

Lumbar ADR: A triumph of technology over reason?

Early clinical results show artificial disk replacement to be promising. But careful patient selection is a critical factor for achieving good surgical outcomes.

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Degenerative disk disease (DDD) is one of the leading causes of pain and disability in adults in the United States.¹ Approximately 80% of Americans have at least one episode of low back pain (LBP) at some point in their lives.^{1,2} This carries with it a large socioeconomic impact with respect to health care dollars and lost days of work. The development of new technology is driven, in part, by the opportunity to potentially and significantly alter the natural history of spinal disease, as well as to improve long-term patient outcomes and reduce health care costs. DDD is often successfully managed nonsurgically. However, a small percentage of patients fail to respond to conservative treatments such as physical therapy, anti-inflammatory or analgesic medications, modification of activities, therapeutic spinal injections, and weight loss. Surgical intervention is recommended for those patients with LBP for 6 months or more and who have exhausted nonoperative treatments. Lumbar fusion continues to be the gold standard for surgical treatment of intractable axial back pain secondary to DDD.^{1,3,4}

Fusion relieves pain by restricting motion. Fusion surgery does not always provide adequate pain relief, however, and

other complications associated with the procedure include pseudarthrosis, development of adjacent-segment disease, and autograft donor site complications.⁵ It is unknown whether these postoperative problems are related to spinal fusion or simply represent the natural progression of the patient's pre-existing disease.⁶ Biomechanical studies have shown that rigid immobilization of one segment of the spine increases stress to the segments above and below the fused segment. This increased workload may factor into accelerated degeneration or instability of the adjacent segments.^{1,2} Additionally, radiographic evidence of fusion success does not always correlate well with clinical relief of symptoms and a return to normal functioning.^{1,2}

HISTORY OF DISK REPLACEMENT

Although total disk replacement is currently a hot topic, the concept dates back to the 1950s.^{5,7,8} Early attempts at constructing artificial disks included an acrylic substance inserted into the disk space after discectomy, a fluid-filled elastic chamber with metal endplates, and a Dacron mesh-covered silicon disk. From the late 1960s through the late 1980s, new prostheses included a nuclear replacement using a stainless steel ball, a polyolefin rubber between two titanium plates, and a posterior-hinged metal prosthesis with interposed titanium springs.^{1,7}

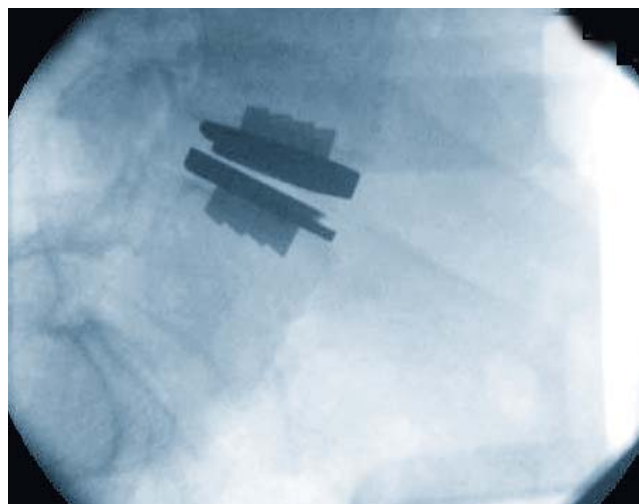
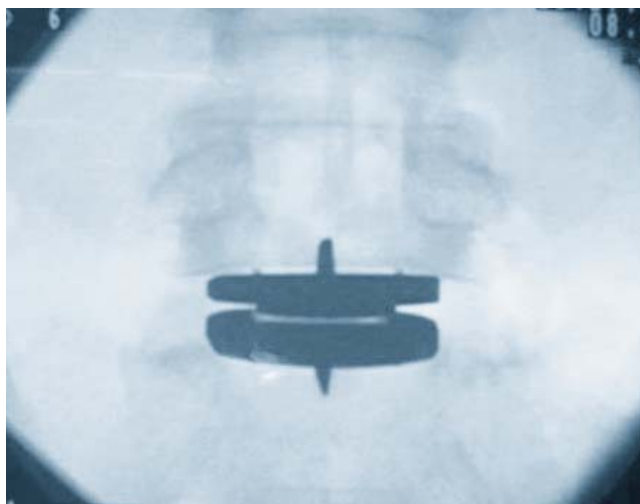


FIGURE 1. Radiographs demonstrating successful placement of a lumbar spine prosthesis.

The goal of modern artificial disk replacement (ADR) technology is to maintain spinal segment motion and prevent adjacent level degeneration.^{4,9} Artificial disks are designed to restore intervertebral disk-space height and maintain proper sagittal balance, thereby reproducing the biomechanical properties of a normal disk with a satisfactory range of motion (see Figure 1). Achieving these goals should eliminate pain and improve functional ability. Newer artificial disks possess long-term durability and stability.¹ Four lumbar spine arthroplasty devices are available in the United States. The Charité artificial disk (DePuy Spine, Inc) and the ProDisc lumbar spine prosthesis (Synthes, Inc) are metal-on-plastic articulating surface devices. Both have received FDA approval. The Maverick lumbar prosthesis (Medtronic Sofamor Danek, Inc) and the Flexicore lumbar prosthesis (Stryker Spine) are metal-on-metal articulating surface devices. These two devices are currently being studied in FDA investigational trials.¹

DISK ANATOMY

A functional spinal unit consists of the two adjacent vertebrae and the intervertebral disk as well as the spinal ligaments that hold the unit together.¹⁰ The lumbar motion segment is a three-joint complex comprised of a disk and two facet joints.¹⁰⁻¹² The interaction of these three articulations allows for normal motion of the lumbar segment including flexion/extension, lateral bending, axial rotation, and axial compression.¹³ Arthroplasty devices are classified by their ability to replicate the range of motion for each of these modes. A device that allows hypermobility beyond the normal physiologic range is classified as *unconstrained* for that mode. A device that allows unrestricted motion within the normal physiologic range is classified as *semiconstrained* for that mode. If the device has mechanical restrictions within the normal physiologic range, it is classified as *constrained* for that mode. None of these four devices allow axial compression; therefore, they are classified as constrained for that mode of segment motion.¹

The Charité artificial disk consists of two concave, cobalt-chrome-molybdenum (CoCrMo) alloy endplates that articulate with a convex, high-molecular-weight polyethylene (PE) sliding core. A radiopaque wire surrounds the core, enabling the core to be seen on radiographs. Fixation teeth on each

endplate secure the device to the vertebral body endplates. The Charité comes in seven endplate footprint sizes, four lordotic angles, and five core heights, allowing the surgeon to match the device to the patient's anatomy.^{7,14,15} This device is classified as unconstrained for flexion, extension, lateral bending, and axial rotation.^{5,11}

In 1997, Lemaire and colleagues reported excellent results in 79% of 105 patients who received this device, with a mean follow-up of 51 months.⁷ The FDA investigational device exemption (IDE) trial, completed in December 2003, compared the Charité artificial disk with standalone Bagby and Kuslich (BAK) cages with iliac crest bone graft (ICBG) harvest. At 1-year follow-up, patient satisfaction with the Charité prosthesis was 93% compared to 81% for patients who underwent BAK spinal fusion.⁷ A retrospective study by David demonstrated the safety and efficacy of the Charité artificial disk at the L4-L5 or L5-S1 level. Long-term clinical outcomes (minimum follow-up of 10 years) were good to excellent in 87 of 106 (82.1%) patients.¹⁵

The ProDisc-II lumbar spine prosthesis consists of two CoCrMo endplates with an ultrahigh-molecular-weight PE core fixed to the lower endplate (see Figure 2, page 32). The prosthesis endplates are affixed to the vertebral endplates by a central keel, and their nonarticulating surfaces are coated with a titanium plasma spray.¹¹ This prosthesis is available in two end plate sizes, three core heights, and two lordotic angles. ProDisc-II is the only device that is being evaluated for the treatment of multiple segment DDD.⁵ This prosthesis is classified as semiconstrained for flexion, extension, and lateral bending but unconstrained for axial rotation.¹¹

The FDA IDE trial compared the ProDisc device with an anterior femoral ring allograft and posterior pedicle screw fixation with autologous ICBG.^{11,16} Delamarter and colleagues reported the results of the first 78 randomized patients (56 patients who received a ProDisc-II prosthesis, 22 patients who underwent the anterior-posterior fusion procedure).¹⁶ Based on Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) scores, the patients who underwent disk replacement had statistically favorable results at 6 weeks and 3 months compared to the patients who underwent spinal fusion. At 6 months and from 6 months to 2 years, the difference was not statistically significant.¹⁶ In a retrospective study

KEY POINTS

- Surgical intervention is recommended for those patients who have exhausted nonoperative treatments for axial back pain secondary to degenerative disk disease. Lumbar fusion continues to be the gold standard for surgical treatment.
- Lumbar fusion relieves pain by restricting motion. However, fusion surgery does not always provide adequate pain relief.
- Artificial disks are designed to restore intervertebral disk-space height and maintain proper sagittal balance, thereby reproducing the biomechanical properties of a normal disk with a satisfactory range of motion.
- A patient is considered to be a candidate for ADR only after a minimum of 6 months of failed conservative treatment.

COMPETENCIES

- Medical knowledge
- Interpersonal & communication skills
- Patient care
- Professionalism
- Practice-based learning and improvement
- Systems-based practice

comparing the clinical and radiographic outcomes of the Charité and ProDisc devices, Shim and colleagues reported no clinically significant difference in either improvement of VAS and ODI scores or clinical success rates between the two devices.¹⁷

The Maverick total disk replacement, also made of CoCrMo, has a ball-and-socket design. Both endplates have a central keel and hydroxyapatite coating. The FDA IDE trial for the Maverick, which began in May 2003, is ongoing. The randomized trial compares the device with a single-level lumbar tapered fusion device combined with a bone morphogenetic protein allograft. The Maverick prosthesis is classified as semiconstrained for flexion, extension, and lateral bending but unconstrained for axial rotation.^{5,11,13}

The FlexiCore artificial disk also has a ball-and-socket design. This device has teeth on the outer ring of the implant for fixation to the vertebral endplates, and both surfaces are covered with titanium plasma to enhance fixation to the bone.¹³ US clinical trials of the Flexicore began in August 2003.¹³ The device is being studied in patients with single-level disk degeneration. The control group consists of patients who underwent a 360-degree fusion with posterior instrumentation.

PATIENT SELECTION

Careful patient selection is critical to surgical outcomes. Only patients with discogenic back pain secondary to DDD are candidates for ADR. The traditional work-up for DDD includes a thorough history and physical examination and multiple imaging techniques.¹⁸ Provocative diskography can help distinguish asymptomatic disks from pain-generating disks. If significant facet joint disease is suspected, diagnostic injection techniques can eliminate facet arthrosis pain. Osteoporosis



FIGURE 2. A lumbar spine prosthesis consisting of two CoCrMo endplates with an ultrahigh-molecular-weight PE core.

must be considered in the differential diagnosis and appropriate studies performed.

Furthermore, a patient is considered to be a candidate for ADR only after a minimum of 6 months of conservative treatment has failed to resolve the problem. Contraindications to ADR include prior lumbar fusion, facet joint arthrosis, osteoporosis, metabolic bone disease, segmental instability, spondylolisthesis, spondylolysis, lumbar scoliosis, and arachnoiditis. Other contraindications are morbid obesity, active infection, neoplasm, chronic steroid use, pregnancy, metal or polyethylene allergy, autoimmune disorders, more than three prior intra-abdominal procedures, and significant psychosocial disorder.^{5,7,19}

The surgical approach varies depending on the segment involved. Typically, a Pfannenstiel incision is used for surgery on the L5-S1 level in female patients, whereas a longitudinal (midline or paramedian) incision is utilized in male patients and is often necessary for procedures on the upper lumbar segments. The retroperitoneal approach is preferred.^{5,7} Dissection is performed with attention on mobilizing the great vessels and exposing the disk space. Once the damaged segment is verified by fluoroscopy, a complete discectomy is performed to remove all disk material except the lateral annulus.

A critical member of the surgical team is the access surgeon, usually a general or vascular surgeon. The access surgeon must be aware that the anterior exposure required to safely and accurately position the prosthesis is far more extensive than that required for a typical transabdominal spine exposure. A complete exposure of the posterior aspect of the disk space must be provided. The spine surgeon needs to remove the dorsal and ventral osteophytes to properly position the prosthesis posterior to the middle of the disk space in the anteroposterior diameter. Proper size and alignment of the prosthesis is of critical importance.⁹ If the prosthesis is placed too anteriorly, it will not flex, negating its advantage as a motion-sparing device.⁵

Risks related to transperitoneal or retroperitoneal surgical exposure include vascular or bowel injury, postoperative ileus, deep venous thrombosis, embolic events, and retrograde ejaculation in males.^{7,20} Implant-related complications include vertebral body fracture, malpositioning of the device, infection, postoperative radiculopathy, expulsion of the implant or core, implant subsidence, mechanical failure, progressive facet arthrosis, and adjacent level disease.²⁰

DISCUSSION

Can two surgical interventions with opposite technical goals (motion preservation versus motion prevention) effectively treat the same problem (discogenic pain)? Indeed, the availability of ADR for the treatment of DDD has further complicated the process of matching patients with this condition to the appropriate surgical intervention.¹¹ Given the inclusion and exclusion criteria for arthroplasty, clinicians may find that many of their patients are, in fact, not good candidates for ADR. Furthermore, many failed procedures can be attributed to inappropriate surgical indications.⁶ Other comor-

bidities that have yet to be clinically evaluated include preoperative narcotic use and addiction, smoking history, and duration of pain before the surgical procedure. There is a well-acknowledged functional overlay that accompanies the workers' compensation patient population.²¹ Psychological factors associated with overcoming pain and returning to work, as well as the secondary gain factor related to a sense of entitlement and impairment ratings, have not been analyzed in the setting of a controlled prospective outcomes study comparing ADR with traditional spinal fusion surgery.

Spine surgeons have found that even after a technically perfect operation, a poor surgical candidate is not likely to have the desired outcome. Although cutting edge technology

“Can the additional cost of ADR be justified when studies so far fail to show a statistical difference in long-term outcomes?”

is exciting, long-term clinical outcomes for patients who undergo ADR are not yet known. Asymptomatic DDD is ubiquitous in the general population and well-documented on MRI. One study of asymptomatic patients found that 25% of them in their fifth decade had degenerative findings. This number increased to 75% by the seventh decade.²² Historically, this patient population does not have a high success rate with any spinal surgical procedure. Furthermore, a controversial test—diskography—is used to determine whether these patients are good candidates for ADR. In the end, ADR is offered to patients with no spinal column instability and no significant spinal cord or nerve root compression. Patients whose pain does not resolve have limited additional surgical options. Posterior instrumented fusion remains the primary revision strategy and is performed as a potential salvage procedure.²³ An anterior revision carries with it even more significant risk because of the markedly increased likelihood of vascular injury and difficulty revising the device.

SUMMARY

The many unanswered questions surrounding ADR beget the question of whether patients would ultimately be better managed with lumbar fusion surgery or even no surgery at all. Lumbar fusion technology has made advances in recent years with the advent of transforaminal lumbar interbody fusion (TLIF) and the use of bone morphogenetic proteins. With a TLIF procedure, spine surgeons are able to obtain a 360-degree fusion through a single posterior incision with more predictable long-term results, especially when patients have confounding issues. Although early clinical results show ADR to be a promising alternative to current surgical options, long-term results are needed to adequately assess the procedure's efficacy.

There will always be a demand for new technology. Cost, quality, and access are performance benchmarks for hospital survival in the current health care industry. Today's health care environment forces surgeons to be fiscally responsible while still providing the best quality care possible. Therefore, the cost of ADR compared to a traditional pedicle screw instrumentation (about \$12,000 per segment vs \$3,500 per segment) must be taken into consideration. Is the additional cost of ADR justified when studies so far fail to show a statistically significant difference in long-term outcomes? How do we justify the added cost when conventional lumbar fusion, the gold standard for intractable cases, has more predictable outcomes? Ultimately, ADR may be a more promising alternative to spinal fusion for patients with multilevel DDD (ie, a three-segment lumbar disk replacement) because it can spare disk decompensation of the adjacent segments. **JAAPA**

Jennifer Madonia-Barr is a physician assistant with Connecticut Neck and Back Specialists, Danbury. She has indicated no relationships to disclose relating to the content of this article.

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