

## Replacement Technology Moves to the Spine— Artificial Disc Offers Motion-Preserving Alternative to Spinal Fusion

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Although still in its infancy, artificial disc replacement is a promising new treatment for people with painful lumbar degenerative disc disease (DDD). Compared with spinal fusion surgery, disc replacement does not restrict movement. Restricted movement can cause adjacent segment disease, which can result from additional stress placed on adjacent discs after spinal fusion.

As the joints of the spinal column, the intervertebral discs have a primarily mechanical role of transmitting loads through the spine and providing flexibility to the spinal column. This permits bending, torsion, and flexion through a range of motions. The spinal disc has relatively few cells embedded in an extracellular matrix. The cells maintain and repair the matrix to keep a balance between tissue breakdown and replacement.

### The Source of Pain

Degradation of the matrix occurs when there is an imbalance between matrix synthesis and matrix breakdown, which leads to DDD. The degraded matrix cannot carry loads effectively, and some cells become necrotic. The endplate of the disc calcifies and disc degeneration begins. Spinal discs degenerate faster than other tissues do.

As disc degeneration progresses, blood vessels and nerves penetrate the previously avascular and aneural disc, creating discogenic pain. This process causes further disc degeneration that changes spinal mechanics and causes painful, debilitating conditions. Degenerative changes in the disc can cause herniation, which produces sciatica and low back pain.

Lumbar  
Degenerative  
Disc  
Disease



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Long-term DDD can cause spinal stenosis (narrowing of the spinal canal), a major cause of pain and disability in the aged. With a gradually increasing lifespan, there is a corresponding rise in the incidence of spinal stenosis. Only approximately 10% of teenagers have DDD, but more than 70% of those aged 50 years and older develop this painful condition.

### Etiology of DDD

What are the causes of DDD? Epidemiologic studies conducted in the last 30 years have pointed to heavy physical labor, truck driving careers, and smoking as significant risk factors. However, these studies are based on an assumption that DDD largely results from overloading of the spine and do not account for the ability of the musculoskeletal system to adapt to external stresses.

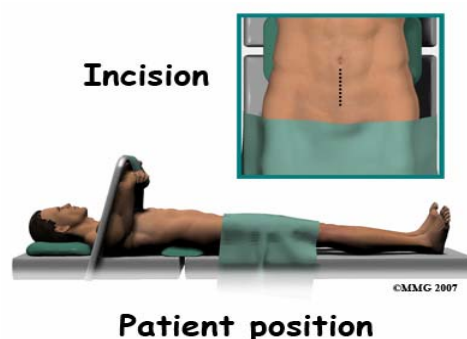
Other population studies conducted in the last decade have identified genetic predisposition as key in DDD and pointed to a possible combination of genetic predisposition, age, and cumulative exposure to environmental stresses.

The best candidates for disc replacements are between the ages of 18 and 60 years, without osteoporosis, whose back pain is greater than leg pain and who have minimal stenosis and one-level DDD with no slips or adjacent-level disease. The patient should not have had any previous fusions or decompressions, except for a one-sided discectomy, and there should be no evidence of scoliosis.

X-rays, magnetic resonance imaging, facet blocks, and lumbar discograms are performed to determine whether disc replacement is appropriate. The lumbar discogram involves injection of the suspected lumbar discs with saline solution to determine whether the same pain is reproduced as reported by the patient. This test is performed by a trained physician with a computed tomography, or CT, scanner and is necessary to pinpoint the source of pain.

The disc replacement procedure, which takes approximately two to three hours, is performed through an anterior retroperitoneal or transperitoneal approach, which means the intestines and anterior blood vessels are moved to the side to allow access to the anterior portion of the spine.

This is routinely performed with low rates of complications. Males have a small risk of retrograde ejaculation, which is usually temporary. Because of the potential risk for infertility in male patients, they may wish to donate sperm preoperatively if planning to have families.



Patients are usually in the hospital for two to four days following surgery, which is actually less of a stay than for those who undergo fusions. Waiting for the abdomen to “wake up” and start moving again if an ileus occurs is the usual cause of delay in patient discharge.

An important benefit of the disc replacement surgery to note is that patients do not need to wear braces following surgery, as with many fusion-type surgeries. This is another positive aspect of the motion-preserving procedure. Patients are ambulatory immediately and gradually resume daily activities over a period of weeks.

### **Positive Results**

Since the Food and Drug Administration (FDA) approved the CHARITÉ™ Artificial Disc in October 2004, more than 350 have been implanted at 15 spine centers in the United States. The disc manufacturer says more than 5,000 devices have been implanted worldwide since first appearing in the 1980s. The device was hailed as “the best disc replacement compromise” in a research paper that covered the outcomes of 105 patients.

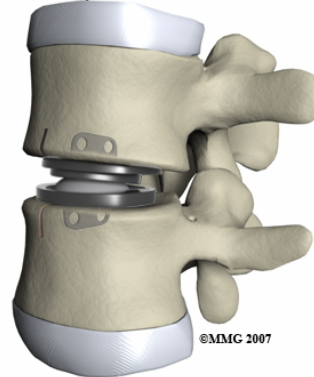
At a 51-month follow-up, 79% of the patients were reported to have “excellent” results with an 87% return-to-work rate. These results mirrored restoration of a well-balanced lordosis with segmental mobility, as confirmed by x-ray. Factors that led to failure were posterior facet arthritis, osteoporosis, structural deformities, and secondary facet pain.

In a two-year, FDA-sponsored, prospective, randomized study that compared lengths of hospital stay, patient satisfaction, and Oswestry questionnaire (a standard patient-outcome instrument) responses to assess improvement after the CHARITÉ disc or anterior lumbar fusion with cages, researchers found that the artificial disc had a higher success rate. Investigators carried out the study at 15 centers with 304 patients randomized to both treatments. Patients ranged in age from 18 to 60 years old and had symptomatic DDD. All had failed at least six months of supervised, nonoperative treatment.

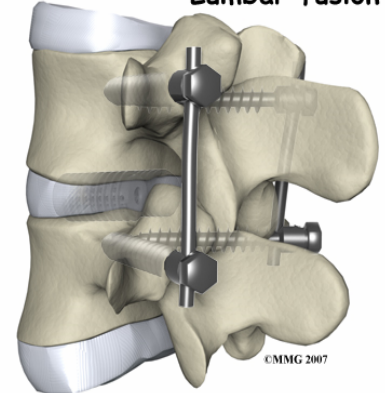
The artificial disc was proved slightly superior to the spinal fusion procedure as measured by a 25% or greater improvement in Oswestry improvement criteria. Patients with the disc showed statistically significant differences at six weeks, three months, six months, and 12 months after surgery.

Patients who received the artificial disc also reported greater satisfaction, with 69% responding they would “definitely choose the same treatment again” and 13% responding they would “probably” choose the disc. Corresponding numbers among patients who received fusion were 52% and 13%, respectively.

Lumbar Artificial Disc Replacement



Lumbar fusion



### Promising New Technology

At present, the full longevity of disc replacement devices is not known, but they are expected to endure for 20 to 40 years, depending on the integrity of the polyethylene insert that fits between two metal plates implanted into vertebrae above and below the implant. In some other discs, there is no plastic insert and the metal plates articulate directly on each other.

Although there is only one artificial disc on the market in the United States now, there are other devices awaiting FDA approval. One of these is PRODISC®, which has demonstrated good to excellent results in 90% of patients in Europe. Approval of this device could come from the FDA in 2005. Other artificial discs include MAVERICK™ and Flexicore™.

Artificial disc replacement is an exciting new addition to the armamentarium of orthopaedic surgeons who offer treatment for DDD. As with other new technologies and therapies, general acceptance will come as the procedure continues to improve with better implants to alleviate pain and suffering.