

The Marketing Bulletin

NOVEMBER 2016

KEY MESSAGE

- ✓ Any change in spinal load results in shift of spinal biomechanics & global spinal imbalance
- ✓ Anterior vertebral body stress --> Increased risk for adjacent level fractures
- ✓ Endplate fractures --> Reduces the ability of the disc to distribute load evenly to the adjacent segments
- ✓ Very low adjacent fracture rates are reported in SpineJack® Clinical Studies

The development, and effects, of spinal deformity on patients with osteoporotic VCFs may be explained by the altered spinal biomechanics that follow vertebral fracture¹.

{ After the first fracture }

the **Risk of a new Fracture** increases:
x5

Osteoporosis is a chronic progressive disease, and patients with one osteoporotic spinal fracture are likely to incur further fractures¹¹.

BIOMECHANICS OF THE OSTEOPOROTIC SPINE

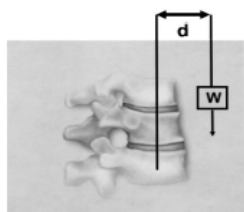
Understanding the biomechanics is essential when considering the osteoporotic spine and the effects of vertebral augmentation.

- **Under normal conditions:** Load is shared by the vertebrae, discs, ligaments, facet joints, and, in the thoracic region, the ribs and sternum.
- **Change in spinal load:** Leads to an unbalance of the system and results in alteration of spinal biomechanics and global spinal imbalance¹.

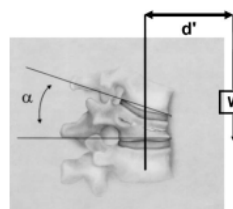
Two major factors likely contribute to anterior vertebral body stress and increased potential for adjacent level fractures after an initial vertebral compression fracture²:

- **Anterior load shift**
- **Changes in load transfer through the intervertebral disc**

Forward bending moment (M):



- **In the normal spine**
 $M = W \times d$

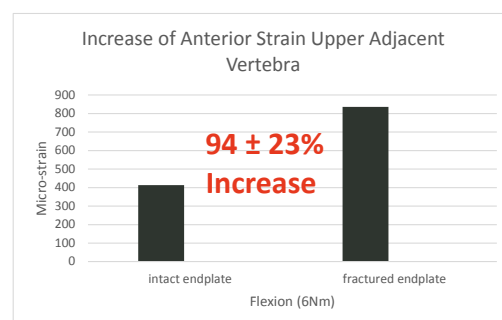


- **In osteoporotic fractured spine**
 $M = W \times d'$

d = is the distance from center of gravity in normal spine / d' = is the distance from center of gravity in osteoporotic fractured spine / W = the axial load or weight

Tzermiadianos showed that VCF provoked endplate deformity that could change the pressure profile of the disc and increase compressive loading of the anterior wall of the adjacent vertebra³.

This may contribute to increased subsequent fracture risk after an osteoporotic VCF.



BIOMECHANICS OF THE INTERVERTEBRAL DISCS

Endplate depression after an osteoporotic VCF diminish the ability of the disc to distribute load evenly to the adjacent segments.

The role of changed disc biomechanics in the risk of adjacent fractures must be considered. During normal flexion (bending forward), intradiscal pressure increases along with increasing load. This load is evenly distributed as the strain increases.

1. When the endplate fractures:
 - The space available for the nucleus pulposus is increased
 - Leads to increasing disc volume
 - Results in diminished intradiscal pressure
2. When the nuclear pressure no longer increases during flexion:
 - There is a loss of the “cushion-effect”
 - The load is distributed to the rim of the disc
 - The anterior strain doubles

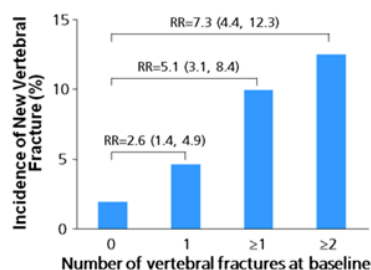
After a cement augmentation procedure, the vertebral body is filled with cement and the vertebral body height may be restored. However, the fractured endplate is not necessarily reduced and the space available for the disc nucleus pulposus may remain increased.

- With flexion, the disc pressure is still lower than normal and the anterior stress still doubles!
- Consequently, the adjacent level fracture usually occurs adjacent to the fractured endplate³.

By using SpineJack® technique, the surgeon will be able to reduce the fracture and restore the endplate before stabilizing with cement.

INFLUENCE OF OSTEOPOROSIS

Factors such as progressing osteoporosis and off-axis loads due to previous vertebral fractures are more likely to be the cause of new adjacent fractures⁴.



Lindsay et al.⁵ could confirm that the presence of prevalent fractures significantly increased the risk of new vertebral fractures.

- Numerous publications points out the importance of treating the osteoporosis to avoid new adjacent fractures^{6, 7, 8}.
- However, treatment with Bisphosphonates will only slowly strengthen the osteoporotic bone, while adjacent fractures most often occurs in the first months after the patient suffered the initial fracture⁹.

ADJACENT FRACTURE RATES

- After experiencing an osteoporotic VCF, patients have around 20% incidence of a subsequent fracture in the following year when no surgical intervention is performed^{5,9}. The great majority of new fractures will occur adjacent to the initially fractured vertebra, and if it was restored, within the first few months after the intervention took place.
- The reported rate of adjacent fractures in the literature is most often in the range of 11% to 21% for vertebroplasty and kyphoplasty techniques¹⁰, even if both higher and lower rates are reported.

Very low adjacent fracture rates reported in SpineJack® Clinical Studies

In the retrospective studies on SpineJack®, by Dr. Renaud and Prof. Noriega, the adjacent fracture rates were 2.6% and 2.2% respectively. In the Trauma registry the adjacent fracture rate was 2.9%.

These rates are very low and thus suggesting a direct link between optimal endplate restoration by SpineJack® and a significant reduction of the risk of further fractures.

References: ¹Yuan et al. Osteoporotic spinal deformity a biomechanical rationale for the clinical consequences and treatment of vertebral body compression fractures. J Spinal Disord Tech 2004;17(3):236–42. / ²Hadley et al. Biomechanics of Vertebral BoneAugmentation. Neuroimag Clin N Am 20 (2010) 159–167. / ³Tzermiadianos et al. Altered disc pressure profile after an osteoporotic vertebral fracture is a risk factor for adjacent vertebral body fracture. Eur Spine J 2008;17(11):1522–30. / ⁴Aquarius et al. Does Bone Cement in Percutaneous Vertebroplasty Act as a Stress Riser? Spine 2013;38:2092–2097. / ⁵Lindsay et al. (2001) Risk of new vertebral fracture in the year following a fracture. JAMA 285(3):320–323. / ⁶Papanastassiou et al. Controversial Issues in Kyphoplasty and Vertebroplasty in Osteoporotic Vertebral Fractures. Biomed Res Int. 2014;2014:934206. / ⁷Lee et al. Analysis of Risk Factors Causing New Symptomatic Vertebral Compression Fractures After Percutaneous Vertebroplasty for Painful Osteoporotic Vertebral Compression Fractures: A 4-year Follow-up. J Spinal Disord Tech. 2013 Oct 30. [Epub ahead of print] / ⁸Rho et al. Risk factors predicting the new symptomatic vertebral compression fractures after percutaneous vertebroplasty or kyphoplasty. Eur Spine J (2012) 21:905–911. / ⁹Fribourg D et al. Incidence of subsequent vertebral fracture after kyphoplasty. Spine. 2004;29:2270–6 / ¹⁰Taylor et al. Balloon kyphoplasty in the management of vertebral compression fractures: an updated systematic review and meta-analysis Eur Spine J (2007) 16:1085–1100. / ¹¹Ross et al. Pre-existing fractures and bone mass predict vertebral fracture incidence in women. Ann Intern Med 1991;113:919–23