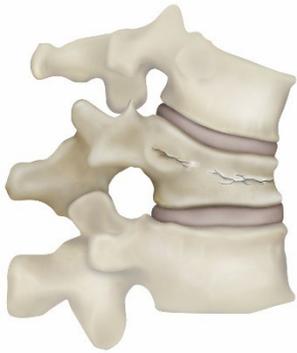


Medtronic

Kyphon™ Balloon Kyphoplasty for Vertebral Compression Fractures (VCF) BACKGROUND

The Condition: Spinal Fractures



Osteoporosis is the most widespread degenerative disease in the developed world. Globally, an osteoporotic fracture is estimated to occur every three seconds with spinal fractures being the most common.¹

Osteoporosis causes more than 700,000 spinal fractures each year in the U.S., more than twice the annual number of hip fractures.^{2,3}

Spinal fractures can also be caused by cancer, the most common forms being multiple myeloma, breast, lung and prostate.⁴ According to the Multiple Myeloma Research Foundation, the majority of patients with multiple myeloma—some 70 to 95 percent—experience

progressive bone destruction, particularly in the spine, because rapidly growing myeloma cells push normal bone-forming cells aside.

Although spinal osteoporotic fractures are the most common type of fragility fracture, they remain largely undiagnosed and untreated. Up to two-thirds are not recognized by doctors.³ Untreated, as many as one in five women with a spinal fracture will sustain another within 12 months, often referred to as the “fracture cascade.” Just 40 percent of older women and less than 20 percent of men with spinal fractures visible on X-ray are tested for osteoporosis.³

Some spinal fractures may collapse immediately while others collapse over time, resulting in a condition called kyphosis, or rounded back. Kyphosis, signified by the so-called dowager’s hump, compresses the chest and abdominal cavity, which can result in serious negative health and quality of life (QOL) consequences such as:

Health Consequences

- Increased risk of falls and fractures³
- Increased patient disability³
- Height loss³
- Chronic and acute pain³

Quality of Life Consequences

- Reduced mobility including slower walking pace and use of walking aids³
- Loss of self-esteem³
- Social isolation³
- Depression³

The current standard of care for a spine fracture is bed rest, pain medication, physical therapy, bracing and local steroid injections.² However, this approach does little to treat or prevent the formation of a kyphosis deformity and the associated “downward spiral” of negative consequences.

Balloon Kyphoplasty Outcomes

Balloon Kyphoplasty is a minimally invasive treatment that corrects vertebral deformity and stabilizes VCFs, thereby providing pain relief.

Short-Term Benefits

- Vertebral Height Restoration

Long-Term Benefits

- Vertebral Height Restoration



- Significant improvement in quality of life³
- Significant improvement in mobility, including the ability to perform daily activities such as walking, hobbies and work⁷
- Low complication rate (<1%)⁷
- Reduction in back pain³
- Maintenance of improvement in quality of life³
- Maintenance of improvement in mobility, including the ability to perform daily activities such as walking, hobbies and work⁷
- Maintenance of reduction in back pain³

Restoring normal spine anatomy can help a patient avoid the negative health and QOL consequences of a rounded back.

The Balloon Kyphoplasty Procedure

Through a pair of small incisions each approximately 1 cm in length, the specialty physician uses a needle and cannula to create a small pathway into each side of a fractured vertebral body. A small balloon is guided through each cannula into the vertebra. Each balloon is carefully inflated in an attempt to raise the collapsed vertebra and return it to its normal position. Inflation of the balloon creates a void (cavity) in the vertebral body.

Once the vertebra is in the correct position, the balloons are deflated and removed. The resultant cavities are filled with bone cement forming an “internal cast” to support the surrounding bone and prevent further collapse.

The Balloon Kyphoplasty procedure typically takes about one hour per fracture and may be performed in an outpatient setting. The procedure can be done using either local or general anesthesia; the specialty physician will determine the most appropriate method, based on the patient’s overall condition. In most cases, Medicare provides coverage for Balloon Kyphoplasty. Other insurance plans often also cover the procedure.

Although the complication rate with Kyphon™ Balloon Kyphoplasty has been demonstrated to be low, as with most surgical procedures, there are risks associated with the procedure, including serious complications. This procedure is not for everyone. A prescription is required. Patients should consult their physician for a full discussion of risks and whether this procedure is right for them.

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