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- Thomas R. Walsh, MD

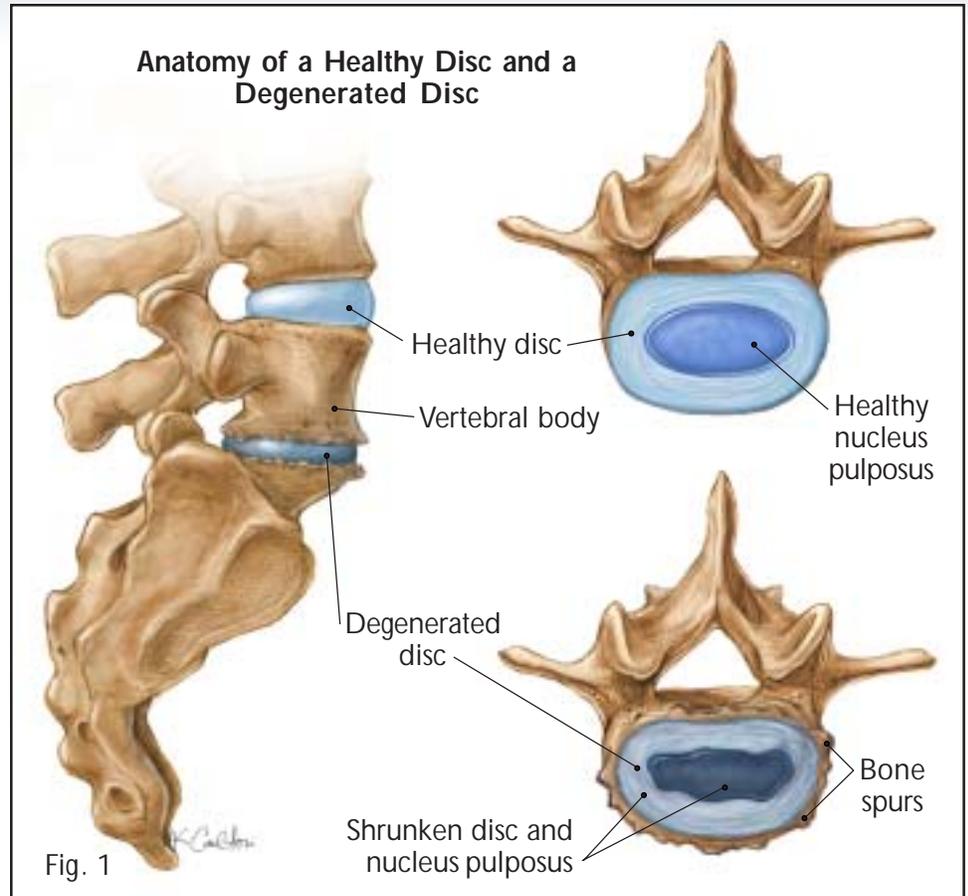
Artificial Disc Replacement in the Lumbar Spine *Are you a candidate?*

Do you find it hard to sit through a movie? When you go to the theater, do you sit near the exit so you can get up and walk around? Do you avoid driving out of town unless someone else drives? Is your lawn shaggy because every time you mow the grass you can hardly get out of bed the next day? Has your work suffered? Does standing, bending, and lifting make life miserable? After activities such as these, do you often go home early and climb into bed? Has depression, anxiety, and despair crept in? Have you tried all types of treatment to no avail; spending time and money, yet your condition has worsened? If any of this sounds like you, welcome to the world of degenerative disc disease.

What is degenerative disc disease?

Degenerative disc disease is one of the most common maladies in the world. It accounts for more missed workdays and lost productivity than any other medical condition, except for the common cold, and it is arguably the most expensive condition related to the workers' compensation system.

Discs allow flexibility of the spine and provide stability between the adjacent bones. A normal intervertebral disc is a rubbery cartilage that provides a cushion between the bones of the spine. It's built like a tire lying on its side, 2 inches across, with a flat surface of bone above and below.



The center of the disc, the nucleus pulposus, is filled with a soft, gooey substance that draws in water to maintain pressure (Fig.1).

The extent of aging or degeneration of the disc is influenced primarily by genetic factors. Individuals in some families tend to have it worse than individuals of other families. Other factors thought to affect disc degeneration include aging, nicotine use, and mechanical stresses. For most of us, aging discs, which almost all of us get to some degree, are not painful most of the time. However, it has been shown that 80% of the US population, at some point in their lives, has had a reportable or memorable episode of low back pain. The back pain usually resolves without treatment within hours, days, or weeks. Then, you return to normal function and mostly forget about it. The pain may return once in a while, but it too will usually go away with time.

As a general rule, a normal disc tends to be stronger than the adjacent bone. During major trauma, the bone often

breaks without direct injury to the disc. Scientific studies have shown that it is very difficult, if not impossible, to make a normal disc rupture. For a disc to rupture, some preexisting structural weakening of the disc must be present.

Nonsurgical treatment

Sometimes a disc can become painful, and the pain just won't let up. During the first 6 months of back pain, you should try nonsurgical treatments, such as anti-inflammatory medications, exercise, physical therapy, bracing, and activity modifications. Often, the pain subsides enough to be tolerable and does not further affect your lifestyle. If the pain remains substantial for more than 6 months, despite efforts made with treatment and exercise, it is less likely it will improve with more time.

Surgical treatment

If, after 6 months, there has been no reasonable improvement in your back pain and you are disabled by it, you should consider surgical options. An x-ray and magnetic resonance imaging (MRI, a scan that shows the bones, muscles, tendons, ligaments, and discs) are the primary diagnostic tools for degenerative disc disease. An additional test, called discography, may be used to confirm

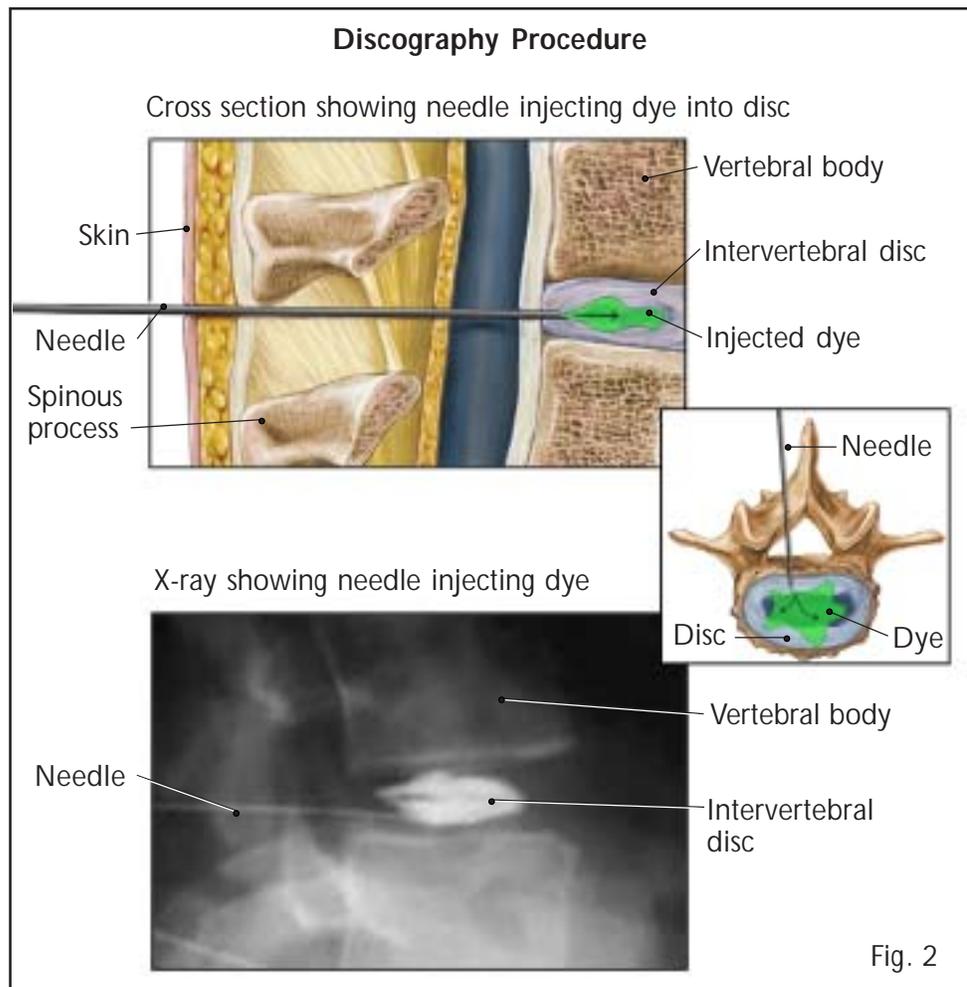
the diagnosis. During discography, a thin needle is placed inside the disc and x-ray dye is injected under a live x-ray machine to see if the disc leaks and if the patient's usual pain is reproduced (Fig. 2). If no more than 1 or 2 degenerative discs are clearly identified, surgery can be a reasonable option. If there are 3 or more painful discs involved, long-term surgical results are less favorable and surgery is often discouraged.

The traditional surgery for degenerative disc disease is lumbar fusion. This involves removing the painful disc, stabilizing the joint with a strong structural spacer, and allowing the adjacent bones to actually fuse together across the spacer. A new and exciting surgical technique has been recently adopted in the US. This new procedure, called artificial disc replacement (ADR), has been used in Europe for over 15 years (Fig. 3). The theoretical advantage of ADR over fusion is that motion of the joint is preserved. The benefit of preserving motion is to diminish stress at the adjacent discs, thereby lessening the likelihood of additional surgery at those discs in the future. Despite more than 15 years of experience with ADR in Europe, there have been no adequate scientific studies to determine for sure if ADR lessens adjacent-disc wear when compared with fusion. For now, it is a theoretical advantage only.

The artificial disc is made of 2 metal end plates that have small teeth on the bone-side surface that attach to the adjacent vertebral bones. Between the 2 metallic end plates, rests a space-age, rounded, plastic spacer that allows flexibility of the joint. These are the same materials used in artificial knee and hip replacements. Currently, there is only 1 artificial disc device approved by the FDA on the market.

The results of ADR and fusion for relief of back pain are comparable. Disc replacement surgery takes between 1 and 2 hours and is usually done at either of the 2 lower lumbar discs. Walking is often begun within 24 hours and discharge from the hospital occurs at approximately 48 hours afterwards. Walking and limited exercises are encouraged. With either procedure, you should expect approximately 60% to 70% pain relief. Patients usually return to their normal activities after 6 to 12 months. Light duty at work can be allowed as early as 3 weeks after surgery.

Some individuals are not good candidates for artificial disc



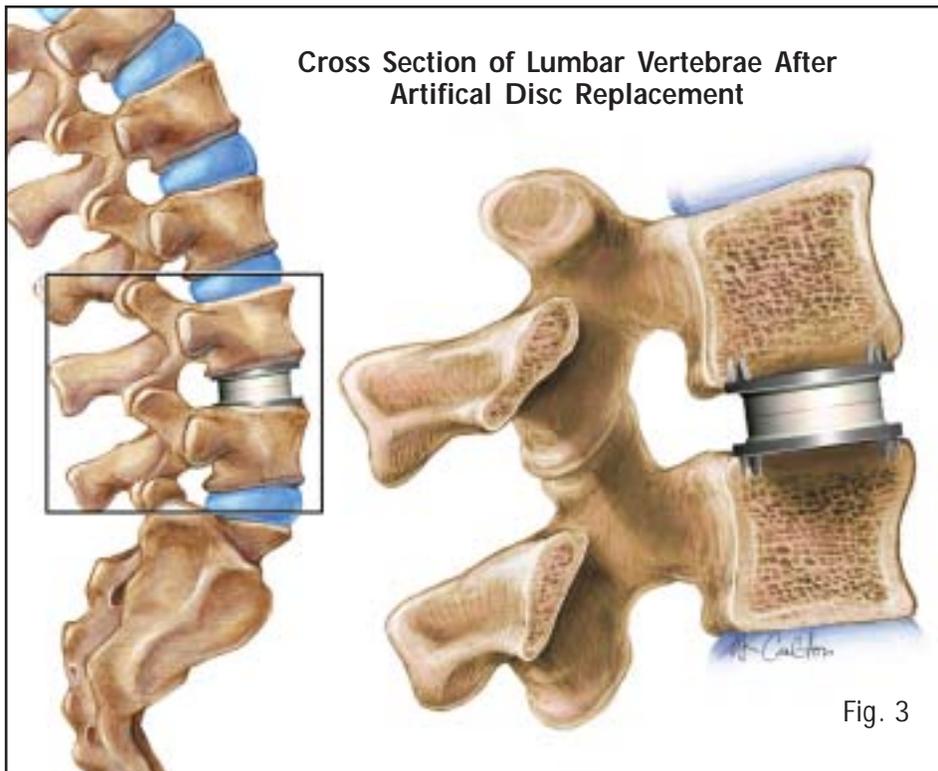


Fig. 3

A History of Lumbar Spinal Fusion

Surgery for low back problems

The year 2003 marked the end of the first 100 years of man's first powered flight in an airplane. No one would dispute that air travel has changed dramatically and has improved during those 100 years. Soon, the 100th anniversary of the first spine fusion will be observed. Using locally harvested bone, Dr. Russell Hibbs of New York City performed the first lumbar spine fusion in 1911 on a 9-year-old patient, who after surgery, "...suffered severe pain which was difficult to control, even with opiates."¹ After the surgery, the child wore a body cast for 3 months.

From that first humbling and what can now be considered primitive experience, lumbar fusions have continued to be

performed. About 258,000 spinal fusions were performed in 1999.² About 119,000 of the procedures involved the cervical (neck) spine and about 139,000 involved the lumbar (low back) spine. Just as with the airplane, lumbar fusion has changed dramatically and has improved over the years, leading to its widespread use to treat low back pain.

Early days of lumbar fusion

Repair of lumbar spine instability became a reality after the invention of anesthesia and antiseptics and Hibb's discovery that bone could be transferred to the spine to fuse 2 vertebrae together. Even then, early spinal fusion patients had to wear an external body cast for months to keep the spine immobile while the transplanted bone healed. It is hard to imagine patients in today's world undergoing such lengthy and difficult treatment. It is also hard to imagine tolerating a body cast before the invention of air conditioning. However, this was the state of spine care in the 1930s and 1940s.³

The spinal implant era

As innovations in spine care progressed, doctors began to consider adding implants to the spine to help stabilize the structure and act as an internal splint. Theoretically, only 4 types of implants are able to help accomplish these goals and aid in the fusion process. The first implant type is hooks that attach to the laminae that project from the spine. The second type is wire or cable that is wrapped around the spinal structures. Screws, the third type, are placed either anteriorly (from the front) into the vertebral

replacement. You should not have artificial disc replacement if you have osteoporosis, bone cancer, bone infection, hardening of the arteries (especially the aorta in front of the lower spine), more than 2 damaged discs, a pinched nerve or spinal stenosis with sciatica, or obesity. The risks of disc replacement surgery include injury to the contents of the pelvis or abdomen and to the ureter, bladder, and intestines because the incision is made in the abdomen. Additional risks include major bleeding, dislodgement of the artificial disc, collapse of the artificial disc into soft bone, and malalignment of the joint. These are in addition to the usual risks of major surgery.

Appropriate candidates for the procedure are young to middle-age adults with 1 or 2 very painful lower lumbar discs that have been debilitating for more than 6 months and have failed to improve with nonsurgical treatments.

Lumbar artificial disc replacement is the most exciting new spine surgery technology to come about in more than 15 years. It can be superior to spinal fusion because motion is preserved and stress on adjacent discs can be decreased. If you are experiencing debilitating low back pain, you may want to discuss lumbar artificial disc replacement with your physician.

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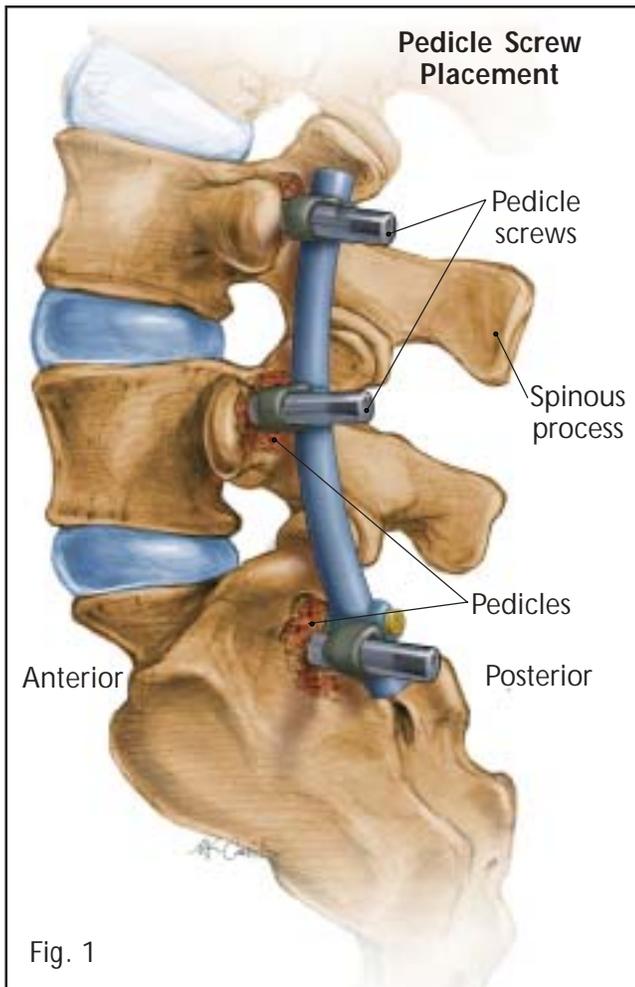


Fig. 1

body or posteriorly (from the back) through the vertebra giving stability during the fusion process. (Fig. 1). The fourth type, now becoming widely accepted in the US, is the interbody cage device (Fig. 2). Cages are hollow, perforated cylinders usually made of metal, that hold bone taken from a patient's hip. The cages are inserted between 2 vertebral bodies to aid fusion.

The surgical navigation era

The idea of using screws for fixation in the US was controversial because the technique of placing screws down the long axis of the pedicle without causing neurological injury was considered by some to be difficult to achieve. An important innovation that aided lumbar spine fusion surgery was the use of navigational devices. Military technology had been developed to guide airplanes close to the surface by means of satellite images taken at different angles. With the use of the same technology, surgical navigational aids were developed in the mid-1990s to make placement of screws into pedicles—or other anatomical structures—much easier.

Use of bone grafts

For spinal fusion procedures, the underlying rationale is that motion causes pain, and, by fusing one vertebral body

to another, motion and, therefore, pain can be eliminated, as well. To achieve fusion, many different materials have been tried, including xenograft, bone from other animal species, such as sheep or cows.

Currently, the graft method of choice for lumbar spine fusion surgery is to transplant the patient's own bone (autograft) taken from another part of the body. Most frequently, bone is taken from the patient's hip because the bone is easily accessible, it is from a nonweight-bearing site, and over time the procedure has been found to have the least number of complications.

The cage era

The use of interbody cages is a mechanical means of achieving interbody fusion. Worn-out collapsed disc spaces can be restored to their normal height using the cage technology. Gary Michelson, MD, developed the first cage of such design. Many variations of the cage design have been developed over the years, but all incorporate his technology. Two such cages were developed and introduced in the US by Medtronic Sofamor Danek (Memphis, TN). The first was the cylindrical threaded cage called the INTER FIX™ Lumbar Tapered Fusion Device,

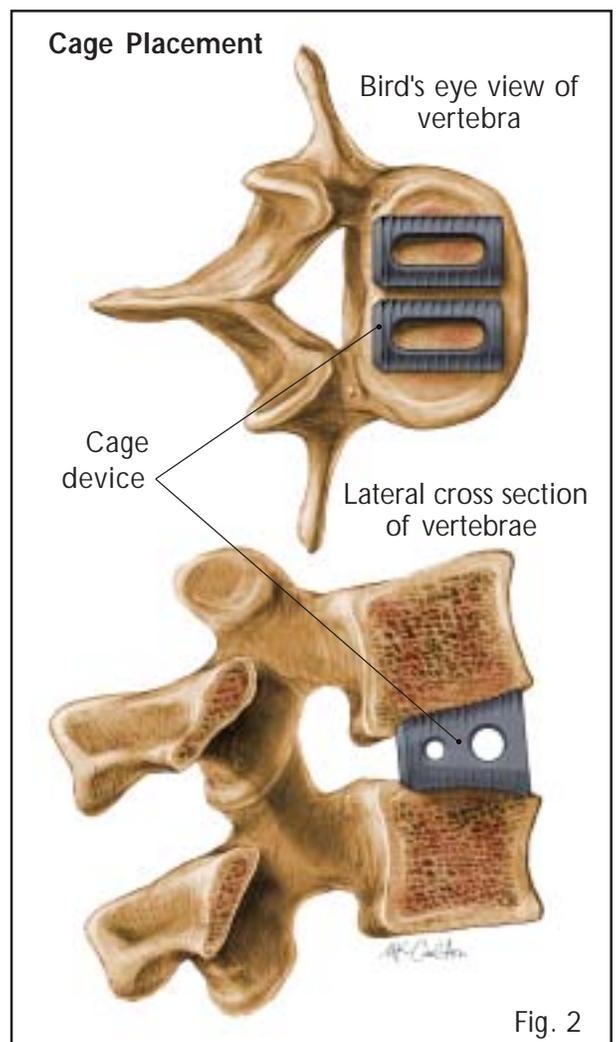


Fig. 2

and the second was the LT-CAGE™

Lumbar Tapered Fusion Device. The second cage is tapered to help restore the normal angular (lordotic) curve of the lumbar spine. Both cages use autograft bone transplanted from the hip and inserted inside the cage before its insertion into the disc space.



The bone morphogenetic protein era

Because problems sometimes persist at the site where bone was taken from the hip in a patient undergoing lumbar fusion, human clinical trials were begun in 1997, to find a substitute that would be as effective as bone graft for filling cage-type devices. Recombinant human bone morphogenetic protein (rhBMP-2) technology was used in clinical trials, and it was found to work as well as autograft for replacing the bone inside a tapered lumbar fusion cage.

Several improvements were noted with the use of rhBMP-2 with cages. Improvements in operative time, hospital stay, and return to work showed that much of the recovery time needed for spinal fusion surgery was apparently related to the second surgery site where bone was harvested from the hip.

Currently, using these new technologies and laparoscopic techniques through a small incision in abdominal cavity, it is possible for some surgeons to perform the surgery on an outpatient basis, allowing the patient to leave the hospital the same day as the surgery. Today, a patient who has spinal fusion surgery has a greater chance of a better outcome than they had 15 years ago.

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Compression Fractures of the Spine

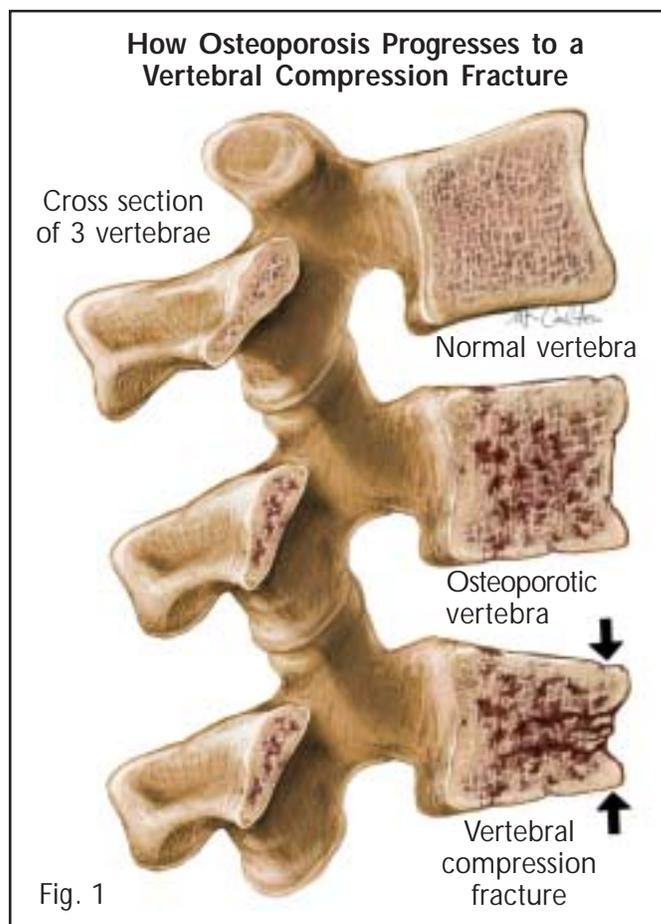
New treatment for an old problem

A **vertebral compression fracture** (VCF) is an injury in which the vertebral body breaks and collapses. A VCF causes abnormal pressure in the spine and results in pain, numbness, tingling, and weakness that can make it difficult to complete everyday activities. In more extreme cases, multiple fractures can cause a hump-like curve in the spine and can lead to pulmonary and respiratory problems. In these extreme cases, VCFs are associated with an increase in mortality.

Osteoporosis is the primary cause of VCFs (Fig.1). Unfortunately, osteoporosis occurs without symptoms and often goes undetected until a fracture occurs. The disorder is characterized by a reduction in bone density as the bone tissue deteriorates leaving the bone fragile and susceptible to fractures.

Treatment

Some VCFs are unstable, which means a loss of function has occurred because of bone pressing on the spinal cord or spinal nerves. Fortunately, most VCFs are stable. Typically, stable fractures heal with a few days of bed rest,



pain medication, and physical therapy. In some cases however, the bone does not heal and the pain increases over time. For unstable fractures, surgery is almost always necessary to restore function.

When a fracture does not heal, surgical treatment can help a patient improve. Until recently, a procedure known as a vertebroplasty was performed. In **vertebroplasty**, the vertebra is injected with bone cement to provide support to the vertebra. While effective for many, studies have shown that cement procedures can present other risks, such as cement leakage, toxicity reactions, and adjacent vertebral fractures.

Today, we have another option known as a **biologic vertebral augmentation** (BVA). BVA is a minimally invasive procedure using a product called OptiMesh® Deployable Grafting System (Spineology, Inc., Stillwater, MN) and using biologically friendly bone graft. OptiMesh® is a polymeric mesh designed to contain and control the deposition of compressed bone graft within the damaged vertebral body.

During BVA surgery, a cavity is created and the OptiMesh® implant is inserted (Fig. 2). The OptiMesh® implant is placed in the center of the damaged vertebra and filled through narrow tubes with granular bone graft. As the volume of bone is increased within the mesh, it frequently reduces any deformity that is present in the bone. When completely full, the graft changes from a fluid-like material to a solid-like structure. The solid structure acts as a support within the center of the vertebra to transmit load and, therefore, eliminates pain and increases mobility.

The benefits of BVA over vertebroplasty are related primarily to the use of bone graft instead of bone cement. Bone graft, unlike bone cement, provides the patient with the opportunity for the vertebra to heal, and the risks associated with bone cement are eliminated. Additionally, biomechanical testing has shown that bone graft is not as hard as bone cement. As such, one of the principle complications of cement, adjacent level vertebral fractures, may be reduced.

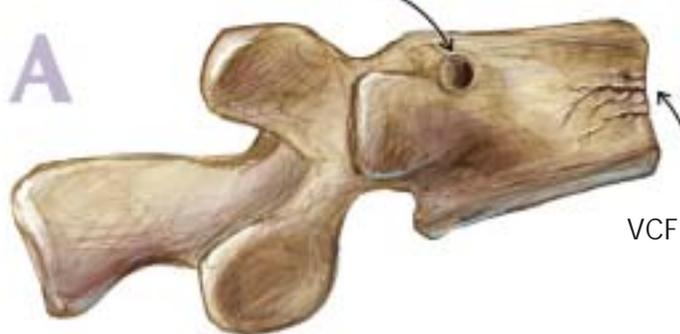
Osteoporosis and BVA

BVA is just one part of a fracture patient's treatment. When a fracture occurs it is important that the underlying osteoporosis is treated, as well. If untreated, osteoporosis will likely continue to cause fractures. New treatments designed to help grow bone are being developed. These treatments include medications like parathyroid hormones and dietary supplements and lifestyle changes. BVA is exciting because it complements the biologic treatments making them more effective.

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Biologic Vertebral Augmentation Procedure

A cavity is created in the vertebra.



The OptiMesh® implant is inserted.



Bone graft is placed inside the implant to open up and support the damaged vertebra.



The instruments are removed and the procedure is complete. The bone graft and implant remain inside the vertebra.

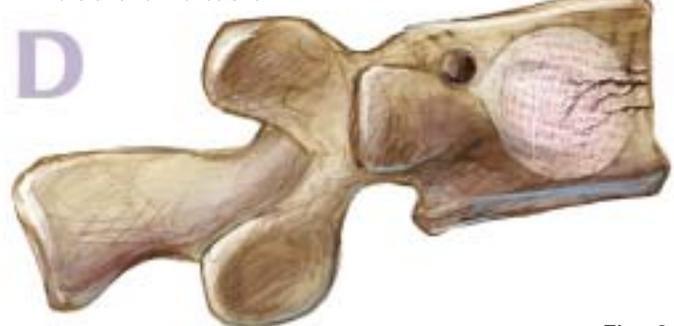


Fig. 2

Recovering from Spine Surgery

Regaining a healthy spine

Less than 1% of people with low back pain have to have surgery. If surgery is necessary, you should start thinking about rehabilitation beforehand. Rehabilitation after surgery helps to improve your strength and agility and helps to reduce the possibility of back problems in the future.

Much of what you do after surgery depends on several factors: the type of surgery you had, your condition before surgery, any complications during surgery, your doctor, and even your geographical location. Some physicians are more adamant about rehabilitation than others; and interestingly enough, in some parts of the country doctors suggest more rehabilitation than others.

Taking it slow

Rehabilitation begins in the hospital. A physical therapist will instruct you with the proper mechanics of moving in the bed, sitting up, and walking (Fig. 1). Short, frequent walks are common in the beginning. Although your exercises can appear simple or unimportant or can cause you discomfort, you must take your rehabilitation seriously. Failure to do what your doctor suggests can result in a poor outcome. A certain amount of soreness is common during recovery. Pain from spine surgery is no different than any other surgery. Physical therapists can help you attain good functional condition in several ways. To help reduce pain, your therapist can teach you how and when to use ice packs, body positioning, movement, and occasionally, TENS units (transcutaneous electrical nerve stimulators that block pain signals traveling to the brain). Some patients may need to make lifestyle changes, such as eating healthier, losing weight, exercising, or perhaps a job change. For a healthy spine, you need back muscle endurance, a normal range of motion, strength, and flexibility. Fitness is the solution to reducing low energy levels, to returning to safe activity, and to preventing reinjury. Basically, some type of exercise is essential after spine surgery. The exercise can be something as simple as a gradual walking program or a more complete program including scar mobilization (movement of area around incision site), flexibility, core stability, strengthening, and conditioning. Your goal is to get back to the maximum level of activity possible.

Going home

After you leave the hospital, you may be prescribed scheduled visits for out-patient therapy and a home-therapy program. The visits to physical therapy should include a review of your home exercises to ensure you are completing the exercises properly. Your therapist can also guide you through other conditioning exercises as well as teaching you correct body mechanics and helping you improve your posture and balance.

After surgery, remember that pacing your actions and keeping active is all part of rehabilitation. Commit to sticking with your



Fig. 1

strength and endurance program to prevent a recurrence. Continue to use pain controlling techniques such as ice packs, TENS devices, body positioning, and movement. You can expect to participate in outpatient therapy 2 to 3 times a week and your rehabilitation program can last from 4 to 8 weeks. However, the time you spend in therapy is a great investment toward a healthy spine.

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Thomas R. Walsh, MD, earned his medical degree and graduated with honors, magna cum laude, from the University of Missouri-Columbia. He completed an orthopaedic surgery residency at the University of Iowa and a one-year Columbia Spine Fellowship in Missouri.

Certified by the American Board of Orthopaedic Surgery, Dr. Walsh is an active member of the American Academy of Orthopaedic Surgeons and the North American Spine Society, where he was awarded the prestigious Acromed Award for Outstanding Spinal Research.

Dr. Walsh is an Eagle Scout. He served in the United States Army at Fort Benning, Georgia, as an orthopaedic surgeon and he is a veteran of Operation Desert Storm.

Dr. Walsh specializes in orthopaedic surgery of the neck and back for adults and children. He is a regional trainer for the recently approved Charité Artificial Disc.

Dr. Walsh and his wife, Dr. Bobbi Farber, have five children. During his free time, Dr. Walsh enjoys golfing, diving, and boating.



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