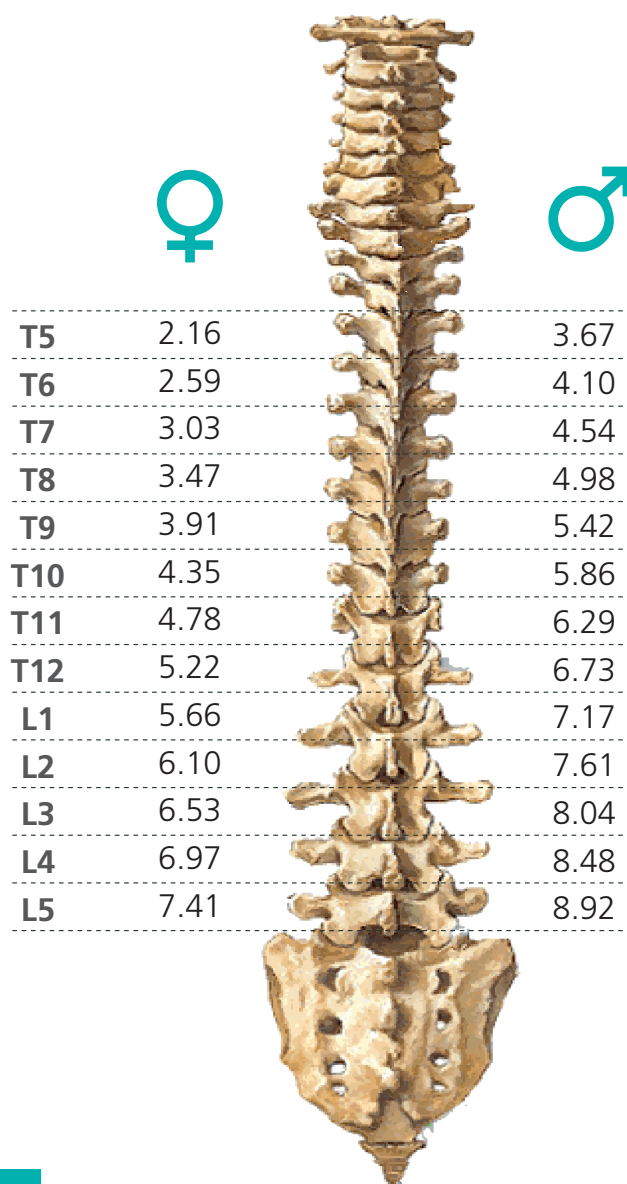




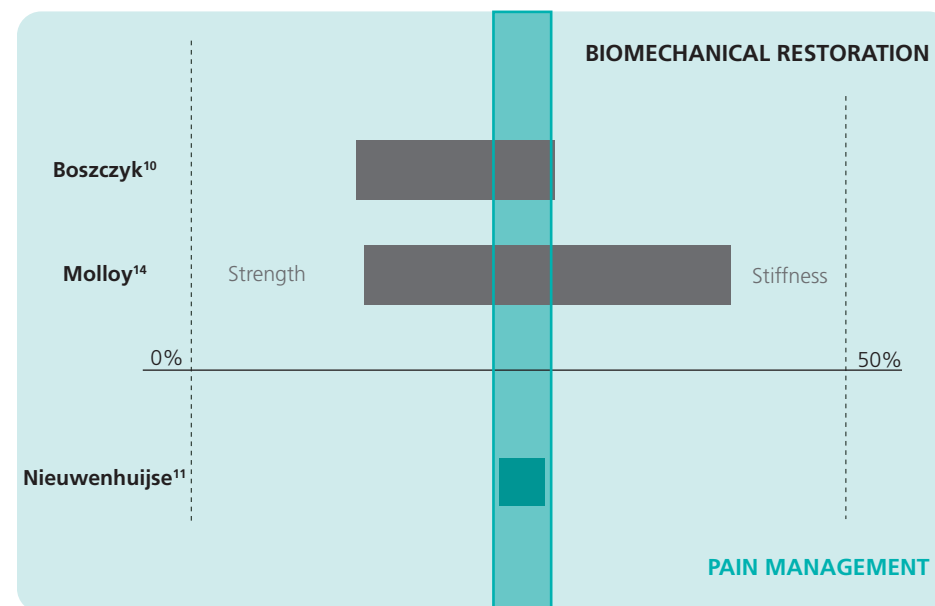
Advanced
Vertebroplasty
Therapy

BASED ON 30 YEARS
OF EXPERIENCE

Suggested minimal intravertebral cement volumes¹¹ (ml)



Cement volume: a review of the literature



REFERENCES:

1. Luo, et al. Mechanical efficacy of vertebroplasty - Influence of cement type, BMD, fracture severity and disc degeneration. BONE 40 (2007) 1110-1119.
2. Galibert P, et al. Note préliminaire sur le traitement des angiomes vertébraux par vertébroplastie acrylique percutanée. Neurochirurgie 1987; 33:166-168.
3. Giannitsios D, et al. High Cement Viscosity Reduces Leakage Risk in Vertebroplasty. European Cells and Materials Vol.10 Suppl. 3, 2005 (page 54)
4. Schlegel UJ et al. Efficacy of vacuum bone cement mixing systems in reducing methylmethacrylate fume exposure: comparison of 7 different mixing devices and handmixing. Acta orthop Scand; 75 (5):559-66.
5. Fuchs M, et al. Exposure of the surgeon to radiation during surgery. International Orthopaedics (SICOT) (1998) 22:153-156.
6. McGraw JK, et al. Prospective Evaluation of Pain Relief in 100 Patients Undergoing Percutaneous Vertebroplasty: Results and Follow-up. J Vasc Interv Radiol 2002; 13:883- 886.
7. Do HM, et al. Prospective analysis of clinical outcomes after percutaneous vertebroplasty for painful osteoporotic vertebral body fractures. Am J Neuroradiol 2005;26:1623-1628.
8. Zoarski GH, et al. Percutaneous vertebroplasty for osteoporotic compression fractures: quantitative prospective evaluation of long-term outcomes. J Vasc Interv Radiol 2002;13:139-48.
9. Molloy S, et al. Effect of Cement Volume and Placement on Mechanical-Property Restoration Resulting from Vertebroplasty. AJNR Am J Neuroradiol 26:401-404, February 2005.
10. Boszczyk B. Volume matters: a review of procedural details of two randomized controlled vertebroplasty trials of 2009. Eur Spine J (2010) 19:1837-1840.
11. Nieuwenhuijse MJ, et al. The Optimal Intravertebral Cement Volume in Percutaneous Vertebroplasty for painful Osteoporotic Vertebral Compression Fractures. SPINE 2012, Volume 37;20:1747-1755.
12. Liebschner MA, et al. Effects of bone cement volume and distribution on vertebral stiffness after vertebroplasty. Spine (Phila Pa 1976). 2001 Jul 15;26(14):1547-54.
13. Baroud G, et al. High-viscosity cement significantly enhances uniformity of cement filling in VP - An experimental model and study on cement leakage. SPINE 2006 Vol.31, Number 22, pp 2562-2568.
14. Molloy S, et al. The Effect of Vertebral Body Percentage Fill on Mechanical Behavior During Percutaneous Vertebroplasty. SPINE 2003 Volume 28, Number 14, pp 1549-1554.

Therapeutic choices

To treat Vertebral Compression Fractures (VCF), among multiple therapeutic choices, the healthcare professional can choose between two Minimally Invasive Surgeries:

- **Anatomical restoration** of the fractured vertebral body: Restoration of the sagittal and coronal profile, and even more important, repositioning of the endplate back to the pre-trauma position. This will restore the global biomechanical balance of the spine as well as the natural motion of local vertebral joints.
- **Vertebroplasty:** Pain reduction, local stabilisation of the vertebral body to prevent further collapse and restoration of the pre-trauma physiological pressure of the disc¹.

Vexim, as a global provider of advanced percutaneous VCF treatments, is committed to offering a full range of advanced solutions. The Cohesion® high-viscosity Bone Cement, in combination with its Mixer and Injector System, is here to provide an innovative VCF therapeutic approach based on the latest clinical and scientific results published.

Advanced Vertebroplasty Therapy

Since the first vertebroplasty 30 years ago², clinical knowledge based on scientific research has dramatically improved, resulting in an evolution and refinement of the vertebroplasty technique.

Today's gold standard to improve patient outcomes in vertebral cement injection includes, along with reproducible results and safety^{3,4,5}, a significant reduction of pain^{6,7,8} combined with a biomechanical stabilisation⁹ of the vertebral body to prevent further collapse.

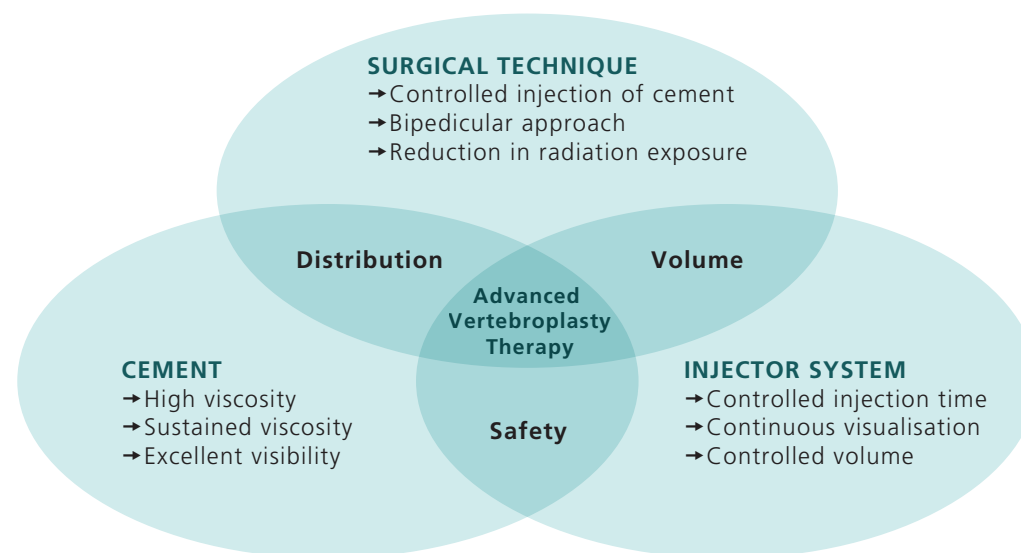
This is the objective of an Advanced Vertebroplasty Therapy, which includes the injection of an optimal cement volume along with controlled cement positioning and distribution made possible by the right cement properties.

Cement volume and position

Although no clear guidelines or recommendations have been proposed by scientific societies, a thorough review of renowned clinical and biomechanical publications indicates a consensus:

- An "ideal" cement volume: 15-25% of the vertebral body volume should be filled with cement to restore the biomechanical properties and significantly alleviate the patient's pain^{10,11}.
- Correct cement positioning and distribution: homogeneous distribution of cement to prevent further collapse¹².
- Adequate cement viscosity and working time: high viscosity cement to ensure safety¹³.

System requirements



Cement Mixer

Technical Pathway

CLOSED SYSTEM

REDUCED EXPOSURE TO FUMES

DUAL AXIS MIXING ROD AND VISUAL CONTROL

HOMOGENEOUS MIXING

QUICK CEMENT TRANSFER

EASY TO USE

APPROPRIATE HIGH VISCOSITY

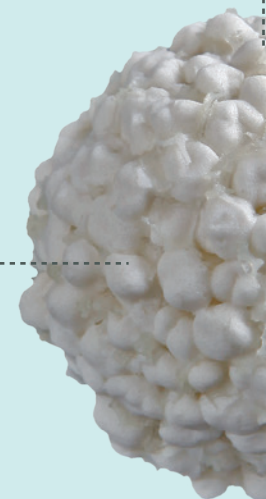
Multiple studies have identified bone cement viscosity as the most important factor influencing the spread of bone cement within the vertebral body and frequency of leakage. Our Cohesion® Bone Cement has been formulated to reach the optimal viscosity of minimum 350 Pa.s during injection time.

**SAFER
FILLING**

SUSTAINED HIGH VISCOSITY

Along with the required high viscosity, enough time is required to control and adapt the injection to the type of pathology and fracture. The working time has been designed to be exceptionally long: 18 min at 18°C.

**LONGER
CONTROL**



Cohesion[®] B o n e C e m e n t



HIGH RADIOPACITY

With 45% of Zirconium Oxide as a radiopacifier, Cohesion[®] Bone Cement has been formulated to provide state-of-the-art visibility during the injection procedure.

**EXCELLENT
VISIBILITY**

Injection System

SYRINGE WITH GRADUATION
CONTROLLED VOLUME

**30 CM FLEXIBLE
REINFORCED INJECTOR TUBE**
REDUCED RADIATION EXPOSURE

**HIGH VISCOSITY
CEMENT INJECTOR**
CONTROLLED INJECTION TIME

Continuum of control

Refer to the Cohesion[®] Bone Cement Brochure (COCEBROINT)

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