Percutaneous vertebroplasty for osteoporotic fractures: Experience with high viscosity cement using a hydraulic injection device, the “CONFIDENCE” system

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Background

- Precise control of cement delivery is necessary to minimize the risk of cement leakage
- Cavity creation had been linked to decreased leakage without scientific evidence
- Higher-viscosity cements associated with lower leakage rates in laboratory vertebral compression model
High-Viscosity Cement Significantly Enhances Uniformity of Cement Filling in Vertebroplasty: An Experimental Model and Study on Cement Leakage

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Study Design. Experimental study using a laboratory leakage model.

Objective. To examine the working hypothesis that high-viscosity cements will spread uniformly, thus significantly reducing the risk of leakage.

Summary of Background Data. In vertebroplasty, forces that govern the flow of bone cement in the trabecular bone skeleton are an essential determinant of the uniformity of cement filling. Extraosseous cement leakage has been reported to be a major complication of this procedure. Leakage occurs due to the presence of a path of least resistance caused by irregularities in the trabecular bone or shell structure. Ideally, cement uniformly infiltrates the trabecular bone skeleton and does not favor specific paths. Cement viscosity is believed to affect the infiltration forces and flow during the procedure. Clinically, altering the time between cement mixing and delivery modifies the viscosity of bone cement.

Methods. An experimental model of the leakage phe-

Conclusions. High-viscosity cement seems to stabilize cement flow. However, the forces required for the delivery of high-viscosity cement may approach or exceed the human physical limit of injection forces. Although the working time of the cement is about 17 minutes, it may not be manually injectable with a standard syringe and cannula after 10 minutes, at which time cement leakage ceased completely.

Key words: vertebroplasty, extraosseous leakage, cement extravasation, filling pattern, cement viscosity. Spine 2006;31:2562–2568

Vertebroplasty is a minimally invasive procedure used to stabilize fractured vertebrae. In this procedure, bone cement is injected percutaneously, through a long cannula and into the vertebred cancellous bone.
Purpose

- To assess the clinical feasibility of performing Vertebroplasty on osteoporotic compression fractures using an ultra viscous cement injected by a hydrolic device to further control cement deposition.
Material and Methods

- Single center retrospective review of post-operative radiographs of 94 consecutive patients treated with Confidence system.
- Total of 163 levels ranged from T3 to L5 vertebral bodies.
- The degree of leakage was assessed at each treated level using a strict 4-point scale (none, minimal, moderate, severe).
- The pattern of any observed leakage was also characterized as: discal, venous, paravertebral, or epidural.
Results

- Pre-operatively the mean degree of vertebral collapse was 29%
- There was no leakage in 50%,
- Minimal leakage in 42%,
- Moderate leakage in 7% of cases
- One case of severe leakage
Mild venous leakage

Moderate Disk leakage

Severe Disc leakage
Results

- The most frequent pattern of leak was venous seen in 52% of leaks, the adjacent disc in 46%, and para-vertebral in 5%.
- The pattern of leakage was always limited to one region except in two cases.
- There were no symptomatic leaks that required surgical intervention.
Inter-digitations
84 Woman, Osteoporotic Fractures
66 y woman, osteoporotic fracture
Pre-op MRI
Introducer Needles Positioning

T9

T13

L4
Conclusion

- Vertebroplasty in osteoporotic fractures using a highly viscous cement that can be safely controlled and injected via a hydraulic system can be performed safely without significant complications.