

Cervical and Lumbar Disc Replacement—The Ease of Revision

a report by

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Revisibility is one of the most important issues facing total disc arthroplasty (TDA)—it affects the adoption of this new technology. At the recent North American Spine Society (NASS) 20th annual meeting (4,000 members) the most well-attended sessions were symposia discussing the complications and revision strategies in cervical disc arthroplasty (CDA) and lumbar disc arthroplasty (LDA). The symposium Chairman Jeff Wang, Chief of Spinal Surgery at University of California Los Angeles (UCLA), aptly stated “The most polarizing issue in spinal surgery today is disc replacement—you are either 100% for it or 100% against it”.

In the first month of availability, more than 2,500 copies of the Quality Medical Publishing (QMP) monograph Roundtables in Spinal Surgery “*Complications and Revision Strategies in Lumbar Spine Arthroplasty*” were distributed.¹ To date, the first and only disc arthroplasty to be approved by the US Food and Drug Administration (FDA) via the investigational device exemption (IDE)/pre-market approval (PMA) process is the Charité disc. More than 2,000 spinal surgeons have already completed a mandatory company-sponsored two-day training course at the Spine Arthroplasty Center in Cincinnati. In fact, there have been more QMP monographs and surgeons trained in Charité implantation since FDA approval in October 2004 than there have been devices actually implanted in the US. The findings of the study are published in two peer-reviewed back to back articles in *Spine*.^{2,3} The key issue stimulating interest, yet dampening enthusiasm in the new technology, is the difficulty of revisions. In addition, the price point of US\$11,600 proved to be too high or higher than insurance

companies and third-party payers were willing to reimburse throughout the first year of introduction.

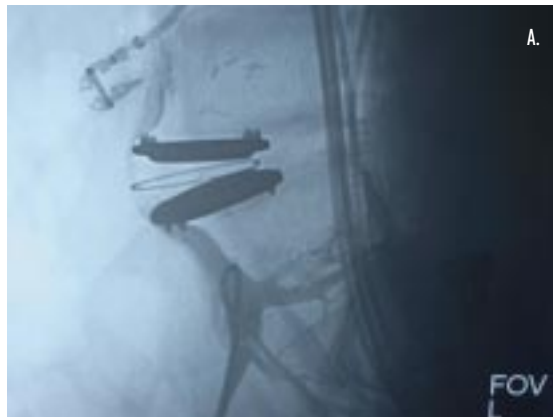
Indications

Although cervical and lumbar disc replacements are in their spinal surgical infancy, with regard to clinical application, the indications are already delineated. LDA is indicated for one- or two-level discogenic mechanical back pain, primarily in the absence of radiculopathy. ProDisc-L™, Maverick®, and Flexicore® are the three devices currently under FDA prospective trials listed in order of expected completion. In contrast, cervical disc replacement can be readily applied in patients presenting with neurologic deficit, radiculopathy, or myelopathy, because the approach and anterior spinal canal decompression are identical for anterior-cervical disc replacement and traditional Smith-Robinson cervical spinal decompression. In addition, the application of more complex spinal osteotomies, repair of pseudarthroses, and deformity correction are much more applicable in CDA procedures. This is due to the fact that even the most experienced vascular access surgeon has difficulty with the formidable revision through a repeat anterior lumbar procedure, whereas most experienced cervical spinal surgeons are familiar with repeat anterior cervical approaches. The first four front-runners in the cervical prospective FDA clinical trials are the BRYAN®, ProDisc-C™, Prestige™, and Porous Coated Motion (PCM™) devices.

Figure 1 shows a very serious complication requiring revision, which, unfortunately, is becoming increasingly commonplace. This is a 50-year-old man who fits the inclusion criteria for a Charité artificial

1. McAfee P C, Geisler F H, Scott-Young M, “*Complications and Revision Strategies in Lumbar Spine Arthroplasty*”, Quality Medical Publishing Volume 1, Number 2 (2005): pp. 133–213.
2. Blumenthal S, McAfee P C, Guyer R D et al., “*A Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemptions Study of Lumbar Total Disc Replacement With the Charité Artificial Disc Versus Lumbar Fusion. Part I: Evaluation of Clinical Outcomes*”, *Spine* (2005);30: pp. 1,565–1,575.
3. McAfee P C, Cunningham B C, Holsapple G et al., “*A Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemptions Study of Lumbar Total Disc Replacement With the Charité Artificial Disc Versus Lumbar Fusion. Part II: Evaluation of Radiographic Outcomes and Correlation of Surgical Technique Accuracy with Clinical Outcomes*”, *Spine* (2005);30: pp. 1,576–1,583.

Figure 1(A&B): Difficult Revision of a Displaced Total Disc Replacement Six Weeks Post-operatively



A 50-year-old white male was transferred to the author's institution following two successive anterior retroperitoneal approaches, both from the right side. He was originally an excellent candidate for an anterior Charité disc replacement and he fitted the FDA inclusion and exclusion criteria. He underwent an anterior retroperitoneal disc replacement at L4-L5. The original position of the implant was thought to be acceptable—size #4 footprint, 0° angled endplates and size 9.5mm ultra high molecular weight polyethylene (UHMWPE) core. A: Within six weeks he had anterior extrusion of 30% of the entire prosthesis. His original spinal surgeon, vascular specialist and a general surgeon all attempted a revision operation. This second procedure was aborted after five hours and over 5,000cc of blood loss. The surgeons could not expose the prosthesis as the left common iliac vein was 'too stuck down' against the anterior aspect of the vertebral column. The patient was transferred to the author's institution four days later where vascular imaging was performed—the lateral venogram is shown. The displaced prosthesis has compressed the left common iliac vein to a large extent. There are clots distal to the compression, meaning, intraoperatively, if the prosthesis is manipulated, the clots could dislodge and create a pulmonary embolism (PE).



B: The first stage of the revision procedure to salvage this failed LDA is to pass ureteral stents to aid in transperitoneal dissection. The second step is to insert an inferior vena caval filter to prevent a PE before manipulating the total disc replacement (TDR) prosthesis. The combined anterior and posterior revision procedure required removal of the prostheses, conversion to a 360° arthrodesis, and both anterior and posterior spinal instrumentation. This case demonstrates the extreme complexity and potential hazards of revision disc arthroplasty.

disc implant and had a size-4 prosthesis inserted at L4-L5. Six weeks after the procedure, the prosthesis slid out anteriorly. The surgeon attempted a revision through a left retroperitoneal approach. During the procedure, the patient lost 5,000ml of blood, and the surgeon was unable to visualize the prosthesis due to

extensive adhesions along the great vessels. Two vascular access surgeons were also unable to mobilize the vessels enough to expose the prosthesis. Five days after the failed revision, the patient was referred to the St Joseph Medical Center, where a venogram showed high-grade compression of the left common iliac vein and base of the inferior vena cava. The venogram disclosed blood clots distal to the displaced prosthesis. One of the potential consequences of removing the prosthesis is an immediate intra-operative pulmonary embolism (PE).

A Common Flaw in FDA Disc Arthroplasty Clinical Trials

Currently, the major deficiency in the rules and experimental design of the cervical and lumbar prospective randomized trials is that they do not differentiate between prostheses that are difficult or easy to revise. Every major review publication and design discussion of total knee arthroplasty (TKA) and total hip arthroplasty (THA) includes a major consideration for the 'ease of revision' or 'revisibility'.⁴ The clinical success of disc replacements, both CDA and LDA, in FDA IDE trials do not. The primary outcomes measure in the cervical spine, common to most studies, is the neck disability index (NDI). Approval of the specific device usually depends on the most frequent statistics—the patients in the arthroplasty group need a 15–20% improvement in outcomes with failures counted for:

- iatrogenic neurological deficit;
- reoperations; and
- device-related major adverse events (device slippage or displacement at the metal–bone interface of 3mm or more).

These are randomized against a population of fusion patients, 1:1 set up as 'non-inferiority studies', at two years follow-up. The problem being that it is to the manufacturer's advantage to utilize the strongest, bulkiest prosthesis to assure bony fixation for the first two years. There is no prioritization in the success criteria to distinguish or separate prosthetic designs, which are difficult or impossible to revise after the two-year clinical monitoring interval. Using the analogy of total hip replacement (THR), if the same FDA guidelines are applied, a long-stem fully-cemented femoral revision style component would have a greater success and FDA approvability compared with a standard length press-fit femoral component, which would be easier to revise beyond the two-year deadline. The FDA argues that revisibility problems would be sorted out in the five-

4. Link H D, McAfee P C, Pimenta L, "Choosing a Cervical Disc Replacement" Spine Journal (2004);4: 294S–302S.

year post-approval surveillance period. However, as every surgeon knows:

- the major period of widespread safety issues occurs after FDA approval when the ‘Joe average’ surgeon implants the device; and
- after FDA IDE approval the patients are not monitored as closely—the complications that are voluntarily reported to the company are the only complications captured in the database.

In the first year of FDA approval of the Charité disc there were two deaths from PE highlighted in the lay press—one in New York and one in Florida. There were no cases of PE reported in the FDA IDE trial of the Charité disc implant.

Evaluation of Prosthesis Stability

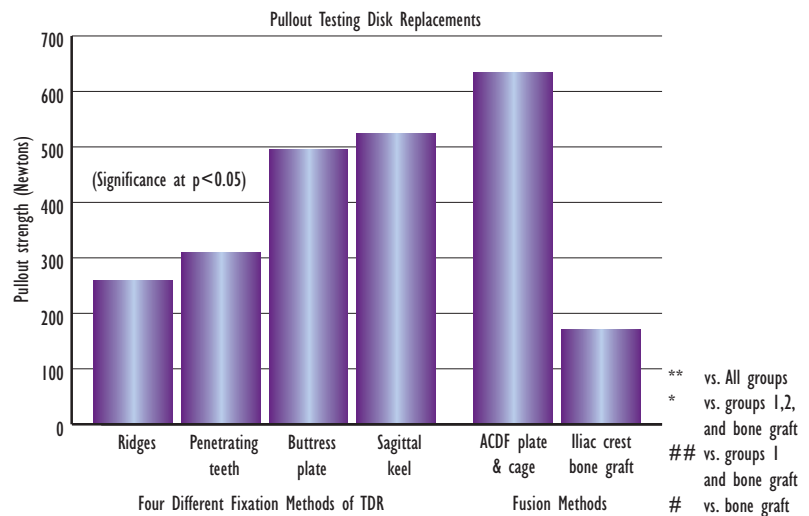
The purest example of differential prosthesis stability is illustrated in *Figure 2*, which shows a pull-out test of disc replacements compared with pull-out loads of spine fusion constructs—an interbody fusion cage combined with an anterior cervical plate (group 5 that had the highest tensile load) and iliac crest bone graft (group 6 having the lowest tensile load). The four disc implants from the lowest to highest pull-out differ in their strength of fixation at the metal–bone interface within the vertebral endplate:

- group 1, ridges;
- group 2, deep penetrating teeth;
- group 3, buttress plate and screw fixation; and
- group 4, midline sagittal keel that penetrates into the vertebral body.

Group 4 obtained the highest acute fixation but would require a complete corpectomy with a two-level spinal fusion if a revision is required (see *Figure 3*). In contrast, group 1 fixation would be more easily revised by sequentially progressing to group 2, group 3 or group 4 means of subsequent fixation as, it is hoped, decades of motion preservation will continue.

The cleanest statistical means of accounting for ease of revisibility is to assign a delta value to each prosthesis according to where they fit along the revision difficulty spectrum. The prostheses that are easily revisible would be assigned a delta value of 15%, giving credit for preserving bone stock and a straightforward mechanism for separating the metal–bone interface without endangering neurovascular structures. Those with keels would receive a delta value of 10%,

Figure 2: Fixation Methods of Total Disc Replacement



The bar graph demonstrates a pure tensile load to failure biomechanical test of four various fixation methods for cervical disc replacements. Six treatment groups (N=8 tests/group). Loading parameters were rate=2.5mm/sec and -267N compressive pre-load. The same principles would apply for lumbar disc replacements but the magnitude of the forces would be higher. The two fusion constructs demonstrate the ends of the spectrum for stability. The lowest situation is tricortical iliac bone graft alone (group 6, approximately 150N) as the interface between the cancellous bone is held in place clinically by ligamentotaxis. The most stable construct is an interbody fusion cage supplemented with an anterior cervical plate and four screws (group 5, approximately 620N). The first four bars represent the four major methods of fixation of cervical disc replacements—ridges, deeper penetrating teeth, buttress plate with screws, and a midline sagittal keel. The groups are arranged from left to right in order of increasing stability; however, this is inversely related to their ease of revisibility in the event that prosthesis removal is indicated. Unfortunately, the current methodology of the FDA prospective clinical trials of disc arthroplasty are heavily weighted in favor of keel fixation without any consideration of the varying difficulty of disc arthroplasty revision.

requiring a larger number of subjects in their clinical trial, requiring a higher success rate, closer to their comparative control group. Particular attention to the estimated blood loss (EBL), length of operative procedure, and incidence of complications with permanent long-term sequelae should be sought out in mandatory reporting of clinical series outside the US (OUS). Experienced spine surgeons and total joint arthroplasty (TJA) surgeons who agonize pre-operatively, worrying about how to remove a stuck prosthesis compressing a neurovascular structure, can easily see the tremendous value of the ‘ease of revisibility’ whereas the commercial manufacturers and members of the regulatory agency do not. Designs that are easier to revise should permit larger deltas and, consequently, lower sample sizes.

Within the first post-approval year of the Charité disc, the NASS 2005 Outstanding Paper was awarded to A G Patwardham for “*Response of the Charité total Disc Replacement under Physiologic Loads: Prosthesis Component Motion Patterns*”.⁵ This demonstrates the overall scientific interest in characterizing what happens at the metal–bone interface, such as prosthesis lift-off at the extension extremes if the prosthetic endplates are not implanted in parallel.

5. Patwardham A G, “Outstanding Paper Award. Response of Charité Total Disc Replacement Under Physiologic Loads: Prosthesis Component Motion Patterns”, *Spine Journal* (2005);5: 75S–76S.

Figure 3: Keeled Prostheses can Require Corpectomy

A: Anteroposterior and lateral radiographs of an extremely symptomatic disabled patient who has failure of the keeled prosthesis at L4-5 with metal on metal articulation and collapse of the polyethylene insert.



B: The revision procedure with removal of the prosthesis and decompression of the spinal canal required a complete corpectomy and removal of both the L4-L5 ProDisc-L prosthesis and the L5-S1 ProDisc-L prosthesis. The resulting 360° salvage fusion and instrumentation construct demonstrates a loss of motion from L4 to the sacrum (courtesy of Jürgen Harms, MD, and Michael Ruff, MD).

The major emphasis by the manufacturers is the economic impact of the various disc prostheses cost data, return to work, and actuarial data to convince insurance

companies to cover the increased cost of LDA and CDAs compared with spinal fusion instrumentation.

Adjacent Level Reoperation Rate

To date, there is only one clinical study showing that spinal arthroplasty has a statistically significant advantage over arthrodesis, focusing on the immediately adjacent vertebral level. Anderson et al.⁶ found an increased reoperation rate at the adjacent level—2.2% in 580 patients with anterior cervical plates and bone graft versus 0.6% in 640 patients after CDA ($p=0.01$). Many benchtop biomechanical investigations have shown reduced stress at the adjacent disc space, reduced intradiscal pressure, and more physiologic movement adjacent to a disc replacement. However, this is a landmark study showing a differential reoperation rate in a clinical series.

Conclusion

With time, the industry will better understand the importance of reoperation, which will be more effectively incorporated into reversible prosthesis fixation, the experimental design of investigational FDA trials (a differential delta percentage based on the ease of prosthesis revision) and product marketing. Revision operations for TDR are already foremost in the minds of experienced spinal surgeons. As the FDA develops new guidance and policies on artificial disc testing, using a differential delta based on ease of revision would be one way to account for an important advantage of revisable designs that is not captured by current primary end-points. ■

6. Anderson P, Sasso R, Metcalf N, Riew D K, "Reoperation Rates for Cervical Arthroplasty Versus Arthrodesis", Spine Journal (2005);5: pp. 76S-77S.