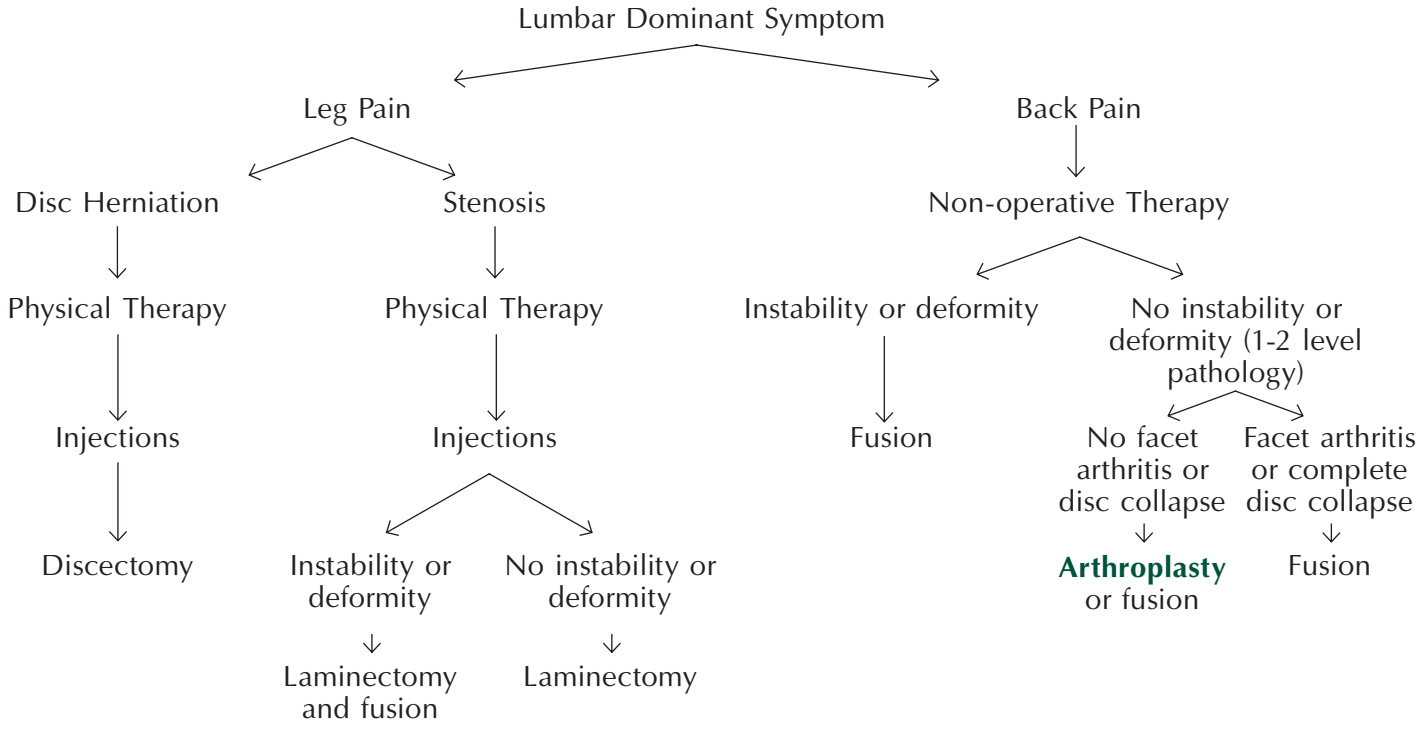


*Figure 2: Treatment algorithm for lumbar spine pathologies.*

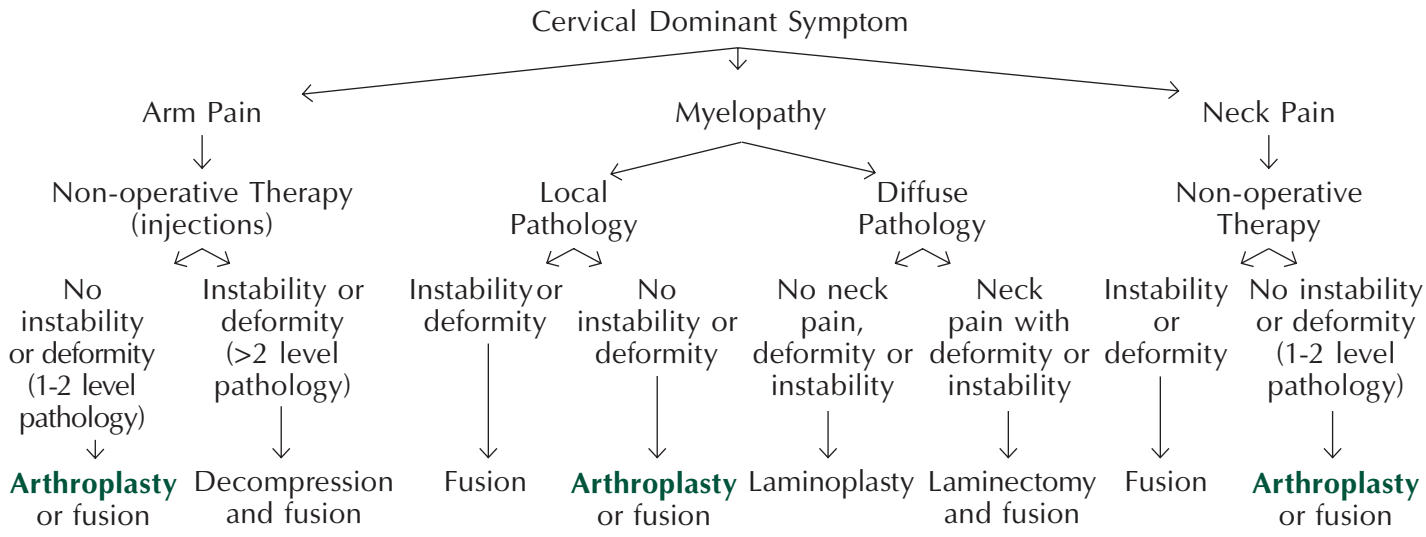


*Figure 3: Treatment algorithm for cervical spine pathologies.*

# REGULATION

Cervical and lumbar disc replacements have been determined by the US Food and Drug Administration (FDA) to be significant risk devices, requiring both pre-clinical and clinical evaluations to determine their safety and effectiveness. Although used in Europe for decades, recent interest in the United States has resulted in increasing numbers of ongoing FDA-sponsored clinical evaluations. The historical role of fusion serves as the concurrent control in these studies. The clinical investigative process has proved to be both arduous and costly, and is influenced by FDA reviewer familiarity with the device, surgeon investigator compliance, patient selection, complexity of surgical approach, as well as an early appreciation of laboratory testing requirements. To-date two lumbar discs have been cleared for marketing and one cervical disc has been recommended for approval with clearance expected during 2007 (Figures 4 - 6). All three have demonstrated that the clinical use of these articulations is "non-inferior" to their fusion control.

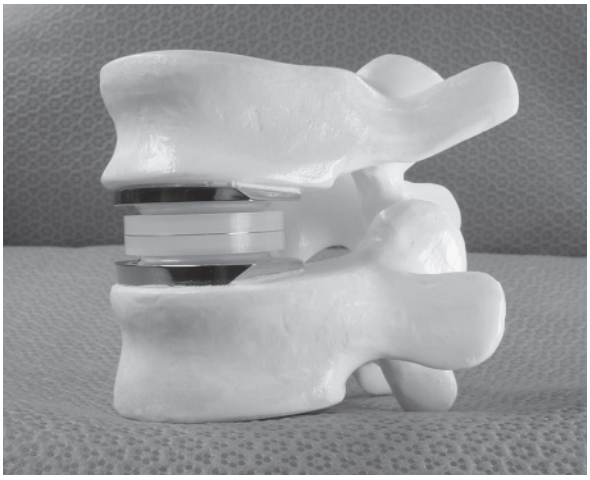

*Figure 4: Charité™ Lumbar Disc Replacement (DePuy Spine, Raynham, MA)*

*Figure 5: ProDisc®-L Lumbar Disc Replacement (Synthes, Paoli, PA)*

*Figure 6: Prestige™ ST Cervical Disc Replacement (Medtronic, Memphis, TN)*

# REIMBURSEMENT

"Necessary and sufficient" is an apt descriptor of the dual interactions a manufacturer must consider when embarking on the development of an artificial disc device. While demonstration of "safety and effectiveness" is a FDA requisite for gaining entry into the marketplace, it is not sufficient for ensuring reimbursement. The Center for Medicaid and Medicare Services (CMS) must further determine that artificial disc devices are "necessary and beneficial" for the majority of degenerative disc disease patients. The non-inferiority level of FDA approval has led CMS to a non-coverage decision for the Charité to-date for patients over 60 years of age. Such decisions influence third-party payers.

# WHAT'S IN THE PIPELINE?

To date, over 43 spinal disc devices are in various stages of development with ongoing clinical trials for many. These involve a variety of articulating as well as elastomeric designs with both contemporary and evolving biomaterials.

## *CERVICAL DISC REPLACEMENTS**

**FDA Clearance Imminent**

| Product Name | Company | Public Release | Description |
|---|---|---|---|
| PrestigeST | Medtronic | 1Q-2007 | Articulating Metal on Metal |

**In Clinical Studies under IDE**

| Product Name | Company | Estimated Release | Description |
|---|---|---|---|
| Bryan | Medtronic | 2Q-2007 | Articulating Metal on Polyurethane |
| ProDisc-C | Synthes | 4Q-2007 | Articulating Metal on PE |
| PCM | Cervitech | 3Q-2009 | Articulating Metal on PE |
| PrestigeLP | Medtronic | 2Q-2008 | Articulating Metal on Metal |
| Discover | DePuy Spine | 1Q-2010 | Articulating Metal on PE |
| CerviCore | Stryker Spine | 2Q-2010 | Articulating Metal on Metal |
| Catalina | SeaSpine | 3Q-2010 | Articulating Ceramic on Ceramic |
| NeoDisc | NuVasive | 4Q-2010 | Non-Articulating Polymer |
| CerPass | NuVasive | 1Q-2011 | Articulating Ceramic on Ceramic |
| Rescue | Biomet | 2Q-2012 | Articulating Pyrocarbon on Pyrocarbon |
| Secure-C | Globus Medical | | Articulating Metal on PE on Metal |
| Kineflex-C | Spinal Motion | | Articulating Metal on Metal on Metal |

**In Pre-clinical Study or non-US Use**

| Product Name | Company | Estimated Release | Description |
|---|---|---|---|
| Physio-C | Nexgen Spine Inc | | Non-Articulating Metal/Polymer |
| Cervidisc | Scient'x | | Articulating Ceramic on Ceramic |
| SaluDisc | Spine Medica | | Non-Articulating Hydrogel |
| CMP | Vertebron Inc. | | Articulating Metal on PE on Metal |
| Mobi-C | LDR Medical | | Articulating Metal on PE on Metal |

* Representation of publicly available information.

## *LUMBAR DISC REPLACEMENTS**

**FDA Cleared**

| Product Name | Company | Public Release | Description |
|---|---|---|---|
| Charité | DePuy Spine | 4Q-2004 | Articulating Metal on PE on Metal |
| ProDisc-L | Synthes | 3Q-2006 | Articulating Metal on PE |

**In Clinical Studies under IDE**

| Product Name | Company | Estimated Release | Description |
|---|---|---|---|
| Maverick | Medtronic | 1Q-2007 | Articulating Metal on Metal |
| FlexiCore | Spinecore/Stryker Spine | 1Q-2008 | Articulating Metal on Metal |
| Regain | Biomet | 2Q-2011 | Articulating Pyrocarbon on Pyrocarbon |
| Truedisc PL | Disc Motion | | Articulating |
| Kineflex-L | Spinal Motion | | Articulating Metal on Metal on Metal |
| TOPS System | Impliant LTD | | Non-Articulating Metal/Polymer |

**In Pre-clinical Study or non-US Use**

| Product Name | Company | Estimated Release | Description |
|---|---|---|---|
| Activ L | Aesculap Spine/B Braun | | Articulating Metal on PE |
| Freedom | Axiomed Corp. | | Non-Articulating Metal/Polymer |
| Mobidisc | LDR Medical | | Articulating Metal on PE on Metal |
| Physio-L | Nexgen Spine Inc | | Non-Articulating Metal/Polymer |
| Cadisc | Ranier Technology Ltd. | | Non-Articulating Polyurethane/Polycarbonate |
| La Jolla | SeaSpine | | Articulating Ceramic on Ceramic |
| SaluDisc | Spine Medica | | Non-Articulating Hydrogel |
| AID | Takiron Co. Ltd. | | Non-Articulating woven PE fibers |
| eDisc | Theken | | Non-Articulating Metal/Polymer |
| Spartacus | U.S. Spine | | Elastomer |
| LMP-S | Vertebron Inc. | | Articulating Metal on PE on Metal |
| LMP-U | Vertebron Inc. | | Articulating Metal on PE on Metal |

* Representation of publicly available information.

## MARKET FORCES

A number of factors will exert pressure on the market for disc replacement devices. Manufacturers must surmount significant challenges to participate in this segment, including the high cost of technology development and/or acquisition, an arduous regulatory clearance process and uncertain navigation of an evolving reimbursement landscape. At present, no fewer than 13 cervical and 8 lumbar disc replacements are undergoing IDE clinical studies. All of these devices may reasonably be expected to receive FDA clearance within 5 years. Additionally, 5 cervical and 12 lumbar designs are in pre-clinical study or in use outside of the United States. Twenty-four distinct manufacturers account for these devices (See Tables). Clinically, disc replacement shares the spine care space with multiple treatment modalities. The sum of these factors hints at a crowded, hyper-competitive environment for manufacturers of disc replacement devices.

## CLINICAL IMPACT - *CAVEAT EMPTOR!*

Manufacturers will necessarily face a return-on-investment imperative. This will almost certainly manifest itself through persistent marketing and sales efforts contributing to expanding clinical use. Cold reason, peer-reviewed literature, and the early suboptimal experience with spinal cages should remain paramount in the minds of spine and neurosurgeons as disc replacement asserts itself in the universe of spine care options.[11] Increasing patient awareness and the specter of direct to consumer advertising may also be a factor impacting clinical practice. Disc replacement, like mobile bearing knees and hip resurfacing, suggests improved functionality and avoidance of complications associated with alternative procedures. These are messages likely to find a receptive audience among potential patients. Spine and neurosurgeons should expect a surge of marketing messages and a confounding horde of disc replacement designs and usage guidelines as new devices enter the market, thus *caveat emptor* may be an appropriate mantra for the short-term and interim future of disc replacement in the US.

## AT THE END OF THE DAY...

- The FDA/CMS approval process is arduous and costly.
- Both lumbar and cervical spinal disc arthroplasty designs fit the significant risk device criteria defined by FDA and require both pre-clinical and clinical evaluation.
- The peer-reviewed literature describes clinical complications arising from their use which are suggestive of a steep learning curve.
- The current clinical indications for cervical and lumbar disc arthroplasty are limited with application emphasis on the former.
- To-date there are no long-term US outcome reports, suggesting that motion restorative devices will succeed and this is a factor in CMS's reimbursement decision.
- Rational, clinical diagnostic judgments by both orthopaedic and neurosurgeons is paramount in patient selection. "One size does not fit all, nor should it!"
- The ability to do something is not always an indication for doing it.
- Spinal disc replacement will define its niche in the paradigm of available treatments for degenerative disc disease as experience is gained from its application.

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