

Balloon Kyphoplasty

*Minimally Invasive Treatment
for Vertebral Compression Fractures*



Information for you and your family

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is to be the recognized global leader
in restoring spinal function through
minimally invasive therapies.

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Introduction

Your doctor has determined that you have a vertebral compression fracture (VCF). This type of fracture can cause severe back pain. Left untreated, one compression fracture can lead to multiple fractures that, in turn, could alter the shape of your spine and adversely affect your overall health.

Traditional treatment for VCFs is limited to bedrest, bracing and management of pain, often with narcotics. Although appropriate in some cases, this type of treatment does not address the deformity that can occur with multiple fractures.

Balloon Kyphoplasty is a minimally invasive treatment that can stabilize the fracture and reduce back pain, as well as restore height and spinal alignment.

This booklet explains why VCFs occur and why Balloon Kyphoplasty may be a viable treatment option for you.



What is a Vertebral Compression Fracture?

The bones in your spine are called vertebrae; the thick portion of bone at the front of each vertebra is referred to as the vertebral body (Fig 1). A vertebral compression fracture (VCF) occurs when the vertebral body fractures and collapses (Fig 2). Most VCFs are caused by osteoporosis, a disease that causes bones to become brittle and break easily. Because osteoporosis usually progresses without obvious symptoms, a person may not know that they have the disease until a fracture occurs. Compression fractures can also occur as a result of certain types of cancer or tumors.



Fig 1
Normal vertebral body
(side view)

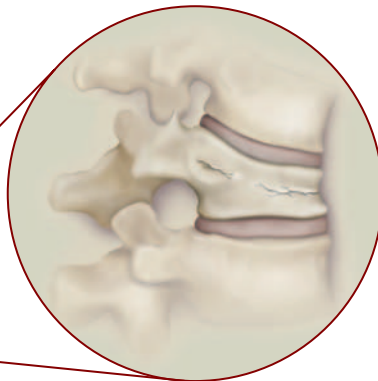
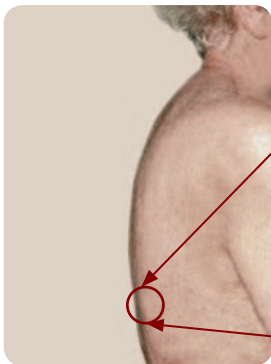


Fig 2
Fractured vertebral body
(side view)

Multiple compression fractures cause your spine to shorten and angle forward, resulting in a stooped posture. This forward curvature of the spine (kyphosis) makes it difficult to walk, reach for things or conduct activities of daily living.

Chronic back pain, loss of height, diminished appetite and difficulty sleeping have been associated with this disorder. Over time, patients with VCFs are at increased risk of suffering from serious, or even fatal, pulmonary complications.

How the Balloon Works

Balloon Kyphoplasty is a **minimally invasive treatment** in which orthopaedic balloons are used to gently elevate the bone fragments in an attempt to return them to the correct position. Before the procedure, you will have diagnostic studies, such as x-rays and magnetic resonance imaging (MRI), to determine the exact location of the fracture.

With a hollow instrument, the surgeon creates a small pathway into the fractured bone. A small, orthopaedic balloon is guided through the instrument into the vertebra. The incision site is approximately 1 cm in length.

Next, the balloon is carefully inflated in an attempt to raise the collapsed vertebra and return it to its normal position.

Balloon Kyphoplasty can be done under **local or general anesthesia**—your doctor will decide which option is appropriate for you. Typically, the procedure takes less than one hour per fracture treated and may require an overnight hospital stay.



Balloon placement



Full inflation



Once the vertebra is in the correct position, the balloon is deflated and removed. This process creates a void (cavity) within the vertebral body.



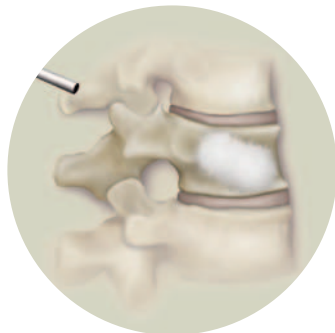
Void within vertebral body

The cavity is filled with a special cement to support the surrounding bone and prevent further collapse.



Filling the cavity with cement

The cement forms an internal cast that holds the vertebra in place. Generally, the procedure is done on both sides of the vertebral body.



The internal cast

After Balloon Kyphoplasty Treatment

Typical postoperative care involves the following:

After the procedure, you will be transferred to the Recovery Room for about an hour. A specially trained nurse will monitor your condition and assess the degree to which your back pain has been alleviated.

During your hospital stay, you will be encouraged to walk and move about. Generally, patients are discharged from the hospital within 24 hours.

Your doctor will have you schedule a follow-up visit and explain limitations, if any, on your physical activity. After treatment with Balloon Kyphoplasty, mobility is often quickly improved. Most patients are very satisfied with the procedure and are able to gradually resume activity once discharged from the hospital.

Procedure Benefits:

- Significant reduction in back pain
- Significant improvement in quality of life
- Significant improvement in mobility
- Significant improvement in ability to perform activities of daily living



Incision sites after
Balloon Kyphoplasty

As with any surgery, there are potential risks. Although Balloon Kyphoplasty is designed to minimize these risks as much as possible, there is a chance that complications could occur. Be sure to discuss the possible risks with your doctor. Also, please note that not all patients are candidates for Balloon Kyphoplasty. For more information on specific risks, please refer to ***Are there risks associated with Balloon Kyphoplasty?*** on page 9 of this booklet.

Frequently Asked Questions

Are vertebral compression fractures (VCFs) difficult to diagnose?

If a compression fracture is suspected during a physical exam, diagnosis can be easily confirmed with radiographic studies. Compression fractures, however, tend to be under-recognized by physicians and patients alike. The difficulty with diagnosis arises when the discomfort from a compression fracture is mistakenly regarded as simply “back pain” or a “normal” part of aging. Sometimes, a person can have a compression fracture and not have any symptoms at all; this too, can be an obstacle to diagnosis.

Over time, the stooped posture and chronic pain associated with multiple compression fractures contribute to an overall poor quality of life. If compression fractures are not diagnosed and consequently, left untreated, the physiological and psychological consequences can be devastating. It is important to have the reason for back pain investigated. Only a complete physical exam, together with an x-ray and MRI, can help your physician determine whether back pain is from a compression fracture or not.

Why is it important to treat VCFs?

After an initial vertebral fracture, the risk for having another fracture is increased fivefold. In addition, just one VCF affects the distribution of weight along the spinal column. Misalignment brought on by a fractured vertebra places more stress on adjacent vertebrae; the front of the spine has to withstand the same amount of stress with fewer functioning parts, resulting in a structure that is now weakened and vulnerable to additional fracture.

What are the symptoms of a VCF?

Most VCFs have a gradual onset, unrelated to specific injury or trauma. Fractures can occur as a result of normal activity; i.e., bending over to pick something up, reaching toward something or carrying a bag of groceries. Patients can experience pain ranging from sudden and severe, to persistent and dull. The fact that symptoms of a VCF can be easily confused with other back problems underscores the importance of obtaining a correct diagnosis and receiving treatment.

Can vertebral fractures adversely affect my overall health?

In cases of multiple fracture, kyphosis can become more pronounced, painful and debilitating. Forward curvature of the spine has a “compression effect” on your organs, making it progressively difficult to breathe, walk, eat or sleep properly. Patients with kyphosis have an estimated 24% increase in mortality compared to patients without VCFs.

What are the psychosocial effects of VCFs?

Studies have shown that patients with multiple compression fractures experience depression, anxiety and lowered self-esteem, in addition to medical complications. The alteration in lifestyle that accompanies severe kyphosis can profoundly affect a patient’s sense of well-being and cause feelings of isolation and sadness.

How common are vertebral compression fractures?

In the United States, approximately 150,000 patients are hospitalized every year with compression fractures (average hospital stay 8 days), resulting in costs in excess of \$1.6 billion. According to the National Osteoporosis Foundation, the annual direct expenditure (hospitals and nursing homes) for osteoporotic and related fractures has been estimated at \$17 billion (2001). This figure translates to \$47 million each day, and the cost is rising.

How long does the procedure take? What kind of anesthesia is used?

Balloon Kyphoplasty typically takes one hour per fracture treated and may require an overnight hospital stay. The procedure can be done using either local or general anesthesia; the surgeon will determine the most appropriate method, based on the patient’s overall condition.

What are the potential benefits of the procedure?

Balloon Kyphoplasty has been shown to restore vertebral body height and correct spinal deformity with a low complication rate. Studies also report:

- Significant reduction in back pain
- Significant improvement in quality of life
- Significant reduction in number of days per month that a patient remains in bed; most patients had a 100% reduction in days in bed, one month post-surgery
- Significant improvement in mobility
- Improved ability to perform activities of daily living, such as walking, hobbies and work
- Significant reduction in number of days where pain interfered with daily activities

Are there risks associated with Balloon Kyphoplasty?

Any type of surgery involves risk. Although the complication rate for Balloon Kyphoplasty is low, serious adverse events can occur, including:

- myocardial infarction (*heart attack*)
- cerebrovascular accident (*stroke*)
- pulmonary embolism (*cement leakage that migrates to the lungs*)
- cardiac arrest (*heart stops beating*)

Other risks (relevant to the anatomy being treated with bone cement) include deep or superficial wound infection, and leakage of cement into the muscle and tissue surrounding the spinal cord. Patients are encouraged to discuss these, and other risks, with their physician.

Is Balloon Kyphoplasty covered by insurance?

In most cases, Medicare provides coverage for Balloon Kyphoplasty. Other insurance plans may also cover the procedure.

Does a physician need special training to do the procedure?

Yes. A physician needs advanced training to perform the procedure. Worldwide, over 4,000 orthopaedic surgeons, neurosurgeons and interventional radiologists who specialize in treating the spine have already been trained. Physicians who manage osteoporosis (general practitioners, rheumatologists, internists, etc.) can refer patients to a trained spine specialist for treatment. To date, approximately 95,000 fractures in over 75,000 patients have been treated with Balloon Kyphoplasty.

Where can I obtain more information about the procedure?

You can get more information on Balloon Kyphoplasty, as well as find a trained spine specialist in your area, by visiting www.kyphon.com.

Patient Stories

*Early and effective treatment—**fixing the fracture**—improves quality of life.*



Ron Luperine

Retired banker. Age: 62

Diagnosis: Steroid-induced fracture

Mr. Luperine suffered from a chronic lung ailment. Doctors prescribed corticosteroids; however, the drugs caused him to lose bone mass and he developed secondary osteoporosis. The resultant compression fracture was so debilitating that he had an infusion pump implanted to manage the pain. Following treatment with Balloon Kyphoplasty, the pump was removed and Mr. Luperine is now happy to be “living and getting around again.”



Chris Kern

Former x-ray technician. Age: 84

Diagnosis: Osteoporotic fracture

Ms. Kern lives with her wheelchair-bound roommate in a house in Northern California. One night, a few hours after helping her roommate to bed, she awoke with severe back pain. Over the next four months, Ms. Kern spent time in and out of the hospital, relying on narcotics to control the pain. She couldn't eat, and lost over 30 pounds. Finally, she insisted that a back x-ray be taken and reviewed by an orthopaedic surgeon. In August, 2003, four compression fractures were found. After having Balloon Kyphoplasty, she says the difference in the way she feels is “like night and day.”



Ellen Simpson, M.D.

Retired pediatric cardiologist. Age: 86

Diagnosis: Osteoporotic fracture

Dr. Simpson had already been diagnosed with osteopenia and was undergoing pharmacologic treatment for her condition. She recalls a Thanksgiving Day party in which she spent most of the day sitting hunched over because of back pain. The morning after the party, the pain made it difficult to get out of bed. Two fractures were treated with Balloon Kyphoplasty in January, 2003. Now, Dr. Simpson takes delight in her renewed ability to bend and move. "My friends," she says, "tell me I look 15 years younger!"



Christine Siegel

Teacher. Age: 57

Diagnosis: Multiple myeloma-induced fracture

Being diagnosed with multiple myeloma is frightening enough; add compression fractures to the devastating complications of the disease, and life becomes even more difficult. Over the course of six months, Ms. Siegel lost 6 inches of height because of fractures in her back. "I was bedridden for over a year. I was on opioids for pain." In May, 2003, she underwent Balloon Kyphoplasty to repair four fractures. "I threw away all the pain killers," she says. "The cancer caused me to fall apart. This procedure put me back together again."

Glossary

Balloon Kyphoplasty

A minimally invasive treatment option for patients with vertebral compression fractures. The procedure uses orthopedic balloons to create an internal cast to repair the fracture.

Bone cement

A surgical adhesive that can be used to fill a void or affix bone and/or orthopaedic hardware to bone.

Bone mineral density (BMD) test

An accurate, low-dose x-ray that measures bone health.

General anesthesia

The administration of anesthetic drugs during a surgical procedure to induce a state of total unconsciousness.

Kyphosis

Excessive curvature of the upper spine resulting in a stooped or “hunchbacked” posture. Often referred to as a dowager’s hump.

Local anesthesia

The administration of anesthetic drugs to confine loss of sensation to a specific area; e.g., a “numbing shot” from the dentist. When local anesthesia is used, the patient is often awake and responsive.

Minimally invasive

Any surgical technique in which a large incision is not required.

MRI

Magnetic resonance imaging is a non-invasive test that produces two-dimensional images for viewing. MRIs do not involve the use of radiation.

Multiple myeloma

A cancer of the bone marrow; specifically a proliferation of the plasma cells. Multiple myeloma destroys bone tissue, in addition to causing anemia and other blood disorders. Myeloma is referred to as “multiple” because more than one area of the bone marrow is usually affected.

Osteoporosis

A disease that causes bones to become weak and susceptible to fracture.

Pulmonary

Having to do with the lungs and respiratory system.

Vertebra

Any one of the 33 bones that form the spinal column. Humans have 7 cervical (neck), 12 thoracic (upper back,) 5 lumbar (lower back), 5 sacral and 4 coccygeal (“tailbone”) vertebrae.

Vertebral body

The round, bony area of a vertebra.

Vertebral compression fracture

Osteoporosis and certain types of cancer can cause the bones of the spine to become weak or brittle, sometimes causing the vertebrae to fracture.

Void, cavity

An empty area or space.

Web Resources

Foundation for Osteoporosis Research and Education

www.fore.org

International Myeloma Foundation

www.myeloma.org

International Osteoporosis Foundation

www.osteofound.org

Multiple Myeloma Research Foundation

www.multiplemyeloma.org

National Osteoporosis Foundation

www.nof.org

National Women's Health Resource Center

www.healthywomen.org

Spine-health

www.spine-health.com

SpineUniverse

www.spineuniverse.com

WebMD

www.webmd.com

To request educational materials and locate physicians trained in the Balloon Kyphoplasty procedure, please visit our Web site.

www.kyphon.com

NOTE: The sites listed above are not managed or monitored by Kyphon Inc. and are listed as a courtesy to the reader. Kyphon makes no representation as to the information presented on any site listed or said site's compliance with applicable laws and regulations.

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KyphX® Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with KyphX® HV-R™ Bone Cement), hand, tibia, radius and calcaneus.

KyphX® HV-R™ Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor.

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