FALL 2007

JOURNAL OF THE SPINAL RESEARCH FOUNDATION

THE JOURNAL OF THE SPINAL RESEARCH FOUNDATION
A multidisciplinary journal for patients and spine specialists

From the Editor

Brian R. Subach, M.D., F.A.C.S.

Welcome to the fall edition of the Journal of the Spinal Research Foundation (JSRF). As we come to the end of our second year of publication, the JSRF continues to grow in both size and complexity. Despite this growth, both the Spinal Research Foundation (SRF) and the Journal itself have not lost sight of their mission to educate patients and healthcare providers alike as well as advance the science of treating spinal disorders.

To accomplish our clinical research, we clearly rely on two groups: our donors and our patients. I have made it a point in each of my previous editorial comments to acknowledge the substantial contributions of both to our efforts. Independent donations for 2007 total nearly 3 million dollars to date with additional funding expected in the fourth fiscal quarter. The work of our dedicated development team has been essential in getting our message to charitable organizations as well as those who have had lives altered by spinal disorders or treatments. I would also like to bring attention to our patients. Through completely voluntary efforts on their part, we ask them hundreds of detailed and personal questions. We ask them to spend time completing computer-based clinical evaluations and submit to x-rays, MRI scans and CAT scans long after their incisions have healed. I am sure that there are a hundred reasons to make a financial contribution to the SRF cause, however I am fascinated by the one reason which seems to unite our patients in their desire to participate: to make a difference. Most feel that they have received excellent care and hope to help others with their participation. Perhaps an observation made while reviewing their records will make a difference in the life of another suffering soul.

Dr. Anne Copay has chosen to tackle one of the most complex issues facing spinal surgery today. In her three part series, she completes an in-depth review of disc replacement surgery. Known as disc arthroplasty, such procedures may be performed in both the cervical and lumbar spine to treat primary disc degeneration or acquired segmental instability. These diagnoses are more commonly treated with fusion surgery or arthrodesis. Fusion essentially eliminates pain by eliminating abnormal motion in the spine. By eliminating motion, stresses may be transferred to neighboring discs, possibly leading to premature failure. Arthroplasty treats the degenerative disc but allows motion to continue, theoretically avoiding stress transfer.

One of our most popular contributions is the SRF version of reality television. Appropriately named Spine Tale, it is simply a before and after look at the life of a patient with a spinal disorder who has been successfully treated. The patients frequently ask to tell their story and want their picture taken in the hope that we may tell their story in an upcoming publication. The names and faces are real; the stories may seem all too familiar. In doing clinical research, we have found numbers alone to be boring. If you put a face with a name and realize that these outcomes after surgery represent a real life, the research is that much more rewarding.

Finally, it is my pleasure to introduce our SRF Centers of Excellence. Initially, the concept arose from a need to collaborate with other spinal healthcare providers to allow for multi-center correlation of research findings. In trying to identify such centers, we found that it was best to use outstanding spinal surgeons also skilled in the non-surgical care of patients with spinal disorders. We looked for surgeons with the facilities and personnel to support the data collection process and outcomes research so vital to our mission. We looked for groups with a multi-specialty composition designed to treat all aspects of the spine patient such as orthopedists, neurosurgeons, physiatrists and pain management specialists. Lastly, we hoped to identify centers with on-site radiology and physical therapy designed to provide the "one-stop shopping" approach to spinal care. We currently have identified a dozen such centers (listed on the inside front cover) and will expand as we continue to identify groups meeting our criteria. In essence, we are giving these surgeons our stamp of approval and are asking their help in forming an alliance of world-class experts in spinal disease. The specific centers will be profiled in detail in upcoming issues.

Spine Tale

Most people clearly remember the significant events in their lives. A wedding, the birth of a child or perhaps a daughter's graduation are so important that the dates become etched in our memories forever. In many cases, the initial onset of low back pain can be unfortunately just as memorable. For Jeffrey D. Kerley, an athletic 44 year old from Tennessee, serious back pain first became an issue in the summer of 1998. How many times had he lifted heavier things in the past? Hundreds. Perhaps it was the weight of the box? Maybe it was the fact that he twisted slightly or that he forgot to bend his knees into a good lifting posture? In any case, the severity of the pain when it first happened nearly brought him to his knees. He felt as if all of the low back muscles had contracted at the same time making it impossible for him to stand upright. Even breathing was difficult with the pain that he was experiencing. The back pain seemed to settle down after a few days; however his left buttock and left calf began to hurt. At first, the leg felt tight, much like he needed to stretch the hamstring and the calf. Soon after, the ache began to burn more deeply into the leg. When he finally had the MRI done on his lower back, after weeks of simply trying to stretch the leg and take ibuprofen for pain, he did not believe that he had actually ruptured a lumbar disc. That was unfortunately exactly what his doctor in Tennessee had told him.

Jeff Kerley

Before 1998, Jeff had not heard of lumbar degenerative disc disease or sciatica and, yet, here he was having both. By late November 1998, he was having back surgery. It was "just" a hemilaminectomy to remove the piece of herniated disc material which was causing his problems. It is funny how differently doctors and patients perceive things. His was just a "small" surgery the doctor said. Here he was not even 40 years old and falling apart. He had been in pretty good shape. Always an athlete in his youth, now he ran some, lifted a few weights and played a little softball and basketball. The former athlete in good health needed a hole cut into his back. A surgery to remove a piece of something from the low back is anything but small as far as he was concerned. The outpatient surgery went well and within a few weeks he was back to work, doing some physical therapy and feeling more and more like his old self. In retrospect, it was a small surgery and a small price to pay for having his life back. Six weeks after surgery, he was declared healed by his surgeon and his level of function was 100%. Life went back to normal until May 2002.

In May of 2002, another one of those memorable events occurred. He was wearing his seat belt and driving the speed limit of 45 mph when a car pulled out in front of him directly crossing his path. Unclear if the driver was not paying attention, it was daylight outside, maybe it was one of those cell phone accidents. They say that when you are on the phone, you cannot concentrate on the traffic around you. In any case, Jeff smacked into that vehicle broadside. He had walked away from the accident a little stunned and a little stiff, but seemingly no worse for wear. The next day was an entirely different situation. He could barely get out of bed due to the stiffness and pain in his lower back. When he called his family physician, Jeff was told that it sounded like a whiplash injury to his low back. After all, "didn't he have previous lumbar surgery?" the doctor asked. Pain after an accident like that was to be expected. Muscle strain, ligament sprain, soft tissue inflammation. If that were the case, time, physical therapy and anti-inflammatory medications should have helped. He did his exercises faithfully but the pain persisted. Then came the x-rays and the MRI scan with intravenous dye. He complained of 95% back pain and 5% leg numbness in the leg that was supposed to have had damage from the previous disc rupture. Next a CT scan, looking for the possibility of a stress fracture, but there was no break in the spinal bones. The MRI only showed scar tissue in the area of his prior surgery and degenerative disc disease in his lumbar spine at the L5-S1 level, the lowest disc in his back. He did his research. Dr. Hodges, his primary care provider, had mentioned some recent advances in artificial disc technology and specifically Dr. Brian Subach.

He first met Dr. Subach in December 2003. Jeff went through his history of low back problems and Dr. Subach reviewed his imaging studies before performing an examination. As he feared would happen, Dr. Subach agreed with the possibility of lumbar degenerative disc disease progressing at the site of his previous surgery. The only way to be sure was discography. Discography is a term used to describe a medieval torture in which needles are placed deep within the discs of the spine, then injecting dye to see if a patient's usual daily back pain may be reproduced by pressurizing the disc. Normal

Spine Tale

discs may sense some pressure but degenerative discs, like the L5-S1 disc in Jeff's back, can be painful. Jeff's disc registered a 10 out of a possible 10 pain score reproducing the exact pain in his back that he felt while standing. Fortunately, the other discs tested normal.

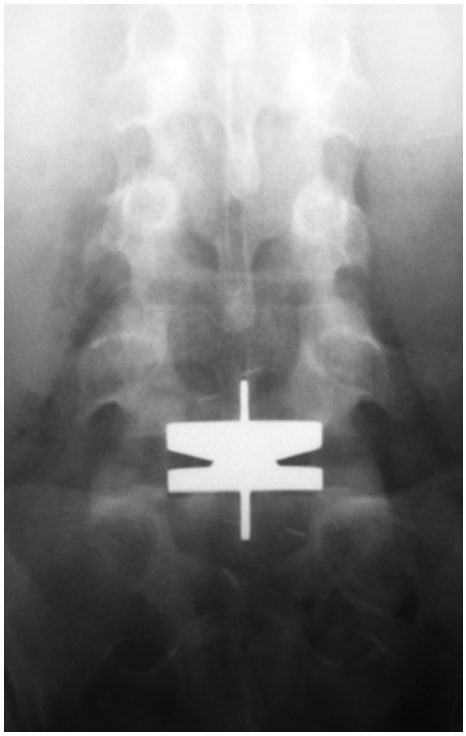
In discussing the possible treatment options for lumbar disc degeneration, there were a number of strategies to consider. The most interesting possibility was that of simply replacing the disc with an artificial one. Dr. Subach was participating in a national investigation of the Maverick™ lumbar disc replacement device. The only problem was that by enrolling in the study you had to open an envelope which randomized you to either the artificial disc or the control group (meaning that you received a fusion operation instead). Jeff considered his options and crossed his fingers. His envelope had a single piece of paper inside. The paper had a single word typewritten on it, "MAVERICK". He was to receive the artificial disc!

Surgery was scheduled a few weeks later to place the device at the L5-S1 level. In an hour long operation performed through a vertical incision below his belly button, the painful, degenerating disc at L5-S1 was completely removed by Dr. Subach and replaced with a new shiny metal disc.

After surgery, the incision was slightly sore, but his back felt immediately better. The second day after surgery he was up walking with essentially no back pain.

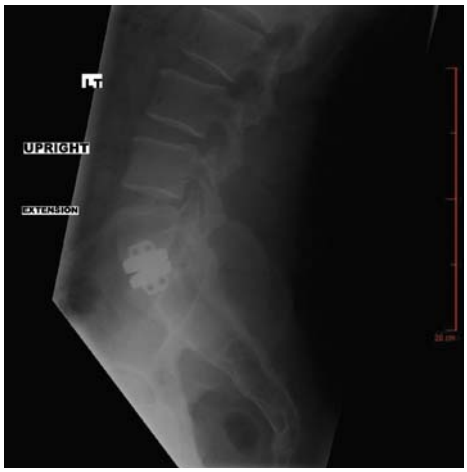
Two weeks later, he was back for x-rays and a brief check up. Everything looked fine and he was returned to work with some restrictions. Two weeks out from surgery with no back pain and not really requiring any pain medications, Jeff was ecstatic. Soon, he was back at the gym, determined to get stronger than ever before. The Maverick surgery was a complete success in alleviating lower back pain and restoring normal motion to a severely degenerative disc in his back.

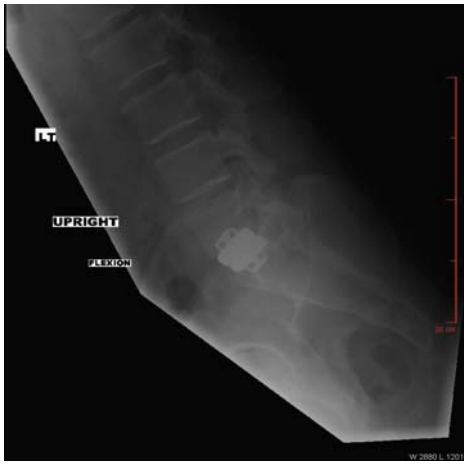
It is true that Jeff has experienced some life-changing events: first, the onset of low back pain, second, the accident and third, the Maverick replacement disc. Jeff's extraordinary story and success makes him the *Spine Tale* for this edition.



X-ray: front view of Jeff Kerley's spine with the Maverick inserted between his 5th Lumbar vertebra and his first sacral vertebra.

A Maverick artificial disc, similar to the disc implanted in Jeff Kerley's spine





X-ray: side view of Jeff Kerley's spine arching backwards and bending forward

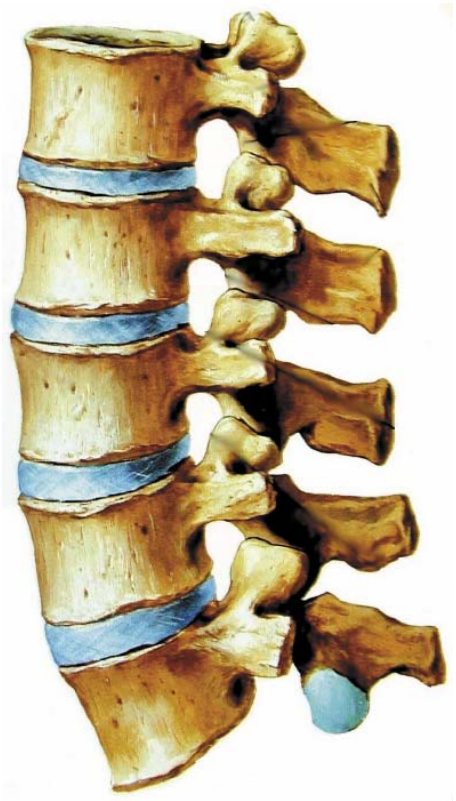
Lumbar Disc Replacement: A Panacea or Potential Nightmare?

By Thomas C. Schuler, M.D., F.A.C.S.

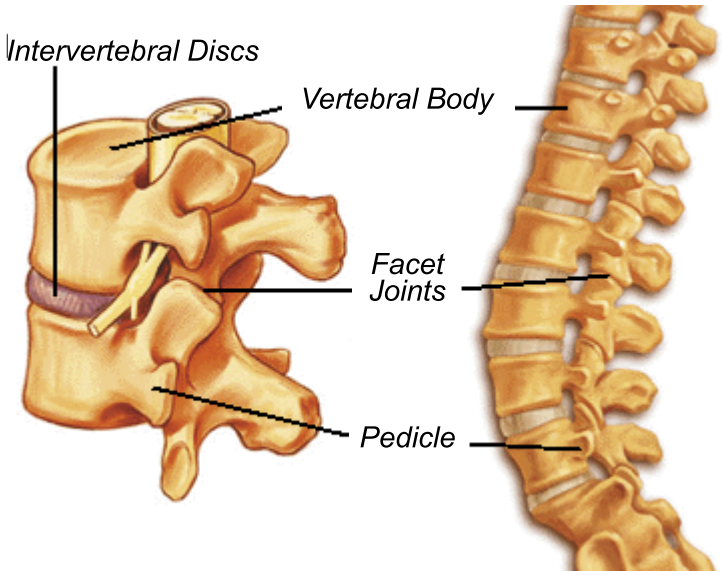
The management of back pain has long been a problem for mankind and for health care providers alike. Even Hippocrates employed traction racks in an initial attempt to solve painful spinal conditions. In 1911, the first spinal fusion was performed for tuberculosis. In the 1930s, lumbar disc surgery was first employed by creative physicians trying to treat a possible spinal origin of painful compression of leg nerves. It was not until the 1950s, that spinal instrumentation was first utilized in the treatment of scoliosis. This landmark effort was pioneered by Dr. Paul Harrington. In the 1960s, 1970s and 1980s, the technology used to treat spinal disorders evolved at a tremendous rate, however the ability to assess the success of surgical procedures and patient outcomes after surgery failed to progress at a similar rate. With the exception of spinal trauma, a predictable and reliable treatment algorithm for back pain eluded surgeons. Success rates and outcomes from surgery have become measures of effectiveness. Now into the 21st century, a new emphasis has been placed upon diagnostic techniques designed to better identify the source of back pain while modifications to existing surgical techniques have allowed less invasive approaches and more predictable results. Specifically, such changes have altered the need for fusion surgery. Fusion is generally defined as the surgical stabilization of a painful motion segment of the spine. In patients with a collapsed disc, inflammatory changes in the end plates and chronic back pain (that has been unresponsive to rest, exercise, medications, cortisone injection therapy and the simple passage of time) stabilization procedures with interbody fusion have proven to be both effective and successful. Using modern instrumentation combined with genetically engineered bone morphogenetic protein (BMP-2), patients with intractable back pain (as the result of one or two degenerating discs) can now be offered a cure for their pain. Although highly effective, fusion or healing of bone across a previously mobile spinal joint results in loss of motion at that level, as well as transfer of bending stress to the discs above and below the fusion. The aspect of fusion surgery which is most troubling to patients is this loss of motion, irrespective of their pain situation. When even an untrained eye looks at a spine, it is clear that the spine is designed for motion. Therefore, the concept of eliminating motion to eliminate pain seems counter-intuitive. It seems more reasonable to replace degenerating discs, arthritic facet joints and worn out ligaments to restore the normal motion and function of the spine.

Unfortunately, this concept has been incorrectly oversimplified in both the comments of some physicians and the presentations from different media sources. The public perception is, quite simply, that motion is good and stabilization or fusion is bad. Much of the excitement surrounding total lumbar disc replacements (TDA), also known as arthroplasty or artificial discs, in the lumbar spine is based upon the erroneous belief that the only goal of surgery should be to keep the spine moving. In theory, this sounds reasonable. I believe that one should understand the facts before agreeing with such a simplistic view.

In the lumbar spine, there are five discs. Each disc sits as a shock absorber between two spinal bones called vertebral bodies. This disc is surrounded by ligaments connecting the vertebral bodies and



adding additional support. The disc and its surrounding ligaments allow for movement to occur in multiple planes. This bone-disc-bone complex is often referred to as the motion segment. For example, normal motion across a single segment in the lumbar spine usually measures approximately five to seven degrees from forward bending (flexion) to arching of the back (extension). Other movements, such as lateral (side) bending and rotation (twisting) may occur as isolated motions or combination (coupled) motions such as flexion – rotation. The extent of such movements depends upon both the integrity of the bones and ligaments but also upon the flexibility of the surrounding muscles. Based upon the elasticity of the disc and forgiving nature of the surrounding ligaments, the spine can achieve an incredible variety of positions.



It is also important to realize that each motion segment has two paired facet joints, located at the back of the spine, which must move in conjunction with the disc. These facet joints have cartilage surfaces and capsule. This capsule is lined by a substance called synovium. The synovial lining produces a lubricating fluid for the joint. When a disc deteriorates as a result of the aging process, these facet joints often deteriorate as well. When disc replacement surgery is currently performed, these two facet joints are not replaced. By coupling a brand-new disc with the same old facet joints, there are significant stresses placed upon these joints which may already be showing signs of degeneration. The cartilage surfaces wear out, the synovial lining stops producing fluid and the joints may become arthritic, painful and stiff. Current disc replacement surgery involves replacement of a living, flexible, shock-absorbing motion structure with a metal or plastic device which lacks the ability of the natural disc to repair itself, moves in multiple directions and limits stress on the facet joints. If you think about it, normal spinal motion is like a three-legged table with the disc as one leg and the facets as the two other legs. Artificial disc replacement does nothing for two thirds of the joints involved in a given motion segment. Only one third, the anterior (front) portion, is being replaced while the two posterior components of this triangular complex are not addressed. If instability is already present due to incompetence of the facet joints, disc replacement will only worsen the instability present at this level. Finally, interbody fusion procedures allow the surgeon to correct posture and spinal alignment. In cases of scoliosis or loss of normal posture due to degeneration, the artificial disc may simply adopt an abnormal alignment once placed into the disc space instead of correcting it. In cases of severe degeneration with significant loss of disc space height, an arthroplasty device may be wedged in to the collapsed space; however the fit is so snug that the device does not function properly. In essence, the device never moves (as planned) and never heals (like a fusion would).

When fusion surgery is done properly in the lumbar spine, the results are generally excellent. We are able to restore disc space height, normal posture and take pressure off the lumbar nerve roots which form the sciatic nerve. Obviously, losing motion in the spine is not an ideal treatment, however fusion is a truly time-proven and successful technique. When fusion is accomplished in such a way that preserves the surrounding muscles, ligaments and joints, an excellent result is obtained with minimal stress transfer from the fused levels to the adjacent discs and facet joints. Unlike the arthroplasty techniques, once a fusion procedure heals, it is completely healed. It will not dislodge. It will not wear out. A fusion does not have to be revised or redone in a few years.

Aside from some of the obvious positives of spinal disc arthroplasty, there are some concerns which are just as obvious. One such concern is the theoretical life expectancy of these devices. Most of the research information to date attempts to simulate wear and tear on a disc prosthesis by subjecting it to millions upon millions of cycles of bending. Despite these simulated decades of wear, there is clearly no frictionless surface. Wear does occur; highly polished and shiny surfaces will grind themselves back to dullness if given adequate time and repetitions. Experience shows that knee replacements and hip replacements are usually revised at least once in a fifteen year time frame. Although revision hip and knee surgery can be complicated, revision surgery performed upon the anterior aspect of the spine can be technically challenging for the surgeon and life-threatening for the patient. Performing the initial anterior (front) approach to the lumbar spine entails moving the major arteries and veins which reside within

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the abdomen. Once a salvage surgery is entertained, these vessels have now scarred to the front of the spine and their mobilization becomes extremely difficult. Attempting to remove this scar tissue to allow for mobilization of the vessels carries with it a significant risk. This seems a potentially high price to pay for the theoretical advantage offered by motion preservation devices. As far as I am concerned, the advantage of motion preservation remains unproven.

When someone develops low back pain as a result of a degenerative condition in the low back, it is rare for that condition to involve only the disc. In the patient who has pure disc pathology with normal facet joints, then disc replacement treatment may provide a desirable, motion-sparing alternative to fusion. This is theoretically even more important to the patients who have multiple levels of disc degeneration with normal facet joints. Unfortunately, patients with multiple levels of disc degeneration in conjunction with normal facet joints are usually the youngest patients in our office, generally ranging between the 20's and 40's. These are the people who will need the longest life expectancy from an implant in order to obtain the best result. If we perform a disc replacement on somebody in their twenties or thirties and we expect to get ten to fifteen years maximum out of that disc replacement before it needs to be revised, then that means that we are revising these disc replacements in patients in their thirties or forties. At the time of revision, they are undergoing a significant and life-threatening operation. If these same patients had undergone a fusion procedure performed with modern technology, it is unlikely that any further surgery would ever be required to revise or replace that fusion. Finally, since there is no frictionless surface, all motion devices lead to formation of wear debris, small particles which may be deposited near the device. Research in total hip replacements has clearly shown implant loosening as an effect of this wear debris. Loosening in the hip joint may be painful, but it is not life threatening. Loosening in a spinal implant is a much more serious condition.

Cervical disc replacements are much more attractive for a number of reasons. First, the weight-bearing characteristics of the cervical spine make it much better suited to arthroplasty. Devices are likely to last longer under decreased loading conditions and less likely to require revision surgery. Second, revision surgery for cervical arthroplasty does not carry with it the same risks as lumbar revision procedure. This is the part of the spine where motion seems more important and where disc replacement seems to make more sense. Unfortunately, artificial cervical discs face some of the same challenges as lumbar discs in attempting to determine exactly which patient should receive the implant.

Having performed both cervical and lumbar disc replacements on my patients, I have witnessed the excellent results that can be obtained with this technology. My point in this discussion is to remind our readers that as time passes, we will accrue additional long-term results which should allow us to better describe the wear patterns, longevity and success rates of these devices.

In conclusion, I believe that disc replacement surgery is in its infancy. The modern treatment of single level discogenic (originating from a disc) pain with lumbar spinal fusion has been extremely successful. To abandon success in favor of an unproven, motion-sparing technique with a limited lifespan and associated life-threatening risks, is foolish. For a very select few patients, this technology is clearly promising. On the other hand, for the majority of the patients presenting to my practice with intractable low back pain, arthroplasty is not a reasonable option. In patients with degeneration of the cervical spine, cervical disc replacement carries with it a lower risk of complications and likely a better pattern of wear. In that sense, arthroplasty may be an alternative to fusion. Unfortunately, there is no one single answer. Just as each patient presents with unique symptoms, each patient will require a unique solution to his problem. A panacea does not exist in any of the options available. I believe that with careful consideration and informed decision-making, the patient and surgeon will identify the most appropriate treatment options.

THOMAS C. SCHULER, M.D., F.A.C.S.

Dr. Schuler is an expert in non-operative and operative cervical and lumbar spinal surgery.

He is an innovator in the field of spinal surgery and a pioneer in the development of non-operative treatment strategies for spinal disorders.

Artificial Discs for the Lumbar and Cervical Spine

By Anne G. Copay, Ph.D.

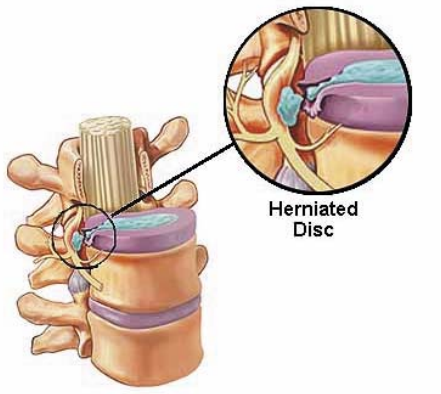
The Spinal Research Foundation regularly receives inquiries about artificial spinal discs. Many people hold the strong hope that artificial discs will be the remedy for their back or neck pain. A few artificial discs have recently been approved by the FDA and a few more are expecting to gain FDA approval by the year 2008. With increasing demand and potential supply of various artificial discs, a close examination of the artificial spinal discs is important. We are presenting an in-depth review of the current knowledge about artificial discs. We will first compare artificial discs to other forms of spinal surgery to delineate the indications for artificial discs. In the second part, we will examine the development of artificial discs, the experience of other countries with artificial discs, and the results of the FDA studies comparing artificial discs to fusion. In the third section, we will explain the critical issues and concerns that still need to be resolved before the widespread use of spinal artificial discs.

1 - The place of artificial discs in the realm of spinal surgery

Spinal surgeries and their indications

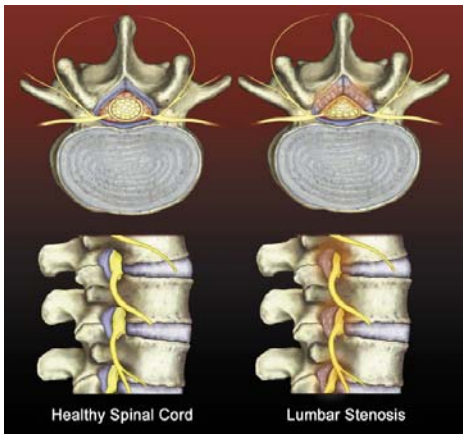
Pain in the back and neck has a variety of causes such as herniated disc, stenosis, spondylolisthesis, and disc degeneration. Specific treatments and surgical techniques have been developed to treat the specific causes of pain: such as discectomy, decompression (laminectomy, facetectomy, discectomy), and fusion. The relative advantages of surgical and nonsurgical treatments are still debated. The main points of the research comparing surgical and nonsurgical back treatments can be summarized as follows.

- **Disc herniation and sciatica.** Patients suffering from sciatica as a result of disc herniation were treated surgically with a microdiscectomy or nonsurgically by their physicians. Recovery took about 4 weeks for the microdiscectomy patients and about 12 weeks for the nonsurgery patients. After 1 year, the pain and disability levels were similar for both patient groups[1]. Another study found that the faster recovery of the microdiscectomy patients lasted only to 6 weeks (even though at 2 years, leg pain of the microdiscectomy patients was half the leg pain of the nonsurgery patients)[2]. Some studies corroborate the short-term advantage of surgery[3, 4] while others maintain an advantage of surgery up to 10 years[5]. *Altogether, there is some agreement about the faster recovery from discectomy but on-going debate about the long-term advantage of surgery. It should also be noted that surgery is considered the recommended treatment for patients showing progressive neurological deficit or increasing leg pain not responsive to medication.*



Herniated disc

- **Stenosis.** One study found that as early as 6 months and up to 2 years after decompression surgery, surgery patients had less leg and back pain and lower overall disability than nonsurgical patients[6]. Another study also found that surgery patients experienced less leg and back pain and had lower disability scores than nonsurgical patients at 1 and 4 years post-op. At 10 years post-op, surgical and nonsurgical patients experienced similar back pain and disability[7-9]. On the other hand, a third study found that surgical patients were still doing better than nonsurgical patients after10 years[10]. *Even though debated, there is reasonable agreement that decompression (with added fusion in case of spinal instability) has a more favorable outcome than non-surgical treatment of stenosis.*



Stenosis

- **Spondylolisthesis.** One study found that fusion patients had greater improvement in leg pain, back pain, and disability than nonsurgical patients already at 3 months and up to 2 years after the surgery[11]. A second study

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1 - The place of artificial discs in the realm of spinal surgery

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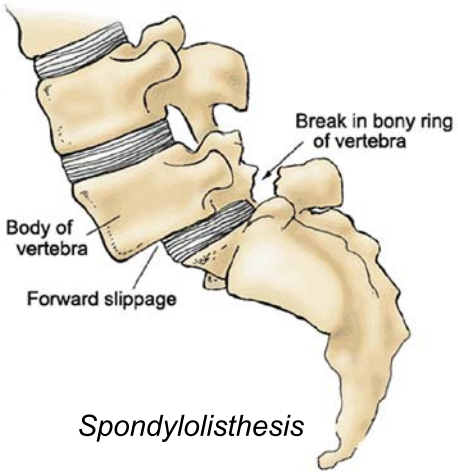
found that fusion patients had less pain and disability than nonsurgical patients after 2 years but fusion and nonsurgical patients were fairly similar after an average of 9 years[12]. *Fusion is considered the most effective treatment for spondylolisthesis. The surgical treatment of spondylolisthesis creates less controversy than the surgical treatment of other spine conditions.*



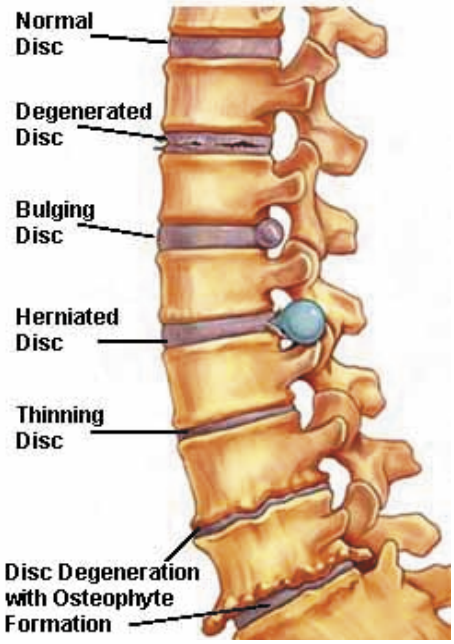
Spondylolisthesis

- **Chronic back pain and degenerative disc disease.**

One study found that fusion patients had slightly lower disability scores than non-operative patients but similar general health scores after two years[13]. A second study found that fusion patients had lower leg pain than nonsurgical patients after one year but similar back pain and disability scores[14]. A third study found that fusion patients had lower back pain, lower leg pain and lower disability scores than nonsurgical patients after two years[15]. *The results of these studies are debated in terms of their methodologies and choice of patients. The use of fusion to treat degenerative disc disease is the object of an on-going and sometimes heated debate.Overall, fusion surgery for lumbar degenerative disc disease is considered effective, however patient selection is critical.*

Artificial discs should be reserved for specific indications

Fusion surgery treats pain by eliminating abnormal motion. Artificial discs are a potential alternative to fusion surgery for degenerative disc disease. Some advertising may make an artificial lumbar disc appear as the solution to anyone's back problem. In reality, artificial discs are indicated only for patients who meet very specific requirements. Three spine surgery hospitals examined whether their patients would have met the exact requirements for an artificial disc. They found that only a small percentage of their patients would qualify, exactly 0%[16], 5%[17], 9%[18] of their patients had no contraindications. *Hence, very few patients would be candidates for an artificial disc. This is an important fact because the results of an artificial disc are less than optimal when the surgery is performed on patients with contraindications[19].*

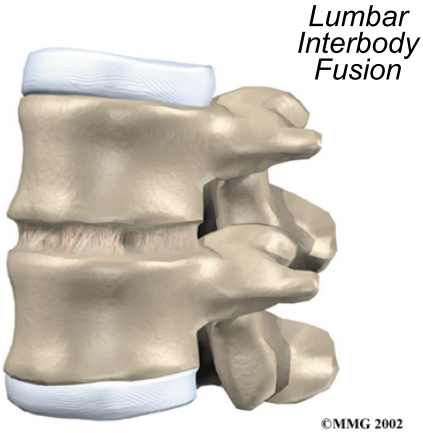


Examples of degenerative changes of the disc and spine

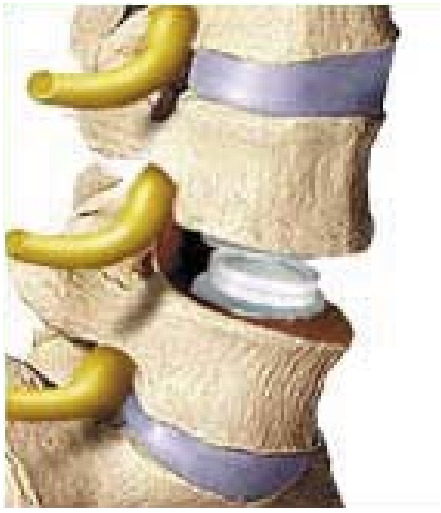
Studies results versus patients experiences

The results of studies are measured in ways that do not necessarily reflect the patients' experiences. Two ways to evaluate studies are through examination of radiographic tests (such as X-rays, MRI, CT scans) and through the definition of clinical success.

- Findings on radiographic tests do not always correspond to patients' symptoms. Many abnormalities or



Fusion: new bone forms between the vertebrae and immobilizes the spine



An artificial disc maintains motion of the spine

problems are found on the MRIs of patients who do not experience any pain or loss of function[20, 21]. Conversely, the X-rays of patients in pain may appear quite normal. Hence, the radiographic results of a study may not correspond to actual patient outcomes.

• Studies also define "clinical success" as a convergence of several results. These are typically accepted by the Food and Drug Administration (FDA) as evidence of success. For instance, in the study of the ProDisc artificial disc, clinical success was a combination of an improvement of at least 15% in disability score, any improvement in general health scores, the absence of reoperation to modify or remove the implant, and the presence of six positive signs on x-rays[22]. A patient may be considered a clinical success according to the study criteria but still experience pain and be in need of daily medication.

There is a gap between the results of the studies published in the scientific literature and the experience of patients. Successful outcomes are not equivalent to full recoveries: many patients still experience pain after a treatment considered successful. For instance, 43% of patients with herniated disc were still taking pain medication after microdiscectomy and 47% after epidural steroid injection[3]. Based on the research of the Spinal Research Foundation, we expect that, after a fusion, 47% of the patients will experience good relief of their back pain, 27% will experience only some pain relief, 15% no pain relief, and 12% will have greater pain than before the fusion.

It is, at this time, difficult to find complete and accurate information about spinal artificial discs. Some insights may be gained through the internet and through patients sharing their experience (http://www.spine-health.com/backtalk/res/btb_res_discs.html, for instance). The Spinal research Foundation (SRF) is currently collecting prospective outcomes data on all fusion patients as well as patients undergoing artificial disc replacement in an attempt to better define the benefits of each surgery as well as the ideal patients for each type of surgery.

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Artificial Discs for the Lumbar and Cervical Spine

By Anne G. Copay, Ph.D.

2. Lumbar and Cervical Artificial Discs

An artificial spinal disc requires a complex design. While many ingenious designs have been conceived, very few have passed the experimental stage. In this section, we will discuss the artificial discs that are available or will likely be available to the general public in the near future.

History of lumbar artificial discs

• **Charité.** The Charité artificial disc was developed in 1982 by two orthopedic surgeons, Kurt Schellnack and Karin Büttner-Janz, at the Charité Hospital in East Berlin. The first model (the Charité I) was implanted in a patient for the first time in 1984. In 1985, the design of the Charité I was modified to Charité II. The Charité I and Charité II were used only at the Charité Hospital and were never commercially available.

Charité

In 1987, the third model, the Charité III, was made commercially available in Europe. Since then, about 4,000 Charité discs have been implanted in Germany, France, the Netherlands, and Great Britain. Johnson & Johnson acquired the rights to the Charité Disc in 2003. A clinical trial was conducted in the U.S. in 2000-2002 and the Charité received FDA approval for single level use in October 2004. Charité is currently commercially available in the U.S. and over 6,000 patients have been implanted in the U.S.

ProDisc

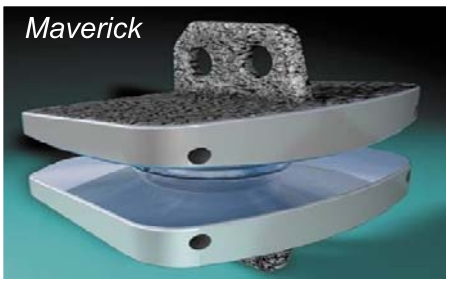
• **ProDisc.** The ProDisc was designed in the late 1980's by Thierry Marnay, a French orthopedic spine surgeon. From 1990 to 1993, Marnay implanted the ProDisc into 64 patients. Two-thirds of these patients had a single ProDisc while one-third had two ProDiscs implanted. The ProDisc has been implanted in over 8,000 patients in Europe since December 1999. A clinical trial was conducted in the U.S. in 2001-2003. The ProDisc has been approved by the FDA for single level use in August 2006 and is currently in limited U.S. release. A second clinical trial for two-level was conducted simultaneously: patients could receive two ProDiscs if they have two adjacent levels of symptomatic disc disease between L3 and S1. ProDisc is the only one of the artificial discs undergoing FDA trials that is investigated for multiple level lumbar disc disease.

• **Maverick, Kineflex,** and **Flexicore** are other artificial discs in the follow-up phases of U.S. clinical trials. Their anticipated public release date is 2008.

Experience with lumbar artificial discs outside the United States

The use of artificial spinal discs outside the U.S. is credited for having provided valuable knowledge concerning disc design, size, placement, insertion technique, and early patient rehabilitation[1].

• **Charité.** The European Charité patients are said to have good to excellent outcomes from 63% to 75% of the times[1]. However, a closer look at the European results reveals a more mixed picture. In Germany, 53 of the patients who received the first Charité discs (between 1984 and 1989) were re-evaluated in 2003. Twelve of them (23%) had undergone fusion surgery due to implant failure or pain. Out of the remaining 41, 32 (83%) showed signs of spontaneous fusion on their x-rays. The 32 patients with spontaneous fusion experienced less pain and disability that the 9 patients whose artificial disc remained mobile[2]. In this long term study, patients' experience is less favorable when the Charité maintains its motion.



Kineflex

Flexicore

In France, 106 patients who received a Charité disc between 1989 and 1995 were re-evaluated in 2005. The study reports that clinical outcomes were excellent overall and that only 10.4% of the patients needed a second operation On the other hand, the study also reports that 42.5% of the patients were pain free, 39.6% still had some pain and needed medication, 7.5% were still in constant pain, and 10.4% had not improved or were worse than before the operation[3].

	ProDisc vs. Fusion		Charité vs. Fusion	
Back Pain Score (0-100)	37	43	25.8	30.1
Disability Score (0-100)	34.5	39.8	30.6	36.3
% Patients maintaining neurological fct	91.2%	81.4%	79.9%	82.3%
% Patients re-operated	3.7%	5.4%	8.8%	10.1%
% Patients using narcotics	54%	56%	72.2%	85.9%

Table 1. Outcomes of ProDisc and Charité compared to fusion two-year post-surgery

• **ProDisc.** Fifty five of the 64 French patients who received the original ProDisc between 1990 and 1993 were re-evaluated in 2001. On average, pain and disability had decreased for the patients and the results were considered excellent for 60% of the patients, good for 15%, and poor for 25%. The study considers the ProDisc effective despite 9% of the patients reporting severe back pain and 35% moderate back pain[4]. The French patients with more than one ProDisc did as well as the patients with a single ProDisc. This contradicts the results of the German patients: those implanted with two ProDiscs had more complications and poorer results than the patients with one ProDisc[5].

Between 2000 and 2005, 215 patients were implanted with a ProDisc in Munich, Germany. The average pain and disability levels decreased by more than half for 92 German patients, two to three years after receiving a ProDisc. About 65% of these patients were completely satisfied, 17% satisfied, and 17% not satisfied[6]. A subgroup of 39 athletic German patients reported better results and satisfaction than overall. Persisting low back pain prevented 2 athletes from resuming physical activity and forced three others to reduce their physical activity. All others were able to resume their participation in cycling, running, swimming, or other activities. Satisfaction seemed to correspond to athletic ability since 33 (84.6%) patients were completely satisfied and 33 had improved or unlimited physical performance, 4 patients were satisfied, and 2 were not satisfied[7].

Another group of 104 German patients were followed for two years after receiving a ProDisc. On average, pain and disability decreased for the patients. After 2 years, 32% of the patients were pain-free, 59% had occasional pain, and 9% had regular pain. Fifty eight percent of the patients were completely satisfied, 39% satisfied, and 3% unsatisfied[8].

• **Maverick.** In 2002 and 2003, 64 French patients were implanted with the Maverick artificial disc. Similarly to other artificial discs, average pain and disability levels decreased but the study does not report on patients satisfaction or the proportion of patients still in pain[9].

Studies typically conclude that lumbar artificial discs are a "safe and effective treatment" of lumbar disc degeneration. Their conclusions are based on average patient scores and do not take into account the proportion of patients who may still be in pain.

Lumbar artificial disc versus fusion

In the U.S., manufacturers of artificial discs have to demonstrate through clinical trials that their artificial discs produce results at least equivalent or better than spinal fusion surgery. The results of the clinical trials for the Charité[10, 11] and the ProDisc[12] have been published and are summarized in Table 1. *The outcomes of fusion and artificial discs appear fairly similar two years after the surgery,* with the exception of a higher proportion of patients maintaining their neurological status with ProDisc than fusion. The results of the artificial lumbar discs awaiting FDA approval (Maverick, Kineflex, and Flexicore) have not been published yet.

History of cervical artificial discs

• **Prestige.** In the late 1980s, Brian Cummins, a British neurosurgeon, designed a cervical artificial disc and had it manufactured in the machine shop of his hospital (the Frenchay Hospital in Bristol, United Kingdom). Starting in 1991, 20 patients were implanted with the Cummins disc. Another pilot study in 1998 included 15 patients at the

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Artificial Discs for the Lumbar and Cervical Spine

2 - Lumbar and Cervical Artificial Discs

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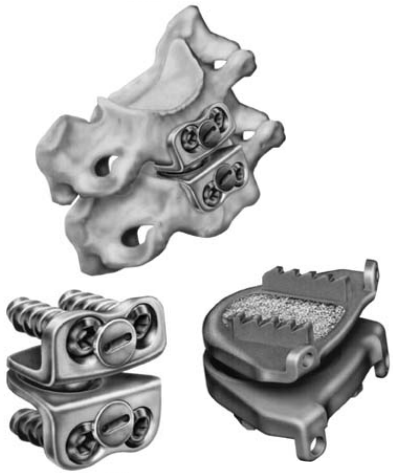
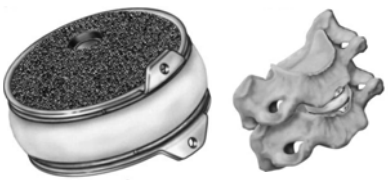


Prestige ST (left) and Prestige LP (right)

same Frenchay hospital. This artificial disc went through several design changes and accompanying name changes: Cummins, Frenchay, Bristol, Prestige I, Prestige II, Prestige ST, and Prestige LP. Prestige has been available in Europe since 1998 and has been implanted in about 12,000 patients worldwide. Prestige ST received FDA approval in July 2007 and will be available in the U.S. in the near future.

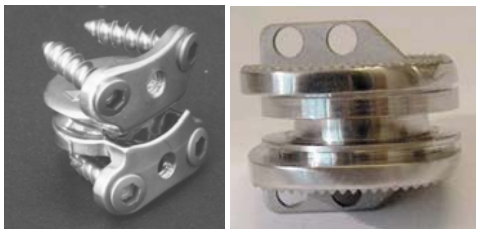
• **Bryan.** The Bryan disc was designed in the U.S. by Vincent Bryan of Spinal Dynamics Corporation in the late 1990's. The Bryan disc is available in Europe and over 4,000 Bryan discs have been implanted worldwide.



Bryan

• **ProDisc-C** is the cervical version of the lumbar ProDisc. It is available on a limited basis in Europe.

• Other discs are currently undergoing clinical trials for FDA approval: **PCM** (which stands for Porous Coated Motion), **Kineflex-C**, **Cervicore**, **Mobi-C** (available in Europe since 2004; FDA clinical trial for 1 and 2 levels), and **SECURE-C**.



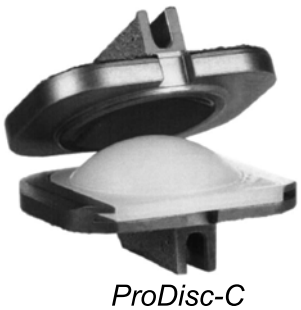
Cervicore *Kineflex-C*

Mobi-C *Secure-C*

Experience with cervical artificial discs outside the United States

The European experience with cervical artificial disc does not appear as extensive as the experience with lumbar artificial discs. A few studies report on small numbers of patients. The small number of patients in these studies precludes any definitive conclusions.

• **Prestige and its precursors.** Fifteen patients who were implanted with the Prestige (named Frenchay at the time) in Bristol were re-evaluated after two years[13]. On average, pain level decreased by 45% and disability level by 31%. Still about half of the patients had some complication or recurring pain.



ProDisc-C

• **Pro Disc-C.** A decrease in pain and disability is reported by 27 patients one year after a ProDisc-C implantation. Fifty-two percent of the patients were completely satisfied, 36% satisfied, and 12% not satisfied[14].

• **Bryan.** Specific pain levels and symptoms are not reported for the 49 patients who received a Bryan in several European countries. After two years, 65% were mostly improved, 4% somewhat improved, 21% had some improvement and some deterioration, and 10% had more deterioration. Outcomes were somewhat better for the patients who had received two Bryan discs[15]. Concerns have been raised about the design of the Bryan disc: patients in Canada[16, 17] and Asia[18] developed some kyphosis (forward bending of the spine) after implantation.

Cervical artificial disc versus fusion

The U.S. clinical trial of the Prestige ST was conducted in 2002-2004 and compared 276 patients receiving the Prestige ST artificial disc with 265 patients undergoing anterior cervical fusion. Average pain and disability decreased for both Prestige and fusion patients. After two years, pain and disability levels were similar for Prestige and fusion patients (even though neck pain had been previously lower for the Prestige patients). Prestige was superior to fusion in that a higher proportion of patients maintained or improved their neurological status and fewer patients needed another surgery for either surgical

failure or adjacent segment disease *(Table 2)*[19]. A small (55 patients) European clinical trial also finds similar reduction in pain and disability for Prestige II and fusion patients[20].

Partial results of the Bryan clinical trial indicate similar neck and arm pain reduction and similar level of patient satisfaction after fusion and the Bryan disc[21] or slightly better pain reduction for the Bryan disc[22].

Published studies report that cervical discs are "safe and effective" based on average patient scores. However, published results indicate that outcomes may depend on the disc design.

	Prestige	Fusion
Neck Pain Score (0-100)	15	16
Arm Pain Score (0-100)	13	14
Disability Score (0-100)	19.3	22.4
% Patients maintaining neurological status	92.8%	84.3%
% Patients needing re-operation	1.8%	8.3%
% Patients needing adjacent segment operation	1.1%	3.4%

Table 2. Fusion and artificial disc outcomes two-year post-surgery

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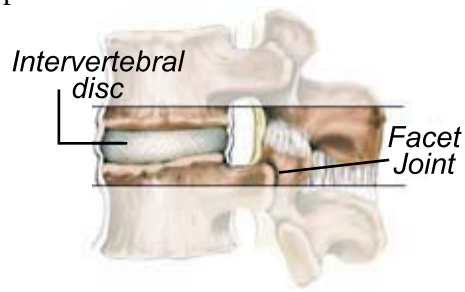
Artificial Discs for the Lumbar and Cervical Spine

By Anne G. Copay, Ph.D.

3. Concerns and Unresolved Issues of Artificial Discs

Motion segment and facet joints

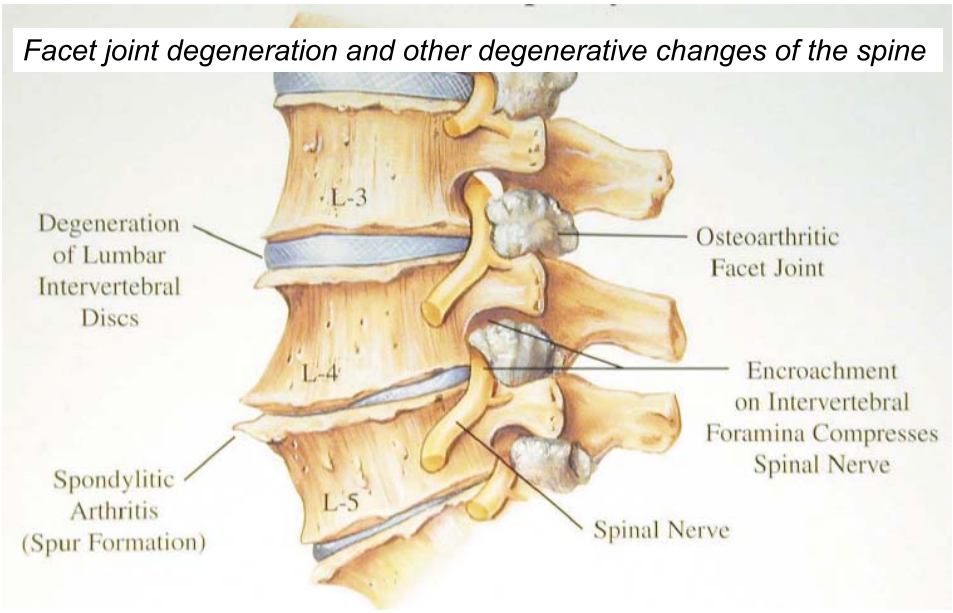
Hip and knee replacement surgery has been the proving ground for spinal disc replacement. There is, however, an important difference between intervertebral joints and hip or knee joints: hip and knee are single joints but a spine motion segment is comprised of three joints: one intervertebral disc and two facet joints. Any change in the intervertebral disc is likely to affect the two facet joints. Specifically, replacing the intervertebral disc with an artificial disc might increase the stress on the facet joints, particularly if there are signs of degeneration already present.



Motion segment

Theoretically, differences in disc design should produce differences in pressure on the facet joints. However, biomechanical studies and mathematical models have shown increased pressure on the facet joints with discs of different designs: Charité[1], Prestige, and ProDisc-C[2]. Patients' examinations also indicate that facet joint arthrosis may be caused or exacerbated by artificial discs. Magnetic resonance images showed progression of facet degeneration in 44% of the patients two years after implantation with Charité[3]. Facet arthrosis was present in 11 of the 27 Dutch patients who had persistent back or leg pain after receiving a Charité[4].

Facet joint degeneration and other degenerative changes of the spine



However, no indication of increased pressure on the facet joints was found in a group of 13 German patients one year after Charité[5]. About 11% of the ProDisc patients had painful facet joints at the implanted level[6]. A comparison of patients in Korea found facet joints degeneration in 36.4% of the Charité patients and 28.6% of the ProDisc patients[7]. A case report explained that a Belgian patient had severe facet joint arthrosis one year after receiving a Maverick and needed the Maverick explanted[8]. On the other hand, Maverick was well tolerated by French patients with mild facet arthrosis[9]. *Artificial discs increase the risk of painful facet joints but not enough information is available yet to determine the severity of this problem.*

Adjacent segment disease and fusion

The range of motion in the total spine results from the added movement of the individual segments of the spine. Fusion restricts movement at a specific level of the spine but the loss of movement at one or two levels is usually well compensated by the adjacent segments. The compensation by the adjacent segments may be responsible for the creation or acceleration of degeneration in segments adjacent to a fusion. This phenomenon is termed "Adjacent Segment Disease" (ASD). We can summarize what we know about ASD as follows:

1. Biomechanical studies and mathematical models have demonstrated increased pressure and increased motion at the segment of the spine adjacent to a fusion both in the cervical[10] and lumbar[11] spine.

2. ASD is apparent on films of patients after fusion but we do not know if these changes are due to the fusion, accelerated by the fusion, or would have happened at the same rate and in the same proportion without the fusion because these are part of the disease process. In the general population, x-rays show that lumbar disc degeneration

progresses at a rate of 3% to 4% per year[12]. There is no definite comparison of disc degeneration rate in individuals with existing degenerative disc disease with and without fusion. However, studies found similar ASD rate between patients who had fusion and patients who had discectomy without fusion[13] or non-operated patients with low back pain[14].

3. There is no definite estimate of the incidence of ASD. Based on examination of x-rays or MRI, studies report a wide range of ASD: from 8% to 100% of the patients are said to have ASD. However, only a small number of patients with ASD will in fact experience pain or need an additional surgery at the adjacent level. Hence, studies report a range of 5.2% to 18.5% of the patients who are affected by ASD[15].

4. Certain factors such as age, number of levels fused, and length of follow-up seem to influence the occurrence of ASD but, here too, some studies found no influence of those risks factors on ASD [16].

It is firmly believed that spinal fusion causes adjacent segment disease. However, there is no clear evidence of three important facts:

- *that ASD is caused or accelerated by the fusion*
- *what proportion of patients will develop ASD subsequently to a fusion*
- *what proportion of patients will be in pain and/or in need of further surgery due to ASD.*

Adjacent segment disease and artificial disc

The cornerstone of artificial discs promotion is their ability to prevent, or at least decrease the incidence of ASD. Since ASD has not been satisfactorily demonstrated yet, this cornerstone appears a bit shaky. This is what we know so far concerning artificial discs and ASD:

1. Biomechanical studies and mathematical models show that artificial discs preserve motion at the implanted level as well as the adjacent levels, while fusion increases motion at adjacent levels[17]. The preserved motion at the implanted level is responsible for the normal motion at the adjacent levels. This is assumed to prevent the occurrence of ASD.

2. Evaluation of artificial disc patients indicates that some patients lose motion of the implanted disc. The reason for this loss of motion is unknown and investigators have reported a high variability in the proportion of patients who lose motion. For instance, 83% of a group of 41 Charité patients showed signs of spontaneous fusion on their x-rays[18] and many ProDisc patients had reduced motion[19, 20].

3. ASD still appears after artificial disc: 10 of 42 ProDisc patients had radiographic signs of ASD. The loss of motion was partially responsible for ASD (59% of the patients who lost motion did not get ASD). ASD had no influence on pain or disability: pain and disability were similar for patients with and without ASD[19]. Also, the preservation of motion minimally reduced pain and disability levels[21]. In another group of ProDisc patients, 13% had painful facet or sacroiliac joints adjacent to the implanted level[6]. In Korea, disc degeneration at the adjacent segment above the artificial disc was found in 19.4% of the Charité patients and 28.6% of the ProDisc patients[7]. Similarly to fusion, the presence of ASD does not necessarily translate into pain and few patients with ASD require a re-operation. For instance, only 2.8% of Charité patients had a re-operation at the adjacent segment over a period of 16 years[22].

4. There is insufficient information about the comparative rates of ASD with lumbar artificial discs and fusion. On the other hand, two studies tilt the balance in favor of cervical artificial discs. Compared to fusion, the Prestige patients had fewer adjacent segment surgeries[23] and fewer Bryan patients needed medical treatment for ASD[24] *(Table 1)*.

	Fusion (158 patients)	Bryan Disc (74 patients)
X-ray signs of ASD	54 (34.6%)	13 (17.5%)
Needed re-operation	5 (3.2%)	3 (4%)
Needed medical treatment	52 (33%)	1 (1.3%)
	Fusion (265 patients)	**Prestige ST (273 patients)**
Needed re-operation	9 (3.4%)	3 (1.1%)

Table 1. Adjacent segment Disease after fusion or cervical artificial disc

In contrast to other studies of ASD, the Bryan study reported the proportion of patients in need of medical treatment. The greatest difference between the fusion and Bryan patients appears in the patients needing medical treatment.

continued on page 16

Artificial Discs for the Lumbar and Cervical Spine

3 - Concerns and Unresolved Issues of Artificial Discs

continued from page 15

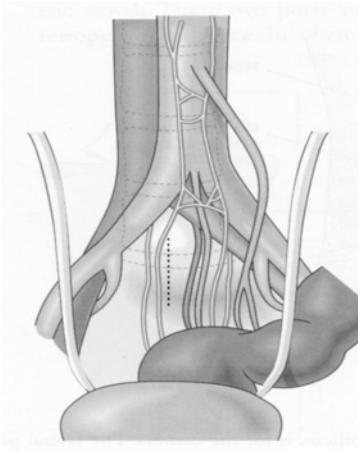
Unfortunately, there is no basis of comparison since the proportion of patients needing medical treatment for ASD is not typically reported in other studies. It would also have been valuable to know the patients' pain level or the extent of the medical treatments in the Bryan study.

While it is firmly believed to be the case, it has not been proven that artificial discs prevent ASD. There is, however, limited evidence that cervical artificial discs may decrease the occurrence of ASD, compared to fusion.

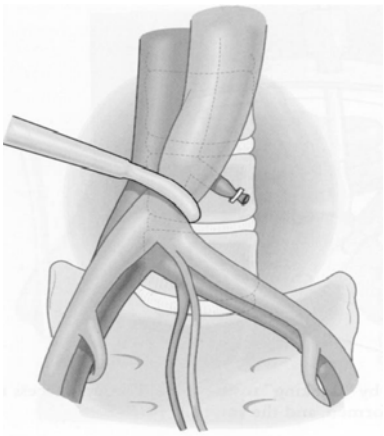
Reoperation rates and risks of revision surgeries

Lumbar discs. Lumbar artificial discs have similar rates of reoperation as fusion: 3.7% ProDisc versus 5.4% fusion[25] and 8.8% Charité versus 10.1% fusion[26]. However, a major concern of lumbar artificial discs is the fact that revision surgery is life-threatening. The implantation of an artificial disc requires 'pulling aside' the major blood vessels in front of the lumbar spine. This will cause some scarring of the blood vessels and will make them adhere to the spine. In a subsequent operation, it will be difficult to again 'pull aside' the blood vessels to gain access to the spine. This creates a significant risk of hemorrhage. Re-operation is thus technically difficult and dangerous despite the revision and explantation strategies that have been successfully used[26].

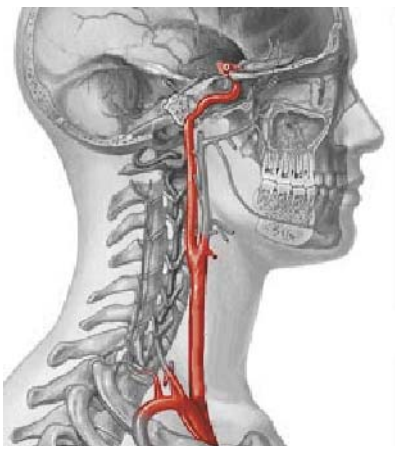
Cervical Discs. The Prestige patients had a lower rate of re-operation (1.8%) than the cervical fusion patients (8.3%)[23]. In contrast to the lumbar spine, no major blood vessels stand in the way to access the cervical spine. Hence, a re-operation in the cervical spine would not be as difficult or dangerous as a re-operation in the lumbar spine.



Blood vessels in front of the lumbar spine



Blood vessels are retracted to gain access to the lumbar spine



Access to the cervical spine is not hindered by blood vessels

(picture courtesy NLM)

Long term wear: debris, breakage, and metal ions release

Due to the risks involved in a re-operation, the longevity of spinal discs is crucial. Typically, artificial hip joints fail after 10 to 15 years and require a replacement. The gliding surfaces of the artificial joint wears out and releases debris in the joint. The debris causes osteolysis (resorption of the bone) around the implant. Osteolysis might cause the loosening of the implant and make it necessary to replace it. Furthermore, metal and polyethylene debris of knee and hip joints accumulate in the liver, spleen, and lymph nodes with unknown long term consequences[27]. Similarly, spinal artificial discs wear out and release debris. The plastic component of some discs is susceptible to breakage. The metal-on-metal discs are not likely to break but release metal particles with unknown health consequences[28]. Table 2 lists the all-metal discs ("metal-on-metal") and the discs with a plastic component ("metal-on-poly").

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Table 2. Classification of discs according to their material

	Metal-on-Metal	Metal-on-Poly
Lumbar Discs	Maverick (Medtronic) Flexicore (Spinecore) Kineflex (Spinal Motion)	Charité (Dupuy Spine, Johnson & Johnson) ProDisc (Synthes Spine)
Cervical Discs	Prestige (Medtronic) Kineflex-C (Spinal Motion) Cervicore (Stryker, Inc.) Secure-C (Globus Medical)	ProDisc-C (Synthes Spine) Bryan (Medtronic) PCM (Cervitech) Mobi-C (LDR Spine)

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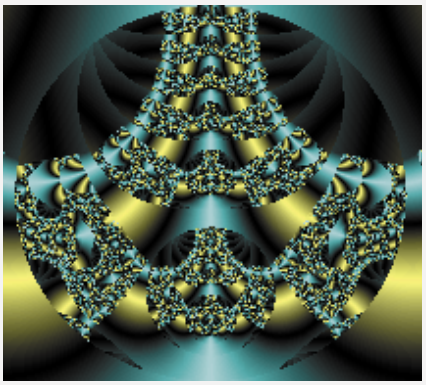

Physical Therapy and Lumbar Artificial Disc Replacement

By Richard A Banton, PT, DPT, ATC and E. Laurence Grine, MSPT, ATC

An estimated 70 million Americans suffer from low back pain every year. Approximately 10% of these individuals fail to benefit from conservative, nonsurgical treatments, and will require surgery[1]. At this point in time, a patient may be given the choice between two types of surgery: artificial disc replacement or spinal fusion. In the past three years, the Virginia Therapy and Fitness Center has treated six patients with artificial disc replacement surgeries. In this article, we will report our observations of the recovery and outcomes of the patients with an artificial disc, as compared to the patients with spinal fusion. We will also discuss the similarities and differences of the rehabilitation treatments for spinal fusion and artificial disc.

Assisting a post-op patient with aquatic rehabilitation during Phase II of the rehabilitation protocol

In comparison to the standard spinal fusion, the artificial disc is reported to allow for quicker recovery time, more spine mobility after surgery, and less stress on adjacent vertebral segments. In our experience, patients with an artificial disc had indeed more spine range of motion (ROM) after surgery. We have observed as much as a ten degree increase in lumbar spine ROM in patients with artificial discs as compared to standard spinal fusion patients. It is important to note here that the benefits of this increased ROM have not been demonstrated. We also observed that our artificial disc patients had a marginally shorter recovery period than fusion patients. Patients who healed without complication, following an artificial disc implant, only demonstrated a two or three week faster recovery period. It would be difficult to attribute these faster recoveries solely to artificial disc technology, considering that normal healing is multi-factored. Skin integrity, age, nutrition, secondary impairments and physical conditioning are equally important to achieving a fast recovery after surgery.

The rehabilitation protocol *(Table 1)* is similar for the artificial disc and lumbar fusion. Rehabilitation takes a minimum of five months and is only shortened by two or three weeks in the case of artificial disc. The rehabilitation protocol is designed to overcome the typical impairments, functional limitations and disabilities following any type of fusion, such as: pain and swelling, decreased ROM, decreased strength and endurance, decreased joint mobility, and limited independence in activities of daily living. The goal for fusion patients over the course of 1 to 8 months is to regain optimal joint mobility, motor function, muscle performance, range of motion, and the highest level of function at home, work, community, and leisure. Many patients receiving a spinal fusion retain the ability to golf, play tennis, run, and ski.

The body continues to remodel and adapt to the fusion for one year following the surgery. It is imperative that patients understand the importance of participating in an exercise program not only for the first year, but for the rest of their life. Lifestyle modifications such as smoking cessation, weight loss, or work conditioning are often necessary to avoid future problems in adjacent vertebral segments. The same lifestyle modifications are likely to be necessary for artificial disc patients.

The Virginia Therapy and Fitness Center has a limited experience in treating patients with artificial spinal discs. We have observed a very similar recovery for patients after artificial disc and spinal fusion. Patients should realize that no surgery can guarantee a full return to pain-free life. The decision to undergo any surgery should be made carefully.

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Phases of Rehabilitation	Goals
Phase I: *1-10 days post-op*	• Protect surgical site • Educate on signs of infection or blood clots • Promote normal gait with assistive device if necessary • Instruct proper body mechanics during independent function
Phase II: *10 days - 2 months* *Aquatic Rehabilitation*	• Control pain and swelling • Improve nerve root mobility • Improve flexibility of lower extremities and thoracic spine • Restore normal gait • Improve endurance with daily activities • Enhance trunk stability through isometrics • Educate patient on stages of healing and protection of fusion
Phase III: *2-5 months* *Land Rehabilitation*	• Progress independence with daily activities • Improve cardiovascular endurance • Enhancing trunk and overall strength • Maintaining neutral spine with functional activities • Return to work as tolerated
Phase IV: *5 months-one year* *Home Program*	• Return to work full status • Progress strengthening and endurance program • Prepare for more strenuous activities such as skiing, golf, etc. • Educate importance of lifestyle change to avoid future problems above or below fusion site

Table 1. Rehabilitation Protocol

Giving

About Us

The Spinal Research Foundation is an international non-profit organization dedicated to improving spinal health care through research and education. The Foundation collaborates with spinal research centers of excellence around the world to prove the success of traditional approaches, as well as develop new techniques and technologies. These results are shared with both the medical profession and the general public to improve the overall quality and understanding of optimal spinal health care.

Neck and Back Pain Affects Millions

More than 85% of the population will suffer from severe neck and/or low back pain during their lifetime. Eight percent of these people develop chronic pain, which means that at any given time, 25 million people in the United States are directly affected by this condition and many more indirectly. Techniques to cure, manage, and prevent this limiting and disabling condition need to be developed. Educating the public, health care providers, and insurance providers is the first step in advancing spinal health care.

According to the National Institutes of Health:

- ❏ At some point, neck or back pain affects an estimated 9 out of 10 people. It is one of our society's most common medical problems.
- ❏ The first attack of neck or low back pain typically occurs between the ages of 30 and 40. Spinal pain becomes more common with age.
- ❏ With symptoms ranging from a dull ache to absolute agony, back pain can put your life on hold.
- ❏ In fact, it is second only to the common cold in causing missed workdays for adults under age 45.
- ❏ Office visits for low back pain: 25 million per year
- ❏ Medical admissions for low back pain: 325,000 per year

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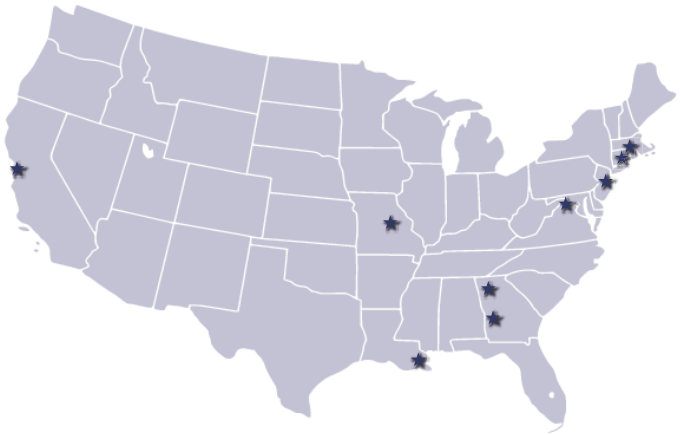

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