

## Kyphon – Consumer Media Relations Outreach Q&A

### OSTEOPOROSIS / RESULTING SPINAL FRACTURES

**Q: What is osteoporosis? How does it cause spinal fractures?**

A: Osteoporosis is a disease in which bones become fragile and easily broken, causing more than 700,000 spinal fractures each year in the U.S.—more than in the hip and wrist combined.

**Q: Are all spinal fractures diagnosed and treated?**

A: No—spinal fractures are under recognized. Approximately two-thirds of all osteoporotic spinal fractures go undiagnosed or untreated due to the absence of symptoms or difficulty determining the cause of symptoms, leading some to call osteoporosis a “silent disease.”

**Q: How will I know if I have a spinal fracture?**

A: Osteoporotic spinal fractures can cause a sudden onset of back pain in the absence of an intervening traumatic event. Consult with your physician to distinguish between back pain caused by a vertebral compression fracture and other causes of back pain. A complete physical exam together with an x-ray and MRI can help physicians differentiate between VCFs and other causes of back pain.

**Q: Who is at risk for suffering an osteoporosis-related fracture?**

A: 50% of women and 25% of men older than 50 will have an osteoporosis-related fracture in their lifetime; however, bone loss in women can begin as early as age 25. Additionally, long-term use of medications such as corticosteroids can cause bone loss.

**Q: Is osteoporosis preventable?**

A: A calcium-rich diet, weight-bearing exercise and avoidance of smoking and excessive alcohol can help prevent bone mass loss.

**Q: What are some risk factors for osteoporosis?**

A: The following are some risk factors for osteoporosis:

- Family history of broken hip after a minor bump or fall
- Broken bone after a minor bump or fall
- Loss of more than 3 cm (just over 1 inch) in height
- Low calcium in diet
- Frequent diarrhea (caused by problems such as celiac disease or Crohn’s disease)
- Smoking, excessive alcohol consumption or certain medications (i.e., glucocorticoids)
- Menopause before the age of 45
- Absence of periods for 12 months or more
- Impotence, lack of libido or other symptoms related to low testosterone levels

**Q: How prevalent is osteoporosis?**

A: At age 50, a woman has a 40% chance of suffering an osteoporosis-related fracture in her lifetime—equal to the risk of breast, uterine and ovarian cancer combined. The National Osteoporosis Foundation cites osteoporosis as a major public health threat affecting 44 million Americans.

## **DISTINGUISHING BETWEEN PAIN CAUSED BY A VERTEBRAL COMPRESSION FRACTURE AND OTHER CAUSES OF BACK PAIN**

**Q: How do other causes of back pain compare with the pain of a VCF?**

A: It is important to determine the underlying cause of back pain. Whereas there are many causes of back pain, a complete physical exam, x-rays, and MRI will help determine whether or not a VCF is present. The first clue to a VCF may be the acute onset of severe back pain and functional limitation in the absence of a traumatic event such as an accident or fall.

**Q: How does a spinal fracture occur?**

A: In osteoporosis, the bones of the spine actually weaken due to loss of bone mass, which may cause them to partially or completely collapse (resulting in what are called vertebral compression fractures or VCFs). After the first fracture, the continued bone loss raises the risk of future fracture fivefold. In addition, just one VCF affects how weight is distributed through the spine, thus placing higher than normal stress on the front of the spine which contributes to the risk of future fracture.

**Q: What happens if the VCF goes undiagnosed?**

A: Left untreated, VCFs may create a curvature of the spine, sometimes referred to as “dowager’s hump.” Over time, this can become more pronounced, painful and debilitating. It doesn’t have to be this way—consult with your physician to determine your condition and appropriate treatment.

## **DOWNWARD SPIRAL**

**Q: How is health affected from a VCF?**

A: One VCF affects how weight is distributed through the spine, thus placing higher than normal stress on other vertebrae, contributing to the risk of future fracture. The spinal deformity in combination with continued bone loss raises the risk of a future fracture fivefold. When left untreated, vertebral compression fractures may result in **spinal deformity** called kyphosis or “dowager’s hump”, making it progressively difficult to breathe, walk, eat and sleep due to pain and the unnatural compression. Patients with kyphosis have a 23-24% increase in mortality compared to patients without a VCF.

**Q: Am I at risk for more fractures after suffering a VCF?**

A: Yes, due to continued bone loss and how weight is distributed through the spine, the risk of a future fracture rises fivefold. The resulting spinal deformity, in addition to reduced lung capacity, compounds to a 23-24% increase in mortality compared to patients without a VCF.

**Q: Do VCF sufferers also experience emotional problems?**

A: VCF patients often experience depression, anxiety and poor self-esteem in addition to their medical complications.

## **BENEFITS OF KYPHOPLASTY / OVERVIEW OF PROCEDURE**

**Q: How have VCFs historically been treated?**

A: Traditional treatment for spinal fractures includes extended bed rest, pain medication and back braces, which can relieve pain but doesn’t correct the deformity caused by the fracture itself.

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

**A:** On average, it takes typically one hour per fracture treated and may require an overnight hospital stay. Kyphoplasty can be performed using either local or general anesthesia; the physician will recommend the most appropriate anesthesia for the patient based on the patient's overall condition. After the procedure, the physician will schedule a follow-up visit and explain limitations, if any.

**Q: Is Balloon Kyphoplasty covered?**

**A:** In most cases, Medicare provides coverage for kyphoplasty. Other insurance may also provide coverage.

**Q: What are the potential benefits of the Balloon Kyphoplasty procedure?**

**A:** Kyphoplasty has been demonstrated to achieve **vertebral body height restoration and correction of spinal deformity** with a **low complication rate**.

Also:

- **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

Favorable patient outcomes have been shown in studies to last throughout two-year follow-up. Studies that document benefits beyond two-year follow-up have not yet been reported.

**Q: Are there risks associated with Balloon Kyphoplasty?**

**A:** Although the complication rate with Balloon Kyphoplasty has been demonstrated to be low, as with most surgical procedures, there are risks associated with Balloon Kyphoplasty, including serious complications. Patients should consult with their doctor for a full discussion of the risks.

**Q: What do patients experience after a Balloon Kyphoplasty procedure?**

**A:** Published studies have cited a significant reduction in pain, sometimes within hours of the procedure, and the ability of patients to change from prescription narcotics to over-the-counter pain medications.

Kyphoplasty has also been shown to improve patients' mobility, improve their ability to return to such simple, everyday activities as walking, bending and lifting, and experience significantly less pain than they had prior to the kyphoplasty procedure. Patients report improved mental health, vitality, social function and emotional health.

**Q: How old can a fracture be when Balloon Kyphoplasty is performed?**

**A:** This varies according to the patient, however, physicians report that the earlier the fracture is treated, the better.

**Q: Can Balloon Kyphoplasty help me if I fell down and have crushed vertebrae?**

A: If you have osteoporosis, simple activities such as lifting a child or tripping on a curb can cause your spine to fracture. However, osteoporotic fractures can also occur spontaneously and are not always caused by an accident. Continuing back pain alone can be a sign of a VCF. However, every situation is unique and should be evaluated by your physician.

**Q: What kinds of doctors perform Balloon Kyphoplasty?**

A: In the U.S., over 4,500 orthopedic surgeons, neurosurgeons, and interventional neuroradiologists who specialize in treating the spine perform Balloon Kyphoplasty. Physicians treating patients with osteoporosis (i.e., general practitioners, rheumatologists, internal medicine, etc.) can refer their patients to a spine specialist.

**Q: How many spine specialists perform Balloon Kyphoplasty?**

A: More than 4,500 physicians in the U.S. and 2,300 outside of the U.S. perform this procedure.

**Q: How many Balloon Kyphoplasty procedures have been performed?**

A: To date, over 150,000 patients with 175,000 spinal fractures have been treated worldwide with Balloon Kyphoplasty.

**Q: Where can I find more information on kyphoplasty?**

A: To get more information on kyphoplasty or to find a local doctor performing kyphoplasty, go to [www.kyphon.com](http://www.kyphon.com).

### **COSTS TO HEALTHCARE SYSTEM**

**Q: What are the healthcare costs associated with the treatment and hospitalization of spinal fracture patients?**

A: Approximately 150,000 people in the U.S. are hospitalized due to pain and medical management associated with spinal fractures (average hospital stay of 8 days), resulting in costs in excess of \$1.6 billion annually.

Estimated national direct expenditures (hospitals and nursing homes) for osteoporotic and associated fractures at \$17 billion in 2001 (\$47 million each day) and the cost is rising, according to the National Osteoporosis Foundation.

**Q: How does this rank with other diseases?**

A: Osteoporosis-related disability confines patients to more immobile days in bed than chronic obstructive pulmonary disease (a lung disease affecting ability to breathe), stroke, heart attack or breast cancer.

**Q: How have VCFs traditionally been treated?**

A: Diagnosed fractures most often are managed in the hospital and at home, predominantly with bed rest, pain medication and back braces.

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