

Understanding Balloon Kyphoplasty and Myeloma-Induced Vertebral Compression Fractures

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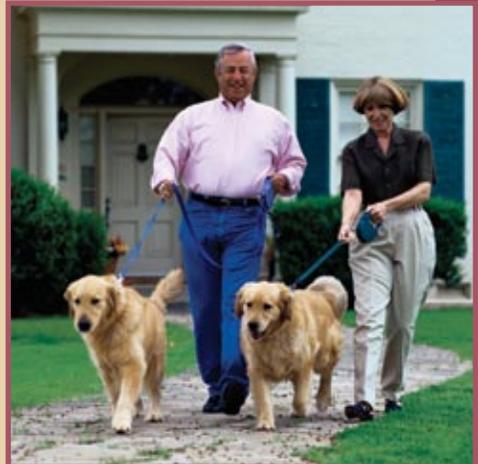


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Introduction

Myeloma is a cancer that affects the plasma cells of the **bone marrow**. This rare and complex disease replaces healthy bone marrow with malignant plasma cells (myeloma cells), often causing widespread development of **lesions** and destruction of bone. Myeloma also prevents the bone marrow from forming cells that are important to the immune system, leaving patients vulnerable to infection and disease.

Lesions occur most commonly in the bones of the spinal column. Most myeloma patients experience pain, especially in the back and the ribs. More often than not, back pain and generalized weakness are what bring many undiagnosed myeloma patients to the doctor in the first place.

Sudden severe back pain can indicate that the **vertebral body**



*Words appearing in **bold** are defined in the glossary at the back of the booklet.

of a **vertebra** has fractured or collapsed. Fractures of the bones of the spinal column are called vertebral compression fractures (VCFs) or simply, spinal fractures.

Treatments to alleviate the pain associated with VCFs range from over-the-counter medications to major open spine surgery. Minimally invasive surgical techniques, like balloon kyphoplasty, fall in the middle of these treatment options. This brochure explains why VCFs occur and presents a number of treatment options. In addition, it provides a step-by-step explanation of balloon kyphoplasty.

Although it is not yet possible to cure myeloma, it is possible to improve the quality of life for patients. With this booklet, you will be better able to discuss your condition with your physician and formulate a treatment plan that's best for you.

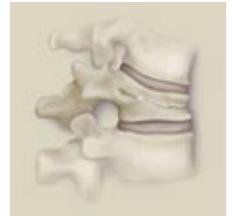
WHAT ARE VERTEBRAL COMPRESSION FRACTURES?

Vertebral compression fractures are fractures of the bones of the spinal column. A VCF occurs when the vertebra fractures or collapses because the bone is too weak to withstand the pressure or stress placed upon it. With multiple fractures, the spine shortens and becomes misaligned, causing a "hunch-backed" condition known as **kyphosis**.

Vertebral compression fractures are usually caused by **osteoporosis**, but they can also be caused by diseases that affect the bone, such



Normal Vertebra



Fractured Vertebra

as myeloma. In myeloma patients, moderate to severe back pain is usually caused by VCFs. Approximately 70% of patients with myeloma and back pain already have one or more VCFs at the time of diagnosis. There are several known facts about how myeloma affects bone and contributes to VCFs.

Bone is living tissue that is maintained by a delicate interplay between the cells that form new bone (**osteoblasts**) and the cells that remove old bone (**osteoclasts**). Myeloma cells do not directly affect bone; however, they indirectly destroy bone by signaling the osteoclasts to resorb (break down) bone uncontrollably. The malignant cells spread throughout the skeletal system, causing bone loss that mimics osteoporosis.

- Because so much bone is lost, high levels of calcium are released into the bloodstream. This condition is called **hypercalcemia**, and is common in patients with myeloma. Hypercalcemia increases bone destruction and frequently impairs kidney function.
- In patients with myeloma, excessive osteoclast activity suppresses the formation of

osteoblasts, the cells that create bone. This imbalance between bone-destroying and bone-creating cells further weakens the skeleton.

TREATMENT OPTIONS FOR VCFs

Analgesics

Analgesics are drugs that relieve pain and include **nonsteroidal anti-inflammatory agents (NSAIDs)**, such as aspirin, and controlled substances available only by prescription. NSAIDs are useful for the alleviation of mild pain. Due to a risk of gastrointestinal, liver, and kidney toxicity, patients taking NSAIDs must be closely monitored. For severe pain, stronger analgesics, such as narcotics, can be used. Treatment with analgesics will neither prevent additional VCFs nor repair the fractures.

Radiation

Radiation therapy provides pain relief in myeloma patients with VCFs by destroying the ability of the myeloma cells to grow and divide. Radiation may be used alone, or as part of the patient's treatment regimen. Pain relief is usually achieved several days after therapy. Analgesics may be used with radiation therapy to alleviate pain until the radiation has an effect. Radiation does not repair the fracture.

Bisphosphonates

Bisphosphonates are drugs that bind to the surface of bone, inhibiting bone breakdown

activity. Bisphosphonate therapy is considered standard treatment for patients with cancer-induced hypercalcemia and myeloma-related bone lesions. Treatment with bisphosphonates significantly reduces bone pain in at least 50% of patients and can reduce the frequency of VCFs by 25%–45%. Bisphosphonate therapy also lessens the need for bone radiation.

Vertebroplasty

Vertebroplasty is a minimally invasive surgical procedure in which bone cement is injected directly into the collapsed vertebra. The purpose of this procedure is to stabilize the fracture and reduce pain. Patients receive either general or local anesthesia. Guided by an imaging device, the physician uses a syringe to inject bone cement into the fracture. Patients remain in bed for a minimum of one hour afterward, to allow the cement to harden. Patients having vertebroplasty may require an overnight stay in the hospital.

Vertebroplasty stabilizes the fracture; however, cement leakage outside the vertebra has been cited as a common occurrence. For most patients, cement leakage has no noticeable effect, but there have been occasional reports of significant complications involving cement leakage following vertebroplasty. Some studies suggest vertebral body height restoration has been noted with vertebroplasty.

BALLOON KYPHOPLASTY

Balloon kyphoplasty is a medical procedure that is similar to vertebroplasty in several ways. Like vertebroplasty, balloon kyphoplasty is a minimally invasive procedure that uses bone cement to stabilize the fracture, which in turn, reduces bone pain and helps increase the patient's overall quality of life. Unlike vertebroplasty, balloon kyphoplasty uses orthopedic balloons in an attempt to correct the vertebral deformity, restore the height of the collapsed vertebra, and create a void before bone cement is deposited. After the void has been created, the balloon is deflated and removed, and then bone cement is used to fill the void. Though some cement leakage has been reported, this controlled filling reduces the risk of cement leakage. It has been reported that in both cancer and osteoporosis patients treated with balloon kyphoplasty, cement leakage is lower than in patients treated with vertebroplasty.

In a prospective evaluation (Khanna et al, Osteoporosis International, 2006 17:817-826), 56 patients with myeloma-induced VCFs that were treated with balloon kyphoplasty at Cleveland Clinic were evaluated at a median time of 12.8 months after the procedure. Improvements in 7 of 8 quality of life categories were not only noted, but were found to be significant. The 7 categories that demonstrated marked improvement were: social functioning, mental component, physical component, physical function, physical role, vitality, and bodily pain. Other stud-

ies also cite significant improvement in quality of life and mobility.

HOW THE BALLOON WORKS

Balloon kyphoplasty is a minimally invasive procedure in which orthopedic balloons are used to gently elevate the fractured vertebra, in an attempt to return it 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 and configuration of the fracture.

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 kyphoplasty begins with two small incisions, approximately 1 cm in length. Using a hollow instrument, the surgeon creates a small pathway into the fractured bone. A small, orthopedic balloon is guided through the instrument into the vertebra. Next, the balloon is carefully inflated in an attempt to raise the collapsed vertebra and return it to its normal position.



Balloon placement



Full inflation



Void within vertebral body



Filling the cavity with bone cement



The internal cast

Once the vertebra is in the correct position, the balloon is deflated and removed. This process creates a void (cavity) within the vertebral body. The cavity is filled with bone cement to support the surrounding bone and prevent further collapse. The cement forms an internal cast that holds the vertebra in place. Generally, the procedure is done on both sides of the affected vertebra.

WHO CAN BENEFIT FROM BALLOON KYPHOPLASTY?

Balloon kyphoplasty is suitable for myeloma patients with adequate white blood cell counts and normal **coagulation** studies. Most VCFs can be treated with balloon kyphoplasty; however, you will need to consult with your doctor to determine if you are a candidate for the procedure.

Because the procedure uses a balloon to correct the compressed vertebra before injecting cement, patients can also expect restoration of some of the vertebral body height they may have lost as a result of the fracture. Patients treated with balloon kyphoplasty can regain more than one-third of the vertebral body height lost due to fracture. This amount may vary from patient to patient.

HOW LONG DOES THE PROCEDURE TAKE?

On average, balloon kyphoplasty takes less than an hour for each vertebra treated. Usually, the balloons are inserted on both sides of the vertebra.

HOW LONG IS THE RECOVERY PERIOD?

Most patients who have balloon kyphoplasty are discharged from the hospital the following day. Patients can typically resume day-to-day activities the day after the procedure.

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, some of which can be fatal, can occur, including myocardial infarction (heart attack), cerebrovascular accident (stroke), pulmonary embolism (blood, fat or cement clot that migrates to the lungs), and cardiac arrest (heart stops beating).

Other risks (relevant to the anatomy being treated) include deep or superficial wound

infection, leakage of bone cement into the muscle and tissue surrounding the spinal cord, and nerve injury that can, in rare instances, cause paralysis. Patients are encouraged to discuss these and other risks with their physician.

Patients with unstable VCFs (due to destruction of the vertebral body), compression of the nerves around the spinal cord, persistent abnormal coagulation, local infection at the intended injection site, or those who cannot tolerate being prone are not considered good candidates for the procedure. Patients are encouraged to consult with their doctor to determine if they are candidates for the procedure.

DOES BALLOON KYPHOPLASTY RELIEVE PAIN?

Many patients treated with balloon kyphoplasty report an almost immediate decrease in pain, varying from partial to complete pain relief. For many patients, if not most, pain relief is sustained in the long term.

IS BALLOON KYPHOPLASTY COMPATIBLE WITH OTHER THERAPIES?

Yes. Balloon kyphoplasty will not interfere with chemotherapy or radiation treatment.

In addition, analgesics may still be taken for pain and bisphosphonates may be continued.

DOES INSURANCE COVER BALLOON KYPHOPLASTY?

For patients with Medicare coverage, balloon kyphoplasty is a covered benefit when the procedure is determined to be medically necessary. For patients with private insurance, coverage varies, depending on the insurance company and the type of coverage. Questions about coverage should be directed to the insurance provider.

QUESTIONS TO ASK YOUR DOCTOR

If you are considering balloon kyphoplasty, you may have questions for your doctor. You may want to ask the following:

- Am I a candidate for balloon kyphoplasty?
- Where will this procedure be done?
- How much experience do you have in performing balloon kyphoplasty?
- Should I receive general or local anesthesia?
- How long will the procedure take in my case?
- Will this interfere with any other treatment I'm receiving?
- What are possible complications that I should be aware of?
- How long will I be in the hospital?

About the IMF

*“One person can make a difference,
Two can make a miracle.”*

Brian D. Novis
IMF Founder

Myeloma is a little-known, complex, and often misdiagnosed bone marrow cancer that attacks and destroys bone. Myeloma affects approximately 75,000 to 100,000 people in the United States, with more than 15,000 new cases diagnosed each year. While there is presently no known cure for myeloma, doctors have many approaches to help myeloma patients live better and longer.

The International Myeloma Foundation (IMF) was founded in 1990 by Brian and Susie Novis shortly after Brian’s myeloma diagnosis at the age of 33. It was Brian’s dream that future patients would have easy access to medical information and emotional support throughout their battle with myeloma. He established the IMF with the 3 goals of treatment, education, and research. He sought to provide a broad spectrum of services for patients, their families, friends, and health care providers. Although Brian died 4 years after his initial diagnosis, his dream didn’t. Today the IMF reaches out to an international membership of more than 125,000. The IMF was the first organization dedicated solely to myeloma, and today it remains the largest.

The IMF provides programs and services to aid in the research, diagnosis, treatment, and management of myeloma. The IMF ensures that no one must brave the myeloma battle alone.

We care for patients today, while working toward tomorrow’s cure.

How Can the IMF Help You?

PATIENT EDUCATION

INFORMATION PACKAGE

Our free IMF InfoPack provides comprehensive information about myeloma, treatment options, disease management, and IMF services. It includes our acclaimed *Patient Handbook*.

INTERNET ACCESS

Log on to www.myeloma.org for 24-hour access to information about myeloma, the IMF, education, and support programs.

ONLINE MYELOMA FORUM

Join the IMF Internet Discussion Group at www.myeloma.org/listserve.html to share your thoughts and experiences.

MYELOMA MINUTE

Subscribe to this free weekly email newsletter for up-to-the-minute information about myeloma.

PATIENT & FAMILY SEMINARS

Meet with leading experts in myeloma treatment to learn more about recent advances in therapy and research.

MYELOMA MATRIX

On our website and in print, this document is a comprehensive guide to drugs in development for myeloma.

MYELOMA TODAY NEWSLETTER

Our quarterly newsletter is available free of charge by subscription.

SUPPORT

MYELOMA HOTLINE: 800-452-CURE (2873)

Toll-free throughout the United States and Canada, the IMF Hotline is staffed by trained information specialists and is in frequent interaction with members of our Scientific Advisory Board.

SUPPORT GROUPS

A worldwide network of more than 100 myeloma support groups hold regular meetings for members of the myeloma community. The IMF conducts annual retreats for myeloma support group leaders.

RESEARCH

BANK ON A CURE®

This DNA bank will provide genetic data research in new drug development.

THE INTERNATIONAL STAGING SYSTEM (ISS)

This updated staging system for myeloma will enhance physicians' ability to select the most appropriate treatment for each patient.

RESEARCH GRANTS

Leading the world in collaborative research and achieving extraordinary results, the IMF Grant Program supports both junior and senior researchers working on a broad spectrum of projects. The IMF has attracted many young investigators into the field of myeloma, and they have remained in the field and are actively pursuing a cure for this disease.

Glossary

Analgesic: A drug that relieves pain, including over-the-counter medications such as aspirin or acetaminophen, and prescription medication such as morphine and other opiates.

Bisphosphonate: A small inorganic molecule that binds to the surface of damaged bone. Bisphosphonates are given to patients with bone disease to inhibit the breakdown of bone.

Bone marrow: The soft, spongy center of the bone. White blood cells, red blood cells, and platelets are formed in the marrow.

Chemotherapy: A class of drugs used to destroy cancer cells.

Coagulation: The process of a liquid changing into a thickened mass, e.g., blood forming into a clot.

Hypercalcemia: Higher than normal levels of calcium in the blood.

Kyphosis: An exaggeration of the normal curve of the spine, often referred to as a "hunchback" or "dowager's hump."

Lesion: Any abnormality involving any tissue or organ, due to disease or injury.

Myeloma: A cancer of the plasma cells found in bone marrow. Cancerous plasma cells are called myeloma cells.

Nonsteroidal anti-inflammatory drug (NSAID): A drug, such as ibuprofen or acetaminophen, used to reduce fever, swelling, pain, and redness.

Osteoblast: A cell that forms bone tissue; a bone-growing cell.

Osteoclast: A cell that resorbs or breaks down bone.

Osteoporosis: A disease that causes weak or porous bones.

Vertebra: Any one of the 33 bony segments of the spinal column.

Vertebral Body: The round bony area of a vertebra.