References

1. Cooper G et al. (2019, April). Nonoperative treatment of osteoporotic compression fractures. Retrieved from: https://emedicine.medscape.com/article/325872-overview
2. Old J et al. Vertebral compression fractures in the elderly. American Family Physician. 2004; 69(1):111-116.
3. National Osteoporosis Foundation. Osteoporosis fast facts. Retrieved from: https://cdn.nof.org/wp-content/uploads/2015/12/Osteoporosis-Fast-Facts.pdf.
4. Riggs B and Melton L. The worldwide problem of osteoporosis: Insights afforded by epidemiology. Bone. 1995; 17(Suppl 5):505S-511S.
5. Kendler D et al 2016. Vertebral fractures: Clinical importance and management. The American Journal of Medicine. 2016; 129: 221.e1-221.e10.
6. Boden S (2013, May). When back pain is a spine compression fracture. Retrieved from: https://www.spine-health.com/conditions/osteoporosis/when-back-pain-a-spine-compression-fracture.
7. American Association of Neurological Surgeons. (2020). Vertebral compression fractures. Retrieved from: https://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Vertebral-Compression-Fractures
8. Alexandru D and So W. Evaluation and management of vertebral compression fractures. The Permanente Journal. 2012; 16(4):46-51.
9. Fribourg D et al. Incidence of subsequent vertebral fractures after kyphoplasty. Spine. 2004; 29(20):2270-2276.
10. Ross P et al. Pre-existing fractures and bone mass predict vertebral fracture incidence in women. Annals of Internal Medicine. 1991; 114(11):919-923.
11. Lindsay R et al. Risk of new vertebral fracture in the year following a fracture. JAMA. 2001; 285(3):320-323.
12. Leech J et al. Relationship of lung function to severity of osteoporosis in women. The American Review Respiratory Disease. 1990; 141(1):68-71.\
13. Wardlaw D et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): A randomised controlled trial. Lancet. 2009; 373(9668):1016-1024.
14. Garfin S et al. Balloon kyphoplasty for symptomatic vertebral body compression fractures results in rapid, significant, and sustained improvements in back pain, function, and quality of life for elderly patients. Spine. 2006; 31(19): 2213-2220.
15. Taylor R et al. Balloon kyphoplasty and vertebroplasty for vertebral compression fractures: A comparative systematic review of efficacy and safety. Spine. 2006; 31(23):2747-2755.
16. Taylor R et al. Balloon kyphoplasty in the management of vertebral compression fractures: An updated systematic review and meta-analysis. European Spine Journal. 2007; 16(8):1085-1100.
17. Bae H et al. Clinical experience using cortoss for treating vertebral compression fractures with vertebroplasty and kyphoplasty: Twenty four-month follow-up. Spine. 2010; 35(20):E1030-E1036.

stryker

Interventional Spine

Manufactured by:

Stryker Instruments
1941 Stryker Way
Portage, MI 49002 U.S.

stryker.com
strykerIVS.com

stryker

Do you have a treatment plan for your patients who are suffering from vertebral compression fractures?

In the United States, more than 700,000 osteoporotic vertebral compression fractures (VCFs) occur each year.[1] Patients may suffer from VCFs due to thinning bones, tumors or other complications. These fractures are a serious and growing problem for older adults, which result in significant morbidity and mortality.[2] It is estimated that 50% of women and 25% of men will experience an osteoporotic fracture during their lifetime.[3]

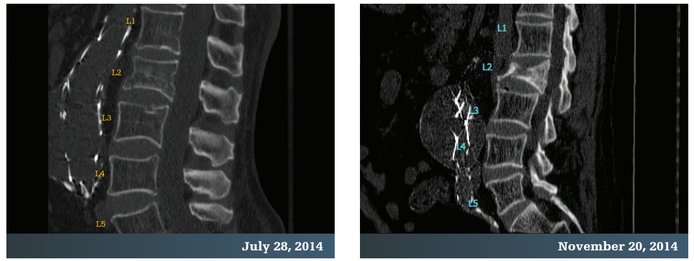
VCFs have a substantial and negative impact on the quality of life and day-to-day functioning of those afflicted. Acute and chronic pain in the elderly is commonly attributed to VCFs, often leading to further health deterioration in a "downward spiral" and a loss of independence. Because there is a substantial risk of subsequent fractures, **it is important that VCFs be diagnosed and treated early.**

Epidemiology and progression
of vertebral compression fractures

In the United States, approximately 1.5 million fractures are attributable to osteoporosis every year, of which 700,000 of these fractures are located in the vertebra.[4] VCFs are the most common type of osteoporotic fracture and are associated with substantial morbidity and decreased survival.[5] Leaving a VCF untreated can result in prolonged and debilitating pain that can lead to a downward spiral in physical and mental health.[6] The primary symptoms of a VCF are sudden back pain, limited spinal mobility, worsening back pain while standing or walking, deformity and/or disability.[7]

Vertebral fracture progression

L2 Vertebral compression fracture



CT scan imaging of progressive changes in the presence of a vertebral compression fracture on July 28, 2014 at 10% progressing to a 70% fracture on November 20, 2014. Images provided by Dr. Deborah Tracy.

Common causes of vertebral compression fractures[7]

- Osteoporosis
- Hemangiomas
- Multiple myeloma
- Metastatic bone disease

Contributing risk factors for vertebral compression fractures[8]

- Increasing age
- Caucasian or Asian ethnicity
- Family history of osteoporosis
- Sedentary lifestyle
- Diet low in calcium and vitamin D
- Cigarette smoking
- Alcohol consumption

Having a vertebral compression fracture
increases the risk of a subsequent fracture

The risk of subsequent fractures increases in patients with a history of osteoporotic VCFs. Additional VCFs can lead to progressive kyphosis of the thoracic spine, which further results in comorbidities such as poor nutrition and decreased pulmonary function.[8] When no surgical intervention is performed, the data suggests that the incidence of subsequent VCFs is 19%.[9] Both bone mass and existing vertebral fractures are powerful predictors of the risk for new vertebral fractures. The risk for new vertebral fractures increases progressively, going from zero to one to two or more prevalent fractures.[10] See Table 1 for additional information provided.

According to an analysis of data from four large 3-year osteoporotic treatment trials, it was **found that approximately 20% of postmenopausal women will experience another vertebral fracture within the first year of an incident vertebral fracture.**[11] See Table 2 for the impact that vertebral fractures have on pulmonary function.

Table 1: Associations between spine fracture prevalence and new vertebral fractures*

* All analyses were adjusted for age. Spine fracture prevalence was based on vertebral measurements.

* For a further explanation of the models used in this graph, see Ross et al. article listed as reference #10.

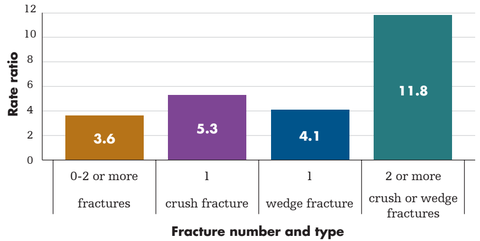


Table 2: Impaired pulmonary function

Impaired pulmonary function is a potential complication associated with osteoporotic VCFs. The flow rates and lung volumes from a study sample of women with osteoporotic VCFs are shown here.[12]

For further explanation on this table, see Leech et al. article listed as reference #12.

*Values are mean ± 1 SEM (minimum-maximum + p-value <0.005 for two-tailed, unpaired t test comparing subjects without fractures (column 1) to subjects with fractures (columns 2 and 3)).

	Pulmonary function tests		
	No thoracic fractures (n=29)	One or two thoracic fractures (n=32)	Three or more thoracic fractures (n=13)
Age, year	65 ± 2 (48-79)	67 ± 2 (45-82)	70 ± 1 (63-80)
Flow rates			
FVC, %*	95 ± 3 (68-127)	90 ± 3 (55-131)	68 ± 3 (52-93)
FEV1, %	97 ± 3 (57-129)	92 ± 3 (61-134)	68 ± 3 (52-93)
FEV1/FVC, %	80 ± 1 (55-92)	80 ± 1 (65-100)	80 ± 1 (74-86)
FEF 25-75, %	114 ± 7 (25-180)	102 ± 6 (42-235)	83 ± 5 (64-121)
Volumes			
TLC, %	99 ± 3 (68-128)	94 ± 3 (62-128)	75 ± 3 (61-89)
IC,% +	113 ± 4 (76-181)	103 ± 4 (50-165)	84 ± 5 (64-121)

Procedure
overview

Patients with VCFs who do not respond to conservative treatment or who experience unmanageable pain may be helped by vertebral augmentation. Vertebral augmentation with balloon kyphoplasty is a minimally invasive procedure proven to significantly relieve pain, increase mobility and/or improve quality of life without open surgery.[13-17] Vertebral augmentation utilizing Stryker's iVAS balloon system is a refinement of vertebroplasty. During this minimally invasive procedure, one or two balloons are used to create a void or cavity in the collapsed vertebra into which an injected material—either bone cement or Cortoss bone augmentation material—is introduced.

Using fluoroscopic visualization, balloon catheters are advanced into the collapsed vertebra utilizing a transpedicular or bipedicular approach. The balloon(s) are then inflated, creating a central void and compacting the remaining trabeculae to the periphery. The balloon catheter(s) are then deflated and withdrawn, and specially formulated acrylic bone cement is injected into the void(s) created by the inflated balloon(s). Once set, the cement forms an internal cast that helps stabilize the bone.

Potential benefits

- Rapid and sustained pain relief[13-17]
- Improved function and/or mobility[13-17]
- Improved quality of life[13-17]

Warning/adverse events

Serious adverse events, some with fatal outcome, associated with the use of bone cements for vertebroplasty, kyphoplasty and sacroplasty include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism and cardiac embolism. Although it is rare, some adverse events have been known to occur up to one year post-operatively. Additional risks exist with the use of bone cement. Please see the iVAS or iVAS Elite IFUs for a complete list of potential risks.

How balloon kyphoplasty works

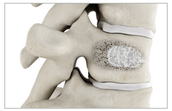
1. Needle is guided into fractured vertebra using fluoroscopy.

2. Hand drill is inserted into the anterior third of the vertebral body to create a pathway.

3. Balloon catheter is inserted into the fractured vertebra.

4. The balloon is inflated, compacting the trabeculae and creating a cavity.

5. Once the balloon is deflated and withdrawn, the cavity is filled with bone cement or bioactive resin.



6. The vertebral body is stabilized.