



Medtronic

Spinal Fractures and KYPHON® Balloon Kyphoplasty Treatment



A Minimally
Invasive Procedure



About Spinal Fractures

A spinal fracture, also known as a vertebral compression fracture (VCF), occurs when one of the bones of the spinal column weakens and collapses. Spinal fractures tend to be painful and, if left untreated, can adversely affect overall health and well-being.



Normal vertebra



Fractured vertebra

It is important that spinal fractures are diagnosed and treated by a physician. A physical exam, along with an X-ray, can help determine if a spinal fracture has occurred.

The information presented is for educational purposes only and cannot replace the relationship that you have with your health care professional. It is important that you discuss the potential risks, complications and benefits of surgery with your doctor prior to receiving treatment, and that you rely on your doctor's judgment. Medtronic does not practice medicine or provide medical services or advice. Only your doctor can determine whether you are a suitable candidate for this treatment.

Long-term Effects

When left untreated, spinal fractures can cause your spine to shorten and angle forward, resulting in stooped posture or a hunched back. This forward curvature of the spine, called “kyphosis”, makes it difficult to walk, reach for things, or conduct normal activities of living. Most spinal fracture treatments merely manage pain and don’t repair the bone or correct spinal deformity.

Because spinal fractures aren’t always accompanied by pain, anyone over age 50 should report differences in spinal mobility, height loss, or postural changes to their doctor.

Over time, this condition may compress the lungs and abdomen, causing additional medical complications, such as:

- » Reduced activity and mobility^{1,2}
- » Decreased appetite and sleep disorders^{1,2}
- » Increased risk for future fracture³
- » Decreased quality of life; feelings of isolation and sadness^{1,2}



KYPHON® Balloon Kyphoplasty

Treating spinal fractures aims to make it easier for patients to return to everyday activities with significantly less pain than they had prior to the procedure. Studies report favorable patient outcomes after a KYPHON® Balloon Kyphoplasty procedure versus non-surgical treatment,^{4,5} such as:

- » 3 times greater pain reduction
- » 4 times greater quality of life
- » 5 more days at one month of unrestricted activity compared to baseline

Balloon kyphoplasty is a minimally invasive treatment that can repair spinal fractures caused by osteoporosis, cancer, or benign lesions.

In this procedure, orthopaedic balloons are used to lift the fractured bone and return it to the correct position. Performed under local or general anesthesia, the procedure typically takes less than an hour and may require an overnight hospital stay as determined by your doctor.



Inflated balloon

The complication for KYPHON® Balloon Kyphoplasty has been demonstrated to be low. There are risks associated with the procedure, including serious complications, and though rare, some of which may be fatal. These include, but are not limited to heart attack, cardiac arrest (heart stops beating), stroke, and embolism (blood, fat or cement that migrates to the lungs, heart, or brain). Other complications include infection and leakage of bone cement into the muscle and tissue. Cement leakage into the blood vessels may result in damage to the blood vessels, lungs, heart, and/or brain. Cement leakage into the area surrounding the spinal cord may result in nerve injury that can, in rare instances, cause paralysis. A prescription is required. Please consult your physician for a complete list of indications, contraindications, benefits, and risks. Only you and your physician can determine whether this procedure is right for you.

Am I at risk for a compression fracture?

- » Do you have sudden onset, sharp back pain that has lasted longer than 3 days?
- » Are you over 50 or postmenopausal?
- » Have you ever been diagnosed with osteoporosis or low bone mineral density?

If one or more of these apply to you, you may benefit from an evaluation.

To take the full assessment or to find a specialist in your area, please visit:

www.StopSpinalFracturePain.com

To learn more about
KYPHON® Balloon Kyphoplasty
or to find a trained specialist in your area,
please call 1-855-SPINE-09 or visit
www.StopSpinalFracturePain.com

References

1. Gold DT. The clinical impact of vertebral fractures: quality of life in women with osteoporosis. *Bone*. 1996 Mar;18(3 Suppl):185S-189S. Review. (Historical information on epidemiology of spinal osteoporosis and QOL; MDT comment March, 2013)
2. Silverman SL. The clinical consequences of vertebral compression fracture. *Bone*. 1992;13 Suppl 2:S27-31. (Historical disease state information on vertebral compression fractures; MDT comment March 2013)
3. Lindsay R, Silverman SL, Cooper C, Hanley DA, et al. Risk of new vertebral fracture in the year following a fracture. *JAMA*. 2001 Jan 17;285(3):320-3.
4. Wardlaw W, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. *Lancet*. Mar 21;373(9668):1016-24. Published on www.thelancet.com on February 24, 2009.
5. Boonen S, Van Meirhaeghe J, Bastian L, Cummings SR, Ranstam J, Tillman JB, Eastell R, Talmadge K, Wardlaw D. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2- year results from a randomized trial. *J Bone Miner Res*. 2011 Feb 17. doi: 10.1002/jbmr.364

www.medtronic.com

MEDTRONIC
Spinal and Biologics
2600 Sofamor Danek Drive
Memphis, TN 38132

1800 Pyramid Place
Memphis, TN 38132

(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

©2013 Medtronic Spine LLC.
All Rights Reserved. PMD010615-1.0



Medtronic